SWISS MEDTECH

Information to the members

Swiss Medtech Code of Ethical Business Practice

Adopted at the Swiss Medtech General Assembly of 25 May 2023

Please note that in case of legal dispute, the official German version of this document is legally binding and shall always prevail.

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Preliminary note

National member associations of MedTech Europe are required to adopt the MedTech Europe Code of Ethical Business Practice («MedTech Europe Code») at national level as a minimum requirement for their members. As a member of MedTech Europe, Swiss Medtech has adapted the MedTech Europe Code to become the Swiss Medtech Code of Ethical Business Practice. By becoming a Member of Swiss Medtech, Member Companies commit to comply with the Swiss Medtech Code from their first day of membership.

A revised version of the MedTech Europe Code entered into force on 1 January 2023. The Swiss Medtech Code was revised in line with the changes made to the MedTech Europe Code. The revised version of the Swiss Medtech Code was adopted at the Swiss Medtech General Assembly of 25 May 2023. Companies have until 1 January 2024 to implement changed and new provisions of the revised Swiss Medtech Code («Code»).

Introduction

Promoting an Ethical Industry

Swiss Medtech represents manufacturers and developers of medical devices and in-vitro diagnostics, companies providing services in this context, distributors, suppliers and subcontractors operating in Switzerland as well as companies/organisations of the broader medical technology network. It is the mission of Swiss Medtech to promote a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of its stakeholders.

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

This Code sets out the minimum standards appropriate to the various types of activities carried out by the Member Companies. The Code is not intended to supplant or supersede national laws or regulations or professional codes (including industry, company and Healthcare Professional («HCP») codes) that may impose more stringent requirements upon Member Companies. All Member Companies must independently ascertain that their activities comply with all current national and local laws, regulations, and professional codes.

Key Legislation

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

- Safety, Quality and Performance Laws
- Advertising and Promotion Laws
- Data Protection Laws
- Anti-corruption Laws
- Environmental, Health and Safety Laws
- Competition Laws (Antitrust law, Law on Unfair Competition)

Competition legislation applies not only to Members Companies in their business operations, but also to Swiss Medtech and all the association's bodies (for instance specialist groups, sections and commissions), irrespective of size and designation. Liability under competition laws may be strict and a Member Company may become liable for the infringement of such laws by other Members Companies of an association body in which it participates. Accordingly, Member Companies must make every effort to observe competition laws in all their interactions.

Aims and Principles of the Code

The interaction between Member Companies and HCPs and Healthcare Organisations («HCOs») is an important factor in achieving the mission of Swiss Medtech to make safe, innovative and reliable technology and related services available to more people. For example:

- **Advancement of Medical Technologies**

The development of innovative Medical Technologies and the improvement of existing Medical Technology require collaboration between Member Companies and HCPs/HCOs. Innovation and creativity are essential to the development and evolution of Medical Technologies and/or related services.

- **Safe and Effective Use of Medical Technology**

The safe and effective use of Medical Technology and related services requires Member Companies to offer HCPs and HCOs appropriate instruction, education, training, service, and technical support.

- **Research and Education**

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

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

- **The Principle of Image and Perception**

Member Companies must, at all times, consider the image and perception of the medical technology industry that will be projected to the public when interacting with HCPs and HCOs.

- **The Principle of Separation**

Interaction between industry and HCPs/HCOs must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of Member Companies' Medical Technology or related services.

- **The Principle of Transparency**

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

- **The Principle of Equivalence**

Where HCPs are engaged by a Member Company to perform a service for or on behalf of a Member Company, the remuneration paid by the Member Company must be commensurate with, and represent a Fair Market Value for, the services performed by the HCP.

- **The Principle of Documentation**

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

Scope of application of the Code

This Code applies to the Member Companies of Swiss Medtech developing, manufacturing or distributing Medical Technology for human use and/or providing services in this context.

Member Companies must comply with the Code as a minimum standard when interacting with HCPs and HCOs, irrespective of where the activity takes place and irrespective of where the HCPs and HCOs are registered and/or practising.

The Code is directly applicable to all activities of Member Companies and their affiliated companies that are active in the Medical Technology sector. If an affiliated company of a Member Company is also in its own name a member of an association, the respective code of this association shall apply to activities of this affiliated company in addition to the Code, which sets out the minimum standards appropriate to the various types of activities conducted by the Member Companies.

Any activity or interaction conducted by an affiliated company of a Member Company located outside Switzerland will be deemed attributable to this Member Company.

PART 1: Interactions with HCPs and HCOs

Chapter 1: General Criteria for Events

1. Event Programme

The Event programme should directly relate to the specialty and/or medical practice of the HCPs who will attend the Event or be sufficiently relevant to justify the attendance of the HCPs.

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

The Faculty must be identified. It is also important that all supporting materials (e.g. flyers, brochures and website) are consistent with the scientific or promotional nature of the programme content, as the case may be.

For Third Party Organised Educational Events, the agenda must be under the sole control and responsibility of the Third Party organiser.

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

2. Event Location and Venue

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

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

3. Guests

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

4. Reasonable Hospitality

Member Companies may provide reasonable hospitality to HCPs in the context of Company Events and Third Party Organised Educational Events when they are attending the Event in person, but any hospitality offered must be subordinate in time and focus to the Event purpose (no home delivery is permitted, for example through catering or food delivery services to the HCP's home). Member Companies must in any event meet the requirements governing hospitality in the country where the HCPs carry out their profession and give due consideration to the requirements in the country where the Event is being hosted.

