MedTech Europe Code of Ethical Business Practice

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Contents

INTRODUCTION

Promoting an Ethical Industry

MedTech Europe represents the medical technology industry in Europe and is an alliance of European medical technology industry associations. The alliance was founded in October 2012 and currently has two members being the European Diagnostic Manufacturers' Association (EDMA), representing the European in vitro diagnostic industry, and Eucomed, representing the European medical devices industry. Our mission is to promote a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of its stakeholders.

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

The Code sets out the minimum standards appropriate to the various types of activities carried out by the Members. The Code is not intended to supplant or supersede national laws or regulations or professional codes (including company codes) that may impose more stringent requirements upon Members and all Members should independently ascertain that their activities comply with all current national and local laws, regulations and professional codes.

Furthermore, Member Companies must be mindful of the fact that they may be liable for the activities of third party intermediaries who interact with Healthcare Professionals or Healthcare Organisations in connection with the sale, promotion or other activity involving Member Companies' products. Accordingly, it is recommended that where such arrangements are entered into, the relevant contractual documentation impose obligations upon the third party (for example, third party sales & marketing intermediaries (SMIs), consultants, distributors, sales agents, marketing agents, brokers, commissionaire commercial agents and independent sales representatives) to comply with provisions set out in the Code or equivalent guidelines[1].

Key Legislation

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

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

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

National and European Union (EU) competition legislation applies not only to Members in their business operations, but also to MedTech Europe, each of the alliance's working groups and any sub-group within the associations, irrespective of size and name. Liability under competition laws may be strict and a Member may become liable for the infringement of such laws by other Members of an association group in which it participates. Accordingly, Members must make every effort to observe EU and national competition laws in all their interactions.

Aims and Principles of the Code

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

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

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

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

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

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

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

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

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

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

Interpreting the Code

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

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

Administering the Code

The Code operates within a Procedural Framework which includes procedures designed to provide an effective and efficient complaint-handling process, at national and European level, to ensure compliance with the Code. MedTech Europe's dispute handling system is based on the principle that disputes are generally national in nature and are therefore best resolved at national level. For complaints between Member Companies, mediation should be considered seriously before further pursuit of the matter via any formal complaint handling process, either at national or MedTech Europe level.

The principles outlined in the Procedural Framework aim at supporting Member Associations when setting up or amending their national dispute-resolution mechanisms. They are based on principles of proportionality, speed, due process, fairness and transparency and have been established under the guidance of the MedTech Europe Compliance Panel, acting independently of MedTech Europe.

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

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

Implementation and Transition Period

This edition of the Code comes into force as follows:

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

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

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

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

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

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

Chapter 1: General Criteria for Events

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

1. Event Programme

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

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

2. Event Location and Venue

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

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

3. Guests

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

4. Reasonable Hospitality

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

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

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

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

5. Travel

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

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

6. Transparency

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

Chapter 2: Third Party Organised Educational Events

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

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

1. Third Party Organised Educational Conferences

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

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

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

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

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

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

[2] For scope of application of CVS please refer to: http://www.ethicalmedtech.eu

2. Third Party Organised Procedure Training

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

- Financial support must comply with the criteria provided in *Chapter 1: General Criteria for Events*. Member Companies may therefore pay travel, hospitality and the registration fee.
- Where applicable, the Third Party Organised Procedure Training has approval via the Conference Vetting System (see the Glossary)[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. Transition Period: Support of Individual Healthcare Professionals to Third Party Organised Educational Events

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

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

Chapter 3: Company Events

1. General Principles

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

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

[3] For scope of application of CVS please refer to: http://www.ethicalmedtech.eu

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.

2. Product and Procedure Training and Education Events

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

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

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.

Chapter 4: Grants and Charitable Donations

1. General Principles

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

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

employee or officer of the qualifying organisation or entity and submits the request in writing on behalf of the qualifying organisation or entity.

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

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

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

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

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

2. Charitable Donations

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

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

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

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

3. Educational Grants

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

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

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

a. <u>Support for Third Party Organised Educational Events:</u>

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]

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.

