MEDICAL TECHNOLOGY
in the German Industry Association
SPECTARIS

SPECTARIS Code of Conduct

Recommendations for Business Practices in the Healthcare Sector

Berlin, September 2023

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The medical technology section of the German Industry Association SPECTARIS aims to improve the general conditions for medical technology companies. It drives forward the creation of suitable framework conditions for companies' business activities while also promoting the medtech sector as an attractive industry to work at to younger generations. SPECTARIS further proposes various improvements of the infrastructural conditions.

SPECTARIS e. V.
September 2023

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Preamble: Initial Situation and Framework conditions

The industry association SPECTARIS e.V. wants to use the following recommendations to emphasise the need for transparent, legally compliant dealings between medical technology companies and homecare providers with healthcare professionals, medical facilities and institutions in the healthcare industry as well as their employees.

The recommendations in the SPECTARIS Code of Code of Conduct correspond 1:1 to the provisions of Parts 1, 2 and 4 of the MedTechEurope Code of Ethical Business Practice in the version dated December 2016 in its German translation. The scope of the recommendations therefore relates both to the national and international context.

Furthermore, medical technology companies are encouraged to inform themselves about the respective applicable laws on the topic of "Cooperation in the healthcare industry". In addition to national laws, consideration is to be given to the applicable laws of the states and countries in which business activities have been or will be commenced, or from which the business partner comes from.

It should be noted that, in addition to statutory regulations in many states and countries, there are also self-obligating codes in existence which can be used by the authorities to interpret the laws.

In Germany, the following laws in particular should be observed:

1. the German Criminal Code (StGB)
2. the German Social Code (SGB), in particular Social Code 5 (SGB V)
3. the professional codes of conduct and professional regulations of the medical professions
4. the Therapeutic Products Advertising Act
5. the European Medical Device Regulation (MDR) and the resulting legal provisions
6. the law against unfair competition
7. the public service law

and the jurisprudence based on these laws.

Code of Conduct

Health is humankind's greatest asset. Medical technology companies in Germany contribute significantly to the further development of new products and treatment methods and therefore represent one of the essential prerequisites for medical progress and the continuous improvement in patient care.

Industry, healthcare professionals and medical facilities depend on close cooperation if they are to be truly committed to improving healthcare for the benefit of patients.

The research and development, as well as the manufacture and distribution of medical technology products for manufacturers, distributors, employees in medical facilities and other service providers, carries a unique responsibility. SPECTARIS e.V. and its Member Companies are fully aware of this responsibility, which they honour by actively promoting and following the recommendations in practice.

In this context, the central principles of separation, transparency, documentation and appropriateness, as well as the principle of external perception, are of extreme importance.

Berlin, September 2023

Introduction

Strengthening Ethical Business Practices in the Healthcare Sector

SPECTARIS represents medical technology companies in Germany. As well as industry representation, networking and further development, our aim is to promote a balanced regulatory environment which will support the medical technology industry in meeting the ever-growing requirements of the healthcare system alongside the growing ethical expectations of industry partners.

SPECTARIS recognises that compliance with applicable laws and regulations and adherence to ethical standards is not only an obligation but also an essential step towards achieving the aforementioned goals. Furthermore, this compliance will positively bolster the reputation and success of medical technology companies.

The Code recommends appropriate minimum requirements in accordance with the various fields of activities of SPECTARIS members. However, the Code is not intended to replace or supersede national laws or guidelines, or any professional codes (including company codes), which impose stricter requirements on members.

Objectives and Principles of the Code

Cooperation between SPECTARIS members and Healthcare Professionals and healthcare organizations is essential, in order to achieve the goal of providing more people with access to safe, innovative and reliable technologies and any associated services. Examples for this include:

Development and Advanced Development of Medical Technologies

Cooperation between member companies, Healthcare Professionals and healthcare institutions is required not only for the development of innovative medical devices, technologies and in-vitro diagnostics, but also for the improvement of existing products. Innovation and creativity are fundamental to the development and advanced development of medical technologies and/or any associated services.

Safe and Effective Use of Medical Devices

In order to ensure the safe and effective use of medical devices and other service provisions, member companies must provide Healthcare Professionals and healthcare facilities with the appropriate guidance, training and educational support, as well as any necessary service provision and technical support.

Research, Education and Training

The support provided by member companies, both for medical research and for education, training and further training, will help to improve the clinical skills of Healthcare Professionals. This support also improves patient safety and facilitates improved access to new technologies and/or any associated service provisions.

In which ever form cooperation takes place, the member companies are obliged to respect the fact that Healthcare Professionals' decisions regarding treatment options must always remain independent.

Furthermore, the nature of the cooperation must guarantee industry integrity will be maintained. To achieve this goal, the Code provides guidance on how member companies should cooperate with Healthcare Professionals and healthcare facilities, based on the following underlying principles:

Principle of Image and Perception

When working together with Healthcare Professionals and healthcare institutions, Member Companies must always strive to maintain the reputation and public perception of the medical technology industry.

Principle of Separation

Cooperation between the medical technology industry and Healthcare Professionals/healthcare institutions must not be misused to influence purchasing decisions through the inappropriate or inadmissible granting of advantages or privileges. Cooperation must also not be dependent upon the purchasing, prescribing or purchasing of any of the member companies' products.

Principle of Transparency

Cooperation between the medical technology and diagnostics industry and Healthcare Professionals/healthcare institutions must be transparent and comply with national laws, guidelines and professional regulations. Furthermore, in those countries in which there are no specific requirements, member companies should maintain appropriate transparency by providing prior written notification when working with Healthcare Professionals/healthcare institutions. This written notification should be provided either to hospital authorities, Healthcare Professionals' supervisors, or the relevant authority, and should fully explain the purpose and scope of the cooperation.

Principle of Equivalency

Should Healthcare Professionals be engaged by a Member Company to perform a service for or on behalf of the Member Company, the compensation paid by the Member Company must be commensurate with, and represent the Fair Market Value for, the services performed by the Healthcare Professional.

Principle of Documentation

Any such services or services in return must be clearly documented in writing. This documentation must be of the standard to ensure that verifiability and traceability are maintained at all times. A written agreement should, above all, document the object and purpose of the cooperation, the reciprocal services provided or to be provided, and the methods of cost reimbursement and financial compensation. The grounds on which the adequacy decisions were founded must also be documented here. Any services provided must be documented by proof of capability and performance. All documentation such as the written agreement, reports, expert opinions, invoices, etc. must be kept by the member company for a reasonable period of time, to prove the need and materiality of the services and the justification of compensation paid.

Terms of the SPECTARIS Code of Conduct

The Glossary explains the most important terms used in this Code of Conduct.

Any sentence introduced by the terms "including" or "in particular" or any similar expressions terms should be construed as exemplary and should not limit the meaning of the words preceding these terms.

Application of the SPECTARIS Code of Conduct

Subject to the applicable individual legal position, the members of the SPECTARIS Medical Technology Association are recommended to follow the SPECTARIS Code of Conduct: Recommendations for Cooperation in the Healthcare Industry.

SPECTARIS deliberately dispenses with a procedural framework with an automatic complaints and sanctioning mechanism, as provided for in the MedTech Europe Code of Ethical Business Practice, and therefore does not act as an arbitration board.

Differences of opinion or disagreements regarding the interpretation of the Code are resolved at national level among the parties involved and without the involvement of SPECTARIS.

