

Information for Members

June 2023

Q&A for Swiss Medtech Code of Ethical Business Practice of 25 May 2023

The revised Swiss Medtech Code of Ethical Business Practice of 25 May 2023 entered into force on 1 January 2024 and has applied to all member companies since this point onwards.

The revised Swiss Medtech Code essentially adopted the principles of Medtech Europe's revised Code of Ethical Business Practice, which came into force on 1 January 2023. The revised Swiss Medtech Code of 25 May 2023 applies globally.

This Q&A document is intended to facilitate application of the Swiss Medtech Code in practice. It entered into force on 21 June and replaces the previous Q&A document of 1 July 2019. The answers to the questions in the Q&A document are binding.

All terms used in the Q&A document correspond to the definitions used in the Swiss Medtech Code (hereinafter referred to as the «Code»).

Swiss Medtech Code of Ethical Business Practice

Introduction	Scope of application of the Code
<p>Q1</p>	<p>The Code applies globally, irrespective of where an event takes place and irrespective of whether Swiss HCPs are participating in an event.</p> <p>The Code applies to all companies which are members to Swiss Medtech, including their affiliates. An affiliate (downstream) is a company in which a majority stake is held by a company. A parent company (upstream) or a sister company is not considered to be an affiliate.</p>
<p>Q2</p>	<p>Can and must the provisions of the Code be applied in all cases in each country in which a member is active?</p> <p>In principle, ethical business practice should not stop at the national borders. The Code is not country-specific, but is rather to be regarded in a European context. It is based on principles that are also recognised in other continents. At the same time, there may be cultural differences that cannot be ignored. Therefore, it is possible in exceptional cases for defined countries to make differing provisions to take cultural needs or constraints into account (e.g. the culture of giving gifts in certain Asian countries). Such exceptions must be kept within reasonable limits, be well-founded, and legal in the respective country as well as being approved by an independent body of the member as part of an independent decision-making/evaluation procedure.</p>
<p>Q3</p>	<p>How does the Code apply to members with company platforms that include different business units e.g., medical devices, pharmaceuticals, research only products? How can educational grants be applied in such organizational structures?</p> <p>The Code applies to all Member Companies' interactions linked to Medical Technologies. Ensuring compliance with the Code may be more challenging for companies with platforms combining different business units, however Member Companies are required to comply with the Code as a minimum standard for all interactions linked to Medical Technologies independent of their organizational set up.</p>

<p>PART 1 Chapter 1</p>	<p>Guidelines on the Interactions with Healthcare Professionals and Healthcare Organisations General Criteria for Events</p>
<p>Q4 Cf. Chapter 1, Section 1</p>	<p>Do the minimum duration requirements apply to Virtual Events? No, Virtual Events are not affected by the duration requirements</p>
<p>Q5 Cf. Chapter 1, Section 1</p>	<p>Can a Member Company organise or support an Event at a hotel or resort that offers significant leisure facilities such as golf, casino or ski/water sports?</p> <p>While hotels generally are accepted venues, it is not appropriate for a Member Company to organise or support Events at hotels or resorts renowned for their entertainment facilities or centred around recreational or sporting activities such as golf, private beach or ski/water sports. Exceptions might be considered for venues well adapted to business meetings in an otherwise compliant geographic location where there is a compelling need to use the chosen venue, for example, a lack of alternative venues or genuine safety or security issues. In certain circumstances, hotel accommodation separate from the Third-Party Organised Event venue might be required for compliance.</p> <p>Where an exception is considered, the Event’s promotional material should not feature or promote the on-site leisure aspects of the conference venue and the Event’s agenda should be arranged in such a way that attending Healthcare Professionals would not be free to make use of the leisure and sporting facilities during any significant part of a normal working day. Further, where hotels require additional payment to use the leisure or sporting facilities, Member Companies may not make such payments on behalf of the Healthcare Professionals. For reasons of perception, cruise ships or hotels with on-site casinos are under no circumstances compliant with the Code, either as an Event venue or for accommodation for Healthcare Professionals.</p>
<p>Q6 Cf. Chapter 1, Section 1</p>	<p>What is the difference between hospitality and entertainment?</p> <p>Hospitality, such as invitations to dinner, refers to the friendly and professional treatment of professionals, which must not primarily be for enjoyment or entertainment. It must always be subordinate in time and subject matter to the primary purpose of the meeting between the company and the professional, and it must remain within reasonable limits. What counts as «reasonable» must be assessed on a case-by-case basis, taking into account all circumstances, such as role and tasks of the professional, local customary use and applicable regulations.</p>