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

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

Member Companies may not pay for or reimburse HCPs' lodging expenses at luxury hotels. If the Event venue is a hotel which complies with the requirements of the Code, it would be acceptable for Member Companies to offer participants meals and accommodation at the same hotel. However, accommodation and/or other services provided to HCPs must not cover a period of stay beyond the official duration of the Event, unless when required by travel arrangements in relation to Company Organised Events arranged around Third Party Organised Educational Events.

5. Travel

Member Companies may only pay or reimburse for reasonable and actual travel. Travel provided to HCPs must not cover a period of stay beyond the official duration of the Event, unless when required by travel arrangements in relation to Company Organised Events arranged around Third Party Organised Educational Events.

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

6. Transparency

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

Event whenever a Member Company engages an HCP or whenever a Member Company makes a financial contribution to the HCP's medical education.

Incidental interactions arising in the normal course of business such as meals associated with educational or business meetings or the receipt of modest promotional items, do not require Employer Notification.

7. Virtual Events

Virtual Events must comply with any part of the Code that is, by its nature, applicable to these. Therefore, Member Companies may provide financial and/or In-Kind support (e.g. Member Company Medical Technology) to Virtual Events in accordance with the rules of Chapters 1: General Criteria for Events, Chapter 2: Third Party Organised Educational Events, Chapter 3: Company Events and Chapter 4: Grants and Charitable Donations of the Code.

Chapter 2: Third Party Organised Educational Events

1. Third Party Organised Educational Conferences

Member Companies may support Third Party Organised Educational Conferences financially and/or In-Kind provided these comply with:

- Chapter 1: General Criteria for Events; and
- Where applicable, have approval via the Conference Vetting System (see Glossary and Annex).

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

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

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

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

2. Third Party Organised Procedure Training

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

- Financial support must comply with the criteria provided in Chapter 1: General Criteria for Events. Member Companies may therefore pay travel, hospitality, and the registration fee.
- Where applicable, the Third Party Organised Procedure Training has approval via the Conference Vetting System (see Glossary and Annex).
- For financial support to Third Party Organised Procedure Trainings Member Companies must apply the requirements governing conduct and attendance at such meetings in the country where the respective HCPs carry out their profession and give due consideration to the requirements in the country where the meeting is being hosted.
- Should the participants' practical, hands-on portion of a Third Party Organised Procedure Training be cancelled or made virtual, Member Companies would only be able to support such an Event via Educational Grants and registration fee/access to the recording to such events. Under no circumstances may travel expenses be paid in such a situation.

Proctorship und Preceptorship are not considered Third Party Organized Procedure Training.

Chapter 3: Company Events

1. General Principles

Member Companies may invite HCPs to Company Events.

Examples of Company Events are, as defined in the Glossary:

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

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

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

2. Product and Procedure Training and Educational Events

Where appropriate, in order to facilitate the safe and effective use of Medical Technologies, therapies and/or services, Members Companies must make product and procedure training and education available to relevant HCPs. This may include paying the cost of attendance of HCPs if allowed under local laws and regulations.

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

Company Organised Educational Events

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

The aim of Educational Events is to directly communicate information concerning or associated with the use of Member Companies' Medical Technologies, e.g. information on disease patterns and the benefits of Medical Technologies to certain patient populations. In all cases the information and/or training must directly concern a Member Company's Medical Technologies, therapies and/or related services. This means that a Member Company must meet the following requirements when organising such an Event in order to be compliant with the Code.

The entire Event must comply with the criteria in Chapter 1: General Criteria for Events and Chapter 3: Company Events:

a. The programme must be sophisticated from a scientific and/or educational point of view. This means that its content must include current scientific information of a nature and quality which is suitable for the HCPs who are attendees at the Event.
b. The programme must be genuine and bona fide educational, and therefore cannot have a primary sales and marketing objective. This means that the educational part must fill most of the programme.
c. Information on the programme, clearly indicating the name of the Member Company organising the Event, must be made available sufficiently in advance in order for invited HCPs to be able to make a reasoned judgment as to the rigor and quality of the programme, provided however that subsequent changes, deletions and additions to the programme are acceptable to the extent that such changes, deletions and additions are reasonable and do not significantly modify the quality or nature of the programme.
d. The programme should in principle involve full days, with the majority of the morning and afternoon parts dedicated to scientific and/or educational sessions, unless the Event is a half day event, commences or ends at midday or lasts less than half a day. Such half-day or less sessions are permissible, but there should not be any non-scientific or non-educational events or activities organized for the other part of the day. Furthermore, there should be no significant gaps in the programme which would permit HCPs to engage in non-scientific or non-educational activities. For example, early morning sessions should not be followed by late afternoon or evening sessions with large blocks of free time in between.

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

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

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

If such an Event overlap occurs, the Member Company may only pay the contractual remuneration and expenses agreed for the provision of the services by the HCP at the Company Organised Education Event itself. Under no circumstances may a Member Company pay for incremental costs relating to the HCP'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 HCPs' travel arrangements – provided there is no additional or incremental cost involved (i.e. registration, hospitality, additional accommodation or travel).

