

Guidance Document

Questions & Answers (Q&As) on the MedTech Europe Code of Ethical Business Practice

2 December 2015

INTRODUCTION

Aims and Principles of the Code

Q1: Does the definition of Healthcare Professional include purchasing professionals employed in the retail sector, such as a purchasing professional employed by a supermarket chain?

A1: No, the definition of Healthcare Professional does not include a purchasing professional employed in the retail sector unless that individual purchaser arranges for the purchase of Member Companies' medical devices for or on behalf of medical or clinical personnel. For example, if a Member Company's medical devices are sold as part of the common merchandise of the retail outlet, interactions between the Member Company and the purchasing professional do not fall under the Code. However, where the Member Company's medical devices are sold in a retail pharmacy (even if this is located within a supermarket unit), interactions between the Member Company and the responsible purchasing professional will fall under the Code.

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

Chapter 1: General Criteria for Events

Q2: What is meant by "legitimate" or "genuine" as used in the definitions of 'Company Event' and 'Third Party Organised Educational Conferences'?

A2: Any Event should be relevant to the Healthcare Professional attendees; the detailed programme should be available sufficient time prior to the Event; present a clear schedule with no gaps during the sessions, , (e.g., the minimum duration for a full day Event should be 6 hours or 3 hours for a half day Event including refreshment breaks). If it is a Third Party Organised Educational Event the Faculty must be identified. It is also important that all supporting materials (e.g. flyers, brochures and website) are consistent with the scientific or promotional nature of the programme content, as the case may be.

Q3: Can a Member Company organise or support an Event at a hotel that offers leisure facilities such as golf, casinos or water sports?

A3: No, it would not be appropriate for Member Companies to organise or support Events at hotels centred around leisure facilities such as golf, casinos or ski/water sports. An important factor in evaluating a hotel is its suitability for business meetings, including the availability of conference facilities. For hotels which include minor leisure and sporting facilities, such as a spa, while it would not be reasonable to exclude these venues if otherwise appropriate, Member Companies must exercise caution. The Event agenda

should be arranged in such a way that Healthcare Professionals attending the Event 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 enable guests to use the leisure and sporting facilities, Member Companies may not make such payments on behalf of the Healthcare Professionals.

Q4: Under the Code, what is meant by "ease of access" in relation to Event location and venue?

A4: When 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.

Q5: Under the Code, how does the "season" impact evaluation of Event location and venue?

A5: For European and international Events, ski resorts in the ski season, island resorts, beach resorts and other geographic locations renowned primarily as seasonal vacation or holiday destinations are not appropriate geographic locations during the season in question. Member Companies must not support or organise Events at these locations during those seasons.

Q6: What does the term "facilitate" mean where used in connection with the Guest expenses?

A6: 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 the Guest of a Healthcare Professional participant. Such organisation or booking is not permitted unless the individual qualifies as a participant in his/her 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.

Q7: 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?

A7: It is not appropriate for a Guest of a Healthcare Professional to attend either Company Events (including Satellite Symposia) or Third Party Organised Educational Events (unless the individual qualifies as a participant in their own right), nor is it appropriate, in the interest of maintaining the scientific exchange, for a Guest to participate in related hospitality during such Events (for example, lunches and coffee breaks) even when the Healthcare Professional pays for the Guest's expenses.

Member Companies, however, may financially support Third Party Organised Educational Events which offer extra-curricular programmes/activities beyond the scientific, educational or training sessions for Guests of Healthcare Professionals (such as touristic activities and hospitality), always provided that such an extra-curricular programme/activity (including attendance of the conference dinner or a cocktail reception) is subject to a separate charge which must not be paid for, facilitated or reimbursed by, a Member Company.

Q8: 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 Professionals' travel or accommodation expenses for attendance at the Event?

A8: 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.

Q9: May Member Companies offer to cover the travel and accommodation expenses of Healthcare Professionals for periods that extend beyond the duration of the Event programme attended?

A9: Generally, travel and accommodation support offered by Member Companies to Healthcare Professionals should be tailored to the duration of the Event. Member Companies must always keep in mind the impression which may be created by the arrangements for any meeting.

Q10: Under the Code, is Employer Notification required for each interaction with a Member Company? For example, is such notification required each time a Member Company pays for a reasonably priced meal or gives a Healthcare Professional a gift, which is otherwise in line with the requirements of the Code?

A10: Employer Notification is required whenever a Member Company engages a Healthcare Professional or whenever a member makes a financial contribution to the Healthcare Professional's medical education. Incidental interactions arising in the normal course of business such as meals associated with educational or business meetings or the receipt of modest gifts related to the Healthcare Professional's practice, do not require Employer Notification.