	Entertainment refers, among other things, to dance events, events with live music, sightseeing excursions, theatre performances, sporting events or similar leisure activities.
<p>Q7</p> <p>Cf. Chapter 1, Section 1</p>	<p>Can a member invite or engage an independent third party to organise an entertainment element for a Company Event if the participants pay for this?</p> <p>No, entertainment elements in connection with a Company Event are not permitted. This applies irrespective of whether the member itself or a third party carries this out, even if the participants pay the third party directly for this.</p>
<p>Q8</p> <p>Cf. Chapter 1, Section 2</p>	<p>Under the Code, what is meant by «ease of access» in relation to Event location and venue?</p> <p>When the originating location of the majority of attendees is considered, Event location and venue need to be in close proximity to an airport and / or train station with appropriate international connections, with associated reliable ground transportation infrastructure to the venue.</p>
<p>Q9</p> <p>Cf. Chapter 1, Section 2</p>	<p>Under the Code, how does the «season» impact evaluation of Event location?</p> <p>In principle, tourist sites are not ruled out as Event locations. However, in such cases, special attention should be paid to the season during which the Event is to be held.</p>
<p>Q10</p> <p>Cf. Chapter 1, Section 2</p>	<p>How is it possible to assess beforehand as to whether only regional professionals attend the Event?</p> <p>While the group of participants is already known in advance for Company Events, this is not necessarily known beforehand for third-party events. To assess the geographical location, the Event's advertising and the target audience addressed in it can be used; for recurring Events, past experience can also be used if applicable.</p>
<p>Q11</p> <p>Cf. Chapter 1, Section 2</p>	<p>What is classed as an «appropriate environment» for a medical event?</p> <p>When choosing an Event location, public perception should also be taken into consideration at all times. In general, suitable venues for medical events are clinics, education institutions, conference centres, commercial meeting venues, as well as conference rooms in suitable conference hotels.</p> <p>Amusement parks, casinos and other facilities for entertainment are generally not suitable as Event locations.</p>

<p>Q12</p> <p>Cf. Chapter 1, Section 2</p>	<p>Do the restrictions on «appropriate environment», geographical location and timing also apply to Third Party Organised Educational Conferences?</p> <p>Yes, regardless of who organises the Event, the suitability of the geographical location and timing should be checked before decisions are made about providing support for the Event, renting exhibition booths or any other type of advertising or promotion for the Event.</p>
<p>Q13</p> <p>Cf. Chapter 1, Section 3</p>	<p>What does the term «facilitate» mean where used in connection with Guest expenses?</p> <p>The term «facilitate» refers to the prior arrangement, organisation or booking of meals, travel or accommodation by or on behalf of a Member Company on behalf of a Guest of a Healthcare Professional participant. Such organisation or booking is not permitted unless the individual qualifies as a participant in their own right, irrespective of who pays. Such actions are open to misinterpretation. If Healthcare Professionals attending the Event wish to be accompanied by a Guest who does not have a professional interest in the information being shared, the Healthcare Professional must take sole responsibility for the payment and organisation of the Guest's expenses, as they have to do for their own activities not related to the Event.</p>
<p>Q14</p> <p>Cf. Chapter 1, Section 3</p>	<p>In the event that a Healthcare Professional is accompanied by a Guest at the Event, may this Guest be admitted to any Company Event, or Third Party Organised Educational Events?</p> <p>a. Company Events It is not appropriate for a Guest of a Healthcare Professional to attend Company Events, including satellite symposia and business meals, unless the individual qualifies as a participant in their own right.</p> <p>b. Third Party Organised Educational Events It is not appropriate for a Guest of a Healthcare Professional to attend Third Party Organised Educational Events, unless the individual qualifies as a participant in their own right. It is also not appropriate, in the interest of maintaining scientific exchange, for a Guest to participate in related hospitality during such Events (for example, lunches, industry booths and coffee breaks) even if the Healthcare Professional pays for the Guest's expenses.</p> <p>Member Companies, however, are permitted to financially support Third Party Organised Educational Events which offer extra-curricular programmes / activities beyond the scientific, educational or training sessions exclusively for Guests of Healthcare Professionals (such as touristic activities and hospitality), always provided that such a programme/activity</p>