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

2) Support for Third Party Organised Educational Events:

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

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

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

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

Member Companies providing Research Grants shall ensure that they do not influence the research. However, in order to ensure that Research Grants are provided on a “restricted” basis, Member Companies shall clarify the intended research scope and purposes for which the Grant is requested and shall ensure

that the written Grant agreement with the recipient organisation includes rights for the Member Company to verify that the Grant is applied solely for the agreed intended research use. Such verification may include a request for study-related documentation, such as a copy of the research protocol, a copy of the ethics committee and/or regulatory approvals or a copy of the study report upon completion or earlier termination of the research.

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

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

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

Chapter 5: Arrangements with Consultants

1. General Principles

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

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

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

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

2. Criteria for genuine consulting arrangements

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

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

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

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

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

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

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

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

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

3. Remuneration and Fair Market Value

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

All payments made for services must comply with all applicable tax and other legal requirements. Member Companies may pay for expenses reasonably incurred by consultants in providing the services which are the subject of the consulting agreement including reasonable travel, meals and accommodation expenses

incurred by consultants if attending meetings with, or on behalf of Member Companies. The written consulting agreement must detail which expenses can be claimed by the consultant in relation to the provision of the services and the basis for payment of these by the Member Company.

4. Disclosure and Transparency

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

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

Chapter 6: Research

1. Member Company-Initiated Research

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

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

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

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

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

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

2. Member Company Post-Market Product Evaluation

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

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

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

3. Third Party-Initiated Research

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

Chapter 7: Royalties

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

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

Arrangements involving the payment of royalties by or on behalf of Member Companies to a Healthcare Professional must be set out in a written agreement providing appropriate and reasonable remuneration in accordance with applicable laws and regulations. For example, royalties paid in exchange for intellectual property should not be conditional on:

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

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

Chapter 8: Educational Items and Gifts

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

a. Educational items and/or gifts may be provided but these must relate to the Healthcare Professional's practice, or benefit patients, or serve a genuine educational function.
b. No educational items and/or gifts should be provided in response to requests made by Healthcare Professionals.
c. Educational items and/or gifts must not be given in the form of cash or cash equivalents.
d. Educational items and/or gifts must be modest in value, and can be branded or non-branded items.
e. A Member Company may occasionally provide educational items of greater value to a Healthcare Organisation always provided that the item serves a genuine educational function for the Healthcare Professionals at that Healthcare Organisation and is of benefit to patients. Such items shall not be provided to Healthcare Professionals for their personal use. The item shall also be related to the therapeutic areas in which the Member Company is interested and/or involved. For higher value educational items, Member Companies must maintain appropriate records of their provision of such educational items to Healthcare Organisations. Such items should not be part of the Healthcare Organisation's normal overheads or routine costs of operation.
f. Provision of educational items and/or gifts must not improperly reward, incentivise and/or encourage Healthcare Professionals to purchase, lease, recommend, prescribe, use, supply or procure the Member Company's products or services.

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

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

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

Chapter 9: Demonstration Products and Samples

1. General Principles

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

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

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

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

This Chapter is limited to the provision of Demonstration Products and/or Samples and related services at no charge and is not intended to apply to provision of products or related services under any other arrangements, for example (but not limited to) provision within the framework for clinical trials and/or other research or commercial supplies by way of rebates or pricing incentives in a public procurement context.

2. Demonstration Products (Demos)

Member Companies may provide examples of their products to Healthcare Professionals and/or Healthcare Organisations in the form of mock-ups (such as unsterilised single use products) that are used for Healthcare Professionals and patient awareness, education and training. For example, a Healthcare Professional may use a Demonstration Product to show a patient the type of technology which will be implanted in the patient or may use the Demo to train other Healthcare Professionals in the use of the product.

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

3. Samples

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

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

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

PART 2: Dispute Resolution Principles

2.1 **General framework:** The principles set out below are intended to design an effective and efficient complaint-handling process, the object of which is to ensure compliance with the Code and the codes of conduct adopted by the Member Associations. It is based on principles of proportionality, speed, due process, fairness and transparency.

Based on these dispute resolution principles, the MedTech Europe Code Committee in consultation with the MedTech Europe Compliance Network shall draft a Procedural Framework and submit it for the approval of the MedTech Europe Board before 1 January 2017. The existing Eucomed Procedural Framework dated 14 April 2014 and the EDMA dispute resolution principles laid down in Part D of EDMA Code of Ethics dated 2007 shall apply to the existing Eucomed and EDMA Codes until a new MedTech Europe Procedural Framework is approved by the MedTech Europe Board.