The HCPs must have an active role at such a Company Organized Event, rather than being mere passive attendees. For example, no support must be provided by Member Companies to HCPs attending a Company Organised Educational Event as a Delegate or trainee where this is organised at or around a Third Party Organised Educational Event.

a. Specific rules for certain Company Events organised in the context of Third Party Organised Educational Events

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

- The HCP's registration fee for the Third Party Organised Educational Event may be covered only if the HCP's access to the satellite symposium or booth at the Third Party Organised Educational Event is conditional upon the payment of the registration fee. Where this applies the registration fee must, where possible, be prorated to the actual attendance required in order to deliver the required services. E.g. if the satellite symposium is held on a single day of the three-day event, and it is possible to choose a one-day registration, that option should be selected.
- The flight and accommodation costs can only be covered if the HCP is not already benefiting from an Educational Grant covering their attendance to the Event.

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

If a Member Company wishes to organise a legitimate business or scientific meeting which includes lunch or dinner with selected HCPs, the following conditions must be met before the Member Company may cover the hospitality costs:

- The meeting should have a legitimate business or scientific purpose and the lunch or dinner must not be the primary purpose of the invitation but must instead be clearly subordinate to the purpose of the meeting.
- The invitation to the lunch or dinner should only be made to a small number of participants, in order to ensure effective contribution by way of transfer of knowledge, discussion and exchange amongst the participants in line with the meeting's legitimate business or scientific purpose. Any such invitation should have regard to the rules of Chapter 4: Grants and Charitable Donations, Section 3: General principles. 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 Code, in particular Chapter 1: General Criteria for Events.

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

4. Sales, Promotional and Other Business Meetings

Where it is appropriate, Member Companies may organise sales, promotional and other business meetings where the objective is to discuss Medical Technology and related services features and benefits, conduct contract negotiations, or discuss sales terms.

In addition to the principles laid down in Chapter 3: Company Events, Section 1: General Principles, 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 HCP's place of business.
- It is not appropriate for travel or accommodation support to be provided to HCPs by Member Companies except where demonstrations of non-portable equipment are necessary.

Chapter 4: Grants and Charitable Donations

1. General Principles

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

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

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

d. In order to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with the provision of a Grant or a Charitable Donation to a specific prospective recipient, Member Companies must implement an independent decision-making/review process with criteria that are not sales and/or commercially oriented. The sales and/or commercial function of the Member Company must not decide upon and/ or approve decisions to provide Grants or Charitable Donations. This process must include a documented, prior evaluation of any such associated risks and of the relevant information concerning the intended recipient organisation or entity.

e. Prior to deciding to provide a Grant or a Charitable Donation, the Member Company must evaluate the appropriateness of the award of the proposed Grant or Charitable Donation to the proposed recipient. It must in all cases be lawful under applicable national

laws and regulations for the Grant or Charitable Donation recipient to receive and benefit of the particular type of Grant/Charitable Donation.

f. Such an evaluation must consider all the circumstances including consideration of the legal status and structure of the requesting (and/or prospective recipient) organisation as well as of the nature and scope of its activities and the terms and conditions to which the Grant or Charitable Donation will be subject. The evaluation must be documented and must be based on information available to the Member Company, such as information or documentation available from public sources. For Educational Grants provided in relation to Third Party Organised Educational Events, this may also include information on how the funds have been applied by the recipient in relation to previous equivalent Events and whether funds have been spent in accordance with the terms and conditions of any previous Grant.

g. All Grants and Charitable Donations must be appropriately documented by the Member Company. Moreover, Grants and Charitable Donations must only be provided in response to a written request submitted by the requesting organisation or documented initiative from a Member Company containing sufficient information to permit an objective evaluation of the request to be carried out by the Member Company, including, as a minimum a detailed description of the scope and purpose of the programme, activity or other project, which is proposed as the object of the Grant or Charitable Donation. It must also contain a description of the proposed recipient, its legal status and structure, and where relevant, a budget. No Grant or Charitable Donation must be provided until a written agreement documenting the terms of this is signed by both parties.

h. 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 must have no control over the final use of funds (or other support) they provide as Charitable Donations beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes.

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

Charitable Donations to non-profit hospitals may be permissible in case of demonstrated Financial Hardship, provided the Charitable Donation benefits patients, is limited to specific needs identified in advance, or is explicitly permitted by applicable national laws.

Chapter 4: Grants and Charitable Donations, Section 2: Charitable Donations is not intended to address legitimate commercial transactions by Member Companies in the form of leasing of stands or booth space at Third Party Organised Educational Events and/ or at any conference or event organised by a charity or other philanthropic organisation. Such activity is considered to be part of Member Companies' normal marketing activity. Member Companies should, however, always consider the appropriateness of the location, venue, and the general arrangements for any such events and the impression that may be created by the arrangements in order not to bring the industry into disrepute.

Fundraisers

Charitable Donations made by Member Companies may take the form of dinner invitations for a fundraising dinner or participating in other recreational events such as a fundraising golf tournament, if arranged by a charitable or other non-profit philanthropic 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 must not invite HCPs to attend such an event at the expense of the Member Company. Furthermore, the Member Company is not permitted to suggest to the sponsoring organisation, the names of HCPs who could be invited to attend the event, irrespective of whether or not the specified HCPs will be seated at the table of the Member Company.

