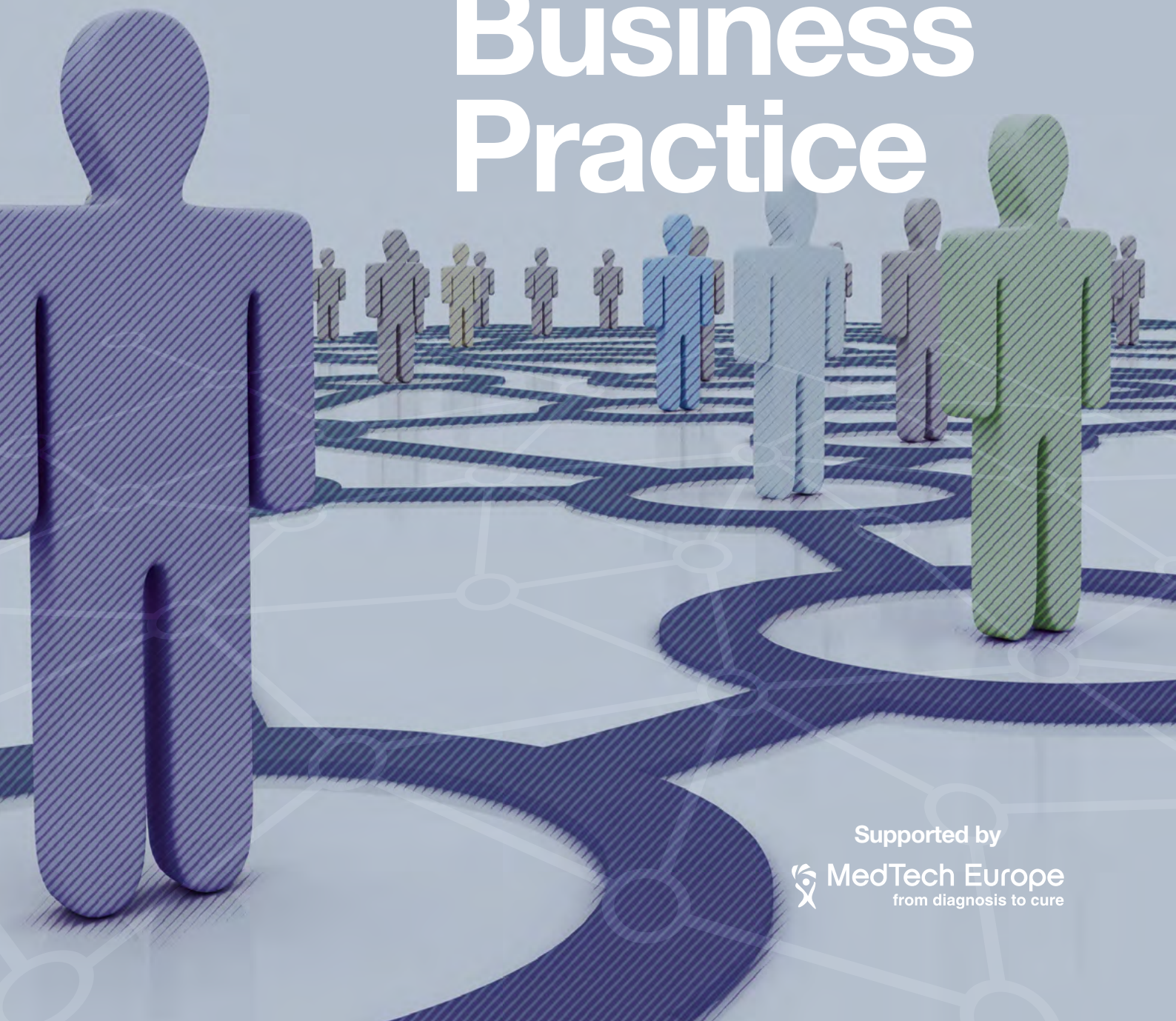
Irish Medtech Association
Ibec

Guidelines on Interactions with Healthcare Professionals

Code of Ethical Business Practice



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Introduction

Promoting an Ethical Industry

The Irish Medtech Association is the business association within Ibec representing the medical technology sector in Ireland. Irish Medtech Association'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 companies.

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 on 1st January 2017. The MedTech Europe Code allowed for an additional year to phase out direct sponsorship, by the entire medtech industry. We are now at this juncture. The Irish Medtech Association as a member association of MedTech Europe has adopted this code and over the past number of years we have been busy providing guidance and information to Members about the Code. The Code is mandatory for all Members of the Irish Medtech Association. 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 Code of Ethical Business Practice for the Irish medical technology industry 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 HCP's
- Provision of educational grants and charitable donations
- Provision of modest hospitality and gifts

The Irish Medtech Association is committed to this code and we look forward to working with our Members and other

stakeholder to oversee its continued implementation. The Irish Medtech Association 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 or Healthcare Organisations in connection with the sale, promotion or other activity involving Member companies' products. Accordingly, it is recommended that where such arrangements are entered into, the relevant contractual documentation impose obligations upon the third party (for example, third party sales & marketing intermediaries (SMIs), consultants, distributors, sales agents, marketing agents, brokers, commissionaire commercial agents and independent sales representatives) to comply with provisions set out in the Code or equivalent guidelines[2].

Key Legislation

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

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

National and European Union (EU) competition legislation applies not only to Members in their business operations, but also to the Irish Medtech Association, 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.

Aims and Principles of the Code

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

Advancement of Medical Technologies

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

Safe and Effective Use of Medical Technology

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

Research and Education

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

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

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

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

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

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

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

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

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

The Principle of Image and Perception

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

The Principle of Separation

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

The Principle of Transparency

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

The Principle of Equivalence

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

The Principle of Documentation

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

Interpreting the Code

The use of capital letters indicates that a word or expression is a defined term, the meaning of which is set out in the Glossary. Any phrase introduced by the terms: including, include, in particular, or any similar expression shall be interpreted as illustrative and shall not limit the sense of the words preceding those terms.

Administering the Code

Compliance with the Code and with this Complaints Procedure and Panel Constitution is mandatory for members of the Irish Medtech Association. 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.

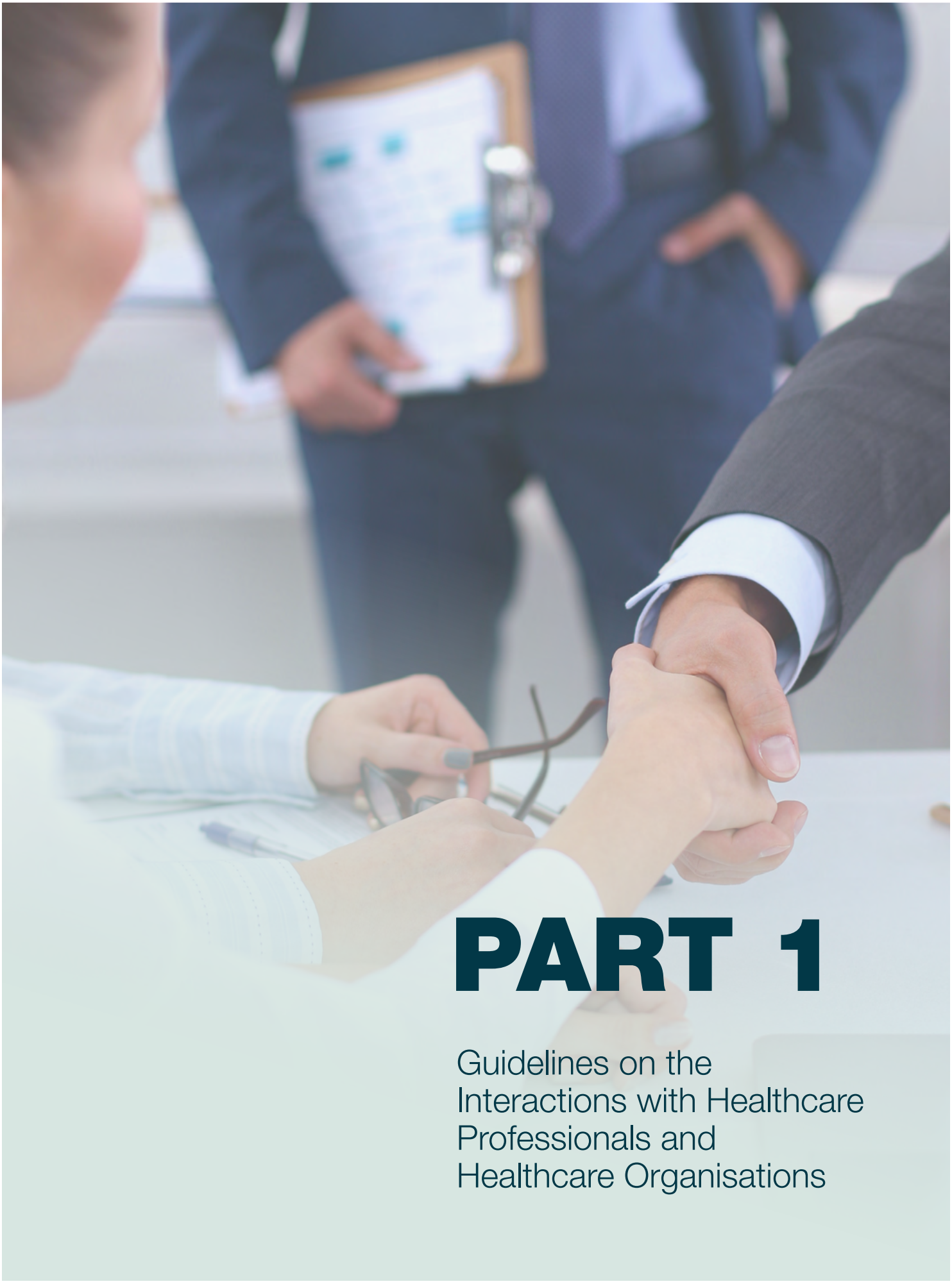
A full overview of complaints procedure and sanctions are available on http:www.irishmedtechassoc.ie/ethics

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 Association members (whether MedTech Europe members or not) access to this portal for disclosure of financial contributions.