2.2 **Transposition obligations:**

- Member Companies shall transpose the Code internally between 1 January 2016 and 31 December 2016 at the latest. No later than 1 January 2018, Member Companies shall cease direct financial and in kind support to individual HCPs to cover the costs of their attendance at Third Party Organised Educational Events. For the avoidance of doubt, the provisions linked to the Transition Period will be transposed as provided in the Code. As soon as a Member Company transposes the Code internally is shall immediately notify the MedTech Europe Secretariat, specifying the date on which such transposition became effective. As soon as a Member Company ceases direct financial and in kind support to individual HCPs to cover the cost of their attendance at Third Party Organised Educational Events, it shall immediately notify the MedTech Europe Secretariat, specifying the date on which such cessation became effective. The MedTech Europe Secretariat shall appropriately document and maintain records of all such notifications.

- Member Associations shall transpose the Code at the national level by 1 January 2020 in accordance with the Memorandum of Understanding dated September 2015. In particular, on 1 January 2017 each Member Association shall submit to the MedTech Europe Board its strategy and action plan on how the Member Association plans to transpose the Code in its country, including plan, timelines, and main milestones as well as strategy as to how enforcement of the Code will be addressed during the transition period as well as after 2020 by a national panel. The Procedural Framework shall outline principles aimed at supporting Member Associations when setting up or amending its national dispute resolution mechanisms.

2.3 **Competent bodies:**

- The MedTech Europe Code Committee shall assist Members to comply with their obligations under the Code, provide and develop guidance on the Code, including the dispute resolution principles set out in the Procedural Framework. In particular, the MedTech Europe Code Committee shall monitor the adoption of compliant national codes, including preparation of updates to the MedTech Europe Board and assist Members to share best practice and harmonized interpretation

of the Code and the dispute resolution principles set out in the Procedural Framework.

- The MedTech Europe Compliance Panel shall ensure the effective and efficient complaint handling process on the Code. As such, it may render decisions directly on complaints and disputes on the Code, as first and last instance in accordance with the Procedural Framework, including but not limited to cases where the Code has not been transposed appropriately by a Member Association nationally or when the dispute is of cross-border nature. In addition, the MedTech Europe Compliance Panel will also be in charge of providing guidance to Member Associations on the dispute resolution principles set out in the Procedural Framework as well as supervision of the Conference Vetting System and other tasks laid down in the Procedural Framework.

  The MedTech Europe Compliance Panel will be composed of at least three individuals. These shall include not only persons having industry experience but also for obvious reasons of independence, transparency and expertise, persons whose knowledge will contribute to the proper functioning of the MedTech Europe Compliance Panel, such as other relevant stakeholders. The term of office of the MedTech Europe Compliance Panel members will be three years, renewable twice.

2.4 **Applicability of the Code**: Member Companies must comply with the Code as a minimum standard when:

a. Member Companies interact with Healthcare Professionals and Healthcare Organisations registered and practising in MedTech Europe Geographic Area irrespective of where the activity takes place; and/or

b. Activities take place in MedTech Europe Geographic Area, irrespective of where Healthcare Professionals and Healthcare Organisations are registered and practicing.

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

2.5 **Procedural Principles**: MedTech Europe's dispute resolution system is based on the principle that disputes are generally national in nature and are therefore best resolved at national level. Nevertheless, in certain cases, adjudication of complaints that fall within the scope of the Procedural Framework shall be a matter solely for the MedTech Europe Compliance Panel.

For complaints between Member Companies, mediation shall be considered seriously before further pursuit of the matter via any formal complaint handling process, either at national or MedTech Europe level.

The MedTech Europe Compliance Panel or national panels shall act impartially and shall respect fair procedure rules allowing all parties to be heard fairly.

Where the MedTech Europe Compliance Panel or national panel rules that there is a breach of the Code, the MedTech Europe Compliance Panel or national panel shall advise the Complainant and the Respondent of such in writing and give the reason for reaching this decision. At the discretion of the MedTech Europe Compliance Panel or national panel, sanctions may be imposed. Such

sanctions must be proportionate to the infringement, predictable and shall be listed in the Procedural Framework.