3. Educational Grants

Member Companies may provide Educational Grants for the advancement of medical education. Member Companies must specify the intended purpose of the Educational Grant in the Grant agreement. A Member Company must also ensure that the Educational Grant agreement with the recipient organisation includes rights to enable it to verify that the Grant is in fact used for the agreed intended purpose.

Member Companies must document and publicly disclose all Educational Grants in accordance with the Transparency Guidelines of Swiss Medtech.

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

a. Support for Third Party Organised Educational Events

As a general principle, any Third Party Organised Educational Event supported by way of an Educational Grant from a Member Company to an HCO must:

- Comply with Chapter 1: General Criteria for Events
- Where applicable, have approval via the Conference Vetting System (see Glossary and Annex)

1) Support for HCP Participation at Third Party Organised Educational Events

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

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

When providing an Educational Grant to Support HCPs' participation at Third Party Organised Educational Events, Member Companies should not proactively seek to receive the names of the HCPs benefiting from the Educational Grant. Generally, when a Third Party Organised Educational Event is supported by more than one company, all companies should receive the same attendance list, from which it should not be possible to identify which HCPs have benefited from a particular Educational Grant of a Member Company.

However, where required by law, a Member Company may, in accordance with the applicable legal requirements, request and obtain the names of the HCPs participating in the Event, who are benefiting from the Educational Grant of the Member Company.

For purposes of auditing, compliance, and monitoring by relevant Company functions, it may be necessary for a Member Company to request and receive the names of the HCPs and their respective HCO, who have benefited from the Educational Grant provided by the Member Company after the Event has taken place.

In either of the above cases, unless required by law, such HCP names should never be received by the Member Company until the Educational Grant agreement has been signed and the independent selection process of the HCPs has been completed.

2) Support for Third Party Organised Educational Events

Where the prospective beneficiary of an Educational Grant is the organiser of the Third Party Organised Educational Event and is also an HCO, the recipient HCO must be solely responsible for:

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

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

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

Member Companies must bear in mind that certain compliance risks may rise from working with intermediary companies for the management of Educational Grants and must therefore take all necessary actions to mitigate these risks.

In particular, Member Companies must ensure that any company receiving funds for the management of Educational Grants manages those funds in accordance with the Code. To the extent the managing company will select particular HCPs to benefit from the Grant, the Member Company must ensure that the managing company has sufficient experience and expertise to make an appropriate selection. Additionally, Member Companies must include appropriate and specific compliance-related criteria in all contractual arrangements relating to management of Educational Grants, to ensure that the funds are used appropriately and in accordance with ethical standards and local rules and regulations.

The contractual arrangements should include appropriate provisions to provide the Member Companies the right to monitor and audit the activity of the companies managing the Educational Grants.

Member Companies may not provide an Educational Grant or funds for education to a third-party travel agency directly. A Member Company may provide an Educational Grant to an HCO or funds earmarked for education to a Professional Conference Organiser («PCO») which has arrangements in place so that payments for travel, accommodation and registration (where applicable) are remitted directly by the Member Company to a third party travel agency on behalf of the HCO/PCO, which is the recipient of the Educational Grant or the funds earmarked for education.

In these circumstances the Member Company may choose to establish a tri-partite contract, with the HCO/PCO and the third-party travel agency. Such a third-party travel agency could in principle include a third-party travel agency also used by the Member Company for its own internal travel arrangements provided this is not a Member Company-internal function or Company-owned entity.

Where a Member Company decides to use any such arrangement involving funding for, or payments to, a third-party travel agency to arrange travel, accommodation and/ or registration (when applicable) it is important that the Member Company carries out appropriate, prior due diligence on a country-by-country and case-by-case basis in order to evaluate and mitigate the particular compliance risks and practicalities where such an arrangement is considered. The Member Company must include in all of the contractual arrangements appropriate and specific compliance-related criteria and conditions for the HCO/PCO to outsource travel arrangements to a third-party travel agency, which should include appropriate provisions to allow effective monitoring and control of the activity of the third-party travel agency.

b. Scholarships and Fellowships

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

A Member Company must 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 must 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 HCPs on general healthcare-related topics through Educational Grants in accordance with the rules of this Chapter.

The topic must directly relate to the area of business, Medical Technologies, therapies, or related services of the Member Company. The Educational Event must be conducted in accordance with, and meet the other requirements of Chapter 3: Company Events 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 HCOs 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 therapies and products of Member Companies, or specific HCOs.

Chapter 5: Consulting Arrangements

1. General Principles

Member Companies may engage HCPs and HCOs to provide consulting and other services to fulfil a Legitimate Business Need, including research, participation on advisory boards and presentations at Company Events. Member Companies may pay HCPs and HCOs reasonable remuneration for performing these services. In all cases, Consulting Arrangements must be permitted under the laws and regulations of the country where the HCO is established, or where the HCP 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 HCPs or HCOs and Member Companies including where a consultant HCP or HCO declines a fee for provision of their services.

Consulting Arrangements must 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 products or services of Member Companies.

When selecting consultants, Member Companies must 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 must 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 HCP or HCO as a consultant for sales reasons does not constitute a Legitimate Business Need. If it is necessary for the sales function of a Member Company to be involved in decisions to engage specific HCPs or HCOs, the independent decision-making/review process should ensure decision-making is exercised to fulfil Legitimate Business Needs.