If an Irish Medtech Association member company is funding a third party conference, 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.

Implementation

This edition of the Code comes into force on [1 January 2018].



PART 1

Guidelines on the Interactions with Healthcare Professionals and Healthcare Organisations

Chapter 1

General Criteria for Events

Member Companies may invite Healthcare Professionals to Company Events and Third Party Organised Educational Events.

01. Event Programme

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

A Member Company shall not organise Events which include social, sporting and/or leisure activities or other forms of Entertainment, nor support such elements where part of Third Party Organised Educational Events. For Third Party Organised Educational Events, Entertainment must be outside of the educational programme schedule and paid for separately by the Healthcare Professionals. Entertainment should not dominate or interfere with the overall scientific content of the programme and must be held during times that do not overlap with a scientific session. The Entertainment should not be the main attraction of the Third Party Organised Educational Event.

02. Event Location and Venue

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

- Potential adverse public perceptions of the location and venue for the Event. The perceived image of the location and venue must not be luxury, or tourist/holiday- oriented, or that of an Entertainment venue.
- The Event location and venue should be centrally located when regard is given to the place of residence of the majority of invited participants.
- The need for ease of access for attendees.
- The Event location and venue should be in or near a city or town which is a recognised scientific or business centre, suitable for hosting an Event which is conducive to the exchange of ideas and the transmission of know- ledge.
- 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.

Q4: What is meant by "legitimate" or "genuine" as used in the definitions of 'Company Event' and 'Third Party Organised Educational Conferences'?

A4: Any Event should be relevant to the Healthcare Professional attendees; the detailed programme should be available sufficient time prior to the Event; present a clear schedule with no gaps during the sessions, (e.g., the minimum duration for a full day Event should be 6 hours or 3 hours for a half day Event including refreshment breaks). If it is a Third Party Organised Educational Event the Faculty must be identified. It is also important that all supporting materials (e.g. flyers, brochures and website) are consistent with the scientific or promotional nature of the programme content, as the case may be.

Q5: Can a Member Company organise or support an Event at a hotel that offers leisure facilities such as golf, casinos or water sports?

A5: 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.

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

A6: When originating location of the majority of attendees is considered, Event location and venue need to be in close proximity to an airport and / or train station with appropriate international connections, with associated reliable ground transportation infrastructure to the venue.

Q7: Under the Code, how does the "season" impact evaluation of Event location and venue?

A7: 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.

03. 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.

04. Reasonable Hospitality

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

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

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

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

05. Travel

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

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

06. Transparency

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

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.

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

A8: The term "facilitate" refers to the prior arrangement, organisation or booking of meals, travel or accommodation by or on behalf of a Member Company on behalf of the Guest of a Healthcare Professional participant. Such organisation or booking is not permitted unless the individual qualifies as a participant in his/her own right, irrespective of who pays. Such actions are open to misinterpretation. If Healthcare Professionals attending the Event wish to be accompanied by a Guest who does not have a professional interest in the information being shared, the Healthcare Professional must take sole responsibility for the payment and organisation of the Guest's expenses.

Q9: In the event that a Healthcare Professional is accompanied by a Guest at the Event, may this Guest be admitted to any Company Event, or Third Party Organised Educational Events?

A9: It is not appropriate for a Guest of a Healthcare Professional to attend either Company Events (including Satellite Symposia) or Third Party Organised Educational Events (unless the individual qualifies as a participant in their own right), nor is it appropriate, in the interest of maintaining the scientific exchange, for a Guest to participate in related hospitality during such Events (for example, lunches and coffee breaks) even when the Healthcare Professional pays for the Guest's expenses.

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

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 Health- care Professionals' travel or accommodation expenses for attendance at the Event?

A10: It is not acceptable to make an advance payment to a Healthcare Professional to cover prospective expenses. Payments should generally be made to the supplier/vendor or intermediary agency. Alternatively Member Companies may reimburse individual Healthcare Professional expenses retrospectively against original invoices or receipts.

Q11: May Member Companies offer to cover the travel and accommodation expenses of Healthcare Professionals for periods that extend beyond the duration of the Event programme attended?

A11: Generally, travel and accommodation support offered by Member Companies to Healthcare Professionals should be tailored to the duration of the Event. Member Companies must always keep in mind the impression which may be created by the arrangements for any meeting.

Q12: Under the Code, is Employer Notification required for each interaction with a Member Company? For example, is such notification required each time a Member Company pays for a reasonably priced meal or gives a Healthcare Professio- nal a gift, which is otherwise in line with the requirements of the Code?

A12: Employer Notification is required whenever a Member Company engages a Healthcare Professional or whenever a member makes a financial contribution to the Healthcare Professional's medical education. Incidental interactions arising in the normal course of business such as meals associated with educational or business meetings or the receipt of modest gifts related to the Healthcare Professional's practice, do not require Employer Notification.

Q13: Are Member Companies required to provide additional written notification under the Code to the hospital administration, Healthcare Professional's superior (or other locally-designated body) for Member Company/ Healthcare Professional interactions in countries where there are compulsory notification systems already in place?

A13: No. Only the compulsory notification is required. Additional notification under the Code is not required in countries where specific notification requirements of law or regulation govern the transparency of interactions between industry and Healthcare Professionals. The transparency provisions of the Code apply only in countries where there is an absence of national transparency laws and regulations.

Q14: 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?

A14: The written notification must comply with national laws, regulations and professional codes of conduct. In countries where specific provision is not made, there is no requirement to notify employers of the amounts involved. Under the Code, Member Companies must ensure that the level of remuneration is commensurate with the services provided and not greater than a fair market value. However, the purpose of the Employer Notification is to provide transparency on the nature of the interaction between the Member Company and the Healthcare Professional and to enable the employer to raise objections if they perceive a potential conflict or have other issues concerning the interaction.

Chapter 2

Third Party Organised Educational Events

01. Third Party Organised Educational Conferences

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

- Chapter 1: General Criteria for Events;
- and where applicable, has approval via the Conference Vetting System (see the Glossary)[2].

Where permitted under national law, 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: Grants and Charitable Donations 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.

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

Q15: What is meant by "in kind support" as used in Chapter 2, Section 1 of the Code in connection with "Third Party Organised Educational Conferences"? (added in September 2016)

A15: "In kind support" must be provided to the Healthcare Orga- nisation (HCO) and Member Companies should ensure that any such in kind support does not, nor is perceived to, circumvent the prohibition of Member Companies providing direct financial support to identifiable Healthcare Professionals to attend Third Party Organised Educational Conferences. Examples of "in kind support" which Member Companies may provide could include modest secretarial and/or logistical support to assist with meeting arrangements. For example, it would not be appropriate for Member Companies to handle the conference registration, travel, or accommodation arrangements for individual (and identifiable) Healthcare Professionals delegates at a Third Party Organised Educational Conference.

Q16: Please provide examples of appropriate booth activties which will be perceived as professional?

A16: Booth activities at Third Party Organised Educational Conferences should aim primarily at displaying Member Companies' products and services and related literature. Therefore, other activities should be limited and reasonable and in principle, only soft drinks and snacks should be served.

Q17: Can a Member Company for example be present via a satellite symposium, rent booth space at a Third Party Organised Educational Conference which organise a satellite symposium and/or rent booth space at a Third Party Organised Educational Conference taking place outside of the Med- Tech Europe Geographic Area and which was assessed as non-compliant by the Conference Vetting System (CVS)? (modified in October 2016)

A17: Yes, Member Company can organise a satellite symposium and/or rent booth space at a Third Party Organised Educational Conference taking place outside of the MedTech Europe Geographic Area and which was assessed as non-compliant by the Conference Vetting System provided that there are no Healthcare Professionals registered and practicing in the MedTech Europe Geographic Area supported by an Educational Grant. Please refer to Annex I for a detailed visualisation of the scope CVS and its impact on commercial activities.

02. Third Party Organised Procedure Training

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

- Financial support must comply with the criteria provided in Chapter 1: General Criteria for Events. Member Companies may therefore pay travel, hospitality and the registration fee.
- Where applicable, the Third Party Organised Procedure Training has approval via the Conference Vetting System (see the Glossary)[3].
- 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.

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

Q18: 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?

A18: Member Companies must ensure compliance with the Code and enter into a consulting agreement with the Healthcare Professional engaged to speak at the satellite symposium. The consulting agreement may include payments in respect of registration fee, travel and/or accommodation where appropriate.

Q19: What are the main differences between Third Party Organised Educational Conferences and Procedure Trainings? (added in September 2016)

A19: Both Third-Party Organised Educational Conferences (see the Glossary) and Third-Party Procedure Trainings (see the Glossary) are a type of Third Party Organised Educational Events. Therefore, they must comply with Chapter 1. General Criteria for Events; and, where applicable, are subject to the Conference Vetting System (see the Glossary). However, unlike Third Party Organised Educational Conferences, Third Party Organised Procedure Trainings are not subject to the phase out of direct support for the attendance of Healthcare Professionals. Nonetheless, for Third Party Organised Procedure Trainings the following three criteria shall apply:

- Programme: Unlike Third Party Organised Educational Conferences which are theoretical in nature, Third Party Organised Procedure Trainings consist of practical, hands-on trainings, generally involving more than one provider/ manufacturer/ sponsor. This must be evident by the programme of the Event.