The Conference Vetting System is an independently administered system that ensures compliance to this code through Third-Party Organised Educational Events (see Glossary).

The Code is reviewed as required and is to be amended if necessary.

Time frame for the Start of the Recommendations

These recommendations replace the previous SPECTARIS recommendations on cooperation in the healthcare sector (SPECTARIS Code of Conduct: Recommendations on Cooperation in the Healthcare Sector of Healthcare Collaboration from September 2017) in full from January 1, 2024.

SPECTARIS recommends that its Member Companies refrain from directly supporting (direct sponsorship) the participation of individual Healthcare Professionals in external educational Events. One exception to this is specialised product application training courses organised by third parties or the involvement of a Healthcare Professional as a speaker at a satellite symposium as part of a consultancy agreement.

This means that direct support for the participation of individual Healthcare Professionals in external training events should be avoided in accordance with the recommendations of the Code.

Part 1
Guidelines on Interactions with Healthcare Professionals and Healthcare Institutions

Chapter 1: General Criteria for Events

Member Companies may invite Healthcare Professionals to internal training events and/or grant subsidies for external training events, provided that this is done in accordance with all local professional codes, laws and regulations, and the requirements set out in Chapters 1, 2 and 3 of the Code.

Through Educational Grants, Member Companies can also support the participation of Healthcare Professionals as listeners and speakers at other Third-Party Organised Events; provided that these training events are organized by third parties, and that this is done in accordance with the rules of Chapters 1, 2 and 4 of the Code.

Members may also purchase advertising space at external training events in accordance with the requirements set out in Chapter 2 of the Code.

The participation costs for Healthcare Professionals who participate as speakers in satellite symposia at external continuing education events may be reimbursed by Member Companies, as can the participation costs of Healthcare Professionals who appear as speakers at internal company events; provided that this is done in accordance with the rules set out in rules of Chapter 5: Consulting Services.

The principles and criteria set out in this Chapter 1 apply to all such events that are supported in any way by Member Companies, regardless of who hosts the Event.

1. Event Programme

The Event programme must be directly related to the specialty and/or medical practice of the Healthcare Professional participating in the Event and/or the Event programme should be sufficiently relevant to justify the participation of the Healthcare Professional. The same applies to external training events organized by third parties. At these events, the responsibility and control for the programme lies with the organizing third party.

A Member Company should not organise Events which include social activities, sporting and/or leisure activities or any other types of entertainment (see Glossary), nor support such elements as part of Third-Party Organised Educational Events, as long as the costs of such activities are not covered by the participants themselves. In the case of external training events, entertainment should only take place outside the education and training programme and should be paid for separately by the Healthcare Professionals.

Entertainment should not interfere with the overall scientific content of the programme and should never overlap with a scientific session, and entertainment should not be the main attraction of the Event, as this would otherwise detract from the scientific character of the Event.

2. Event Location and Venue

The venue in which the Event will be held should not be the main attraction of the Event. When choosing the venue, Member Companies should always consider the following aspects:

- Any possible negative public perception of the venue: the venue should not give the impression of being luxurious or touristy, a vacation resort or a venue for entertainment Events.
- The venue should be centrally located in relation to the place of residence of the majority of the invited of the invited participants, and easy accessibility for the participants should be guaranteed.
- The venue should be located in or near a city known as a recognised scientific or business centre, a city which is suitable for an Event programme where ideas and knowledge can be exchanged.
- Member Companies should take also into account the time of year in which the Event is to take place. The selected timing of the Event must not coincide with the tourist season for the selected geographic location.

3. Guests

The Member Companies may not in any way pay for or cover the costs of meals, travel, accommodation or other expenses of Guests (see glossary) of the Healthcare Professionals. Furthermore, they may not bear they bear the costs of other persons who have no professional interest in the information provided at the Event.

4. Reasonable Hospitality

The costs for reasonable hospitality for Healthcare Professionals in the context of internal company events and Third Party Organised Education Events can be covered under the following conditions

Any hospitality offered must be subordinate in time and focus to the Event purpose (home delivery is not recommended, for example, through catering or food delivery services to the Healthcare Professionals' home) In all cases, member companies should comply with the hospitality regulations in the country in which the Healthcare Professional practises their profession, as well as the regulations in the country in which the event takes place.

The Code is intended to ensure a balance between courteous and professional treatment of Healthcare Professionals by member companies. It is intended to avoid creating any impression that the hospitality provided by Member Companies is used as a means to encourage Healthcare Professionals to buy, prescribe or recommend products from Member Companies.

Member Companies must therefore carefully assess what is considered "appropriate" in a particular situation, taking into account regional differences. What is considered "appropriate" is the normal standard for the respective location, which corresponds to the national laws, guidelines and professional regulations. The term "hospitality" includes meals and accommodation, and it is important that member companies distinguish between permitted "hospitality" and unauthorized entertainment.

Member Companies should not pay for or reimburse the accommodation costs of Healthcare Professionals in luxury hotels. As a rule, accommodation in the congress hotel is permissible, provided that the requirements of the requirements of the Code are met. The cost of accommodation and/or other reimbursable expenses of Healthcare Professionals should not exceed the official duration of the Event, however, unless this is due to travel organised by third parties for Third Party Organised Educational Events.

5. Travel Expenses

Member Companies should only pay or reimburse travel expenses that are reasonable and have actually been incurred. Furthermore, Healthcare Professionals' travel cost reimbursement should not cover a period of stay longer than the Event.

For air travel, Member Companies should only pay for or reimburse economy or standard tickets, unless the flight time is longer than 5 hours including connecting flights. In this case, business class travel may be considered. First class travel is never considered appropriate.

6. Transparency

Member Companies must ensure full compliance with applicable laws, guidelines and professional codes regarding the disclosure or approval of financial support. At a minimum, appropriate transparency should ensure that Employer Notification (see Glossary) has been made prior to the Event.

In accordance with this Code, Member Companies may provide financial or material support in the context of external educational events (such as products from Member Companies, for example).

This may refer to the following events:

- External Educational Conferences;
- External Product Application Educational Events

7. Virtual Events

Virtual Events must comply with all parts of the Code that is by its nature applicable to them.

Therefore, Member Companies may sponsor Virtual Events in accordance with the rules set out in Chapters 1, 2, 3 and 4 of the Code, either through financial support and/or with contributions in Kind (e.g. medical technology from the Member Company).

Chapter 2: Third-Party Organised Educational Events

Member Companies are advised to only provide financial or material support (such as products from Member Companies, for example) in accordance with the guidelines of this Code and in compliance with applicable legal regulations.

These Events include:

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

1. Third-Party Organised Educational Conferences

Member Companies may support Third-Party Organised Educational Conferences (see Glossary) financially and/or materially, provided that:

- the requirements set out in Chapter 1: General Criteria for Events have been met
- where applicable, approval has been granted by the Conference Vetting System (see Glossary)
- to do so is permitted by national laws, guidelines and professional regulations.

This support may be provided through means of grants or other forms of funding. Evaluation by the Conference Vetting System is recommended, for example:

a. Educational Grants

See Chapter 4: Charitable Donations and Grants for more guidance.

b. Promotional Activities

Member Companies may purchase congress packages which include promotional and advertising services, for example, advertising space and booth space to present products and services in company displays. When doing so, Member Companies are to ensure that the overall image projected by the promotional activities is perceived as professional at all times. It must never bring the medical technology industry into disrepute or reduce confidence in the medical technology industry.

c. Satellite Symposia

Member Companies may purchase packages for satellite symposia 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 are responsible for the content of these satellite symposia and for the selection of speakers.

