SWISS MEDTECH

Information to the members

Swiss Medtech Code of Ethical Business Practice

Adopted at the founding meeting of Swiss Medtech.

12. Juni 2017

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

FASMED and Medical Cluster have joined forces to form Swiss Medtech. FASMED was a member of MedTech Europe prior to the merger. As a result of the union, this European umbrella organisation membership will be transferred to Swiss Medtech.

MedTech Europe implemented the MedTech Europe Code of Ethical Business Practice as of 1 January 2016. Its enforcement shall take place in several steps. The MedTech Europe Code of Ethical Business Practice is valid for members of the MedTech Europe Association, as well as for national Organisations such as Swiss Medtech, which are required to adopt the European Code at national level as minimum requirements for their members.

In principle, Swiss Medtech does not wish to adopt provisions deviating from the European Code. The Association has adopted the meaning of the European Code to the greatest possible extent and has adapted it as part of the present Swiss Medtech Code of Ethical Business Practice (*«Code»*). The definitions used in the European Code have been adopted and are listed in the Glossary of this *Code.*

All terms and phrases in italics and bold print are defined in Part 3: Glossary. The Acrobat PDF electronic version contains short versions of the definitions which appear when the curser is positioned over the terms or phrases. Legal liability applies solely to the definition listed in the Glossary and not to the short definition which appears upon mouse click.

Concerning future developments, the Swiss Medtech Executive Board is authorised to issue implementation decrees based on the *Code*.

The present *Code* was approved at the founding meeting of the Swiss Medtech Association on 12 June 2017. *Members and Member Companies* commit to comply with the *Code* upon the granting of their Swiss Medtech Association membership.

Introduction

Promoting an Ethical Medical Technology Industry

Swiss Medtech represents the medical technology industry in Switzerland. In addition to representing, networking, and advancing the medical device industry, our mission is to promote a balanced policy environment which enables the medical technology industry to meet the growing Healthcare needs and ethical 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 an critical step to the achievement of the aforementioned goals; they also enhance the reputation and success of *Members and Member Companies*.

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

Should a *Member or Member Company* engage third parties (such as sales & marketing intermediaries, consultants, distributors, sales agents, marketing agents, brokers, commissionaire commercial agents or independent sales representatives) who interact with *Healthcare Professionals* or *Healthcare Organisations* in connection with the sale, promotion or other activities related to the *Member's and Member Company's* products and services, it is recommended that these third parties be contractually obliged to comply with provisions set out in this *Code* as a guideline for conduct, provided that these third parties are not members of Swiss Medtech themselves.

Key Legislation

Swiss Medtech underlines compliance with the following laws as having particular relevance to *Members and Member Companies*:

- 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 and Member Companies* in their business operations, but also to Swiss Medtech and all its Specialist Groups, regardless of size and name. A *Member or Member Company* may be held liable for violations of antitrust laws by other *Members and Member Companies*. Therefore, *Members and Member Companies* must make every effort to observe competition laws in all their interactions.

Aims and Principles of the Code

The interaction between *Members and Member Companies* and *Healthcare Professionals*, and *Healthcare Organisations* is an important feature in achieving the mission to make safe, innovative, and reliable technology and related services available to more people, for example through the:

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

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

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

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

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

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

- **The Principle of Transparency:**
  Interactions between *Members and Member Companies* and *Healthcare Professionals / Healthcare Organisations* must be transparent and comply with national and local laws, regulations, or professional codes of conduct. *Members and Member Companies* shall maintain appropriate transparency by requiring prior *written notification to the hospital administration*, fully disclosing the purpose and scope of the interaction.

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

- **The Principle of Documentation**
  All such services and reciprocal services return must be documented in writing and retained so that the information may be traced and verified at all times. Among other things, the following must be documented: the objective and purpose of the interaction, the services needing further definition and / or those which have already been performed, as well as the financial remuneration, and which party is responsible for bearing the costs.

Interpreting the Code

The most important terms of this *Code* are set out in the Glossary. Terms such as «among», «including», «in particular», or similar words are to be defined as clearly as possible and should not limit the meaning of the terms and concepts.

Administering the Code

The *Members and Member Companies*, as well as the companies which fall under common control, are required to implement the *Code* as a minimum standard in the following cases:

a. The *Members and Member Companies* collaborate with *Healthcare Professionals* and *Healthcare Organisations* which are active in Switzerland; and

b. The activities take place in Switzerland, regardless of where the *Healthcare Professionals* and *Healthcare Organisations* are registered and practicing.