PART 3: Glossary and Definitions

- **Charitable Donations**: means provision of cash, equipment, company product or relevant Third Party product, for exclusive use for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause. Charitable Donations may only be made on an unrestricted basis and to *bona fide* charities or other non-profit entities or bodies whose main objects are genuine charitable or philanthropic purposes.
- **Company Events:** means activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of Member Companies to fulfil a legitimate, documented business need of the Member Company, including but not limited to a legitimate business need to interact with customers including Healthcare Professionals and/or Healthcare Organisations.
- **Conference Vetting System (CVS):** means the centralised decision-making process which reviews the compliance of Third Party Organised Educational Events with the Code and which is managed independently of MedTech Europe under the supervision of the MedTech Europe Compliance Panel. For more information see: http://www.ethicalmedtech.eu.
- **Code:** means this MedTech Europe Code of Ethical Business Practice (including the incorporated Questions and Answers), the Disclosure Guidelines, the Procedural Framework and the Dispute Resolution Principles. For the avoidance of doubt the Dispute Resolution Principles shall be replaced by the Procedural Framework and shall cease to have effect once the MedTech Europe Board approves the Procedural Framework.
- **Disclosure Guidelines**: means the Code provisions setting out the public disclosure requirements under the Code.
- **Demonstration Products (Demos)**: means either single-use or multiple-use products provided free of charge by or on behalf of a Member Company to HCOs or HCPs, who are equipped and qualified to use them. Demos are supplied solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use. Demos do not include the following:
    - Samples;
    - Evaluation Products;
    - Products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant; or
    - Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.
- **Educational Grants**: means provision of funding, Member Company or third party products or other in kind support to a Healthcare Organisation by or on behalf of a Member Company on a restricted basis for use solely for the support and the advancement of genuine medical education of Healthcare Professionals, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved.
- **Employer Notification**: means the prior written notification provided to a Healthcare Organisation (e.g. hospital administration), a Healthcare Professional's superior or other locally-designated competent authority of any interaction, collaboration or other matter concerning any Member Company and any Healthcare Professional, the purpose and/or scope of which requires notification under this Code.

- **Entertainment:** Entertainment includes, but is not limited to, dancing or arrangements where live music is the main attraction, sight-seeing trips, theatre excursions, sporting events (e.g. skiing, golf or football match) and other leisure arrangements. For the avoidance of doubt, incidental, background music shall not constitute Entertainment.
- **Evaluation Products**: means either single-use or multiple-use products and/or equipment provided free of charge to a healthcare institution by or on behalf of a Member Company for purposes of obtaining defined, evaluative user feedback over a defined period of use when used within the scope of their intended purpose, as per the authorisation in the country where the supply occurs. Evaluation Products do not include the following:
    - Demos;
    - Samples;
    - Products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant; or
    - Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.
- **Event**: means either a Company Event or Third Party Organised Educational Event.
- **Faculty**: means a podium speaker, moderator and/or chair, who presents during a Third Party Organised Educational Event. Poster- and abstract-presenters are not considered to be Faculty.
- **Financial Hardship**: means in relation to a Healthcare Organisation extreme and unavoidable financial distress resulting from matters outside the Healthcare Organisation's control where the Healthcare Organisation is unable to operate and where patient care is consequently jeopardised. Financial distress resulting in whole or in part from mismanagement of the Healthcare Organisation's funds or other matters within its control is not considered to be financial hardship. Financial Hardship must be documented and objectively substantiated.
- **Grants**: means either an Educational Grant or a Research Grant, or both.
- **Guests**: means spouses, partners, family or guests of Healthcare Professionals, or any other person who does not have a *bona fide* professional interest in the information being shared at an Event.
- **Healthcare Organisation (HCO):** means any legal entity or body (irrespective of its legal or organisational form) that is a healthcare, medical or scientific association or organisation which may have a direct or indirect influence on the prescription, recommendation, purchase, order, supply, utilisation, sale or lease of medical technologies or related services such as a hospital or group purchasing organisation, clinic, laboratory, pharmacy, research institution, foundation, university or other teaching institution or learned or professional society (except for patient organisations); or through which one or more Healthcare Professionals provide services.
- **Healthcare Professional (HCP):** means any individual (with a clinical or non-clinical role; whether a government official, or employee or representative of a government agency or other public or private sector organisation; including but not limited to, physicians, nurses, technicians, laboratory scientists, researchers, research co-ordinators or procurement professionals) that in the course of their professional activities may directly or indirectly purchase, lease, recommend, administer, use, supply, procure or determine the purchase or lease of, or who may prescribe medical technologies or related services.
- **Members**: means all full and associate corporate members ("**Member Companies"**) of Eucomed and/or EDMA (or as applicable MedTech Europe) as well as full and associate national association members of Eucomed and/or EDMA (or as applicable MedTech Europe) ("**Member Associations"**),