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 through direct financial support for the participation of individual Healthcare Professionals in accordance with the following principles:

- Financial support must comply with the criteria set out in Chapter 1: General Criteria for Events. This means, in principle, that Member Companies may pay for travel expenses, hospitality and registration fees.
- Where applicable, Third-Party Organised Procedure Training is also to be approved via the Conference Vetting System (see Glossary).
- When providing financial support for Third-Party Organised Procedure Training, Member Companies must take into account the relevant country-specific regulations in which the Healthcare Professional practices their profession and in which the Event takes place.
- Should the practical, hands-on part of a Third-Party Organised Procedure Training be cancelled or conducted virtually, the Event itself is no longer considered to be a Third-Party Organised Procedure Training. In this case, Member Companies would be able to support such an Event exclusively through Educational Grants and the covering of registration fees/access to the recording of such Events. In these cases, no travel expenses should be covered.

3. Direct Financial Support for the Participation of Healthcare Professionals in Third-Party Organised Educational Events

Insofar as the law and jurisprudence still permit Member Companies to provide direct financial support to individual Healthcare Professionals by paying the participation fee for Third-Party Organised Educational Events, direct financial support for the participation of healthcare professionals in Third-Party Educational Events remains possible. However, Member Companies are advised not to do so.

However, if they wish to do so, financial support may be provided if the following criteria is met:

- Financial support should meet the criteria from Chapter 1: General Criteria for Events. In addition, Member Companies can cover the registration fee.
- Where applicable, the Third Party Organised Educational Events has approval via the Conference Vetting System (see the Glossary)
- When providing financial support for Third Party Organised Educational Events, Member Companies must give due consideration to the relevant regulations of the country in which the HCP practices their profession and in which the Event takes place.

Chapter 3: Company Events

1. General Principles

Member Companies may invite Healthcare Professionals to internal Company Events, and if applicable, in some cases cover the costs of attendance. Examples of such Events, as defined in the Glossary, include:

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

Internal Company Events should comply with the principles set out in Chapter 1: General Criteria for Events

Where there is a Legitimate Business Purpose, Company Events (including company or factory tours) may take place in Member Company's manufacturing plant or at Healthcare Organisations used by the Member Company as reference centres, including in countries outside the country of residence of the Healthcare Professional, provided that the tour complies with the Code in all respects.

2. Product and Procedure Training and Education Events

Member Companies may provide Product and Procedure Training and Educational Training Events to relevant Healthcare Professionals, in order to ensure the safe and effective use of medical technologies, therapies and/or services. This may include bearing the participation costs for the Healthcare Professionals, if allowed by applicable laws and regulations.

Member Companies should ensure that the Product and Procedure Training and Education Events are carried out by professionals who have the relevant expertise.

a. Company Organised Educational Events

Company Organised Educational Events are corporate events whose purpose is genuine medical education and the improvement of professional skills.

The aim of the Educational Events is to directly communicate information concerning or associated with the application of the Member Companies' medical technologies, or to communicate information about the application in different contexts, for example in relation to specific patient populations. In all cases, the educational training and/or guidance provided should relate directly to the Member Companies' medical technologies, therapies, or services in question.

Therefore, when organising such an Event, Member Companies must ensure that the Event meets the following requirements in order to be compliant with the Code:

a. The entire Event programme complies with the criteria set out in Chapters 1 and 3.

b. The Event programme should be rigorous and demanding from an academic and educational perspective. This means that its content must include current scientific information of a nature and quality which is appropriate to the Healthcare Professionals attending the Event.

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

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 rigour and quality of the programme. Subsequent changes, deletions and additions to the programme are only justifiable to the extent that such changes, deletions and additions are reasonable and do not significantly modify the quality or nature of the programme.

e. In principle, the programme should involve full days, with the majority of the morning and afternoon sessions dedicated to scientific and/or educational content, unless the Event is a half day event, commences or ends at midday or lasts less than half a day. Sessions lasting half a day or less 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.

3. Company Events taking part in the Context of Third-Party Organised Events

Member Companies must not directly support travel and/or accommodation or other expenses of individual Healthcare Professionals participating in Company Events which take place during, around, or at the same time and in the same approximate location as a Third-Party Organised Event.

However, Company Events – including fee-for-service arrangements such as Advisory Boards and Clinical Investigator Meetings - may be organised at or around a Third-Party Organised Educational Event, for reasons of efficiency and convenience, should the attendance of the Healthcare Professionals at that Third-Party Event be a given.

Should such an overlap occur, the Member Company may only pay the contractual compensation and expenses agreed for the provision of the services by the Healthcare Professional at the Company Organised Education Event itself. Under no circumstances should Member Companies be responsible for any additional costs associated with the Healthcare Professional's attendance at the Third Party Organised Educational Event, such as registration costs, hospitality, additional travel or accommodation.

Member Companies may provide flexibility in the Healthcare Professionals' travel arrangements—provided there is no additional or incremental cost involved (i.e. registration, hospitality, additional accommodation or travel).

Healthcare Professionals must play an active role at such a Company Organised Event, rather than being passive participants. For example, Member Companies should provide no support for Healthcare Professionals attending Company Organised Educational Events, if these Events are organised at or around a Third-Party Organised Event.

a. Specific Rules for Certain Company Events Organised in the Context of Third-Party Organised Educational Events

Satellite symposia or booth speaker engagements taking place during the Third Party Organised Educational Event (i.e. as part of that Third-Party Organised Educational Event):

- the Healthcare Professional's registration fee for the Third Party Organised Educational Event may be covered only if the Healthcare Professional's access to the satellite symposium or booth at the Third-Party Organised Educational Event is conditional upon the payment of the registration fee. Should this apply, the registration fee must, where possible, be prorated to the actual attendance required in order to deliver the required services. For example, if the satellite symposium is held on a single day of the three-day event, and it is possible to choose a one-day registration, this option should be selected.
- Flights and accommodation costs are only to be covered if the Healthcare Professionals is not already receiving an Educational Grant covering their attendance of the Event.

b. Hospitality at Company Events Organised in the Context of Third-Party Organised Educational Events

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

- The meeting should have legitimate business or scientific purpose and lunch or dinner should not the main purpose of the invitation, but clearly subordinate to the meeting.
- The invitation to lunch or dinner should only be made to a small number of participants, in order to facilitate productive knowledge sharing, exchange and discussions amongst the participants, in line with the meeting's legitimate business or scientific purpose. Any such invitation should pay consideration to the rules set out Chapter 4, Section 3, subsection a), point 1, "Support for Healthcare Professionals' Participation at Third-Party Organised Educational Events". In no case may a Member Company issue a blanket invitation to all the participants at the Third-Party Organised Educational Event.

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

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

Sales, Promotional and Other Business Meetings

Member Companies may organise sales, promotional and other business meetings, in order to discuss Medical Technology and related services features and benefits, conduct contract negotiations, or discuss sales terms.

In addition to the principles set out in Chapter 3, Section 1, sales, promotional and other business meetings should also comply with the following more stringent requirements:

- Such meetings should, as a general rule, occur at, or close to, the Healthcare Professional's place of business;
- There should be no travel or accommodation costs reimbursed to the Healthcare Professional, unless the demonstration of non-portable equipment is necessary.