	(including conference dinner or cocktail reception for Educational Event attendees) takes place on an extra-curricular basis.
<p>Q15</p> <p>Cf. Chapter 1, Section 4</p>	<p>Is it acceptable to offer a cash advance by way of a cheque or bank transfer payable to a Healthcare Professional for a specific amount to cover all or part of the Healthcare Professional’s travel or accommodation expenses for attendance at the Event?</p> <p>It is not acceptable to make an advance payment to a Healthcare Professional to cover prospective expenses. Payments should generally be made to the supplier/vendor or intermediary agency. Alternatively, Member Companies may reimburse individual Healthcare Professional expenses retrospectively against original invoices or receipts.</p>
<p>Q16</p> <p>Cf. Chapter 1, Section 6</p>	<p>Must a Member Company require Employer Notification to be given whenever Company personnel meet employed HCPs?</p> <p>No. Unless the Member Company’s interaction with an HCP entails a transfer of value there is no requirement for Employer Notification.</p>
<p>Q17</p> <p>Cf. Chapter 1, Section 6</p>	<p>When making Employer Notification, are Member Companies required to provide details of the proposed financial contribution Member Companies will make to the Healthcare Professional in exchange for the services rendered?</p> <p>The written notification must comply with national laws, regulations and professional codes of conduct. In Switzerland, there is no requirement to notify employers of the amounts involved. Under the Code, Member Companies must ensure that the level of remuneration is commensurate with the services provided and not greater than a fair market value. However, the purpose of the Employer Notification is to provide transparency on the nature of the interaction between the Member Company and the Healthcare Professional and to enable the employer to raise objections if they perceive a potential conflict or have other issues concerning the interaction.</p>
<p>Q18</p> <p>Cf. Chapter 1, Section 6</p>	<p>Can a celebration dinner or other type of social Event be supported?</p> <p>No. Social events, such as anniversaries, semester parties, retirement celebrations, Christmas dinners or other similar events may not be supported by Member Companies, neither as stand-alone events nor as part of Third Party Organised Events. For the avoidance of doubt, Member Companies may also not invite Healthcare Professionals to attend such an event at the Member Company’s expense.</p>

Chapter 2	Third Party Organised Educational Events
<p>Q19</p> <p>Cf. Chapter 2</p>	<p>Can a Member Company support a Third-Party Organised Educational Event, where the organisers are individual Healthcare Professionals without involvement of a legal entity, such as a Professional Congress Organiser, a Healthcare Organisation or a travel agency?</p> <p>In no event can financial support be transferred directly to the bank account of an individual HCP.</p> <p>In-Kind support may be provided to this kind of Event provided it complies with all the requirements of the Code. Such In kind support may include the (temporary) loaning of multiple use Medical Technologies, the provision of single-use Demonstration Products, but also the direct payment of catering, venue rental invoices, and/or speakers through Consulting / Speaker Agreements provided that these comply with all requirements of Chapter 5 of the Code.</p> <p>This type of support carries significant risks for all parties involved, which need to be managed carefully, even where such an Event complies with all other aspects of the Code, including the prohibition of support for attendance of identifiable HCPs at Third Party Organised Educational Events.</p>
<p>Q20</p> <p>Cf. Chapter 2, Section 1</p>	<p>What is meant by «In Kind support» as used in Chapter 2, Section 1 of the Code in connection with «Third Party Organised Educational Conferences»?</p> <p>Examples of «In Kind support» which Member Companies may provide could include modest secretarial and/or logistical support to assist with meeting arrangements but also provision of non-sterile samples for hands-on trainings. «In Kind support» can be provided to Healthcare Organisations but Member Companies should take care to ensure such In Kind support does not, nor is perceived to, circumvent the prohibition against Member Companies providing direct financial support to identifiable Healthcare Professionals to attend Third Party Organised Educational Conferences. For example, it would not be appropriate for Member Companies to directly handle the conference registration, travel, or accommodation arrangements for individual (and identifiable) HCP delegates at a Third Party Organised Educational Conference.</p>