as defined in the respective Eucomed, EDMA or MedTech Europe statutes, as applicable and as amended from time to time.

- **Professional Conference Organiser (PCO)**: a for-profit company or organisation which specialises in the management of congresses, conferences, seminars and similar events.
- **Product and Procedure Training and Education Event**: means a type of Company Event that is primarily intended to provide Healthcare Professionals with genuine education, including information and/or training on:
    - The safe and effective use of medical technologies, therapies and/or related services, and/or
    - The safe and effective performance of clinical procedures, and/or
    - Related disease areas.

  In all cases the information and/or training directly concern a Member Company's medical technologies, therapies and/or related services.
- **Research Grants**: means the provision by or on behalf of a Member Company of funding, products/equipment and/or in kind services to any organisation that conducts research which is made for the sole, restrictive purpose of supporting the development or furtherance of *bona fide*, scientifically valid and legitimate research by the recipient the purpose of which is to advance medical, scientific and healthcare knowledge, medical technologies and/or clinical techniques designed to improve patient outcomes.
- **Sales, Promotional and Other Business Meetings:** means any type of Company Event the objective of which is to effect the sale and/or promotion of a Members Company's medical technologies and/or related services, including meetings to discuss product features, benefits and use and/or commercial terms of supply.
- **Samples**: means single-use or multiple-use products provided free of charge by or on behalf of a Member Company to HCOs or HCPs who are equipped and qualified to use them in order to enable HCPs to familiarise themselves with the products in clinical use. Samples do not include the following:
    - Demos;
    - Evaluation Products;
    - products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant; or
    - products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.
- **Scholarships and Fellowships**: means Educational Grants provided to a Healthcare Organisation by or on behalf of a Member Company to support fellowships or scholarships offered by the Healthcare Organisation. Scholarships in this context means an Educational Grant provided to support a medical school undergraduate whereas a fellowship is a period of intensive training for post-graduate physicians in a chosen clinical sub-specialty (e.g. medical training after a residency). "Scholars" and "Fellows" shall be understood accordingly.
- **Third Party Organised Educational Events:** means activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of a person or entity other than a Member Company to fulfil Healthcare Professional medical educational needs.
- **Third Party Organised Educational Conferences:** means a type of Third Party Organised Educational Event that is a genuine, independent, educational, scientific, or policy-making

conference organised to promote scientific knowledge, medical advancement and/or the delivery of effective healthcare and are consistent with relevant guidelines established by professional societies or organisations for such educational meetings. These typically include conferences organised by national, regional, or specialty medical associations/societies, hospitals, Professional Conference Organisers (PCOs), patients organisations or accredited continuing medical education providers.

- **Third Party Organised Procedure Training***:* means a type of Third Party Organised Educational Event that is primarily intended to provide Healthcare Professionals with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:
    - Specific therapeutic, diagnostic or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of medical technologies); and
    - Practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment.

  For the avoidance of doubt, proctorship and preceptorship are not considered to constitute Third Party Organised Procedure Training.
- **Transition Period:** means the period from 1 January 2016 up to and including 31 December 2017, following which Member Companies shall no longer provide financial or in kind support direct to Healthcare Professionals to cover costs of their attendance at Third Party Organised Educational Events with the exception of Third Party Organised Procedure Training meetings or pursuant to a consulting agreement with a Healthcare Professional speaker engaged by a Member Company to speak at a satellite symposium.