Chapter 4: Grants and Charitable Donations

1. General Principles

a. Although this Code does not cover Grants or Charitable Donations provided to patient organisations, MedTech Europe has published Patient Organisation Guidelines to support and guide Member Companies when interacting with patient organisations. Research Grants are covered in the Code in Chapter 6: Research.

b. Grants and Charitable Donations (see Glossary) should not be contingent in any way on past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the Member Company's products or services. It is important that support of charitable and/or philanthropic programmes and activities by Member Companies is not viewed as a price concession, reward to favoured customers or as an inducement to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services. If Grants are provided on more than one occasion to the same recipient, Member Companies should be mindful of the contractual risks which may arise, as

well as the potential damage to public perception. Member Companies should therefore establish internal checks and controls which can mitigate these risks.

c. Member Companies are not to provide any Grants or Charitable Donations to individual Healthcare Professionals. Grants and Charitable Donations must be provided directly to recognised institutions, organisations or facilities. Grants and Charitable Donations should not be provided in response to requests made by Healthcare Professionals unless the Healthcare Professional in question is an employee or officer of the relevant organisation or institution and submits a written application on behalf of said organisation or institution.

d. Any financial compensation (or provision of any other support) by way of Grants or Charitable Donations should always be made out in the name of the recipient organisation and paid directly to the organisation. A Member Company should not provide Grants or Charitable Donations in the name of any individual Healthcare Professional. Furthermore, all Grants and Charitable Donations must identify the Member Company as the provider of the Grant or Charitable Donation.

e. Member Companies should establish an independent decision review process in order to identify, prevent and mitigate against possible bribery and corruption risks associated with the provision of Grants and Charitable Donations to specific prospective recipients. The criteria for this process must not be sales or otherwise commercially oriented. Member Companies' Sales Departments must not be solely responsible for deciding upon or approving decisions to provide Grants or Charitable Donation. This process is to include a documented assessment of the potential risks and relevant information about the organisation, institution or facility intended as a possible beneficiary. This process must be carried out before any further action may be taken.

f. Before deciding to award Grants and Charitable Donations, the Member Companies must first evaluate the appropriateness of awarding the proposed recipient with said Grant or Charitable Donation. In all cases, it must be ascertained that all relevant national laws and regulations allow the intended recipient to benefit from the Grant or Charitable Donation in question. The evaluation must cover several issues: the legal status and structure of the organisation (whether an applicant or potential recipient) in question must be considered, as well as the nature and scope of their activities and the terms and conditions under which the Grant/Donation is to be subject. The evaluation is to be documented and based on information available to the Member Company, such as information and documentation available from public sources. In the case of Educational Grants provided in relation to Third Party Organised Educational Events, this evaluation may also include information on how funds from previous equivalent Events have been used by the recipient, and whether funds have been spent in accordance with the terms and conditions of any previous Grants.

g. All Grants and Charitable Donations must be documented by the Member Company appropriately. Furthermore, Grants and Charitable Donations should only be made to in response to a written application from an organisation, institution, or facility, or if based on a documented initiative a Member Company. This documentation must contain as much information as is necessary, in order to enable an objective assessment of the application by the Member Company. The minimum requirement for this documentation is that it must include a detailed description of the scope and purpose of the project which is to be supported by the Grant or Charitable Donation, as well as a description of the potential recipient, outlining the legal form and organisational structure of the institution. Where relevant, a financial plan must also be provided. No Grant or Charitable Donation should be provided until a written agreement documenting the terms of this is signed by both parties.

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

2. Charitable Donations

Member Companies may make Charitable Donations for charitable or other philanthropic purposes. Member Companies should 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 forms of support) are used for charitable and/or philanthropic purposes. These kinds of Charitable Donations may be made only to charitable organisations or other non-profit entities which have charitable and/or philanthropic aims and are objectively engaged in charitable or philanthropic activities. Charitable Donations should always be made in accordance with the general principles set out in Chapter 4: Grants and Charitable Donations. For tax purposes a receipt of donation should be demanded.

In the case of demonstrable financial hardship (see Glossary), Charitable Donations to non-profit hospitals may be permissible, provided that the Charitable Donation provided will benefit the patients, is limited in value or is expressly permitted by the relevant laws, guidelines and professional regulations.

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 activities are considered to part of Member Companies' normal promotional activity. Member Companies should, however, always consider the appropriateness of the location, venue and the general arrangements for any such events, and the impression which may be created by said arrangements, in order to avoid damaging the industry's public perception and image.

Fundraisers

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

3. Educational Grants

Member Companies may provide Educational Grants (see Glossary) to promote medical education. Member Companies should specify the intended purpose of the Educational Grant in the Grant agreement. The Member Company should also ensure that the Educational Grant agreement with the recipient organisation includes rights that enable the Member company to verify that the Grant is in fact used for its agreed intended purpose.

Member Companies should document and publicly disclose all Educational Grants in accordance with the Code's Disclosure Guidelines.

Member companies may offer Educational Grants for the following purposes (this list is not exhaustive):

a. Support for Third-Party Organised Educational Events

All Third-Party Organised Educational Events which are supported by Educational Grants from a Member Company to a healthcare institution are to:

- comply with the requirements laid out in Chapter 1: General Criteria for Events
- where applicable, have approval from the Conference Vetting System (see the Glossary).

1. Supporting the Participation of Healthcare Professionals in Third-Party Organised Educational Events

If the purpose of the Educational Grant is to support the participation of Healthcare Professionals in Third-Party Organised Educational Events, making the decision on the selection of participants is the sole responsibility of the Healthcare Institution receiving the grant. This must be expressly stated in a written grant agreement.

For the sake of clarity, it must be noted that, subject to local laws and regulations, Educational Grants intended to support Healthcare Professionals' attendance of Third-Party Organised

Educational Events may include items such as travel and accommodation costs, as well as hospitality and meals. However, Member Companies are be mindful of any specific reporting or disclosure obligations linked to the provision of hospitality support.

When providing an Educational Grant to support Healthcare Professionals' attendance at Third-Party Organised Educational Events, Member Companies are not to proactively seek to obtain the names of the Healthcare Professionals receiving said Educational Grants. Generally speaking, if a Third-Party Organised Educational Event is supported by more than one company, all companies should receive the same attendance list. This list should not state which Healthcare Professionals received Educational Grants from specific Member Companies.

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

After the Event has taken place, it may be necessary for auditing, compliance and monitoring purposes for a Member Company to request the names of the Healthcare Professionals and their respective healthcare organisations who have benefited from the Educational Grant provided by the member company.

In either of the above cases, unless required by law, the Member Company should only receive the names of the Healthcare Professionals once the contract for the Educational Grant has been signed and the independent selection procedure for the Healthcare Professionals has been completed

2. **Financial Support for the Realisation of Third-Party Organised Educational Events**
In those cases where the organiser of a Third-Party Organised Educational Event is the potential beneficiary of an Educational Grant and also a healthcare institution, the recipient is solely responsible for:

   - the programme content;
   - the selection of the speakers
   - the payment of said speakers, where applicable

   Member Companies may not influence the content of the Third-Party Organised Educational Event and the selection of speakers or the Faculty (see the Glossary). This is to be set out in the written Grant agreement. Should Member Companies be expressly requested to do so, they may recommend individual speakers or make comments on the programme.