Entry into Force

This *Code* enters into force on the occasion of the Swiss Medtech founding meeting of 12 June 2017. The prohibitions defined in Chapter 2: Third Party Organised Education Events and in Chapter 4: Grants and Charitable Donations, Section 3: Educational Grants of the Swiss Medtech Code of Ethical Business Practice, direct financial or material support for *Healthcare Professionals* to cover their cost of participation in *Third Party Organised Educational Events* shall enter into force on 1 January 2018.

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

Chapter 1: General Criteria for Events

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

1. Event Programme

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

A *Member or Member Company* shall not organise Events which include social, sporting and/or leisure activities or forms of *Entertainment*. For *Third Party Organised Educational Events*, *Entertainment* must be outside of the educational programme schedule and paid for separately by the *Healthcare Professionals*. *Entertainment* should not dominate or interfere with the overall scientific content of the programme and must be held during times that do not overlap with a scientific session. The Entertainment should not be the main attraction of the *Third Party Organised Educational Event*.

2. Event Location and Venue

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

- Potential adverse public perception of the location and venue for the *Event*. The perceived image of the location and venue must not be luxury, or touristic/holiday-oriented, or that of an Entertainment venue.
- The *Event* location and venue should be centrally located when regard is given to the place of residence of the majority of the invited participants.
- The need for ease of access for attendees
- The Event location and venue should be in or near a 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 and Member Companies* must take into account the season during which the *Event* is held. The selected time of year must not be associated with a touristic season for the selected geographical location.

3. Guests

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

4. Reasonable Hospitality

Members and Member Companies may provide reasonable hospitality to *Healthcare* P*rofessionals* in the context of *Company Events* and *Third Party Organised Educational Events* but any hospitality offered must be subordinate in time and focus to the *Event* purpose.

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

Accordingly, *Members and Member Companies* must assess what is «reasonable» in any given situation.

Members and Member Companies may not pay for or reimburse *Healthcare Professionals'* lodging expenses at top category or luxury hotels. As a rule, accommodation in a congress hotel is permitted, provided the requirements of the *Code* are met. The cost of accommodation and/or other services provided to the *Healthcare Professionals* should not cover a period of stay beyond the official duration of the *Event*.

5. Travel

Members and Member Companies may only pay or reimburse for reasonable and actual travel. Complete (or partial) assumption of costs may be undertaken so long that legal requirements are taken into account. Travel provided to *Healthcare Professionals* should not cover a period of stay beyond the official duration of the *Event*.

For air travel, in principle, this means that *Members and Member Companies* can only pay for or reimburse economy or standard class unless the flight time) is of a duration of greater than 5 hours including connection flights, in which case business class can be considered. Tickets for a higher class than business (e.g., first class) are never appropriate.

6. Transparency

Members and Member Companies must ensure full compliance with applicable laws, regulations, and professional codes of conduct regarding the disclosure or approval requirements associated with financial support. An *Employer Notification* must be completed prior to every *Event*.

Chapter 2: Third Party Organised Educational Events

Members and Member Companies may provide financial and/or in kind support (e.g. products) to *Third Party Organised Educational Events*. Such events include:

- *Third Party Organised Educational Conferences; and*
- *Third Party Organised Procedure Training meeting.*

1. Third Party Organised Educational Conferences

Members and Member Companies may support in cash and/or in kind Third Party Organised Educational Conferences provided that:

- The requirements according to Chapter 1: General Criteria for Events are met;
- Approval by the *Conference Vetting System* has been granted for international participants and
- The provision of support is permitted under applicable laws, regulations and professional codes of conduct.

Such forms of support could be, for example:

a. Educational Grants

Please refer to Chapter 4: Grants and Charitable Donations, Section 3: Educational Grants for guidance on Educational Grants

b. Promotional Activity

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

c. Satellite Symposia

Members and 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. *Members and Member Companies* may determine the content at these satellite symposia and be responsible for speaker selection.