<p>Q21</p> <p>Cf. Chapter 2, Section 1</p>	<p>Please provide examples of appropriate booth activities which will be perceived as professional?</p> <p>Booth activities at Third Party Organised Educational Conferences should aim primarily at displaying Member Companies' Medical Technologies and/or related services and related literature. Therefore other activities should be limited and reasonable and in principle only soft drinks and snacks should be served.</p>
<p>Q22</p> <p>Cf. Chapter 2, Section 2</p>	<p>What are the main differences between Third Party Organised Educational Conferences and Procedure Trainings?</p> <p>Both Third-Party Organised Educational Conferences (see the Glossary) and Procedure Trainings (see the Glossary) are a type of Third Party Organised Educational Event. Therefore, they must comply with Chapter 1. General Criteria for Events; and, where applicable, are subject to the Conference Vetting System (see the Glossary). However, unlike Third Party Organised Educational Conferences, Third Party Organised Procedure Trainings are not subject to the prohibition of direct support for the attendance of HCPs. Nonetheless, for Third Party Organised Procedure Trainings the following three criteria shall apply:</p> <ul style="list-style-type: none"> ▪ Programme: Unlike Third Party Organised Educational Conferences which are theoretical in nature, Third Party Organised Procedure Trainings consist of practical, hands-on training, generally involving more than one provider/manufacturer/sponsor. This must be evident from the programme for the Event. The programme, which is often referred to as a «course», rather than a conference or seminar, must be focused on acquiring specific medical skills relevant to certain medical procedures (rather than products, or Medical Technologies). Examples may include courses aimed at acquiring or improving the Healthcare Professional's skills in minimally invasive surgery; orthopaedic trauma surgery; or the implantation of cardiac rhythm devices; etc. The programme must also include practical demonstrations (and/or actual live surgeries, where allowed). Examples of practical demonstrations may include surgery simulations where Medical Technologies are used on cadavers; skin models; synthetic bones; cath labs; etc. ▪ Venue: Third Party Organised Procedure Trainings are typically organized in a clinical environment, as opposed to, e.g., a classroom setting. For the avoidance of doubts, the adjective «clinical» includes places suitable for the simulation of medical procedures, rather than just the medical treatment of real patients. Examples of clinical environment include hospitals or clinics, where medical treatment on real patients may be given; as well as conference rooms which are appropriately set up to simulate medical procedures, for example with the presence of Medical Technologies to be used on cadavers; skin models; synthetic bones; etc

	<ul style="list-style-type: none"> ▪ Stand-alone event: Third Party Organised Procedure Trainings must stand alone. Where the majority of the training is not given in a clinical environment, for example, where the training is organized in connection with, adjacent to, or at the same time as, a larger Third Party Organised Educational Conferences, that training will not qualify as a Third Party Organised Procedure Training, as defined in the Code.
<p>Q23</p> <p>Cf. Chapter 2, Section 2</p>	<p>Do Proctorships and Preceptorships require CVS approval before they can be provided and/ or supported by a Member Company?</p> <p>Proctorships and Preceptorships normally take place on HCO premises and are not subject to CVS approval as it is not considered to be either a Third Party Organised Educational Event or a Third Party Organised Procedural Training.</p>
<p>Q24</p> <p>Cf. Chapter 2, Section 2</p>	<p>Is it possible to have a virtual procedure training if the trainees perform the practical parts live under the supervision of the instructor in the same way they would do in a classroom training (e.g. on models they have received before)?</p> <p>Yes, provided the practical parts are comparable and have the same educational value as in a classroom training procedure training may be virtual events as well.</p>
Chapter 3	Company Events
<p>Q25</p> <p>Cf. Chapter 3, Section 2</p>	<p>Are cruise ships or golf clubs appropriate venues for Product and Procedure Training or other Educational Events?</p> <p>No. Cruise ships, golf clubs or health spas and venues renowned for their Entertainment facilities are not appropriate venues and should not be used. Appropriate examples include hospital, clinic or surgical centre laboratory, educational, conference, or other appropriate settings, including Member Companies' own premises or commercially available meeting facilities, that are conducive to effective transmission of knowledge and any required «hands on» training</p>
<p>Q26</p> <p>Cf. Chapter 3, Section 2</p>	<p>What criteria should a Member Company apply when considering the country location of Product and Procedure Training or other Educational Events?</p> <p>If the participants are primarily from one country, the venue should be in the specific country involved. If the participants are from multiple countries in Europe, then a European country affording ease of access for participants should be chosen. It is expected that the country selected will be the residence of at least some of the participants of a Product and Procedure Training and Education Event.</p>