2. Criteria for genuine Consulting Arrangements with HCPs and HCOs

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

a. Consulting Arrangements must be entered into only where a Legitimate Business Need for the services is identified in advance, prior to the selection of the consultant(s).
b. The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified Legitimate Business Need.
c. Selection of consultants must be based on criteria directly related to the identified business need and the relevance of the consultant's qualifications, expertise, and experience to address the identified Legitimate Business Need. Some examples of these qualifications include the years of experience, geographic location, practice setting, clinical research experience, podium presence, speaking and publication experience, or experience with, usage of, or familiarity with a specific Medical Technology. The volume or value of business generated by a prospective consultant is not a relevant criterion.

d. Consulting Arrangements with HCPs or HCOs 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 an HCP or HCO 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 HCP or HCO in particular.
f. The engaging of the consultant must not be an inducement to purchase, lease, recommend, prescribe, use, supply or procure the products or services of the Member Company.
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 must follow the rules for Events set out in Chapter 1: General Criteria for Events.

3. Compensation and Fair Market Value

The compensation paid to HCPs and HCOs engaged as consultants by Member Companies must reflect Fair Market Value for the services provided and must be determined by Member Companies based on a documented internal method to determine FMV. Amongst other matters, this must take account of the consultant's qualifications, expertise and experience as well as the actual services to be provided to the Member Company. It must 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 the provision of services which are the subject of the consulting agreement, including reasonable travel, meals and accommodation expenses incurred by consultants when 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 must 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 HCPs as consultants.

All required consents and approvals must be obtained prior to commencement of the services, including from the hospital/HCO administration or from the HCP's superior (or locally designated competent authority), as applicable.

Where no such requirements apply, Member Companies must nevertheless maintain appropriate transparency and notify the Employer about the purpose and scope of the Consultancy Arrangement.

Member Companies must 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

1. Introduction

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

2. 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 economics, including clinical and cost-effectiveness and outcomes data relevant to health technology assessments (HTA) and reimbursement decision-making.

Where a Member Company uses an HCP as a consultant – for example to lead a study on behalf of the Member Company (i.e. act as principal investigator), to provide advice as an advisory committee member or adverse event committee member – the Member Company must ensure that such Consulting Arrangements comply fully with Chapter 5: Consulting Arrangements.

In accordance with the Documentation Principle, any arrangements made by a Member Company to procure research-related services must be set out in a written agreement which must 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 must also ensure appropriate clinical trial transparency in relation to their research activities and results. This must include appropriate disclosure of information about clinical trials of Member Companies, 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 must 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.

3. 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 HCOs in relation to the Evaluation Products. Evaluation Products may be provided on a no charge basis in return for the requested user feedback from HCPs at the HCO, which must 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 must 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 HCO's location at the conclusion of the evaluation period, unless these are purchased or leased by the HCO.

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

4. Third Party-Initiated Research: Research Grants

Where permitted by national laws, regulations, national guidelines and professional codes of conduct, Member Companies may provide Research Grants 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 must ensure that they do not unduly influence the research. However, Member Companies must clearly specify the intended research scope and purposes for which the Grant is requested and must 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 regard 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 must include provisions relating to adverse event reporting where appropriate and must 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.

5. Collaborative Research

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

Each collaborator must actively contribute significant skills, experience and/or resources 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 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 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 must 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 must ensure that the pooling of all collaborators' skills, experience and/or resources is clearly specified in a collaborative research agreement and all activities falling within the scope of the responsibility of the Member Company are performed in accordance with all applicable national laws and regulations, professional codes of conduct and ethical requirements as well as with applicable good practice guidelines.

Chapter 7: Royalties

HCPs, 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 an HCP may be entered into only where the HCP 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 HCP 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 an HCP 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 HCP 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 and
- a requirement to market the product or Medical Technology upon commercialisation.

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

Chapter 8: Educational Items and Promotional Items

It is prohibited to provide gifts to HCPs and HCOs.

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

a. Educational items and/or promotional items may be provided but these must relate to the HCP's practice, or benefit patients, or serve a genuine educational function.
b. No educational items and/or promotional items should be provided in response to requests made by HCPs.
c. Educational items and/or promotional items must not be given in the form of cash or cash equivalents.
d. Educational items and/or promotional items must be modest in value and can be branded or non-branded items.
e. Educational items and/or promotional items must not be given to mark significant life events (e.g., birthday, birth, wedding, etc.).
f. A Member Company may occasionally provide educational items of greater value to an HCO always provided that the item serves a genuine educational function for the HCPs at that HCO and is of benefit to patients. Such items must not be provided to HCPs purely for their personal use. The item must 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 HCOs. Such items may not be part of the HCO's normal overheads or routine costs of operation.
g. Provision of educational items and/or promotional items must not improperly reward, incentivise and/or encourage HCPs to purchase, lease, recommend, prescribe, use, supply or procure the Medical Technology of the Member Company or related services.
h. The educational items and/or promotional items must not be intended mainly for personal use.