2. Third Party Organised Procedure Training

Members and Member Companies may support *Third Party Organised Procedure Training* either via *Educational Grants* (in accordance with Chapter 4: Grants and Charitable Donations, Section 3: Educational Grants), or by providing financial support directly to individual *Healthcare Professionals* to cover the cost of attendance at *Third Party Organised Educational Events*, in accordance with the following rules:

- The requirements defined in Chapter 1: General Criteria for Events are met;
- Approval by the Conference Vetting System has been granted for international participants and
- Such provision of support is permitted under applicable laws, regulations, and professional codes of conduct.

Chapter 3: Company Events

1. General Principles

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

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

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

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

2. Product and Procedure Training and Education Events

Where appropriate, in order to facilitate the safe and effective use of medical technologies, therapies and/or services, *Members and Member Companies* should make *Product and Procedure Training and Education Events* available to relevant *Healthcare Professionals*.

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

3. Sales, Promotional and Other Business Meetings

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

In addition to the principles laid down in Chapter 3: Company Events, Section 1: General Principles, *Sales, Promotional and Other Business Meetings* should also comply with the following requirements:

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

Chapter 4: Grants and Charitable Donations

1. General Principles

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

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

c. The payment (or provision of other support) by way of any ***Grant*** or ***Charitable Donation*** shall always be made out in the name of the recipient *Healthcare Organisation* and shall be paid directly to the organisation. ***Grants*** and ***charitable donations*** may not be provided in the name of any *Healthcare Professional* and all *Grants* and *Charitable Donations* shall identify the *Member or Member Company* as the provider of the *Grant* or *Charitable Donation*.

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

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

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

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

2. Charitable Donations

Charitable Donations within the meaning of this *Code* may be made only to entities which have charitable and/or philanthropic purposes as their main purposes and which are objectively engaged in genuine charitable and/or philanthropic activities.

The differences between limited and unrestricted *Charitable Donations* must be distinguished. «Restricted» in this context means that the *Member or Member Company* determines the purpose of the *Charitable Donation*. «Unrestricted» in this context means that *Member or Member Company* shall have no control over the final use of funds (or other support) beyond general restrictions to ensure that the *Charitable Donation* is applied for charitable and/or philanthropic purposes.

In principle, the *Charitable Donations* are to be granted without restriction.

Restricted *Charitable Donations* to non-profit hospitals may be permitted in case of demonstrated financial hardship, when *Charitable Donations* serve exclusively the benefit of the patient, are limited in value, or are explicitly permitted by applicable laws, regulations, and professional codes of conduct. A Healthcare Organisation is considered to be in financial hardship in the event of extreme and unavoidable financial distress resulting from matters outside the Healthcare Organisation's control where the Healthcare Organisation is unable to operate and where patient care is consequently jeopardised. Financial distress resulting in whole or in part from mismanagement of the Healthcare Organisation's funds or other matters within the Healthcare Organisation's control is not be considered to be financial hardship.

This Chapter 4 is not intended to address the legitimate commercial transactions by *Members or Member Companies* in the form of leasing 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 or Member Company's* normal marketing activity**.** *Members and Member Companies* should, however, always consider the appropriateness of the location, venue and the general arrangements for any such *Events* and the impression that may be created by the arrangements in order not to bring the industry into disrepute.

3. Educational Grants

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

Members and Member Companies shall disclose all *Educational Grants* in accordance with the transparency regulations issued by the Swiss Medtech Executive Board.

Members and Member Companies may offer *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 or Member Company* to a *Healthcare Organisations* for must:

- Comply with Chapter 1: General Criteria for Events; and
- Secure approval for international participants from the *Conference Vetting System*.

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

2. **Support for Third Party Organised Educational Events:**
   Where the prospective beneficiary of an *Educational Grant* is a *Healthcare Organisation*, they are solely responsible for:

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

   The above points shall be stated in the written agreement. If expressly requested to do so, *Members and Member Companies* may recommend speakers or comment on the programme.

b. Scholarships and Fellowships

Members and Member Companies may provide *Educational Grants* on a restricted basis in the form of *Grants* for *Scholarships and Fellowships* to support advancement of genuine medical education of *Healthcare Professionals*. Only *Healthcare Organisations* where *Healthcare Professionals* are in training shall be eligible for request and/or receive such *Educational Grants*. A *Member or Member Company* shall not provide *Educational Grants* to support

Scholarships and Fellowships upon request of individual *Healthcare Professionals*. Similarly, *Members and Member Companies* shall not have any involvement in the selection of the *Healthcare Professionals* who will benefit from the *Educational Grant* and this shall be reflected in the written *Grant* agreement between the *Member or Member Company* and the recipient *Healthcare Organisation*.

c. Grants for Public Awareness Campaigns

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

4. Research Grants

Where permitted by applicable laws, regulations and professional codes of conduct, *Members or Member Companies* may provide restricted *Research Grants* to support clearly defined third-party initiated research studies for clinical or non-clinical research programmes. *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.