<p>Q27</p> <p>Cf. Chapter 3, Section 2</p>	<p>Can a Member Company use a meeting venue outside Switzerland?</p> <p>Yes, provided the participants are from multiple countries outside Switzerland. If the participants are primarily from within Europe, the venue should be in Europe. It is expected that the country selected (and the state, if the location is in the United States) will be the residence of at least some of the participants of the Product and Procedure Training or other Education Event.</p>
<p>Q28</p> <p>Cf. Chapter 3, Section 4</p>	<p>Can Member Companies directly support travel and/or accommodation of individual Healthcare Professionals at Company Events, which include new product launches, even if only portable equipment or solutions are being demonstrated?</p> <p>Member Companies can pay for travel and/or accommodation of individual Healthcare Professionals to attend Company Events which include product launches provided that such Events fall within the scope of Chapter 3, Section 2, of the Code («Product and Procedure Training and Educational Events»).</p>
<p>Chapter 4</p>	<p>Grants and Charitable Donations</p>
<p>Q29</p> <p>Cf. Chapter 4, Section 1, lit. d</p>	<p>Could you provide an example of an «independent decision-making/review process»?</p> <p>Such a process could be led by a Member Company's legal, finance or compliance functions, operating within a robust governance framework and according to clear, consistent and transparent criteria for decision-making and review.</p>
<p>Q30</p> <p>Cf. Chapter 4, Section 2</p>	<p>Under the Code, can a Member Company make a Charitable Donation to support the general running of hospital or other Healthcare Organisation?</p> <p>No, a Charitable Donation shall only be given to a legal entity or body which has charitable and/or philanthropic purposes as its main objects. For the purpose of the Code and irrespective of their legal status, hospitals and Healthcare Organisations are considered to generally have health functions as their main purposes and accordingly are not generally considered to have charitable and/or philanthropic functions as their main purposes. Exceptions are possible if the hospital does not invoice its expenses.</p>

<p>Q31</p> <p>Cf. Chapter 4, Section 2</p>	<p>Is it permissible for a Member Company to specify restrictions in relation to the final use of a Charitable Donation where a Member Company wishes its Charitable Donation to be applied as part of a specific aid programme or as part of the relief effort following a specific natural disaster, such as a major earthquake in a particular country?</p> <p>Member Companies may specify the broad, general purpose for which a Charitable Donation shall be applied, such as the relief of a specific disaster in a particular country (e.g. for use to aid reconstruction and/or re-equipping of healthcare facilities following an earthquake in that country). However, Member Companies must take care that such specifications do not amount to control over the specific, final use of the Charitable Donation by the recipient which is not allowed under the Code.</p>
<p>Q32</p> <p>Cf. Chapter 4, Section 2</p>	<p>Is it permissible for a Member Company to make a Charitable Donation to a Healthcare Professional’s designated charity in instances where the Healthcare Professional has requested the Member Company to do so in lieu of receiving a professional fee for the provision of consultancy or speaking services to the Member Company?</p> <p>No. Under the Code it is not appropriate for a Member Company to support the favourite charity of a Healthcare Professional in response to a request by that Healthcare Professional irrespective of the underlying reasons. No exception can be made for sport events, such as payment of the registration charge to participate in a charity run.</p>
<p>Q33</p> <p>Cf. Chapter 4, Section 2</p>	<p>Is it permissible for Member Companies to give away free products for philanthropic reasons?</p> <p>Member Companies are permitted to provide Healthcare Professionals/Organisations with free products for philanthropic reasons, if it is ensured that the Healthcare Professional/Organisation also waives the right to charge its own costs to the patient and his/her health insurance company for philanthropic reasons (pro bono treatment) for the specific case. For example, an implant is placed in a patient for humanitarian reasons and all Healthcare Professionals and Organisations involved waive the right to charge their costs and receive their wages.</p>
<p>Q34</p> <p>Cf. Chapter 4, Section 3</p>	<p>What are the differences between an Educational Grant and a commercial sponsorship?</p> <p>Commercial sponsorships in the context of Third Party Organised Educational Events would involve objective consideration, such as access to the participants for marketing purposes, advertising opportunities or booth space.</p>