3. **Support for Third-Party Organised Educational Events from Commercial Organisations Not Involved in the Organisation of the Event (or Events)**

Member Companies must be aware that working with intermediary companies in the administration of Educational Grants may entail certain compliance risks; therefore, they should take all necessary measures to mitigate these risks.

In particular, Member Companies should ensure that any company receiving funds for the administration of Educational Grants manages such funds in accordance with the Code. If the managing company selects certain Healthcare Professionals to benefit from the Educational Grant, the Member Company is to ensure that the managing company has sufficient experience and expertise to make an appropriate selection. Furthermore, Member Companies should be involved in all contractual agreements for the management of Education Grants, to ensure that funds are used appropriately and in accordance with ethical standards and local rules and regulations.

The contractual agreements should contain appropriate provisions granting Member Companies the right to monitor and audit the activities of the companies administering the Educational Grants.

Member Companies are not to award Educational Grants or funds for training purposes directly to third-party travel agencies. For the avoidance of doubt, a Member Company may provide an Educational Grant or provide educational funding to a professional conference organiser who has made arrangements so that payments for travel, accommodation and registration (if applicable) are made directly by the Member Company to a third-party travel agent on behalf of the organisation (healthcare facility or professional conference organiser) receiving the Educational Grant or funds earmarked for education.

In these circumstances the Member Company may choose to establish a tri-partite contract, with the HCO/ PCO and the third-party travel agency. Such a third-party travel agency could in principle include a third-party travel agency also used by the Member Company for its own internal travel arrangements. provided this is not a Company department or a Company-owned entity. Where a Member Company decides to use any such arrangement involving funding for, or payments to, a third-party travel agency to arrange travel, accommodation and/ or registration (when applicable) it is important that the Member Company carries out appropriate, prior due diligence on a country-by-country and case-by-case basis, in order to evaluate and mitigate the particular compliance risks and practicalities where such an arrangement is considered. The Member Company must include in all of the contractual arrangements appropriate and specific compliance-related criteria and conditions for the HCO/PCO to outsource travel arrangements to a third-party travel agency, which should include appropriate provisions to allow effective monitoring and control of the activity of the third-party travel agency

b. Scholarships and Fellowships

Member Companies may provide Educational Grants in the form of Grants for Scholarships and Fellowships to support advancement of genuine medical education of Healthcare Professionals (see the Glossary). Only Healthcare Organisations where Healthcare Professionals are in training should be eligible to request and/or receive such Educational Grants. A Member Company should not provide

Educational Grants to support Scholarships and Fellowships upon request of individual Healthcare Professionals. Similarly, the Member Company should not have any involvement in any way in the selection of the HCPs who will benefit from the Educational Grant and this should be reflected in the written Grant agreement between the Member Company and the recipient HCO. A Member Company may not additionally pay for, or reimburse, the travel or other participation costs incurred by a Scholar or Fellow attending a Third Party Organised Educational Event. Such costs should be included in the Educational Grant supporting the Scholarship or Fellowship if it is intended that the Grant should extend to such attendance.

c. Educational Grants for General Medical Education Topics

Member Companies may support genuine medical education for Healthcare Professionals on general healthcare-related topics through Educational Grants in accordance with the rules of this Chapter. The topic must directly relate to the Member Company's area of business, Medical Technologies, therapies or related services. The Event must be conducted in accordance with, and meet the other requirements of Chapter 3 of the Code. Additionally, Member Companies can also support genuine medical training on general healthcare-related topics through Member Company-organised Product and Procedure Training and Education Events.

d. Grants for Public Awareness Campaigns Member

Companies may also provide Educational Grants to Healthcare Organisations for the legitimate purpose of providing information, promoting awareness and/or educating patients, carers or the general public about relevant healthcare topics or medical conditions or diseases in therapeutic areas in which the Member Company is interested and/or involved. Additionally, a Member Company may provide an Educational Grant to support the provision of high-quality information, promoting awareness and/or educating patients, carers, and the public about health and disease provided there is an objective patient or public need for such information and the topics covered are linked to the therapeutic areas in which the Member Company is interested and/or involved. Such disease awareness campaigns must not, however, be designed or used to promote the use of Member Company therapies, products or specific HCOs.

Chapter 5: Consulting Arrangements

1. General Principles

Member Companies may engage Healthcare Professionals and Healthcare Organisations to provide consulting and other services to fulfil a Legitimate Business Need, including research, participation on advisory boards, presentations at Company Events and product development. Member Companies may pay Healthcare Professionals and Healthcare Organisations reasonable remuneration for performing these services. In all cases, Consulting Arrangements must be permitted under the laws and regulations of the

country where the Healthcare Organisation is established, or where the Healthcare Professional is licensed to practise and be consistent with applicable professional codes of conduct in that country.

The principles in this chapter are applicable to all Consulting Arrangements between Healthcare Professionals or Healthcare Organisations and Member Companies, including those where a consultant Healthcare Professional or Healthcare Organisation declines a fee for provision of their services.

Consulting Arrangements should 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 should 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 should include a documented, prior evaluation of any such associated risks and of the relevant background information concerning each prospective consultant. For example, the decision to engage a specific Healthcare Professional or Healthcare Organisation as a consultant for sales reasons does not constitute a Legitimate Business Need. If it is necessary for a Member Company's sales function to be involved in decisions to engage specific Healthcare Professionals or Healthcare Organisations, the independent decision-making/review process should ensure decision-making is exercised to fulfil Legitimate Business Needs.

2. Criteria for Genuine Consulting Arrangements with Healthcare Professionals and Healthcare Organisations

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

a. Consulting Arrangements must be entered into only where a Legitimate Business Need for the services is identified in advance, prior to the selection of the consultant(s).

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

c. Selection of consultants must be based on criteria directly related to the identified business need and the relevance of the consultant's qualifications, expertise and experience to address the identified Legitimate Business Need. Some examples of these qualifications include the years of experience, geographic location, practice setting, clinical research experience, podium presence, speaking and publication experience, or experience with, usage of, or familiarity with a specific Medical Technology. The volume or value of business generated by a prospective consultant is not a relevant criterion.

d. Consulting Arrangements with Healthcare Professionals or Healthcare Organisations must be documented in a written agreement, signed by the parties in advance of the commencement of the

services, which must specify the services to be provided and the basis for compensation for the performance of those services.

e. When engaging a Healthcare Professional or Healthcare Organisation as a consultant, Member Companies should be mindful of any potential conflict of interest that might arise from the specific project or from the engagement of that specific Healthcare Professional or Healthcare Organisation in particular.

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

g. The compensation for the services rendered must be reasonable, comply with local laws and regulations imposing limits on it and reflect the Fair Market Value of the services provided.

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

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

3. Compensation and Fair Market Value

The compensation paid to Healthcare Professionals and healthcare organisations engaged as consultants by Member Companies should reflect Fair Market Value for the services provided and should be determined by Member Companies based on a documented internal method to determine FMV. Amongst other matters, this should take account of the consultant's qualifications, expertise and experience, as well as the actual services to be provided to the Member Company. It should not be in any way contingent upon the value of products or services which consultants may purchase, lease, recommend, prescribe, use, supply or procure in the course of their own professional practice and/or business operations. All payments made for services must comply with all applicable tax and other legal requirements. Member Companies may pay for documented and actual expenses reasonably incurred by consultants in providing the services which are the subject of the consulting agreement including reasonable travel, meals and accommodation expenses incurred by consultants if attending meetings with, or on behalf of Member Companies. Such expenses must comply with local laws and regulations. The written consulting agreement must detail which expenses can be claimed by the consultant in relation to the provision of the services and the basis for payment of these by the Member Company.