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

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

Chapter 9: Demonstration Products and Samples

1. General Principles

Member Companies may provide their own Medical Technologies as Demonstration Products and/or Samples at no charge in order to enable HCPs and/or HCOs (as applicable) to evaluate and/or familiarise themselves with the safe, effective and appropriate use and functionality of the Medical Technology and/or related service and to determine whether, or when, to use, order, purchase, prescribe or recommend the Medical Technology and/or service in the future.

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

Provision of Demonstration Products and/or Samples must not improperly reward, induce and/or encourage HCPs and/or HCOs to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services. Any offer and/or supply of such products must always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct. Member Companies must in all cases maintain appropriate records in relation to the provision of Demonstration Products and/or Samples to HCPs and/or HCOs, 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 must clearly record in the Member Company's records as well as clearly disclose to HCPs and/or HCOs 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 HCPs and HCOs must 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 HCO's premises.

2. Demonstration Products (Demos)

Member Companies may provide examples of their products to HCPs and/or HCOs in the form of mock-ups (such as unsterilised single use products) that are used for HCPs and patient awareness, education, and training. For example, an HCP 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 HCPs 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.

3. Samples

Member Companies may provide a reasonable number of Samples at no charge to allow HCPs and/or HCOs to familiarise themselves with the products and/or related services, to acquire experience in dealing with them safely and effectively in clinical use and to determine

whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

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

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

Chapter 10: Third Party Intermediaries

Member Companies must be mindful of the fact that they may be liable for the activities of Third Party Intermediaries who interact with HCPs or HCOs in connection with the sale, promotion or other activity involving products and/or services of Member Companies.

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

The level of pre-engagement scrutiny and post-engagement oversight may vary based on several risk factors and should be evaluated by Member Companies. Depending on the situation, elements of such scrutiny and oversight may be:

- Risk assessment (evaluation of risk profile) of proposed and utilised Third Party Intermediary arrangements
- Due diligence process
- Training of Third Party Intermediaries
- Written contract including relevant terms of compliance
- Monitoring and/or Auditing programme(s) for Third Party Intermediaries

PART 2: Interpretation and Mediation Procedures

Chapter 11: General Conditions

The principles set out below are intended to design effective and efficient interpretation and mediation processes, the object of which is to ensure compliance with the Code. They are based on the principles of proportionality, swift due process, fairness and transparency.

Chapter 12: Competent Bodies

1. Swiss Medtech Legal & Compliance Commission

Swiss Medtech Legal & Compliance Commission («the Commission») is committed to implementing the Code and assisting Member Companies in the sharing of best practices and harmonised interpretations of the Code. Member Companies of the Commission have industry experience.

2. Swiss Medtech Legal Counsel

The Swiss Medtech Legal Counsel complies with the work assigned by the Association. The Legal Counsel ensures the implementation of mediation procedures and is a member of the Commission.

Chapter 13: Procedural Principles for Interpretation Issues

Member Companies may consult the Commission concerning interpretation of the Code and related regulations (e.g. regarding transparency).

The Commission may issue recommendations.

The Commission will publish interpretations of the Code in the form of Q&As on the Swiss Medtech website.

Chapter 14: Mediation

The initiation of a mediation procedure should be considered carefully.

A Member Company may, at any time, request the Legal Counsel (in writing and in a language of the proceedings) to assess the conduct of another Member Company, with a view to the proper implementation of this Code and related regulations.

The Legal Counsel must forward the petition to the Member Company concerned and request that they comment (in writing) on the alleged conduct within a reasonable time limit set by the

Legal Counsel. The Legal Counsel may also, if deemed appropriate, invite the Member Company concerned to a round table discussion.

The Legal Counsel may examine the situation described with regard to the requirements of the Code and related regulations, consult with the Commission, and issue written recommendations to the parties involved.

Proceedings made take place in either German, French or English.

The mediation process is free of charge for Member Companies concerned.

Part 3: Glossary

- **Charitable Donations:** means provision of cash, equipment, Member Company product or relevant Third Party product, for exclusive use for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause. Charitable Donations may only be made to bona fide charities or other non-profit entities or bodies whose main objects are genuine charitable or philanthropic purposes.
- **Clinical Research:** a type of research that studies tests and treatments and evaluates their effects on human health outcomes. This includes clinical investigations or interventional and non-interventional clinical performance studies where people volunteer to take part in order to test medical interventions including drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, and preventive care.
- **Code:** means the Swiss Medtech Code of Ethical Business Practice and the Swiss Medtech Transparency Guidelines.
- **Company Events:** means activities of any type that are planned, budgeted, managed, and executed in whole or in part by or on behalf Member Companies to support Third Party Organised Educational Events which fall within their scope, as provided in the Annex.
- **Conference Vetting System (CVS)**: The central decision-making process that verifies compliance with the Code for educational events organised by third parties and which is independent of MedTech Europe under the supervision of the MedTech Europe Compliance Panel. For more information, please visit: http://www.ethicalmedtech.eu.
- Approval through the Conference Vetting System is required for companies to sponsor educational events organised by third parties that fall within the scope described in the Annex. Decisions made through the Conference Vetting System in relation to specific educational events organised by third parties are binding on all companies.
- **Consulting Arrangement:** means any provision of service by an HCP or HCO 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 HCPs, providing training on how to use the Company's Medical Technology, participating in research-related meetings, etc.
- **Delegate:** means HCPs that attend an Event neither as Faculty, nor as HCPs providing services to Member Companies for the specific Event.
- **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
  - Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.
- **Educational Grants:** means provision of funding, Member Company or third party products or other in kind support to an HCO by or on behalf of a Member Company solely for the support and advancement of genuine medical education of HCPs, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic

areas in which the Member Company is interested and/or involved and where such support is provided solely for a specified intended purpose within this category.