	<p>On the other hand, an Educational Grant is exclusively provided for the advancement of medical education in situations where the Member Company neither requests, expects nor receives any consideration for the support.</p> <p>Public notes or mentions thanking the providers of Educational Grants do not amount to consideration for these purposes.</p>
<p>Q35</p> <p>Cf. Chapter 4, Section 3</p>	<p>Can a small Healthcare Organisation receive Educational Grants to support Healthcare Professionals participation at Third Party Organised Educational Events?</p> <p>Yes, in principle. There are no size limits for HCOs to receive Educational Grants; however, Member Companies must ensure that the final beneficiaries of the Educational Grant cannot be identified beforehand. For example, HCOs composed of a single Healthcare Professional will in practice not be allowed to receive Educational Grants to support Healthcare Professionals participation at Third Party Organised Educational Events as the final beneficiary is known upfront</p>
<p>Q36</p> <p>Cf. Chapter 4, Section 3</p>	<p>Can an Educational Grant or funds earmarked for education be provided to a specific hospital or department or specify individual hospital or department as criteria for HCOs and/or PCOs?</p> <p>One of the guiding principles in the Code is that Member Companies should not receive or be able to determine the names of the ultimate HCP beneficiaries. The inclusion of a criterion specifying an individual hospital or hospital department is not prohibited under the Code. However, Member Companies should bear in mind that the smaller the hospital or department the greater will be the risk that Member Companies will be able to identify individual beneficiaries if making use of such criteria inappropriate under the Code. In addition, Member Companies should be mindful of any proximate or ongoing tender proceedings with a specific hospital, as such tenders may raise additional red flags.</p>
<p>Q37</p> <p>Cf. Chapter 4, Section 3</p>	<p>How can Member Companies in practice ensure that Educational Grants are only made available for Third Party Organised Educational Events which receive a positive review from CVS (where this is required under the Code)?</p> <p>It is the responsibility of Member Companies to individually ensure compliance with this Code obligation. For example, Member Companies may themselves consider submitting relevant Third Party Organised Educational Events for CVS review or they may decide to include appropriate contractual obligations making it a pre-condition for an Educational Grant that the Third Party Organised Educational Event be submitted and positively assessed via the CVS, for example by the prospective Grant recipient or by a third party</p>

<p>Q38</p> <p>Cf. Chapter 4, Section 3</p>	<p>Can Member Companies give criteria for HCOs and/or PCOs to allocate their Educational funds?</p> <p>Yes, objective criteria for HCOs and/or PCOs to select HCPs to benefit from Educational funds may be provided as long as such selection criteria are relevant to the HCPs' educational needs and are not so specific that it would effectively select individual HCPs. Examples of criteria for selecting Educational Grant recipients are Healthcare Professionals' specialty, years of practice, country, city/region of practice and/or academic criteria such as number of publications, participation in clinical trials in a given pathology, or specific hospital, provided the HCP beneficiaries are not identifiable (see Q&As 31 and 32).</p>
<p>Q39</p> <p>Cf. Chapter 4, Section 3</p>	<p>Does Chapter 4: Donations and Grants – Educational Grants of the Code apply to requests received by Member Companies in the context of public procurement processes for educational support for Third Party Organised Educational Events from Healthcare Organisations and purchasing bodies?</p> <p>No. Such requests and any subsequent financial or other support provided by a Member Company are not considered to be Educational Grants for the purpose of the Code. Such arrangements are commercial in nature and not philanthropic and should be documented in a written commercial agreement in accordance with normal business practice.</p>
<p>Q40</p> <p>Cf. Chapter 4, Section 3</p>	<p>In the event that a commercial organisation, such as a Professional Conference Organiser organises a Third Party Organised Educational Event independently of any Healthcare Organisation, is it appropriate for Member Companies to sponsor such events and what rules shall apply?</p> <p>Member Companies may enter into a commercial sponsorship arrangement with a Professional Conference Organiser that is organising a Third Party Organised Educational Event and acting independently of any Healthcare Organisation. However, such arrangements do not fall within the definition of Educational Grant as Professional Conference Organisers are for-profit organisations. Sponsorship arrangements are therefore commercial in nature and Member Companies should consequently document these in a written commercial agreement in accordance with normal business practice and the requirements of the Code (Chapter 2: Third Party Organised Educational Events). Where a Member Company provides funds earmarked for the advancement of genuine educational purposes to a Professional Conference Organiser, acting independently of any Healthcare Organisation, all the Code provisions governing Educational Grants shall apply. For example, if a Member Company provides funding to a Professional Conference Organiser to fund Healthcare Professional Delegate places and expenses at a Third Party Organised Educational Conference, such Event,</p>