“...unlike Third Party Organised Educational Conferences, Third Party Organised Procedure Trainings are not subject to the phase out of direct support for the attendance of Healthcare Professionals”

A19: Contd.

The programme, which is often referred to as a “course”, rather than a conference or seminar, must be focused on acquiring specific medical skills relevant to certain medical procedures (rather than products, or medical technologies). Examples may include courses aimed at acquiring or improving the Healthcare Professional’s skills in minimally invasive surgery; orthopaedic trauma surgery; or the implantation of cardiac rhythm devices; etc. The programme must also include practical demonstrations (and/or actual live surgeries, where allowed). Examples of practical demonstrations may include surgery simulations where technologies are used on cadavers; skin models; synthetic bones; cath labs; etc.

- Venue: Third Party Organised Procedure Trainings are typically organised in a clinical environment, as opposed to, e.g., a classroom setting.

  For the avoidance of doubts, the adjective “clinical” includes places suitable for the simulation of medical procedures, rather than just the medical treatment of real patients.

  Examples of clinical environment include hospitals or clinics, where medical treatment on real patients may be given; as well as conference rooms which are appropriately set up to simulate medical procedures, for example with the presence of medical technologies to be used on cadavers; skin models; synthetic bones; etc.

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

Chapter 3

Company Events

01. General Principles

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

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

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

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

02. Product and Procedure Training and Education Events

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

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

3. Sales, Promotional and Other Business Meetings

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

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

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

Q21: Is it appropriate for Member Companies to invite Healthcare Professionals on company plant or factory tours where the Healthcare Professionals reside outside the country of location of the plant or factory?

A21: Yes, it is appropriate for Member Companies to invite Healthcare Professionals to plant or factory tours in countries outside their country of residence if there is a legitimate business purpose and the tour complies with the Code in all respects.

Q22: Under the Code, Chapter 3, Point 2, what is meant by "Company Organised Education Events"? (added in September 2016)

A22: "Company Organised Education Events" is a Company Event as defined in the Glossary, whose objective is genuine and bona fide medical education, and the enhancement of professional skills. "Educational" or "education" means communicating information directly concerning or associated with the use of Member Companies' medical technologies, e.g., information about disease states and the benefits of medical technologies to certain patient populations. In all cases the information and/ or training must directly concern a Member Company's medical technologies, therapies and/or related services.

This means that a Member Company must meet the following tests when organizing such an Event in order to be compliant with the Code:

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

b) 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.

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

A22: Contd.

d) 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.

e) The programme should in principle involve full days, with the majority of the morning and afternoon parts dedicated to scientific and/or educational sessions, unless the Event is a half day event, commences or ends on a mid-day or lasts less than half a day. Such half-day or less sessions are permissible, but there should not be any non-scientific or non- educational events or activities organised 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.

Q23: Are cruise ships or golf clubs appropriate venues for Product and Procedure Training and Education Events?

A23: 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.

Q24: What criteria should a Member Company apply when considering the country location of Product and Procedure Training and Education Events?

A24: If the participants are primarily of one country, the venue should be in the specific country involved. If the participants are from multiple countries in Europe, then a European country affording ease of access for participants should be chosen. It is expected that the country selected is the residence of at least some of the participants of the Product and Procedure Training and Education Event.

Q25: Can a Member Company use a meeting venue outside Europe?

A25: Yes, provided the participants are from multiple countries outside Europe. If the participants are primarily from within Europe, the venue should be in Europe. It is expected that the country selected (and the state, if the location is in the United States) is the residence of at least some of the participants of the Product and Procedure Training and Education Event.

"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."

Chapter 4

Grants and Charitable Donations

01. General Principles

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

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

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

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

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

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

Q26: Under the General Principles in Chapter 4. Grants and Charitable Donations, what is meant by an "independent decision-making/ review process"?

A26: In accordance with the Principle of Separation, an "independent decision-making/review process", is a process where the decision-making criteria are not primarily sales-driven and where the Member Company's sales function does not decide upon and/or approve a decision to provide a Grant or Charitable Donation. For example, such a process could be led by a Member Company's legal, finance or compliance functions, operating within a robust governance framework and according to clear, consistent and transparent criteria for review and decision-making.

Q27: Under the Code, what is meant by "prior evaluation of any associated risks and of the relevant information" relating to a Grant or a Charitable Donation??

A27: 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 pro-posed recipient. Such an evaluation shall consider all the circumstances including, but not limited to, consideration of the legal status and structure of the requesting (i.e. prospective recipient) organisation as well as of the nature and scope of its activities and the terms and conditions to which the Grant or Charitable Donation will be subject. The evaluation shall be documented and shall be based on information available to the Member Company, such as information or documentation available from public sources.

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

Q28: What does "sufficient information" mean where used in connection with documentation of Grants and Charitable Donations?

A28: The written request by a requesting organisation should include as a minimum a detailed description of the scope and purpose of the programme, activity or other project, which is the object of the Grant or Charitable Donation. It shall also contain a description of the proposed recipient, its legal status and structure, and where relevant, a budget.

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

02. Charitable Donations

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

Charitable Donations may be made only to charitable organisations or other non-profit entities which have charitable and/or philanthropic purposes as their main purposes and which are objectively engaged in genuine charitable or philanthropic activities. Charitable Donations shall always be made in accordance with the general principles set out in Chapter 4: Grants and Charitable Donations.

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

This section of the Code (Chapter 4: Grants and Charitable Donations– Charitable Donations) is not intended to address legitimate commercial transactions by Member Companies in the form of leasing of stands or booth space at Third Party Organised Educational Events and/or at any conference or event organised by a charity or other philanthropic organisation. Such activity is considered to be part of Member Companies' normal marketing activity.

Member Companies should, however, always consider the appropriateness of the location, venue and the general arrangements for any such events and the impression that may be created by the arrangements in order not to bring the industry into disrepute.

03. Educational Grants

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

Member Companies shall document and publicly disclose all Educational Grants in accordance with the Code's Disclosure Guidelines, and publication shall commence no later than 31 December 2017.

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)[4]

a.1. Support for HCP Participation at Third Party Organised Educational Events:

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

Q29: Under the Code, can a Member Company make a Charitable Donation to support the general running of hospital or other Healthcare Organisation?

A29: No, a Member Company cannot make available a Charitable Donation to support the general running of a hospital or other Healthcare Organisation. A Charitable Donation shall only be given to a legal entity or body which has charitable and/or philanthropic purposes as its main purposes. For the purpose of the Code and irrespective of their legal status, hospitals and Healthcare Organisations are considered to generally have health functions as their main purposes and accordingly are not generally considered to have charitable and/or philanthropic functions as their main purposes. It is not therefore appropriate to provide Charitable Donations to support their general running.

Q30: Is it permissible for a Member Company to specify restrictions in relation to the final use of a Charitable Donation where a Member Company wishes its Charitable Donation to be applied as part of a specific aid programme or as part of the relief effort following a specific natural disaster, such as a major earthquake in a particular country? (added in September 2016)

A30: Under the Code it is not appropriate for a Member Company to apply conditions or restrictions to the final use of a Charitable Donation which go beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes. Member Companies may therefore impose general restrictions concerning the final use, such as the relief of a specific disaster in a particular country (e.g. for use to aid reconstruction and/or re-equipping of healthcare facilities following the earthquake in that country). However, Member Companies must take care that such general restrictions are not so specific that the Charitable Donation is no longer unrestricted. The Charitable Donation must not be misused or be perceived to influence through undue or improper advantages, purchasing decisions, nor should such Donation be contingent upon sales transactions or use or recommendation of Member Companies' products.

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

Q31: 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?

A31: 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.

Q32: Under the Code, may a Member Company make a Charitable Donation such as the purchase of a table of dinner invitations at a fundraising dinner or entries to participate in, or attend at, a fundraising sports or other event?

A32: Yes, Charitable Donations made by Member Companies may take the form of dinner invitations for a fundraising dinner or participating in other recreational events such as a fundraising golf tournament, if arranged by a charitable or other non-profit philanthropic organisation. The Member Company may use some or all of its ticket allotment for its own employees and return any unused portion to the sponsoring charitable or non-profit philanthropic organisation for use as the sponsoring organisation sees fit. However, the Member Company should not invite Healthcare Professionals to attend such an event at the Member Company's expense. Furthermore, the Member Company is not permitted to suggest to the sponsoring organisation, the names of Healthcare Professionals who could be invited to attend the event, irrespective of whether or not the specified Healthcare Professionals will be seated at the Member Company's table.