Q11: Are members required to provide additional written notification under the Code to the hospital administration, Healthcare Professional's superior (or other locally-designated body) for Member Company/Healthcare Professional interactions in countries where there are compulsory notification systems already in place?

A11: No. Only the compulsory notification is required. Additional notification under the Code is not required in countries where specific notification requirements of law or regulation govern the transparency of interactions between industry and Healthcare Professionals. The transparency provisions of the Code apply only in countries where there is an absence of national transparency laws and regulations.

Q12: 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?

A12: The written notification must comply with national laws, regulations and professional codes of conduct. In countries where specific provision is not made, 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.

Chapter 2: Third Party Organised Educational Events

Q13: Please provide examples of appropriate booth activities which will be perceived as professional?

A13: Booth activities at Third Party Organised Educational Conferences should aim primarily at displaying Member Companies' products and services and related literature. Therefore, other activities should be limited and reasonable and in principle, only soft drinks and snacks should be served.

Q14: Can a Member Company for example be present via a satellite symposium, rent booth space at a Third Party Organised Educational Conference which was assessed as non-compliant by the Conference Vetting System (CVS)?

A14: For conferences within the scope of CVS, if the Third Party Organised Educational Conference is assessed as not compliant by CVS, Member Companies cannot have any, whether educational or promotional, support or presence, including via Member Company-sponsored satellite symposia.

Q15: Can Member Companies directly support attendance by Healthcare Professionals engaged to speak only at satellite symposia at Third Party Organised Educational Conferences, e.g. registration fee, travel and/or accommodation?

A15: Member Companies must ensure compliance with the Code and enter into a consulting agreement with the HCP speaker engaged to speak at the satellite symposium. The consulting agreement may include payments in respect of registration fee, travel and/or accommodation where appropriate.

Chapter 3: Company Events

Q16 Is it appropriate for Member Companies to invite Healthcare Professionals on company plant or factory tours where the Healthcare Professionals reside outside the country of location of the plant or factory?

A16 Yes, it is appropriate for Member Companies to invite Healthcare Professionals to plant or factory tours in countries outside their country of residence if there is a legitimate business purpose and the tour complies with the Code in all respects.

Q17: Are cruise ships or golf clubs appropriate venues for Product and Procedure Training and Education Events?

A17: 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.

Q18: What criteria should a Member Company apply when considering the country location of Product and Procedure Training and Education Events?

A18: If the participants are primarily of 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 is the residence of at least some of the participants of the Product and Procedure Training and Education Event.

Q19: Can a Member Company use a meeting venue outside Europe?

A19: Yes, provided the participants are from multiple countries outside Europe. 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) is the residence of at least some of the participants of the Product and Procedure Training and Education Event.

Chapter 4: Grants and Charitable Donations

Q20: Under the General Principles in Chapter 4. Grants and Charitable Donations, what is meant by an "independent decision-making/review process"?

A20: In accordance with the Principle of Separation, an "independent decision-making/review process", is a process where the decision-making criteria are not primarily sales-driven and where the Member Company's sales function does not decide upon and/or approve a decision to provide a Grant or Charitable Donation. For example, 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 review and decision-making.

Q21: Under the Code, what is meant by "prior evaluation of any associated risks and of the relevant information" relating to a Grant or a Charitable Donation?

A21: Prior to deciding to provide a Grant or a Charitable Donation, the Member Company must evaluate the appropriateness of the award of the proposed Grant or Charitable Donation to the proposed recipient. Such an evaluation shall consider all the circumstances including, but not limited to, consideration of the legal status and structure of the requesting (i.e. prospective recipient) organisation as well as of the nature and scope of its activities and the terms and conditions to which the Grant or Charitable Donation will be subject. The evaluation shall be documented and shall be based on information available to the Member Company, such as information or documentation available from public sources.

For Educational Grants provided in relation to Third Party Organised Educational Events, this may also include information of how the funds have been applied by the recipient in relation to previous equivalent Events and whether funds have been spent in accordance with the terms and conditions of any previous Grant.

Q22: What does "sufficient information" mean where used in connection with documentation of Grants and Charitable Donations?

A22: The written request by a requesting organisation should include as a minimum a detailed description of the scope and purpose of the programme, activity or other project, which is the object of the Grant or Charitable Donation. It shall also contain a description of the proposed recipient, its legal status and structure, and where relevant, a budget.

Q23: Under the Code, can a Member Company make a Charitable Donation to support the general running of hospital or other Healthcare Organisation?