Members or Member Companies providing *Research Grants* shall ensure that they do not influence the research. However, in order to ensure that *Research Grants* are provided on a «restricted» basis, *Members and Member Companies* shall clarify the intended research scope and purposes of the *Grant.* In addition, the written research grant agreement shall include the *Member or Member Company* the right to verify that the Grant is applied solely for the agreed intended research use. To this end, the *Member or Member Company* may request 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 of the research.

Chapter 5: Arrangements with Consultants

1. General Principles

Members or member companies may engage *Healthcare Professionals* as consultants and advisors to provide bona fide consulting and other services, including but not limited to research, participation on advisory boards, presentations at Company Events and product development. *Members or member companies* may pay Healthcare Professionals reasonable remuneration for performing these services.

The principles in this Chapter 5 are applicable to all consultancy arrangements between *Healthcare Professionals* and *Members or Member Companies*, including where a consultant *Healthcare Professionals* declines a fee for provision of their services.

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

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

2. Criteria for genuine consulting arrangements

In addition to the general principles above, the agreements which cover genuine consultancy or other services must fulfil all the following criteria:

a. Consultancy arrangements must be entered into only where a legitimate business need for the services is identified in advance by the *Member or Member Company*;

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

c. Selection of consultants must be based on criteria directly related to the identified business need of the *Member or Member Company* and the relevance of the consultant's qualifications, expertise and experience to address the identified need. The volume or value of business generated by the prospective consultant or *Healthcare Organisation* is not a relevant criterion;

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

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

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

g. *Members and Member Companies* must maintain records of the services, and associated work products, as well as documents detailing the utilisation of the services;

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

3. Remuneration and Fair Market Value

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

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

4. Disclosure and Transparency

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

Members and Member Companies shall also include appropriate obligations on the consultant to ensure that the consultant's status as a consultant for the *Member or 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.

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Chapter 6: Research

1. Member Company-Initiated Research

Where there is a legitimate business need to do so, *Members and Member Companies* may initiate, conduct, manage and finance scientifically valid research to generate, whether pre- or post-market. In this context, legitimate business needs for data include, among other things:

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

Where a *Member or Member Company* uses a *Healthcare Professional* as a consultant, for example, to lead a study on the *Member or Member Company's* behalf (i.e., act as Principle Investigator), the *Members or Member Company* shall ensure that these consultancy agreements comply fully with Chapter 5: Agreements with Consultants.

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

Members and Member Companies must ensure that their research activities comply with all applicable laws, regulations, and 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, *Members and Member Companies* shall also ensure appropriate clinical transparency in relation to their research activities and results. This shall include appropriate disclosure of information about *Member's and Member Companies'* clinical trials, for example in external public registries and peer-reviewed journals.

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

2. Member Company Post-Market Product Evaluation

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

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

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

3. Third Party-Initiated Research

Please refer to Chapter 4: Grants and Charitable Donations, Section 4: Research Grants

Chapter 7: Royalties

Healthcare Professionals, acting independently or as part of a group in which they are as active participants, often make valuable contribution to improve products or medical technologies. They may develop intellectual property, for example patents, trade secrets or know-how.

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

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

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

Members and Member Companies should exclude from the calculation of royalties the number of units purchased, prescribed, used, or ordered by the *Healthcare Professional* and/or *Healthcare Organisation*.

Chapter 8: Educational Items and Gifts

Members and Member Companies exceptionally may provide inexpensive educational items and/or gifts, in accordance with applicable laws, guidelines, and professional codes of conduct. *Members and Member Companies* may only provide such educational items and/or gifts in accordance with the following principles:

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

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

c. Education items and/or gifts must not be given in the form of cash, check or similar equivalents (vouchers etc.);

d. Educational items and/or gifts must be modest in value, and can be branded with the *Member or Member Company's* logo;

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

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

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

This Chapter 8 is not intended to address the legitimate practice of providing appropriate *Evaluation Products, Demonstration Products* or Samples. For guidance on providing *Evaluation Products, Demonstration Products*, or *Samples*, please refer to Chapter 6: Research and Chapter 9: Demonstration Products and Samples.