Q33: Can a small sized Healthcare Organisation receive Educational Grants to support Healthcare Professionals participation at Third Party Organised Educational Events? (added in September 2016)

A33: Yes, in principle. There are no size limits for Healthcare Organisations to receive Educational Grants; however, Member Companies must ensure that the final beneficiaries of the Educational Grant cannot be identified beforehand. For example, Healthcare Organisations 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.

a.2. Support for Third Party Organised Educational Events:

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

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

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

b. Scholarships and Fellowships

Member Companies may provide Educational Grants on a restricted basis in the form of Grants for Scholarships and Fellowships to support advancement of genuine medical education of Healthcare Professionals (see the Glossary). Only Healthcare Organisations where Healthcare Professionals are in training shall be eligible to request and/ or receive such Educational Grants. A Member Company shall not provide Educational Grants to support Scholarships and Fellowships upon request of individual Healthcare Professionals. Similarly, the Member Company shall not have any involvement in any way in the selection of the HCPs who will benefit from the Educational Grant and this shall be reflected in the written Grant agreement between the Member Company and the recipient HCO.

c. Grants for Public Awareness Campaigns

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

4. Research Grants

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

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

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

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

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

Q34: How can Member Companies in practice ensure that Educational Grants made available for Third Party Organised Educational Events which are subject to the Conference Vetting System, are positively reviewed by CVS?

A34: 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.

Q35: 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?

A35: 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.

Q36: 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? (modified in September 2016)

A36: Member Companies may enter into a commercial sponsorship arrangement with a Professional Conference Organiser organising a Third Party Organised Educational Event independently of any Healthcare Organisation. However, such arrangements do not fall within the definition of Educational Grant as Professional Conference Organiser are for-profit organisations. Sponsorship arrangements are therefore commercial in nature and Member Companies should consequently document these in a written commercial agreement in accordance with normal business practice and the requirements of the Code (Chapter 2: Third Party Organised Educational Events). In addition, where a Member Company provides funds earmarked for

A36: Contd.

the advancement of genuine educational purposes to a Professional Conference Organiser, acting independently of any Healthcare Organisation, all the Code provisions governing Educational Grants shall also apply. For example, if a Member Company provides funding to a Professional Conference Organiser to fund Healthcare Professional delegate places and expenses at a Third Party Organised Educational Conference, such Event, where applicable, must have CVS approval and the Member Company shall publicly disclose such funding in accordance with the Code's Disclosure Guidelines.

Q37: Can a Member Company pay for or reimburse travel costs to a Third Party Organised Educational Event for a Scholar or Fellow?

A37: No, a Member Company cannot additionally pay for, or reimburse, the travel or other participation costs incurred by a Scholar or Fellow attending a Third Party Organised Educational Event. Such costs shall be included in the Educational Grant supporting the Scholarship or Fellowship if it is intended that the Grant should extend to such attendance.

Q38: What are examples of relevant disease awareness and health education for patients, carers and the general public for which a Member Company may legitimately provide an Educational Grant?

A38: A Member Company may provide an Educational Grant to support the provision of high quality information to patients and the public about health and disease provided there is an objective patient or public need or such information and the topics covered are linked to the therapeutic areas in which the Member Company is interested and/or involved. Such disease awareness campaigns must not, however, promote the use of particular therapies, services or promote specific Healthcare Organisations, nor may they aim to stimulate demand by the public for specific therapies or for specific Healthcare Organisations

"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."

"A Member Company may provide an Educational Grant to support the provision of high quality information to patients and the public about health and disease provided there is an objective patient or public need or such information and the topics covered are linked to the therapeutic areas in which the Member Company is interested and/or involved."

Chapter 5

Arrangements with Consultants

01. General Principles

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

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

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

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

02. Criteria for Genuine

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

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

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

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

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

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

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

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

03. Remuneration and Fair Market Value

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

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

04. Disclosure and Transparency

Member Companies shall ensure they fully comply with all applicable national laws, regulations and professional codes of conduct requiring any publication, disclosure or approval in connection with the use by Member Companies of Healthcare Professionals as consultants. All required consents and approvals shall be obtained, including from the hospital or other Healthcare Organisation administration or from the Healthcare Professional's superior (or locally-designated competent authority), as applicable. Where no such national requirements apply, Member Companies shall nevertheless maintain appropriate transparency by requiring the relevant Employer Notification which shall disclose the purpose and scope of the consultancy arrangement.

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

Q39: What is meant by Fair-Market-Value (FMV) in the context of consulting arrangements?

A39: Fair-market-value is the value of the specified consultancy services which would be paid by the Member Company to the consultant, each dealing at arm's length in an open and unrestricted market, and when neither party is under any compulsion to buy or sell, and both parties have reasonable knowledge of the relevant facts.

Q40: How should Member Companies determine Fair-Market- Value (FMV) for a service?

A40: A Member Company must be able to demonstrate internal methodology to determine fair market value. Amongst other matters this shall take account of the consultant's qualifications, expertise and experience as well as the actual services to be provided to the Member Company.

Chapter 6

Research

01. Member Company-Initiated Research

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

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

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

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

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

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

02. Member Company Post-Market Product Evaluation

Where there is a legitimate business need to do so, Member Companies may initiate, post-market third party evaluation of their products, therapies and/or related services and may therefore provide Evaluation Products under a written contract for services in order to obtain defined user evaluation by Healthcare Organisations in relation to the Evaluation Products.

Evaluation Products may be provided on a no charge basis in return for the requested user feedback from Healthcare Professionals at the Healthcare Organisation, which shall be formally described in a written protocol or questionnaire forming part of the contract.

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

Provision of Evaluation Products and/or related services must not improperly reward, induce and/or encourage Healthcare Professionals and/or Healthcare Organisations to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services. Any offer and/or supply of Evaluation Products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of con- duct.

"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"

03. Third Party-Initiated Research

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

Q41: What is an example of an external public registry for clinical trial transparency?

A41: Examples of an external public register for clinical trial transparency are www.clinicaltrials.gov or www.who.org

Chapter 7

Royalties

Healthcare Professionals, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve products or medical technologies.

They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement.

A royalty arrangement between a Member Company and a Healthcare Professional should be entered into only where the Healthcare Professional is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method, such that the Healthcare Professional would be considered to be the sole or joint owner of such intellectual property under applicable laws and regulations. The foregoing is without prejudice to Member Companies' obligations to comply with any applicable obligations to pay royalties which may arise under applicable laws and regulations in some countries.

Arrangements involving the payment of royalties by or on behalf of Member Companies to a Healthcare Professional must be set out in a written agreement providing appropriate and reasonable remuneration in accordance with applicable laws and regulations. For example, royal- ties 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 royal- ties the number of units purchased, prescribed, used, or ordered by the Healthcare Professional and/or members of the Healthcare Professional's practice or Healthcare Organisation.

Chapter 8

Educational Items and Gifts

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

Member Companies may only provide such educational items and/or gifts in accordance of the following principles:

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

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

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

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

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

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

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

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

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

Q42: 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".

A42: Stationery items, calendars, diaries, computer accessories for business use and clinical items such as wipes, nail brushes, surgical gloves and tourniquets are examples of modest value items that could be appropriately provided as gifts to Healthcare Professionals provided their value falls within the maximum value prescribed under national laws, regulations and industry and professional codes of conduct. Food, alcohol and items which are primarily for use in the home or car are not appropriate as they are not related to the Healthcare Professional's practice nor are they for the benefit of patients.

Q43: May a Member Company provide a small gift to a Healthcare Professional to mark significant life events such as a marriage, birth, birthday or death?

A43: The Code restricts the types of gift that may be given to a Healthcare Professional and it would not be appropriate to give gifts to mark significant life events such as a marriage, birth or birthday. However, in the case of death, it is for each Member Company to determine the appropriateness of making a tasteful gift as a mark of respect.

Q44: Where Healthcare Professionals engaged by Mem- ber 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?

A44: No, it would not be acceptable for the Member Company to make such a gift because to do so could be open to misinter- pretation and would be likely to breach the Principle of Image and Perception. Moreover such gifts would not comply with Chapter 8. Educational Items and Gifts as they neither relate to a Healthcare Professional's practice nor serve an educational function.

Q45: Please provide examples of educational items of greater value that can be provided to Healthcare Organisations under the Code?

A45: Examples of educational items of greater value that can be provided may include medical textbooks or anatomical models, but only if those relate to the therapeutic areas in which the Member Company is interested and/or involved.

Chapter 9

Demonstration Products and Samples

01. General Principles

Member Companies may provide their own products as Demonstration Products and/or Samples (see the Glossary) at no charge in order to enable Healthcare Professionals and/or Healthcare Organisations (as applicable) to evaluate and/or familiarise themselves with the safe, effective and appropriate use and functionality of the product and/ or related service and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

Demonstration Products and/or Samples may be either single- or multiple-use products. Member Companies may also provide products from another company in conjunction with the Member Company's own Demonstration Products and/or Samples on an exceptional basis if those other company's products are required in order to properly and effectively demonstrate, evaluate or use the Member Company's products, e.g. computer hardware and software produced by a company other than the Member Company.

Provision of Demonstration Products and/or Samples must not improperly reward, induce and/or encourage Healthcare Professionals and/or Healthcare Organisations to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services. Any offer and/or supply of such products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct.

Member Companies shall in all cases maintain appropriate records in relation to the provision of Demonstration Products and/or Samples to Healthcare Professionals and/or Healthcare Organisations, for example recording proof of delivery for any Demonstration Products and/or Samples provided and receipt of return for multiple-use Demonstration Products and/or Samples. Member Companies shall clearly record in the Member Company's records as well as clearly disclose to Healthcare Professionals and/or Healthcare Organisations the no-charge basis and other conditions applicable for the supply of such Demonstration Products and/or Samples no later than the time of the supply. The disclosure to Healthcare Professionals and Healthcare Organisations shall be in writing.

This Chapter is limited to the provision of Demonstration Products and/or Samples and related services at no charge and is not intended to apply to provision of pro- ducts 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.

