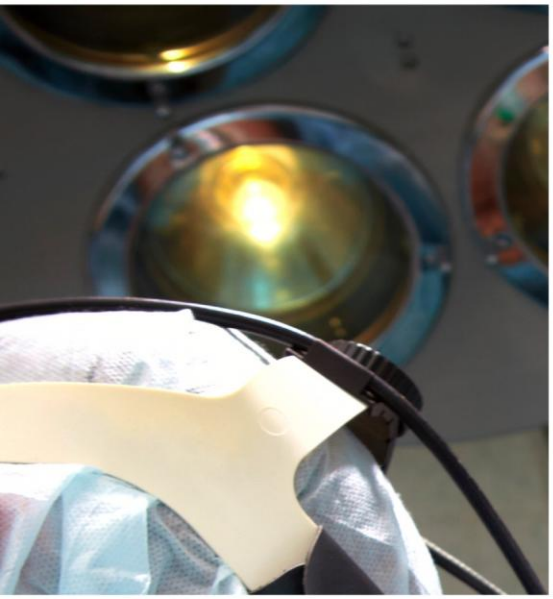
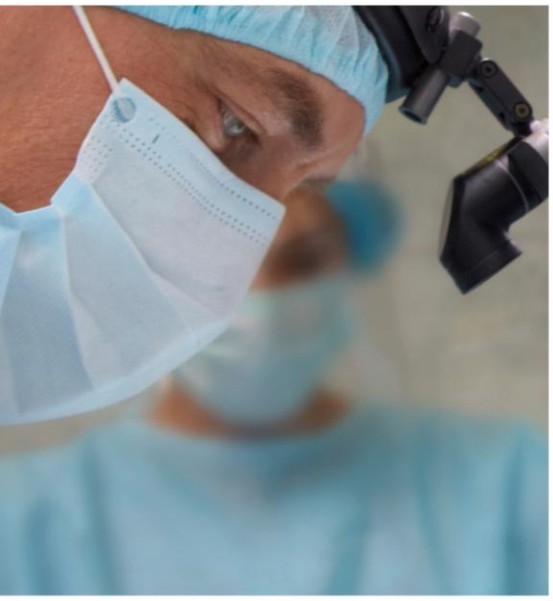
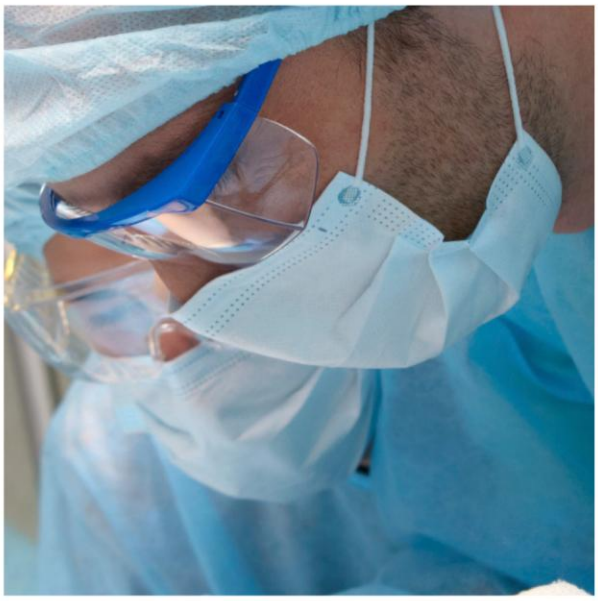
Eucomed
Medical Technology

GUIDANCE DOCUMENT
December 2011 (v7)



Q&A on the Eucomed Guidelines On Interactions with Healthcare Professionals





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Q1 What is the "Eucomed Code of Ethical Business Practice"? *(Added in March 2011)*

A1 "Eucomed Code of Ethical Business Practice" comprises all of the following documents:

1. The Eucomed Guidelines on Interactions with Healthcare Professionals, as amended from time to time;
2. The Eucomed Guidance Document – Q&A on the Guidelines on Interactions with Healthcare Professionals , as amended from time to time;
3. The Eucomed Competition Law Compliance Guidelines, as amended from time to time;
4. The Eucomed Code of Ethical Business Practice: Procedural Framework, as amended from time to time; and
5. The opinions and advisory interpretations of the Eucomed Compliance Panel.