4. Disclosure and Transparency

Member Companies should 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 should be obtained prior to commencement of the services, including from the hospital or other Healthcare Organisation administration or from the Healthcare Professional's superior (or locally-designated competent authority), as applicable.

Where no such national requirements apply, Member Companies should nevertheless maintain appropriate transparency by requiring the relevant Employer Notification which should disclose the purpose and scope of the Consultancy Arrangement. Member Companies should impose appropriate obligations on the consultant to ensure that the consultant's status as a consultant for the Member Company and their involvement in the research for, or the preparation of, material for scientific publication is disclosed at the time of any publication or presentation

Chapter 6: Research

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

1. Member Company-Initiated Research

Where there is a Legitimate Business Need to do so, Member Companies may initiate, conduct, manage and finance scientifically valid research to generate data, whether pre- or post-market. In this context, Legitimate Business Needs for data include

- medical needs, including patient safety;
- research and development;
- scientific purposes (e.g. performance indicators, comparing objective scientific parameters); regulatory, including post-market surveillance (PMS) and post-market clinical or performance follow up (PMCF/PMPF), vigilance, safety,
- or reimbursement and health economic, including clinical and cost-effectiveness and outcomes data relevant to health technology assessments (HTA) and reimbursement decision-making.

Where a Member Company uses a Healthcare Professional as a consultant - for example to lead a study on the Member Company's behalf (i.e. act as principal investigator); to provide advice as an advisory committee

member or adverse event committee member – the Member Company should 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 should be set out in a written agreement which should 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 should also ensure appropriate clinical trial transparency in relation to their research activities and results. This should include appropriate disclosure of information about Member Companies' clinical trials, for example, in external public registries and peer-reviewed journals, and having regard to local transparency laws and regulations. Where Member Companies engage third party intermediaries for research (e.g. contract research organisations (CROs)), they should ensure that the contractual arrangements impose obligations on the third-party intermediaries to ensure that the research conducted by these third parties on behalf of the Member Company is carried out in accordance with all applicable legal and ethical requirements, including the applicable requirements of the Code

2. Member Company Post-Market Product Evaluation

Where there is a legitimate business need to do so, Member Companies may initiate post-market third-party evaluation of their Medical Technology, therapies and/or related services and may therefore provide Evaluation Products under a written contract in order to obtain defined user evaluation by Healthcare Organisations in relation to the Evaluation Products. Evaluation Products may be provided on a no charge basis in return for the requested user feedback from Healthcare Professionals at the Healthcare Organisation, which should be formally described in a written protocol or questionnaire forming part of the contract. Where the Evaluation Products are multiple-use Evaluation Products the defined period of time necessary for the evaluation and feedback to occur will depend on the frequency of anticipated use; the nature of the user evaluation feedback requested; the duration of any required training and similar considerations that should be reasonable in the context. Member Companies should in all cases ensure that they retain title to multiple-use Evaluation Products and that they have a process in place for promptly removing such multiple use Evaluation Products and/or any unused single-use Evaluation Products from the Healthcare Organisation's location at the conclusion of the evaluation period, unless these are purchased or leased by the Healthcare Organisation. Provision of Evaluation Products and/or related services must not improperly reward, induce and/or encourage Healthcare Professionals and/or Healthcare Organisations to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or related services. Any offer and/or supply of Evaluation Products should always be done in full compliance with

applicable national laws, regulations and industry and professional codes of conduct and ethical requirements.

3. Third Party-Initiated Research: Research Grants

Where permitted by national laws, regulations, national guidelines and professional codes of conduct, Member Companies may provide Research Grants (see 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 should ensure that they do not unduly influence the research.

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

All requests for Research Grants from prospective Grant beneficiaries must be in writing and must detail, as a minimum, the type, nature and objectives of the research activity, the milestones and budget, the approximate duration of the research, and where applicable, the requirements for ethics committee, regulatory and/or other authorisations or approvals. Bearing in mind that the investigator is at all times responsible with regards to compliance with local laws and regulations a Member Company may give consideration to a request for a Research Grant prior to ethics committee approval for the specific research project.

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

4. Collaborative Research

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

Each collaborator must actively contribute significant skills, experience and/or resource complementary to the collaboration, for example study objectives and design, methodology, protocol development, study conduct, statistical analysis plan, clinical study report and publication. Before engaging in research collaborations, it is critical for Member Companies to take into account key considerations such as the

review and approval/authorisation process; due diligence criteria; budgeting and contracting processes; permissible interactions during the execution of the research and other relevant considerations. Items within scope and out of scope of the collaborative research should be clearly defined to justify the treatment of a research project as collaborative research as opposed to Member Company-initiated research or third-party-initiated research (for which a Research Grant is appropriate).

In accordance with the Documentation Principle, any arrangements made by a Member Company to conduct collaborative research should be set out in a written agreement to define roles and responsibilities transparently and in accordance with the study protocol. Examples include identification of the study [initiator and] sponsor; intellectual property ownership; financial support; transparency of involvement; reporting; rights to data; registration of publications; adverse event reporting procedures and dispute resolution. Member Companies should ensure that the pooling of all collaborators' skills, experience and/ or resources is clear expressed in a collaborative research agreement and all activities falling within the scope of the Member Company's responsibility are performed in accordance with all applicable national laws and regulations, professional codes.

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.

Chapter 8: Educational and Promotional Items

It is generally not recommended to provide gifts to Healthcare Professionals and healthcare organisations. However, in some exceptional cases, Member Companies may provide inexpensive educational and/or promotional items, provided that this is done in accordance with nationally applicable laws, guidelines and professional regulations. Member Companies may only provide educational and/or promotional items in accordance with the following applicable principles:

a. Educational and/or promotional items must be intended for use in the medical practice of the Healthcare Professional, serve the well-being of patients or serve a genuine educational function.

b. Educational and/or promotional items are not to be provided at the request of Healthcare Professionals.

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

d. Educational and/or promotional items must be modest in value and may be branded or non-branded products.

e. Educational items and/or promotional items must not be given to mark significant life events (for example, for birthdays, births, weddings, etc.).

f. A Member Company may occasionally provide educational items of greater value to a Healthcare Organisation, provided that the item serves a genuine educational function for the Healthcare Professionals at that Healthcare Organisation and is of benefit to patients. These items must not be provided to Healthcare Professionals purely for their personal use. The item should 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. The applicable legal limits must be observed.

g. Provision of educational items and/or promotional items must not improperly reward, incentivise and/or encourage Healthcare Professionals to purchase, lease, recommend, prescribe, use, supply or procure the Member Company's Medical Technology or related services.

h. The educational items and/or promotional items should not be intended mainly for personal use.

Member Associations should provide guidelines in accordance with the above principles regarding appropriate limits for educational materials and/or promotional items.

Sweepstakes and other types of contests at Events are only recommended if the proposed prize meets the requirements in Chapter 8: Educational and/or Promotional Items. In addition, national laws, guidelines and professional regulations must be complied with.