	<p>where applicable, must have CVS approval and the Member Company shall publicly disclose such funding in accordance with the Code's Disclosure Guidelines.</p>
<p>Q41 Cf. Chapter 4, Section 3</p>	<p>Is it appropriate for a Member Company to provide an Educational Grant to a Healthcare Organisation for the limited purpose of covering, in whole or in part, the cost of some form of peer-to-peer, general public or patient education or training? If so, under what circumstances can such Grants be provided and which criteria would need to be applied?</p> <p>As a matter of principle, Member Companies should not cover an HCO's normal overhead or routine costs of operation («overheads»). These routine costs are to be understood as those costs that would fall under the normal budgeting of a particular HCO. Different types of HCOs may have different kinds of routine costs and whether an activity and its costs are to be understood as «routine» for a particular HCO must be assessed on a case-by-case basis. For the avoidance of doubt, where a particular activity cannot be run due to lack of funding, it does not necessarily mean that such activity is not routine activity and cost for that type of HCO as per the definition of «overheads» above. It may be helpful to consider previous experiences with that HCO or similar HCOs to assess whether such activity would usually be internally funded. If so, the activity would typically be considered a routine activity. As an exception to the above and provided that local laws do not prohibit such setups, Member Companies may support peer-to-peer or public/patient training/education via Educational Grants under the following conditions:</p> <ol style="list-style-type: none"> 1. Support of legitimate educational programs which benefit the delivery of care, and/or provide specific expertise to either an internal or external audience. For such educational support, Member Companies must, however, consider the following to ensure appropriate safeguards against conflicts of interest between the aims of the Member Company and the aims of the HCO, particularly in relation to procurement and competition: <ul style="list-style-type: none"> ▪ the purpose and scope of the support should be transparent and fully disclosed to the hospital administration as well as, where required, any other locally-designated competent authority; ▪ such support should be limited in time and not renewed for indeterminate periods; 2. If part of a lawful tender, which include internal educational set-ups as «value adds» which would cover, in whole or in part, hospital overheads where these are related to the requirements of that specific tender; 3. Fellowships and Scholarships, in accordance with the provisions of the Code;

	<p>The supported programme/activity should genuinely aim to improve patient safety and/or clinical outcomes. As such, it must go above and beyond supporting normal hospital capacity and capability, considering the primary purpose of the hospital. It would not be appropriate to support routine or administrative capacity. This support should be brand-agnostic, meaning that it should not promote specific Member Company Medical Technology. Additionally, while respecting the need for transparency, it should not promote the specific HCO.</p>
Chapter 5	Arrangements with Consultants
<p>Q42</p> <p>Cf. Chapter 5, Section 3</p>	<p>How should a Member Company justify «market value»?</p> <p>A Member Company should have an internal methodology by which «market value» can be defined. This should include the consultant's qualifications, experience and the services under discussion, among other things.</p>
Chapter 6	Research
<p>Q43</p> <p>Cf. Chapter 6, Section 2</p>	<p>What is an example of an external public register for clinical trial transparency?</p> <p>Examples of an external public register for clinical trial transparency are www.clinicaltrials.gov or www.who.org.</p>
<p>Q44</p> <p>Cf. Chapter 6, Section 4</p>	<p>Can Member Companies support the participation of Poster or Abstract Presenters in Third Party Organised Educational Conferences?</p> <p>Poster or Abstract Presenters at Third Party Organised Educational Conferences are not to be considered as Faculty, as defined in the Code («Glossary»). As such, if Member Companies want to support their participation in the Third Party Organised Educational Conference, such support may be provided through an Educational Grant (if it complies with the requirements of the Code, specifically those of Chapter 4). Alternatively, the support can be included in a Research Agreement, whether it relates to Member Company initiated or third party initiated research. However, if the support is included in a research agreement, Member Companies may only support attendance of poster and abstract presenters to Third Party Organised Educational Conferences provided the following considerations are met:</p> <ul style="list-style-type: none"> ▪ The selection of the poster or abstract presenters is done independently by the third party organiser of the Event, ▪ The support envisioned must be specific and detailed in the research agreement between the Member Company and the Healthcare Organisation, and ▪ The Member Company is not directly involved in the selection of the specific investigator who would benefit from the support (for the avoidance of doubt principal investigators with whom a company might have

	<p>a direct relationship would be eligible to receive support for the dissemination of the research results). Member Companies should also consider including in the research agreement a clause which stipulates that funds will be made available only once the poster or abstract presenter has been selected independently by the third party organiser of the Event.</p>
<p>Q45 Cf. Chapter 6, Section 4</p>	<p>What is the difference between Member Company-initiated research, third party-initiated research (Research Grant) and collaborative research?</p> <p>Member Company-initiated research is sponsored by the Member Company, it is the Member Company who is responsible for all aspects of the research and who owns the data (e.g. used for regulatory purposes). Member companies may contract researchers to conduct the research on their behalf (i.e a fee-for-service agreement).</p> <p>Third party-initiated research (investigator-initiated) is sponsored by the third party and it is the third party who is responsible for independently managing all aspects of the research. Member Companies may support the research e.g. financially (Research Grant).</p> <p>Collaborative research is usually sponsored by a third party investigator, but may also be sponsored by a Member Company, so that there is a pooling of skills, experience and/or resources from all the parties that jointly complement the objectives of the collaborative research project as a shared commitment. The scope of the collaboration must be agreed in advance by the Member Company and third party or parties (collaborative research agreement).</p>
<p>Q46 Cf. Chapter 6, Section 5</p>	<p>What is meant by «legitimate purpose» in the context of collaborative research?</p> <p>A collaborative research project must enhance patient care or be for the benefit of patients, or alternatively benefit the HCO and, as a minimum, maintain patient care. It must, therefore, always be ensured that none of the benefits of any collaborative research project go to individual HCPs or their practices. If there are benefits which are due to the HCO in the collaborative research project, these must go to the HCO or similar organization.</p> <p>A collaborative research project shall not constitute an inducement to HCPs or other relevant decision makers to prescribe, supply, recommend, buy or sell a Member Company’s Medical Technology or any related service. It shall be legitimate from a scientific and ethical viewpoint and ethical approval must be obtained where required by national laws and regulations, professional codes of conduct and ethical requirements as well as</p>