A23: No, a Member Company cannot make available a Charitable Donation to support the general running of a hospital or other Healthcare Organisation. A Charitable Donation shall only be given to a legal entity or body which has charitable and/or philanthropic purposes as its main purposes. 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. It is not therefore appropriate to provide Charitable Donations to support their general running.

Q24: 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?

A24: 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.

Q25: Under the Code, may a Member Company make a Charitable Donation such as the purchase of a table of dinner invitations at a fundraising dinner or entries to participate in, or attend at, a fundraising sports or other event?

A25: Yes, Charitable Donations made by Member Companies may take the form of dinner invitations for a fundraising dinner or participating in other recreational events such as a fundraising golf tournament, if arranged by a charitable or other non-profit philanthropic organisation. The Member Company may use some or all of its ticket allotment for its own employees and return any unused portion to the sponsoring charitable or non-profit philanthropic organisation for use as the sponsoring organisation sees fit. However, the Member Company should not invite Healthcare Professionals to attend such an event at the Member Company's expense. Furthermore, the Member Company is not permitted to suggest to the sponsoring organisation, the names of Healthcare Professionals who could be invited to attend the event, irrespective of whether or not the specified Healthcare Professionals will be seated at the Member Company's table.

Q26: How can Member Companies in practice ensure that Educational Grants made available for Third Party Organised Educational Events which are subject to the Conference Vetting System, are positively reviewed by CVS?

A26: 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.

Q27: 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?

A27: 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.

Q28: In the event that a Professional Conference Organiser (PCO) organises a Third Party Organised Educational Event independently of any Healthcare Organisation, is it appropriate for Member Companies to sponsor such events?

A28: Member Companies may enter into a commercial sponsorship arrangement with a PCO organising a Third Party Organised Educational Event independently of any Healthcare Organisation. However, such arrangements do not fall within the definition of Educational Grant as PCOs are for-profit conference organisations. These 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*).

Q 29: Can a Member Company pay for or reimburse travel costs to a Third Party Organised Educational Event for a Scholar or Fellow?

A29: No, a Member Company cannot additionally pay for, or reimburse, the travel or other participation costs incurred by a Scholar or Fellow attending a Third Party Organised Educational Event. Such costs shall be included in the Educational Grant supporting the Scholarship or Fellowship if it is intended that the Grant should extend to such attendance.

Q30: What are examples of relevant disease awareness and health education for patients, carers and the general public for which a Member Company may legitimately provide an Educational Grant?

A30: A Member Company may provide an Educational Grant to support the provision of high quality information to patients and the public about health and disease provided there is an objective patient or public need for such information and the topics covered are linked to the therapeutic areas in which the Member Company is interested and/or involved. Such disease awareness campaigns must not, however, promote the use of particular therapies, services or promote specific HCOs, nor may they aim to stimulate demand by the public for specific therapies or for specific Healthcare Organisations.

Chapter 5: Arrangements with Consultants

Q31: What is meant by fair market value (FMV) in the context of consulting arrangements?

A31: Fair-market-value is the value of the specified consultancy services which would be paid by the Member Company to the consultant, each dealing at arm's length in an open and unrestricted market, and when neither party is under any compulsion to buy or sell, and both parties have reasonable knowledge of the relevant facts.

Q32: How should Member Companies determine FMV for a service?

A32: A Member Company must be able to demonstrate internal methodology to determine fair market value. Amongst other matters this shall take account of the consultant's qualifications, expertise and experience as well as the actual services to be provided to the Member Company.

Chapter 6: Research

Q33: What is an example of an external public registry for clinical trial transparency?

A33: Examples of an external public register for clinical trial transparency are www.clinicaltrials.gov or www.who.org

Chapter 8: Educational Items and Gifts

Q34: Under Chapter 8, what are examples of items of modest value that are “related to the Healthcare Professional’s practice or for the benefit of patients”.

A34: 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 gifts 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.

Q35: May a Member Company provide a small gift to a Healthcare Professional to mark significant life events such as a marriage, birth, birthday or death?

A35: The Code restricts the types of gift that may be given to a Healthcare Professional and it would not be appropriate to give gifts to mark significant life events such as a marriage, birth or birthday. However, in the case of death, it is for each Member Company to determine the appropriateness of making a tasteful gift as a mark of respect.

Q36: 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?

A36 No, it would not be acceptable for the Member Company to make such a gift 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 *Chapter 8. Educational Items and Gifts* as they neither relate to a Healthcare Professional's practice nor serve an educational function.

Q37: Please provide examples of educational items of greater value that can be provided to Healthcare Organisations under the Code?

A37: 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.