This chapter is not intended to change the common practice of providing an appropriate amount of evaluation products, demonstration products or samples. Further requirements for the provision of Evaluation Products, Demonstration Products or Samples are set out in 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 Glossary) free of charge to enable Healthcare Professionals and/or healthcare organisations, (as appropriate) to evaluate and/or familiarize themselves with the safe, effective and appropriate use and functionality of the product and/or associated 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 samples may be either disposable or reusable 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 should 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 should always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct.

Member Companies should always 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 should 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 should be in writing.

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

2. Demonstration Products

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 should 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 (see Glossary) free of charge to enable Healthcare Professionals or healthcare organisations to familiarise themselves with the products and/or related associated services in order to gain experience in the safe and effective use of the products on a clinical basis, and to determine if or when the products and/or services may be used, ordered, purchased the products and/or services should be used, ordered, purchased, prescribed or recommended in the future.

In the case of single-use samples for testing, no more samples may be made available than are necessary to gain sufficient experience in handling the products.

In the case of reusable samples, the specified duration of the trial depends, among other things, on the frequency of intended use, the duration of the training itself, the number of Healthcare Professionals who are to gain experience in the product and other similar considerations. Member Companies must in any case

ensure that they retain ownership of the reusable samples and return them promptly upon completion of the demonstration.

Chapter 10: Third-Party Intermediaries

Member Companies must be aware that they may be liable for the activities of Third-Party Intermediaries when they interact with Healthcare Professionals or Healthcare Organisations in connection with the sale, promotion or other activities involving member company products and/or services.

Accordingly, where such arrangements are entered into, and providing laws and regulations permit it, Member Companies are recommended that the third-party intermediary be contractually obligated to comply with the provisions of the Code and other applicable guidelines, as well as to maintain appropriate supervision to ensure this is duly implemented.

1. Risk Assessment

Member Companies should assess the risk profile for intended and implemented third-party referral arrangements. The following points should be taken into account:

- the risk in the country concerned and specific risk profiles of the third-party intermediary planned or used.
- Information on the legal and ethical requirements of the local market
- Information from the third-party intermediaries for potentially unusual agreements
- Information from public sources or from employees about potential risks associated with the third-party intermediaries

2. Due Diligence - Duty of Care

Before engaging a Third-Party Intermediary, as well as when intending to renew an engagement, the Member Companies are to fulfill their due diligence obligations by carrying out a risk-based due diligence review process to identify risks in relation to the market in which the third-party intermediary operates and in relation to the specific activities carried out by the third-party intermediary on behalf of the Member Company.

Due diligence may also be considered during the performance of the contract. to continuously update any relevant information regarding the Third Party Intermediary, and in any case whenever required by local laws and regulations.

3. Training

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

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

4. Written Contract

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

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

5. Control and Audit

Member Companies should, where possible, make reasonable efforts to ensure risk-based routine monitoring, auditing or other assessment of third-party intermediaries for compliance with applicable laws, industry and professional codes, the member's best practice principles and company policies, and relevant contractual terms; and should request regular confirmation of Third Party Intermediaries' compliance with applicable laws, industry and professional codes, best practice principles and Member Company policies and relevant contractual terms.

6. Appropriate Corrective Action

Member Companies are encouraged to take necessary and appropriate remedial action in accordance with applicable local laws if a third-party intermediary violates applicable laws, industry or professional codes, best practice principles, member company policies and/or applicable contractual terms and conditions or otherwise behaves inappropriately.

Part 2
Disclosure Guidelines

Under the SPECTARIS Code of Conduct, Member Companies should refrain from paying registration fees, travel or hospitality expenses directly to individual Healthcare Professionals for their participation in Third-Party Organised Educational Conferences.

Further medical education may be supported in accordance with the rules set forth in the Code by the provision of advanced Educational Grants to healthcare institutions in accordance with the rules set out in the Code. Specific (security) measures have been developed to prevent abuse, including the voluntary obligation to disclose these Educational Grants.

Section 3 of Chapter 4 states that Member Companies should document all Educational Grants and make them public in accordance with these disclosure guidelines. These disclosure guidelines are therefore a central part of the Code and should be interpreted accordingly.

For the avoidance of doubt, any grant provided by a Member Company to a Professional Conference Organizer ("PCO") that operates independently of a Healthcare Organization for the promotion of actual educational purposes falls within the scope of this Disclosure Policy and is subject to the same terms and conditions as Continuing Education Grants. To the extent that these educational grants relate to healthcare institutions, they also include professional conference organizers.

All capitalised concepts in the guidelines are concepts defined in the Code.

Chapter 1: Applicability of these Guidelines

1. Scope

These Disclosure Guidelines apply to Member Companies and their interactions with healthcare organisations based or registered in Germany and Europe.

Separate entities that are part of the same multinational company ("subsidiaries") - this can be the company (e.g. headquarters, company headquarters or parent company of a commercial company), the subsidiary or any other form of company or organization - are to be considered a single entity and as such should be committed to complying with these disclosure guidelines.

Transfers of assets that are not included in the definition of Educational Grants (as described in Chapter 4, Section 3 of the Code) and which therefore cannot be assigned to any of the categories listed in Section 2.2.are not subject to these disclosure guidelines.

2. Applicability of these Disclosure Guidelines

Member Companies should not provide the same information twice if disclosure requirements are imposed on them by national laws, regulations or professional codes with respect to educational benefits (see Chapter 4, Section 3 of the Code) that are the same as those contained in this Disclosure Policy.

3. Applicability to Non-Member Companies

Non-member companies may also apply these disclosure guidelines, provided that they have committed to ethical standards equivalent to those recommended in this Code.

Chapter 2: Disclosure Obligations

1. General Obligation

In accordance with the disclosure provisions of these guidelines, each Member Company should disclose all payments relating to Educational Grants (as described in Chapter 4, Section 3 of the Code) that it makes to a European-based or registered healthcare organization, without limitation.

The disclosure of Educational Grants from subsidiaries of Member Companies, as described above, but which are not registered in Germany or Europe, should be made by all branches of the member company that are registered in Germany and Europe.

2. Collective Disclosure

Educational Grants should be disclosed collectively. Each branch of a member company should disclose, separately for each clearly identifiable recipient, the amounts received in Educational Grants made to that recipient in the relevant reporting period that could be reasonably attributable to one of the categories listed below. These amounts are aggregated and presented on a category-by-category basis, but itemised disclosure should be provided upon request by the Member Company, as appropriate, for (i) the relevant recipient, or (ii) the relevant authority. Member companies should disclose a collective amount, allocated to one of the following categories:

a. Educational Grants to support Third-Party Organised Events (including support for the participation of Healthcare Professionals in Third-Party Organised Events) and

b. other Educational Grants to Healthcare Professionals (including scholarships, fellowships or grants for awareness campaigns).

3. Optional Object Specifications

If desired, Member Companies may specify the purpose of the grant in one or both categories under Section 2.2. collective disclosure.

4. Methodology

Each Member Company should prepare a report summarising the methodology used to prepare the disclosure and identification of training awards for each category described in Section 2.2 Collective Disclosure. The report, including a general summary or country-specific considerations, should describe the methods of identification and the treatment of VAT and other aspects of tax and currency, as well as other tax and currency, as well as other issues relating to the timing and amount of the education benefits. The methodology report should be made available upon request by any of the parties involved.

Chapter 3: Nature of Disclosure

1. Reporting Period

Disclosures are made annually and each reporting period covers an entire calendar year.

2. Time of Disclosure

Disclosures are made by each Member Company within 6 months of the end of the respective reporting period.