Chapter 9: Demonstration Products and Samples

1. General Principles

Companies may provide their own products as *Demonstration Products* and/or *Samples* at no charge to enable *Healthcare Professionals* and/or *Healthcare Organisations* to:

a. evaluate the safe, effective and appropriate use and functionality of the product and/or related services and/or

b. familiarise themselves with the product and/or service

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

Demonstration Products and *Samples* may be either single- or multiple-use products. *Members and Member Companies* may also provide products from another company in conjunction with the *Member or Member Company's 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 or Member Company's* products, e.g. computer hardware and software produced by a company other than the *Member or Member Company*

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

Members and Member Companies shall in all cases maintain appropriate records in relation to the provision of *Demonstration Products* and/or *Samples* to *Healthcare Professionals* and/or *Healthcare Organisations*, for example recording proof of delivery, and in the case of multiple-use products, their return. *Members and Member Companies* shall clearly disclose to *Healthcare Professionals* and/or *Healthcare Organisations* the no-charge basis and other conditions applicable for the supply of such *Demonstration Products* and/or *Samples* no later than the time of the supply. The disclosure to Healthcare Professionals and *Healthcare Organisations* shall be in writing and include any other terms associated with the provision.

This Chapter 9 is limited to the free provision of *Demonstration Products* and/or *Samples* and related services at no charge and is not intended to apply to provision of products or related

services under any other arrangements, for example (but not limited to) provision within the framework for clinical trials and/or other research or commercial supplies by way of rebates or pricing incentives in a public procurement context.

2. Demonstration Products (Demos)

Members and Member Companies may provide examples of their products to *Healthcare Professionals* and *Healthcare Organisations* in the form of mock-ups (such as unsterilised single use products) that are used for *Healthcare Professionals* and patient awareness, education and training.

A *Healthcare Professional* may, for example, use a *Demonstration Product* to show a patient the type of technology which will be implanted in the patient or may use the Demo to train other *Healthcare Professionals* in the use of the product. *Demonstration Products* are not intended for clinical use in any patient care, nor are they intended for on-sale or other transfer.

3. Samples

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

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

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

PART 2: Interpretation and Mediation Procedures

Chapter 10: 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 11: Competent Bodies

Swiss Medtech Legal & Compliance Commission Specialist Group («L&C»)

Swiss Medtech's Legal & Compliance Specialist Group is committed to implementing the *Code* and assisting *Members and Member Companies* share best practices and harmonised interpretations of the *Code*. L&C Specialist Group members have industry experience.

Swiss Medtech General Counsel

The General Counsel is elected by the Swiss Medtech Executive Board and complies with the work assigned to them by the Association. They ensure the implementation of mediation procedures. The Swiss Medtech General Counsel is a member of the L&C Specialist Group.

Chapter 12: Procedural Principles for Interpretation Issues

Members and Member Companies may consult the L&C Specialist Group concerning the interpretation of the *Code* and related regulations (e.g. for transparency etc.). *Members and Member Companies* that are also members of MedTech Europe may also request the L & C Specialist Group for interpretation of the MedTech Europe Code of Ethical Business Practice (and related regulations).

The Specialist Group can issue recommendations.

The Specialist Group will periodically publish interpretations of the Code in the Q&A section of the Swiss Medtech homepage.

Chapter 13: Mediation

The initiation of a mediation procedure should be considered carefully.

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

Members or Member Companies which are also members of MedTech Europe may also request mediation to assess the conduct of another *Member or Member Company* which is also a member of MedTech Europe with a view to the appropriate implementation of the MedTech Europe Code of Ethical Business Practice and related regulations, provided that all *Members and Member Companies* accept (unconditionally and in written form) the competency of the General Counsel.

The General Counsel shall forward the petition to the *Member or Member Company* concerned and request that they comment (in writing) on the alleged conduct within a reasonable time limit set by the General Counsel. The General Counsel may also, if deemed appropriate, invite the *Member or Member Company* concerned to a round table discussion.

The General Counsel may examine the situation described with regard to the requirements of the ***Code*** and related regulations, consult with the L & C Specialist Group, and issue written recommendations to the parties involved.