02. 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

> *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.*

Healthcare Professional may use a Demonstration Product to show a patient the type of technology which will be implanted in the patient or may use the Demo to train other Healthcare Professionals in the use of the product.

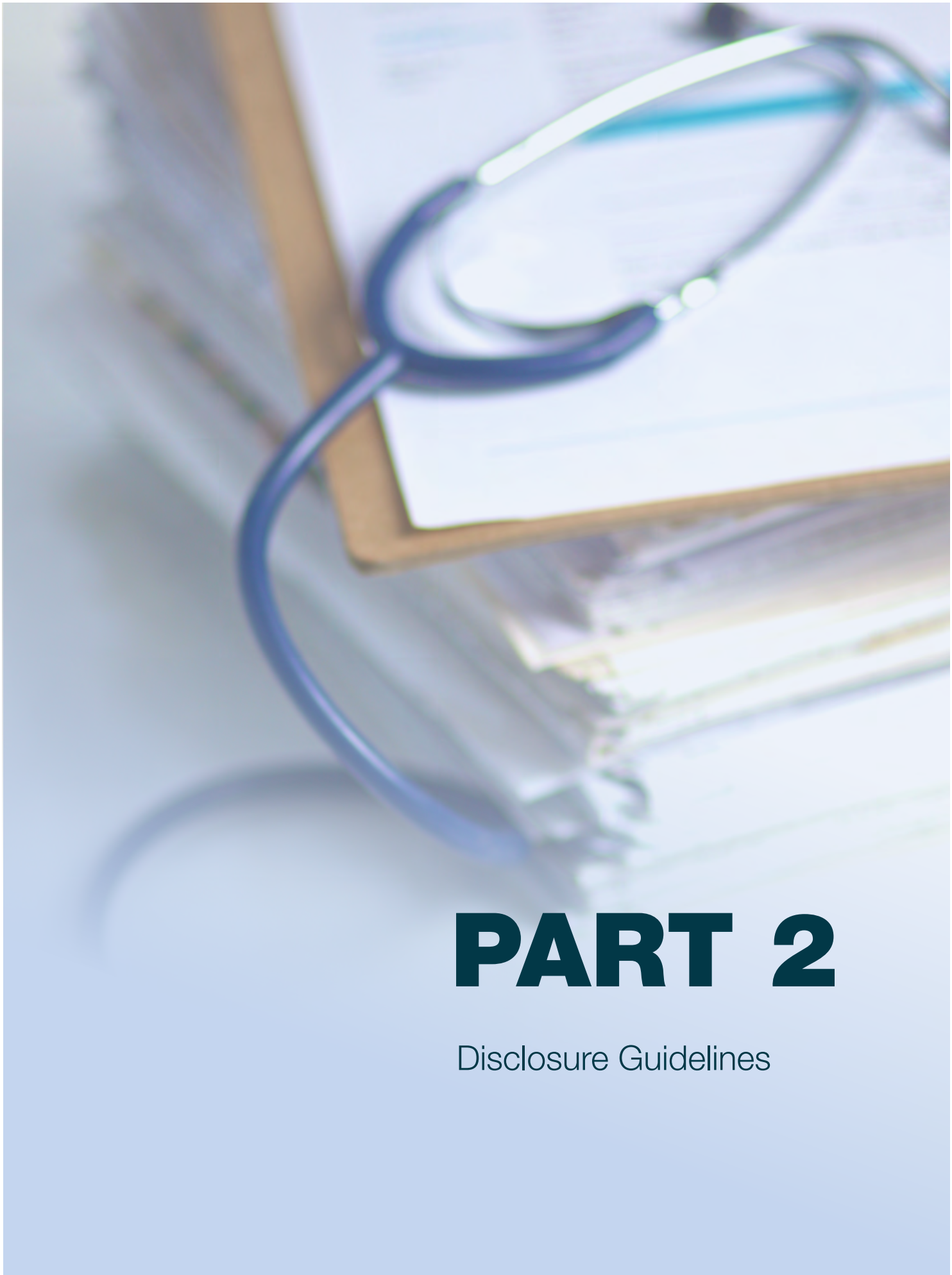
Demonstration Products are not intended for clinical use in any patient care nor are they intended for on-sale or other transfer. Member Companies shall clearly record in the Member Company's records as well as clearly disclose to Healthcare Professionals and/or Healthcare Organisations the no-charge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

03. Samples

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

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

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



PART 2

Disclosure Guidelines

Preamble

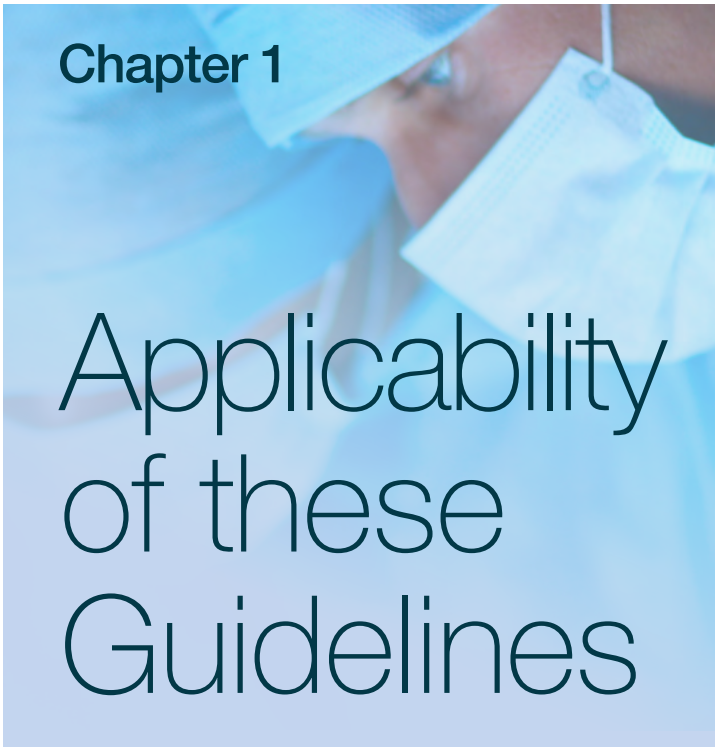
Under the Irish Medtech Association Code of Ethical Business Practice (the "Code"), Member Companies are not permitted to pay registration fees, travel or hospitality expenses directly to individual Healthcare Professionals for their participation in educational conferences organised by third-parties 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 3 of Chapter 4 of the Code states that Member Companies shall document and publicly disclose all Educational Grants in accordance with these Disclosure Guidelines. These Disclosure Guidelines are therefore an integral part of the Code, and need to be interpreted as such.

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

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



Chapter 1

Applicability of these Guidelines

01. 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 3 of the Code) and that consequently cannot be allocated to any of the categories set forth in Section 2.2 Aggregate Disclosure are not within the scope of these Disclosure Guidelines.

02. 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

3 of the Code) equivalent to the ones imposed by these Disclosure Guidelines.

3. 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[2].

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

A1: Yes. Educational Grants made by Affiliates (parent companies are included in the definition of Affiliates to the effect of the Disclosure Guidelines) incorporated outside of 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.

2. 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.

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

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

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

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

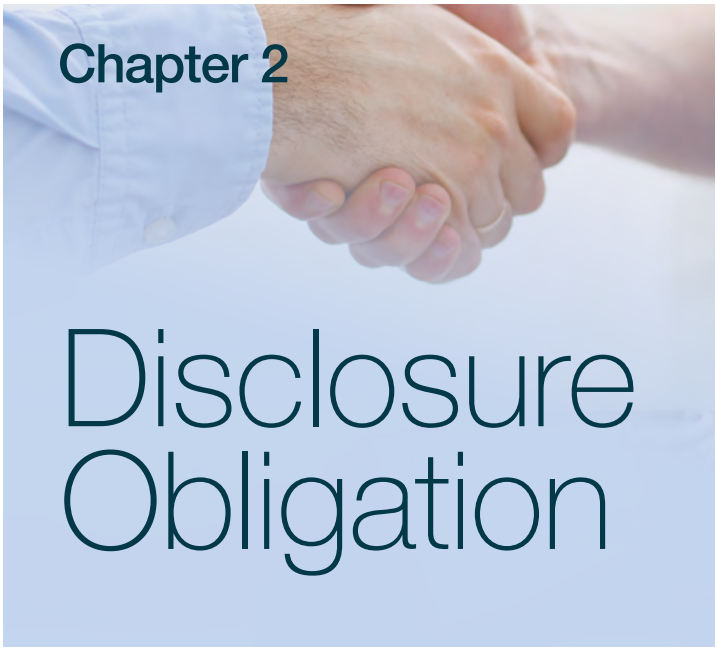
Corporate Members who are bound by this national code may choose either:
– To disclose only on the national platform or
– To disclose both on the MedTech Europe platform and the national platform.
This selected option shall be included in the Methodology Note.

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?

A4: 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 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



Chapter 2

Disclosure Obligation

01. General Obligation

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

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 MedTech Europe Geographic Area.

02. 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 Period3 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).