3. Time of Publication

Disclosure is made at the time of publication. The time of publication is

August 31 of the year of the respective date of disclosure.

4. Presentation and Language of Disclosure

For consistency purposes, disclosures under these Disclosure Guidelines should be made in English using the template set out in the Glossary.

5. 5. Disclosure Platform

Disclosures should be made on the EthicalMedTech website, unless a Member Company is already required to make disclosures by national laws, regulations or codes of practice (regulated in section 1.2 Applicability of these guidelines). Member Companies remain liable for the accuracy of the data disclosed. MedTech Europe is not liable for (i) the maintenance, correction or deletion of the published data, nor for (ii) the storage of the data after the 3-year period of disclosure in the public domain.

6. Retention and Adjustment of Disclosures

Member Companies may modify their disclosures at any time before or after publication, delete or change in any other way.

Disclosed information will remain in the public domain for three years after the initial disclosure of that information.

7. Inquiries Regarding Reported Disclosures

Member companies should provide healthcare organisations with all data related to their contractual relationships that have been disclosed pursuant to this Disclosure Policy at any time. Disclosure Guidelines at any time while the disclosed information remains in the public domain as described in Section 3.3.

Part 3
Glossary and Definitions

- **Charitable Donations**
  Provision of cash, equipment, Member Company product or relevant third party product, for exclusive use for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause. Charitable Donations should only be made to bona fide charities or other non-profit entities or bodies whose main objects are genuine charitable or philanthropic purposes.

- **Clinical Research**
  A type of research that studies tests and treatments and evaluates their effects on human health outcomes. This includes clinical investigations or interventional and non-interventional clinical performance studies where people volunteer to take part in order to test medical interventions including drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments and preventive care.

- **Company Events**
  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)**
  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**
  This SPECTARIS Code of Conduct for Ethical Business Practice including the Disclosure Guidelines.

- **Consulting Arrangement**
  Any provision of service by a Healthcare Professional or Healthcare Organisation for or on behalf of a Member Company. Consulting arrangements include, but are not limited to marketing and Clinical Research activities, providing technical expertise for the development, testing, etc. of Medical Technology, providing feedback in post-market evaluations and market research, providing speaking services at Events, teaching other Healthcare Professionals, providing training on how to use the Member Company's Medical Technology, participating in research-related meetings, etc.

- **Delegate**
  Healthcare Professionals that attend an Event neither as Faculty, nor as Healthcare Professionals providing services to Member Companies for the specific Event.

- **Disclosure Guidelines**
  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**
  Provision of funding, Member Company or third party products or other in kind support to a Healthcare Organisation by or on behalf of a Member Company solely for the support and advancement of genuine medical education of Healthcare Professionals, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved and where such support is provided solely for a specified intended purpose within this category.

- **Employer notification**
  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**
  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**
  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**
  Either a Company Event or Third Party Organised Educational Event.

- **Faculty**
  A podium speaker, moderator and/or chair, who presents during an Event. Poster- and abstract-presenters are not considered to be Faculty.

- **Fair Market Value (FMV)**
  The value of the specified services (or products, if applicable) which would be paid by the Member Company to the other party (for example a Healthcare Professional or a Healthcare Organisation), each dealing at arm's length in an open and unrestricted market, and when neither party is under any compulsion to buy or sell, and both parties have reasonable knowledge of the relevant facts.

- **Financial Hardship**
  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**
  An Educational Grant or a Research Grant, or both.

- **Guests**
  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)**
  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**
  Any individual (with a clinical or non-clinical role; whether a government official, or employee or representative of a government agency or other public or private sector organisation; including but not

limited to, physicians, nurses, technicians, laboratory scientists, researchers, research co-ordinators or procurement professionals) that in the course of their professional activities may directly or indirectly purchase, lease, recommend, administer, use, supply, procure or determine the purchase or lease of, or who may prescribe Medical Technologies or related services. This definition does not include a purchasing professional employed in the retail sector unless that individual purchaser arranges for the purchase of Member Companies' Medical Technologies or related services for or on behalf of medical or clinical personnel. For example, if a Member Company's Medical Technologies or related services are sold as part of the common merchandise of the retail outlet, interactions between the Member Company and the purchasing professional do not fall within the Code. However, where the Member Company's Medical Technologies or related services are sold in a retail pharmacy (even if this is located within a supermarket unit), interactions between the Member Company and the responsible purchasing professional will fall within the Code.

- **In kind**

  The provision of Grants, Charitable Donations and other types of support in the form of goods or services other than money, including the provision of labour, lent or donated goods, or lent or donated services (e.g. catering services for Events, provision of venue space, company products and other services).

- **Legitimate Business Need**

  A current and actual business objective pursued by a Member Company such as the advancement of medical education, Clinical Research and/or the safe and effective use of the Member Company's Medical Technology . Engaging a Healthcare Professional or a Healthcare Organisation for the purpose of influencing the prescription, recommendation, purchase, order, supply, utilisation, sale or lease of Medical Technologies or related services directly or indirectly by a Healthcare Professional or Healthcare Organisation is never deemed a Legitimate Business Need.

- **Medical Technology or Medical Technologies**

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

- **Members**

  All member companies of the SPECTARIS association's medical technology section.

- **Preceptorship**

  A type of clinician-to-clinician training funded by a Member Company where the supervising clinician oversees the procedural training of the trainee clinician and the trainee does not have primary responsibility for the patient undergoing the procedure.

- **Proctorship**
  A type of clinician-to-clinician training funded by a Member Company where the trainee clinician performs a procedure under the supervision of another clinician and where the trainee clinician has primary responsibility for the patient undergoing the procedure.

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

- **Product and Procedure Training and Education Event**
  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**
  The provision by or on behalf of a Member Company of funding, products/equipment and/or In Kind services to any organisation that conducts research which is made for the sole purpose of supporting the development or furtherance of clearly specified bona fide, scientifically valid and legitimate research by the recipient the purpose of which is to advance medical, scientific and healthcare knowledge, Medical Technologies and/or clinical techniques designed to improve patient outcomes.

- **Sales, Promotional and Other Business Meetings**
  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**
  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**

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

- **Third Party Intermediary**

  Any legal entity or person that markets, sells, promotes or otherwise brings to end-users Member Companies’ products or related services, and may include distributors, wholesalers, distribution or sales agents, marketing agents, brokers, commissionary commercial agents and independent sales representatives.

- **Third Party Organised Educational Events**

  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**

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

- **Third Party Organised Procedure Training**

  A type of Third Party Organised Educational Event that is primarily intended to provide Healthcare Professionals with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:

  - Specific therapeutic, diagnostic or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of Medical Technologies); and
  - Practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment.

  For the avoidance of doubt, Proctorship and Preceptorship are not considered to constitute Third Party Organised Procedure Training.

- **Virtual Event**

  A Third-Party Organised or Company Organised Event that is characterised by the participation of Healthcare Professionals Delegates who attend exclusively remotely. As a result, a Virtual Event is not connected in any way with a physical Third Party Organised Educational Event. For example, the filming of presentations, discussions, etc. taking place during a Third Party Organised Educational

Event (“hybrid” events), and their broadcasting to audiences not present at the physically attended Event—whether contemporaneously or after the Event—do not qualify as a Virtual Event, and therefore should comply with all requirements of (in person) Third Party Organised Events.