- **Employer Notification:** means ensuring prior notification provided to an HCO (e.g. hospital administration), an HCP's superior or other locally-designated competent authority of any interaction, collaboration or other matter concerning any Member Company and any HCP, the purpose and/or scope of which requires notification under this Code by one of the following means:
  - Written notification by the Member Company
  - Co-signature of the superior or an authorised person of the HCO
  - Written notification by the HCP available to the Member Company (e.g. e-mail copied to Member Company)
  - Written confirmation by the HCP that they have performed the notification themselves
- **Entertainment:** Entertainment includes, but is not limited to, dancing or arrangements where live music is the main attraction, sight-seeing trips, theatre excursions, sporting events (e.g. skiing, golf or football match) and other leisure arrangements. For the avoidance of doubt, incidental, background music must not constitute Entertainment.
- **Evaluation Products:** means either single-use or multiple-use products and/or equipment provided free of charge to a healthcare institution by or on behalf of a Member Company for purposes of obtaining defined, evaluative user feedback over a defined period of use when used within the scope of their intended purpose, as per the authorisation in the country where the supply occurs. Evaluation Products do not include the following:
  - Samples
  - Demonstration Products
  - Products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant
  - Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.
- **Event:** means either a Company Event or Third Party Organised Educational Event.
- **Faculty:** means a podium speaker, moderator and/or chair, who presents during an Event. Poster- and abstract-presenters are not considered to be Faculty.
- **Fair Market Value (FMV):** means the value of the specified services (or products, if applicable) which would be paid by the Member Company to the other party (for example an HCP or an HCO), each dealing at arm's length in an open and unrestricted market, and when neither party is under any compulsion to buy or sell, and both parties have reasonable knowledge of the relevant facts.
- **Financial Hardship:** means in relation to an HCO extreme and unavoidable financial distress resulting from matters outside the HCO's control where the HCO is unable to operate and where patient care is consequently jeopardised. Financial distress resulting in whole or in part from mismanagement of the HCO's funds or other matters within its control is not considered to be Financial Hardship. Financial Hardship must be documented and objectively substantiated.
- **Gifts:** An item voluntarily transferred by a Company to an HCP or an HCO without compensation. Gifts do not include the following:
  - Promotional items
  - Educational items
  - Evaluation products
  - Demonstration products
  - Samples
  - Products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant

  - 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
- **Grants:** means either an Educational Grant or a Research Grant, or both.
- **Guests:** means spouses, partners, family or guests of HCPs, or any other person who does not have a bona fide professional interest in the information being shared at an Event.
- **Healthcare Organisation (HCO):** means any organisation or government 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 HCPs provide services.
- **Healthcare Professional (HCP):** means any individual (with a clinical or non-clinical role; whether a government official, or employee or representative of a government agency or other public or private sector organisation; including but not limited to, physicians, nurses, technicians, laboratory scientists, researchers, research co-ordinators or procurement professionals) that in the course of their professional activities may directly or indirectly purchase, lease, recommend, administer, use, supply, procure or determine the purchase or lease of, or who may prescribe Medical Technologies or related services. This definition does not include a purchasing professional employed in the retail sector unless that individual purchaser arranges for the purchase of Medical Technologies or related services of a Member Company for or on behalf of medical or clinical personnel. For example, if the Medical Technologies or related services of a Member Company 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 Medical Technologies or related services of the Member Company are sold in a retail pharmacy (even if this is located within a supermarket unit), interactions between the Member Company and the responsible purchasing professional will fall within the Code.
- **In-kind:** means the provision of Grants, Charitable Donations and other types of support in the form of goods or services other than money, including the provision of labour, lent or donated goods, or lent or donated services (e.g. catering services for Events, provision of venue space, company products and other services).
- **Legitimate Business Need:** means a current and actual business objective pursued by a Member Company such as the advancement of medical education, Clinical Research and/or the safe and effective use of the Member Company's Medical Technology. Engaging an HCP or an HCO 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 an HCP or HCO is never deemed a Legitimate Business Need.
- **Member Company or Member Companies:** means all companies which are members of Swiss Medtech and which develop, manufacture or distribute medical devices for human use and/or provide services in this context.
- **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 the Swiss Medical Device Ordinance of 1 July 2020 (SR 812.213) and in the Ordinance on In Vitro Diagnostic Medical Devices of 4 May 2022 (SR 812.219), as periodically amended.
- **Preceptorship:** means a type of clinician-to-clinician training funded by a Member Company where the supervising clinician oversees the procedural training of the trainee

clinician and the trainee does not have primary responsibility for the patient undergoing the procedure.

- **Proctorship:** means a type of clinician-to-clinician training funded by a Member Company where the trainee clinician performs a procedure under the supervision of another clinician and where the trainee clinician has primary responsibility for the patient undergoing the procedure.
- **Professional Conference Organiser (PCO**): a for-profit company or organisation which specialises in the management of congresses, conferences, seminars, and similar events.
- **Product and Procedure Training and Education Event:** means a type of Event that is primarily intended to provide HCPs 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
  - diseases related to the Medical Technologies, therapies, related services and/or clinical procedures.