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

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

PART 3: Glossary and Definitions

Charitable Donations: means provision of cash, equipment, company product or relevant Third Party product, for exclusive use for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause. *Charitable donations* may only be made on an unrestricted basis and exclusively to bona fide charities or to other non-profit entities whose main objects are genuine charitable and/or philanthropic activities. *Limited Charitable Donations* may only be made according to Chapter 4: Grants and Charitable Donations, Section 2: Charitable Donations.

Code: means this Swiss Medtech Code of Ethical Business Practice.

Company Events: means activities of all type that are planned, managed and executed in whole or in part by or on behalf of a *Member or Member Company*, to fulfil a legitimate, documented business need of the *Member or Member Company* to interact with customers; for example, with *Healthcare Professionals* and/or *Healthcare Organisations*.

Conference Vetting System: means the centralised decision-making process which reviews the compliance of *Third Party Organised Educational Events* with the applicable MedTech Europe Code of Ethical Business Practice and the Eucomed Code of Business Practice concerning international participants and which is managed independently of MedTech Europe under the supervision of the MedTech Europe Compliance Panel. For more information see: http://www.ethicalmedtech.eu.

Demonstration Products: means either single-use or multiple-use products provided free of charge or on behalf of a *Member or Member Company to HCOs* or HCPs, who are equipped and qualified to use them. *Demos* are supplied solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use. *Demos* do not include the following:

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

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

Employer Notification: means the prior written notification provided to a *Healthcare Organisation* (e.g. hospital administration)*Healthcare Professional*'s superior or other locally-designated competent authority of any interaction, collaboration or other matter concerning any *Member or Member Company* and any *Healthcare Professional*, the purpose and/or scope of which requires notification under this *Code*.

Entertainment: includes, but is not limited to dancing or arrangements where live music is the main attraction, sightseeing trips, theatre excursions, sporting events (e.g. skiing, golf, or football match) and other leisure arrangements. For the avoidance of doubt, incidental, background music shall not constitute *Entertainment.*

Evaluation Products: means either single-use or multiple-use products and/or equipment provided free of charge to a *Healthcare Organisation* by or on behalf of a *Member or 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, in accordance with any applicable laws. *Evaluation Products* do not include the following:

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

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

Faculty: means a podium speaker, moderator, and/or chair, who presents during a *Third Party Organised Educational Event. Healthcare Professionals* who present posters and abstracts at congresses are not considered to be *Faculty*.

Grant: means either an *Educational Grant* and/or a *Research Grant*.

Guests: means spouses, partners, family or guests of *Healthcare Professionals*, or any other person who does not have a bona fide professional interest in the information being shared at an *Event*.

Healthcare Organisation (HCO): means any legal entity or body (irrespective of its legal or organisational form) that is a healthcare, medical or scientific association or organisation which may have a direct or indirect influence on the prescription, recommendation, purchase, order, supply, utilisation, sale or lease of medical technologies or related services such as a hospital or group purchasing organisation, clinic, laboratory, pharmacy, research institution, foundation, university or other teaching institution or learned or professional society (except for patient organisations); or through which one or more *Healthcare Professionals* provide services.

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

Members and Member Companies: means all *Members and Member Companies* of Swiss Medtech who develop, manufacture or distribute medical devices for human use and/or provide services in this context.

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

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

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

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

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

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

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

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

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

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

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

- Special therapeutic, diagnostic or rehabilitative procedures; namely clinical courses of action, methods or techniques; and
- Practical demonstrations and/or training for *Healthcare Professionals*, where the majority of the training programme is delivered in a clinical environment.

Work shadowing visits to analyse and assess the skills of the *Healthcare Professional* in the usage of products as well as Proctorships (procedure supervision) are not included in this category of the *Educational Event*. For the purposes of this *Code*, work shadowing visits are practice procedures amongst physicians which are sponsored by a *Member or Member Company*, and include the following situations:

- A trainee practitioner performs a procedure under the supervision of another physician, whereby the trainee physician is responsible for the patient's well-being.
- A supervising physician oversees the practice of the trainee practitioner who does not have the primary responsibility for the patient's well-being.

Such work shadowing visits usually take place on the premises of a *Healthcare Organisation* and in cases of international participants do not require auditing by the *Conference Vetting System*.