03. Optional Object Specification

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

04. Methodology

Each Member Company shall create a note summarising the methodologies used by it in preparing the disclosures

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

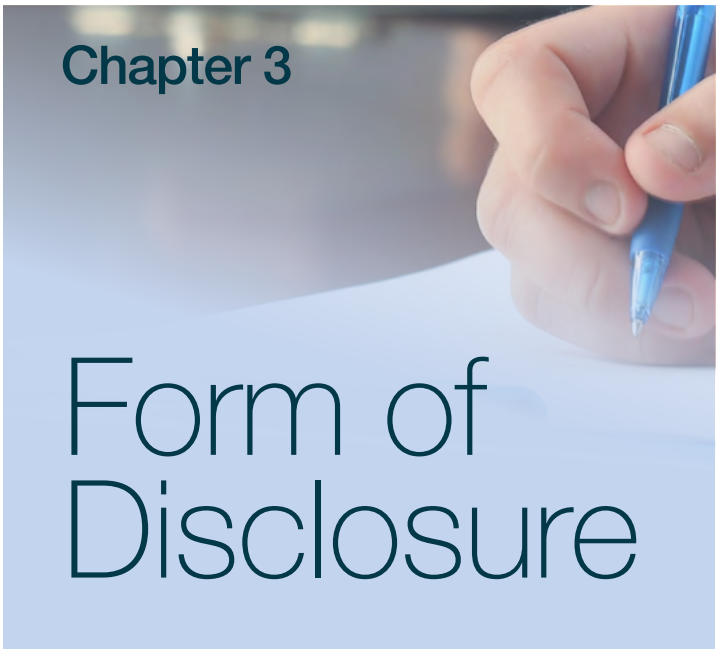
Q5: Which Affiliate should disclose a particular Educational Grant?

A5: 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.

Q6: When should a Methodology Note be made available?

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



Chapter 3

Form of Disclosure

01. Reporting Period

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

02. Time of Disclosure

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

03. Time of Publication

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

04. 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.

05. Disclosure Platform

Disclosures shall be made on the EthicalMedTech website[4] unless the Member Company is already bound by national laws, regulations or professional codes as regulated in Section 1.2 Applicability of these Disclosure Guidelines.
Member Companies will remain liable for the accuracy of the disclosed data. For the avoidance of doubt, neither the Irish Medtech Association nor 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.

4. www.ethicalmedtech.org

06. Disclosures Retention and Modification

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.

07. 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.

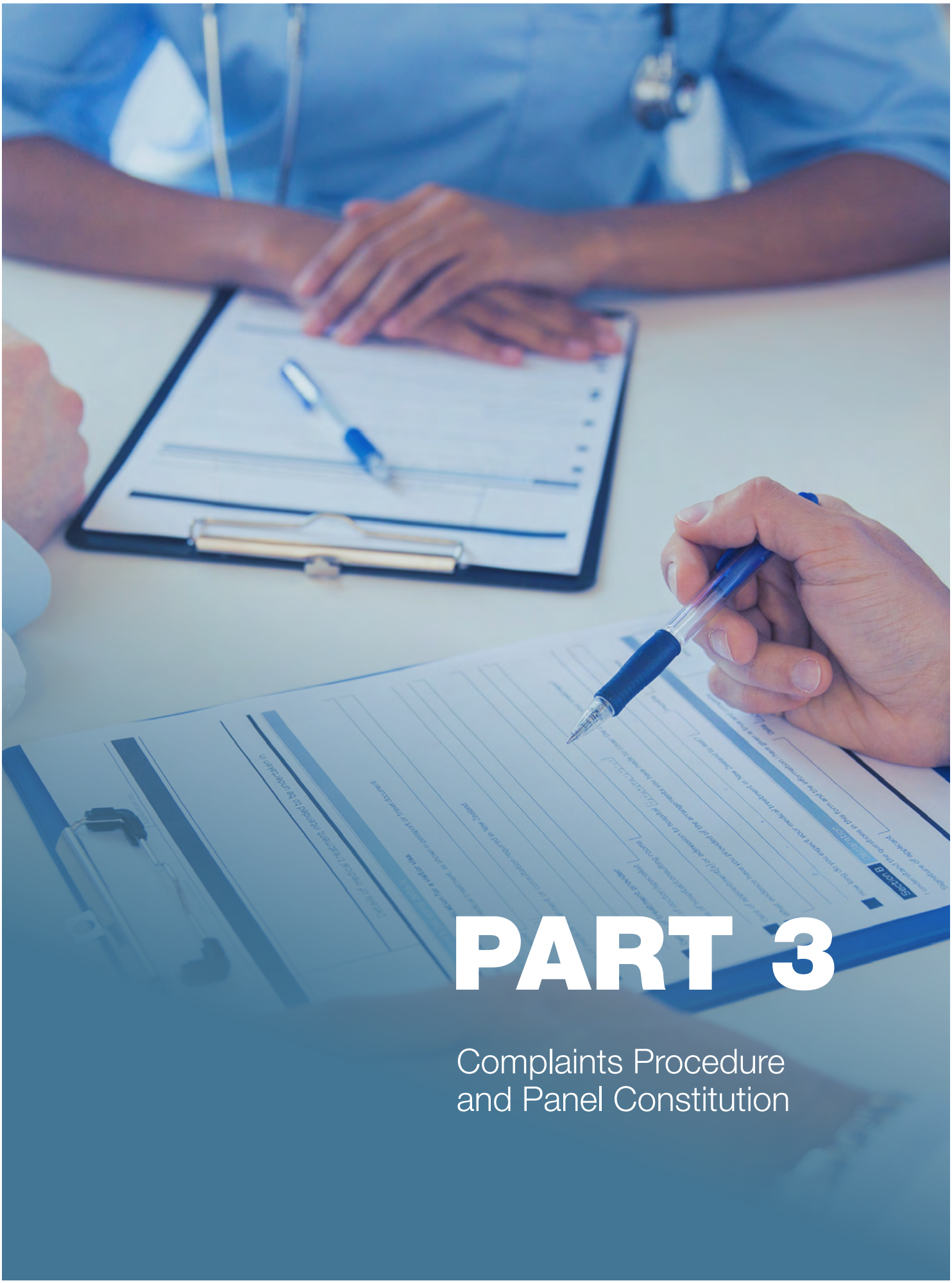
Member Companies shall make available to Healthcare Organisations upon request any data concerning their common contractual relations published in accordance with these Disclosure Guidelines at any time while the dis-closed information remains in the public domain as stated in Section 3.3 Time of Publication.

Q7: When will the first Reporting Period start?

A7: The first Reporting Period is the calendar year 2018, starting on the 1st January 2018, and ending on 31st December 2018.

Q8: In what currency should the amounts payed be disclosed?

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



PART 3

Complaints Procedure and Panel Constitution

Revised: [December 2017][1]

To be read in conjunction with the Irish Medtech Association Code of Ethical Business Practice
(Guidelines on Interactions with Health Care Professionals)

CONTENTS

1. Introduction

A Code of Ethical Business Practice ("the Code") has been adopted by the Irish Medtech Association. Compliance with the Code and with this Complaints Procedure and Panel Constitution ("the Procedure") is mandatory for members of the Irish Medtech Association. Anyone (individuals and non-member companies) can submit a complaint against a member company of the Irish Medtech Association, 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 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 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.

2. Structure and Responsibilities

Role of the Panel

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

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

1. To be finalised

2.3 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 the Irish Medtech Association.

The Panel – Constitution and Procedure

2.4 The Panel is appointed yearly by a majority vote at the Irish Medtech Association AGM (upon nomination by the Board of the Irish Medtech Association) 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 Association Code of Ethical Business Practice website.

2.5 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 2.4 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.

2.6 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).

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

2.8 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.

2.9 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 the Irish Medtech Association will appoint another member of the Panel to act in the role of Chairman.

2.10 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 the Irish Medtech Association.

2.11 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.

2.12 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.

2.13 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.

3. Complaints Procedure

Action on Complaints

3.1. 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 3.2 below with the Respondent and, if necessary, enter into mediation. Mediation 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 mediation has been undertaken.

3.2. 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.

3.3. 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.

3.4. 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 3.2 above and/or mediation in accordance with paragraph 3.3 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).

3.5. 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.

3.6. Any individual or company making a complaint under the Procedure that is not a member of the Irish Medtech Association 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.

3.7. Three hard copies of the complaint (draft template available online www.irishmedtechassoc.ie/ethics[2]) to be dealt with by the Panel shall be submitted in writing, in English and in hard copy to the Panel Administrator (at Irish Medtech Association Code of Ethical Business Practice Panel Administrator, Irish Medtech Association, Ibec, 84-86 Lower Baggot Street, Dublin 2), by way of registered post and shall include at a minimum:-

- the name in full, description and address of the Complainant and Respondent;
- proof of compliance with paragraph's 3.1 to 3.3 or if applicable, paragraph 3.5 above;
- detailed description of the nature and circumstances of the dispute giving rise to the complaint(s);
- 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);
- detailed reasoning explaining the nature of the alleged infringement;
- 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
- supporting documentary evidence.

3.8. 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.

3.9. The Chairman shall undertake an initial review of the complaint and will determine (if appropriate, in consultation with the Complainant and/or Respondent)

2. Check before finalising.

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 paragraph's 5.6 and 5.7 below.

3.10. 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 the Irish Medtech Association shall be so advised. The Chairman's decision in this regard shall be final.

3.11. 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.

3.12. 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.

3.13. 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.

3.14. 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.

3.15. 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 3.9 above.

3.16. 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.

4. Panel Rulings

4.1. 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 the Irish Medtech Association 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.

4.2. 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.

4.3. 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 the Irish Medtech Association of such ruling in writing and give their reasons for the ruling.

4.4. 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:

- issue a formal letter of reprimand to the member company;
- issue a formal letter of reprimand to the member company and also direct the Board of the Irish Medtech Association to suspend that member company from membership of the Irish Medtech Association for a specified period and/or to impose conditions for readmission;
- request the Board of the Irish Medtech Association to expel the offender from the Association.