  In all cases the information and/or training directly concern the Medical Technologies, therapies and/or related services of a Member Company.
- **Research Grants:** means the provision by or on behalf of a Member Company of funding, products/equipment and/or In-kind services to any organisation that conducts research which is made for the sole purpose of supporting the development or furtherance of clearly specified bona fide, scientifically valid and legitimate research by the recipient the purpose of which is to advance medical, scientific and healthcare knowledge, Medical Technologies and/or clinical techniques designed to improve patient outcomes.
- **Sales, Promotional and Other Business Meetings:** means any type of Company Event the objective of which is to effect the sale and/or promotion of Medical Technologies and/or related services of a Member Company, including meetings to discuss product features, benefits and use and/or commercial terms of supply.
- **Samples:** means single-use or multiple-use products provided free of charge by or on behalf of a Member Company to HCOs or HCPs who are equipped and qualified to use them in order to enable HCPs to familiarise themselves with the products in clinical use. Samples do not include the following:
  - Demonstration Products
  - Evaluation Products
  - products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant
  - products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.
- **Scholarships and Fellowships:** means Educational Grants provided to an HCO by or on behalf of a Member Company to support fellowships or scholarships offered by the HCO. 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» must be understood accordingly.
- **Swiss Medtech Transparency Guidelines:** means the public disclosure requirements of Swiss Medtech which are integral part of the Code.
- **Third Party Intermediary:** means any legal entity or person that markets, sells, promotes or otherwise brings to end-users Member Companies' products or related services, and may include distributors, wholesalers, distribution or sales agents, marketing agents, brokers, commissionary commercial agents and independent sales representatives.

- **Third Party Organised Educational Events:** means activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of a person or entity other than a Member Company to fulfil HCP medical educational needs.
- **Third Party Organised Educational Conferences:** means a type of Third Party Organised Educational Event that is a genuine, independent, educational, scientific, or policy-making conference organised to promote scientific knowledge, medical advancement and/or the delivery of effective healthcare and is consistent with relevant guidelines established by professional societies or organisations for such educational meetings. These typically include conferences organised by national, regional, or specialty medical associations/societies, hospitals, PCOs, patient organisations or accredited continuing medical education providers.
- **Third Party Organised Procedure Training:** means a type of Third Party Organised Educational Event that is primarily intended to provide HCPs with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:
- Specific therapeutic, diagnostic, or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of Medical Technologies); and
- practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment.
- **Virtual Event:** means a Third Party Organised Event or Company Organised Event that is characterised by the participation of HCP Delegates who attend exclusively remotely. Thus a Virtual Event is not connected in any way with a physical Third Party Organised Educational Event. For example, the filming of presentations, discussions, etc. taking place during a Third Party Organised Educational Event («hybrid» events), and their broadcasting to audiences not present at the physically attended Event – whether contemporaneously or after the Event – do not qualify as a Virtual Event, and therefore need to comply with all requirements of (in-person) Third Party Organised Events.

ANNEX: CVS Scope

When is the CVS assessment of an Event required?

<table>
<tr><td colspan="2" rowspan="2"></td><td colspan="4">Geographic Location of Event</td></tr>
<tr><td colspan="2">In MedTech Europe Geographic Area[1]</td><td colspan="2">Outside MedTech Europe Geographic Area[1]</td></tr>
<tr><td colspan="2">Type of activities at Third Party Organised Educational Events</td><td>National Events attended by delegates who are local HCPs only</td><td>International Events attended by delegates coming from at least two countries of MedTech Europe Geographic Area[1,2]</td><td>International Events attended by delegates registered and practising in MedTech Europe Geographic Area[1]</td><td>International Events not attended by any delegates from MedTech Europe Geographic Area[1]</td></tr>
<tr><td rowspan="3">Educational Grants[3] provided to support a Third Party Organised Educational Event</td><td>Ed. Grant to support the general running of a conference</td><td rowspan="3">Not subject to CVS decision[4]</td><td rowspan="3">Subject to CVS decision</td><td>Not subject to CVS decision[4]</td><td rowspan="4">Not subject to CVS decision[4]</td></tr>
<tr><td>Ed. Grants that include funds to support the faculty</td><td rowspan="2">Subject to CVS decision</td></tr>
<tr><td>Ed. Grants that include funds to support HCP attendance to the conference</td></tr>
<tr><td rowspan="2">Commercial Activities at Third Party Organised Educational Event</td><td>Consultancy agreement for speakers in satellite symposia</td><td rowspan="2">Not subject to CVS decision[4]</td><td rowspan="2">Subject to CVS decision</td><td rowspan="2">Not subject to CVS decision[4]</td></tr>
<tr><td>Booths/advertising</td></tr>
</table>

[1] MedTech Europe Geographic Area includes the countries in the European Economic Area (EEA), as well as countries where MedTech Europe Company Associations are located (to date, this includes CH, GB, RU, TR and members of Mecomed).

[2] Formerly referred to as «Cross-Border Events».

[3] Refer to the glossary for the definition of Educational Grants.

[4] Also if an Event is not subject to CVS decision, the provisions of the Code, national laws and regulations still apply.