	with applicable good practice guidelines and it shall be carried out in an open and transparent manner.
Chapter 8	Educational Items and Promotional Items
Q47 Cf. Chapter 8	<p>What are examples of promotional items of modest value that are «related to the Healthcare Professional’s practice or for the benefit of patients»?</p> <p>Stationery items, calendars, diaries, computer accessories for business use and clinical items such as wipes, nail brushes, surgical gloves and tourniquets are examples of modest value items that could be appropriately provided as promotional items to Healthcare Professionals provided their value falls within the maximum value prescribed under national laws, regulations and industry and professional codes of conduct. Food, alcohol and items which are primarily for use in the home or car are not appropriate as they are not related to the Healthcare Professional’s practice nor are they for the benefit of patients.</p>
Q48	<p>Where Healthcare Professionals are engaged by Member Companies as consultants or speakers and receive a professional fee for their services, would it be appropriate for the Member Company to show its appreciation by giving the Healthcare Professional a small gift such as a bottle of wine or a bouquet of flowers?</p> <p>No, such gifts should not be made because to do so could be open to misinterpretation and would be likely to breach the Principle of Image and Perception. Moreover, such gifts would not comply with the principles of Chapter 8 «Educational Items and Gifts». Such gifts would also not have any use in the Healthcare Professional’s practice nor serve an educational function.</p>
Q49 Cf. Chapter 8	<p>Where Healthcare Professionals engaged by Member Companies as consultants or speakers decline a professional fee for their services, would it be appropriate for the Member Company to show its appreciation by giving the Healthcare Professional a small gift such as a bottle of wine or a bouquet of flowers?</p> <p>Yes, such a benefit in kind as consideration would be acceptable provided that it is defined in the contract with the consultant or speaker.</p>
Q50 Cf. Chapter 8	<p>Please provide examples of educational items of greater value that can be provided to Healthcare Organisations under the Code?</p> <p>Examples of educational items of greater value that can be provided may include medical textbooks or anatomical models, but only if those relate to the therapeutic areas in which the Member Company is interested and/or involved.</p>

Chapter 9	Third Party Intermediaries
<p>Q51</p>	<p>What could be elements of a risk assessment of Third-Party Intermediaries?</p> <p>Typical elements include:</p> <ul style="list-style-type: none"> ▪ Risk in the relevant country ▪ Risk profile of the planned or utilized Intermediary ▪ Information regarding local market legal and ethics requirements ▪ Information from Third Party Intermediaries for potentially unusual arrangements ▪ Information available from public sources or employees for potential risks associated with the Third Party Intermediaries
<p>Transparency Guidelines of 1 January 2018</p>	
<p>Q52</p>	<p>Does the scope of the Transparency Guidelines also cover all countries in which a Member is active?</p> <p>No, the Transparency Guidelines are limited to Educational Grants to Healthcare Organisations established in Switzerland or to people working there. This enables companies that are also members of Medtech Europe MTE to continue publishing all relevant grants on their platform.</p>
<p>Q53</p>	<p>In accordance with the Transparency Guidelines, it is sufficient to publish disclosures regarding Educational Grants on the Member Company’s own website or on the association’s website. Does a Medtech Europe member that publishes Educational Grants on the MTE Transparent MedTech platform also have to publish them on its own website or on Swiss Medtech’s website?</p> <p>If a Medtech Europe corporate member discloses Grants on the MTE Transparent MedTech platform https://www.ethicalmedtech.eu/transparent-medtech/, it is sufficient to add a corresponding note with related link on the member’s own website or on Swiss Medtech’s website.</p>