4.5 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 the Irish Medtech Association of the imposition by it of any sanction under the Code.

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

5. General Provisions

Amendments to Time Periods

5.1. 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.

Withdrawal of Complaints

5.2. 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.

Charges

5.3. The administrative charge referred to in paragraph 4.1 above is determined by the Chairman based on the costs of formally convening the Panel and in dealing with the complaint.

5.4. 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.

5.5. Failure to pay any of the administrative charges must be reported by the Panel Administrator, to the Board of the Irish Medtech Association.

Anonymous Complaints

5.6. 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 3.8 to 3.16 will also apply to anonymous complaints.

5.7. The Chairman will consider the following factors when determining whether to accept an anonymous complaint:

- the significance/seriousness of the complaint;
- whether sufficient information has been provided to assess the anonymous complaint and respond appropriately;
- the potential to obtain independent information; and
- the potential for ongoing risk if the anonymous complaint is not assessed.

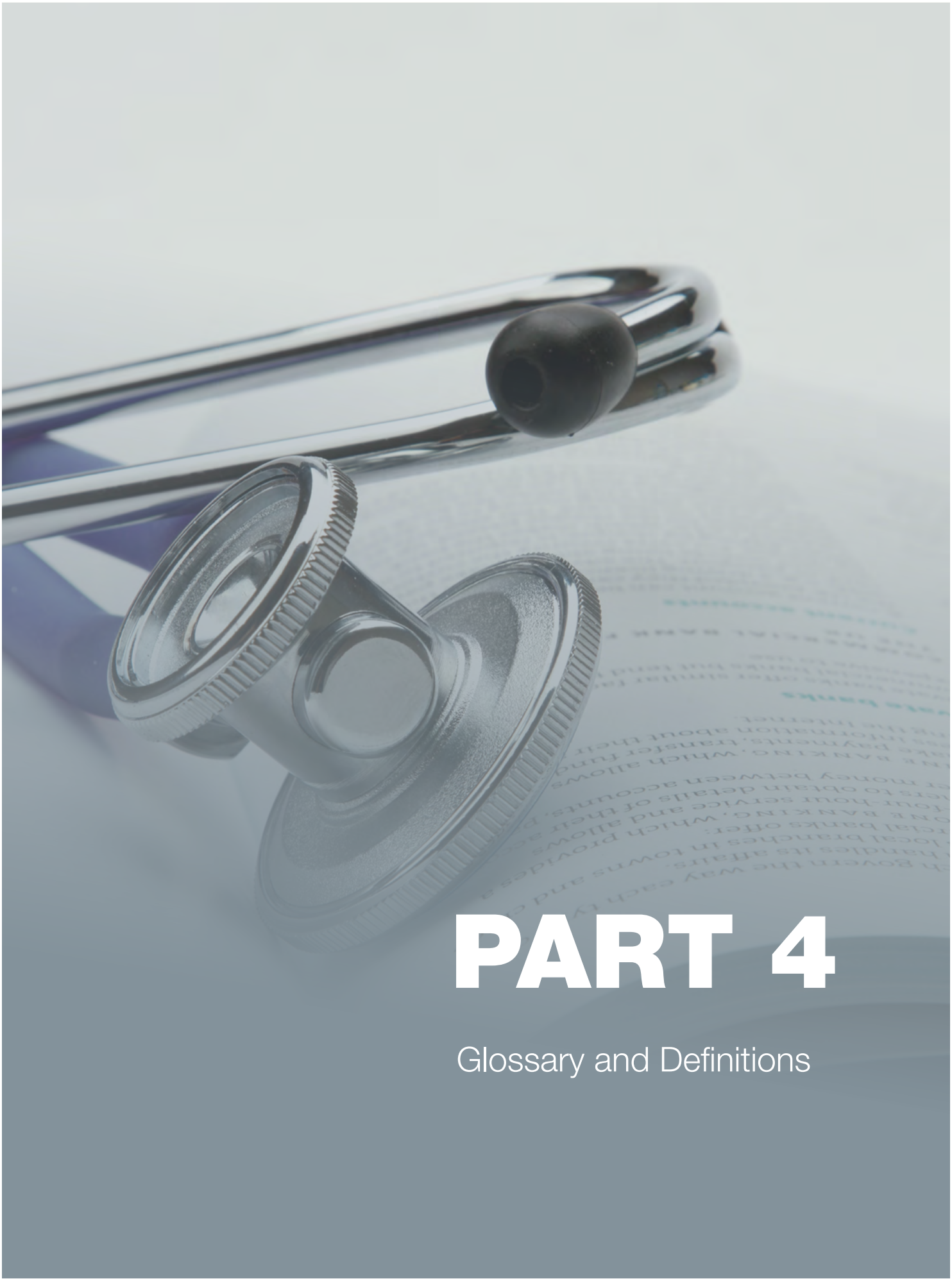
5.8. Anonymous Complainants do not have the right to challenge the outcome of either the Chairman or the Panel's decision or be kept informed of the progress of the Complaint.

Amendments to the Code and the Procedure and Governing Law

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

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

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



PART 4

Glossary and Definitions

Charitable Donations: means provision of cash, equipment, company product or relevant Third Party product, for exclusive use for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause. Charitable Donations may only be made on an unrestricted basis and to bona fide charities or other non-profit entities or bodies whose main objects are genuine charitable or philanthropic purposes.

Company Events: means activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of Member Companies to fulfil a legitimate, documented business need of the Member Company, including but not limited to a legitimate business need to interact with customers including Healthcare Professionals and/or Healthcare Organisations.

Conference Vetting System (CVS): means the centralised decision-making process which reviews the compliance of Third Party Organised Educational Events with the Code and which is managed independently of MedTech Europe under the supervision of the MedTech Europe Compliance Panel. For more information see: http://www.ethicalmedtech.eu.

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

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 be- half of a Member Company to HCOs or HCPs, who are equipped and qualified to use them. Demos are supplied solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use. Demos do not include the following:

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

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

Employer Notification: means the prior written notification provided to a Healthcare Organisation (e.g. hospital administra- tion), 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 health- care institution by or on behalf of a Member Company for purposes of obtaining defined, evaluative user feedback over a defined period of use when used within the scope of their intended purpose, as per the authorisation in the country where the supply occurs. Evaluation Products do not include the following:

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

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

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

Financial Hardship: means in relation to a Healthcare Organisation extreme and unavoidable financial distress resulting from matters outside the Healthcare Organisation's control where the Healthcare Organisation is unable to operate and where patient care is consequently jeopardised. Financial distress resulting in whole or in part from mismanagement of the Healthcare Organisa- tion'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 -in- stitution or learned or professional society (except for patient organisations); or through which one or more Healthcare -Profes- sionals provide services.

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

Members: means all member companies of the Irish Medtech Association.

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

Product and Procedure Training and Education Event: means a type of Company Event that is primarily intended to provide Healthcare Professionals with genuine education, including information and/or training on:

- The safe and effective use of medical technologies, therapies and/or related services, and/or
- The safe and effective performance of clinical procedures, and/or
- Related disease areas.

In all cases the information and/or training directly concern a Member Company's medical technologies, therapies and/or related services.

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

Sales, Promotional and Other Business Meetings: means any type of Company Event the objective of which is to effect the sale and/or promotion of a Members Company's medical technologies and/or related services, including meetings to discuss product features, benefits and use and/or commercial terms of supply.

Samples: means single-use or multiple-use products provided free of charge by or on behalf of a Member Company to HCOs or HCPs who are equipped and qualified to use them in order to enable HCPs to familiarise themselves with the products in clinical use. Samples do not include the following:

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

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

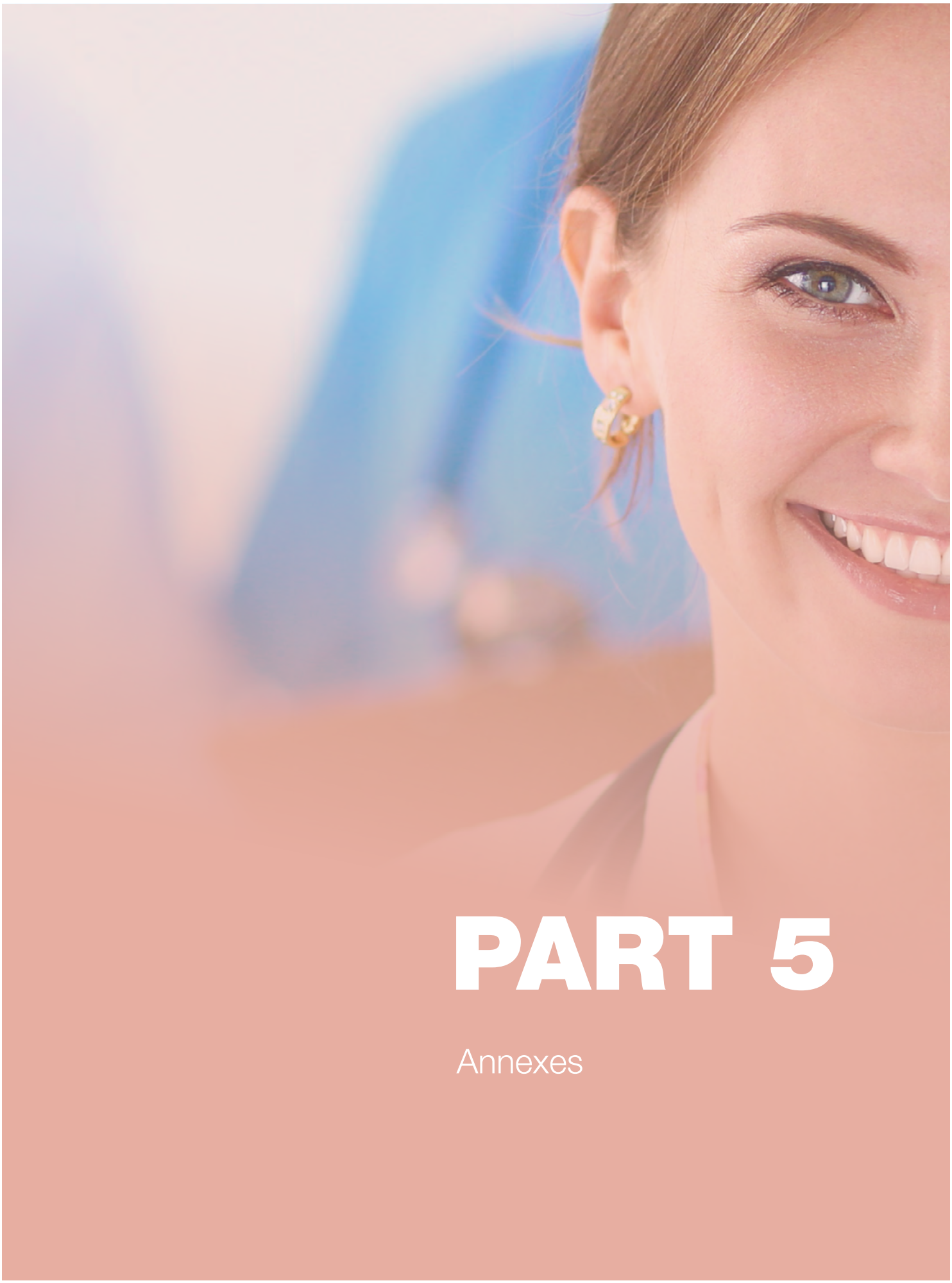
Third Party Organised Educational Events: means activities of any type that are planned, budgeted, managed and ex- ecuted in whole or in part by or on behalf of a person or entity other than a Member Company to fulfil Healthcare Professional medical educational needs.

Third Party Organised Educational Conferences: means a type of Third Party Organised Educational Event that is a genuine, independent, educational, scientific, or policy-making conference organised to promote scientific knowledge, medical advancement and/or the delivery of effective healthcare and are consistent with relevant guidelines established by professional societies or organisations for such educational meetings. These typically include conferences organised by national, regional, or specialty medical associations/societies, hospitals, Professional Conference Organisers (PCOs), patients organisations or accredited -continuing medical education providers.

Third Party Organised Procedure Training: means a type of Third Party Organised Educational Event that is primarily in- tended 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.



PART 5

Annexes

ANNEX I (added in October 2016)

CVS scope: When are CVS assessments required?

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 **MedTech Europe** Geographic Area[1],[2])	**INTERNATIONAL** (Third Party Organised Professionals registered and practising in the **MedTech Europe** Geographic Area[3])	**INTERNATIONAL** (Third Party Organised Educational Events to which no Healthcare Professionals registered and practicing in the **MedTech Europe** Geographic Area attend, neither as speakers or delegates)
EDUCATIONAL GRANTS[4] PROVIDED	Educational Grant to support the general running of a conference	2017 – Allowed[5] 2018 – Allowed	2017 – Allowed. Not subject to CVS decision 2018 – Subject to CVS decision	2017 – Allowed. Not subject to CVS decision 2018 – Allowed. Subject to CVS decision	Out of scope of the application of the Code[6]
TO SUPPORT A THIRD PARTY ORGANISED CONFERENCE	Educational Grants that includes funds to support HCP attendance to the conference	2017 – Allowed 2018 – Allowed	2017 – Allowed. Not subject to CVS decision 2018 – Subject to CVS decision	2017 – Allowed. Not subject to CVS decision 2018 – Allowed. Subject to CVS decision	N/A
	Educational Grants that includes funds to support Faculty	2017 – Allowed 2018 – Allowed	2017 – Allowed. Not subject to CVS decision 2018 – Subject to CVS decision	2017 – Allowed. Not subject to CVS decision 2018 – Allowed.	N/A
	Consultancy agreement for speakers in satellite symposia	2017 – Allowed 2018 – Allowed	2017 – Allowed.Not subject to CVS decision 2018 – Subject to CVS decision	Not subject to CVS decision 2017 – Allowed. Not subject to CVS decision	N/A
COMMERCIAL ACTIVITIES	Booths/ advertising	2017 – Allowed 2018 – Allowed	2017 – Allowed. Not subject to CVS decision 2018 – Subject to CVS decision	2018 – Allowed. Not subject to CVS decision	Out of scope of the application of the Code
	Direct sponsorship of HCPs as delegates (passive participation)	2017 – Allowed 2018 – Not allowed	2017 – Subject to CVS decision 2018 – Not allowed	Not subject to CVS decision 2018 – Allowed. Not subject to CVS decision	N/A
DIRECT SPONSORSHIP OF HCPs REGISTERED AND PRACTISING IN the **MedTech** Geographic Area	Direct sponsorship of HCPs as Faculty (active participation)	2017 – Allowed. 2018 – Not allowed	2017 – Allowed. Not subject to CVS decision[7] 2018 – Not allowed	2017 – Subject to CVS decision 2018 – Not allowed	N/A
				2017 – Allowed. Not subject to CVS decision 2018 – Not allowed	

1. **MedTech Europe** Geographic Area includes the countries in the European Economic Area (EEA), as well as those other countries where Member Associations are located.
2. Formerly referred to as "Cross-border Events".
3. For avoidance of doubt, in 2018, this category of "Third Party Organised Educational Events attended by delegates who are Healthcare Professionals registered and practicing in the **MedTech Europe** Geographic Area" has to be understood as covering only Healthcare Professionals from the **MedTech Europe** Geographic Area benefiting from an Educational Grant.
4. Educational Grants: means provision of funding, Member Company or third party products or other in kind support to a Healthcare Organisation by or on behalf of a Member Company on a restricted basis for use solely for the support and the advancement of genuine medical education of Healthcare Professionals, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved.
5. Allowed means no CVS decision is required but the provisions of the **MedTech Europe** Code of Ethical Business Practice and national laws and regulations still apply.
6. Out of scope: Means the Code does not apply given that the situation does neither involve a Member Company interacting with an HCP or HCO registered and practicing in the **MedTech Europe** Geographic Area nor does the activity take place in the **MedTech Europe** Geographic Area.
7. Please note that although international/cross-border Events are eligible to be submitted in CVS, the decisions rendered by CVS in 2017 will only pertain to the direct sponsorship of HCPs to Third-Party Organised Events.

ANNEX II (added in May 2016)

Disclosure Guidelines Template Example*

Full HCO Name	HCO/PCO 1	HCO/PCO 2	etc.
HCOs: city where registered			
Country of Principal Practice / Activity			
Registered Address			
Unique country local identifier			
A. Educational Grants to Support Third Party Organised Events /or to Support HCP Participation at Third Party Organised Educational Events)	Yearly amount	Yearly amount	Yearly amount
Object (Optional)	Optional	Optional	Optional
B. Other Educational Grants to HCOs (including Scholarships, Fellowships and Grants for Public Awareness Campaigns).	Yearly amount	Yearly amount	Yearly amount
Object (Optional)	Optional	Optional	Optional

* Please note that this template is for illustrative purposes only. The template to be used for reporting purposes is available in the Transparent **MedTech** website.

ANNEX III (added in May 2016)

Example of Disclosure Guidelines Methodology Note

STRUCTURE

1 - Introduction

2 - Executive summary of the methodologies used for disclosure purposes and countries specificities

3 - Definitions
- Recipients
- Types of Educational Grants

4 - Disclosure scope and timelines

5 - Disclosures in case of partial performance or cancellation

6 - Cross-border activities

7 - Specific considerations:
- Multi-year agreements
- Consent management (please note that some jurisdictions may require the legal entity's consent for publication of data)
- Consent collection
- Management of recipient consent withdrawal
- Management of recipient's request
- Partial consent

8 - Disclosure Form
- Date of submission
- Currency in case of aggregated payments made in different currencies
- VAT included or excluded and any other tax aspects

9 - Disclosure financial data and amount of Educational Grants provided

10 - 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 it complies with the general requirements set out in Section 2.4 Methodology.

ANNEX IV (added in November 2016)

MedTech Europe Geographical Area

The MedTech Europe Geographic Area currently includes

D) countries with National Associations:

- Austria,
- Belgium,
- Bulgaria,
- Czech Republic
- Denmark
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- the countries where Mecomed is active
- The Netherlands
- Norway
- Poland
- Portugal
- Romania
- Russia
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Turkey
- The United Kingdom

E) countries party to the European Economic Area agreement without a MedTech Europe National Association:

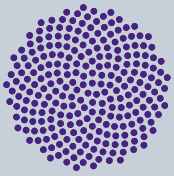
- Croatia
- Cyprus
- Estonia
- Iceland
- Latvia
- Liechtenstein
- Lithuania
- Luxembourg
- Malta.

3OHDVH QRWH WKDW Fountries covered by Mecomed, the Middle East Medical Devices and Diagnostics association, are not currently under the scope of the Disclosure Guidelines.

Notes

Notes

Notes



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