Q2 Does the definition of Healthcare Professional include purchasing professionals employed in the retail sector, such as a purchasing professional employed by a supermarket chain? *(Added in July 2011)*

A2 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 members' medical devices for or on behalf of medical or clinical personnel. For example, if members' medical devices are sold as part of the common merchandise of the retail outlet, interactions between the member and the purchasing professional do not fall under the guidelines. However, where the members' medical devices are sold in a retail pharmacy (even if this is located within a supermarket unit), interactions between the member and the responsible purchasing professional will fall under the guidelines.

Q3 Under the guidelines, is written notification to the Healthcare Professional's employer (or other locally-designated body) required for each interaction with a member? For example, is such notification required each time a member pays for a reasonably priced meal or gives a Healthcare Professional a gift which are otherwise in line with the requirements of the guidelines?

A3 Written notification to the Healthcare Professional's employer (or other locally-designated body) is required whenever a member engages a Healthcare Professional as a consultant or whenever a member makes a financial contribution to the Healthcare Professional's medical training. 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 notification.

Q4 Are members required to provide additional written notification under the guidelines to the Healthcare Professional's employer (or other locally-designated body) for member/Healthcare Professional interactions in countries where there are compulsory notification systems already in place?

A4 No. Only the compulsory notification is required. Additional notification under the Code is not required in countries where specific 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 local transparency laws and regulations

Q5 When providing written notification to the Healthcare Professional's employer, are members required to provide details of the proposed financial remuneration members will make to the Healthcare Professional in exchange for the services rendered? *(Added in July 2011)*

A5 The written notification must comply with national and local 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 guidelines, members must ensure that the level of remuneration is commensurate with the services provided and set at 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.

Q6 Under the guidelines, what is meant by the term "appropriate location"? *(Amended in December 2011)*

A6 An "appropriate location" is a recognised institution, conference or business centre which is centrally located, providing ease of access when regard is given to the place of origin of the invited participants. The location selected should not become the main attraction of the event and members must consider at all times the image that may be projected to the public by their choice of location. The appropriateness of the location applies irrespective of who organises the event and members should consider the location of the event and the image that may be projected to the public when supporting an event whether this is by leasing booth space for company displays or any form of event sponsorship.

<u>Perception (e.g. ski or beach resort), ease of access, time of the year (i.e. high seasons) and venue are key elements to assess the appropriateness of a specific location.</u>

<u>Given the above, appropriateness of location may be assessed differently depending on whether it is only a local event attended by local healthcare professionals or if it is a European and /or international event.</u>

Q7 Under the guidelines (Section III), what is meant by the term "bona fide" conference ("bona fide independent, educational, scientific or policy-making conferences")? *(Added in March 2011)*

A7 The term "bona fide" conference means any national or international independent educational, scientific, or policy-making conference, congress or meeting organised by a third-party (i.e. non-member of Eucomed), which promotes and facilitates the exchange of scientific knowledge, medical advancement and the delivery of effective healthcare and is consistent with relevant guidelines established by professional societies or organisations for such meetings. Such "bona fide" conference will typically have independent scientific accreditation and provide for CME (continued medical education) and/or CPD (Continuing Professional Development) credits. A "bona fide" conference should be organized in such a way as to be conducive to, and perceived to be conducive to effective exchange and transmission of knowledge. The principles defined under section II of the Guidelines ("Member-Sponsored Product Training and Education") with respect to appropriateness of location, venue, guest and spouse as well as the clarifications provided by this Q&A and the Advisory Interpretations of the Eucomed Compliance Panel, also apply to conferences addressed under Section III.

Q8 What criteria should a member apply when considering the country location of product training or education?

A8 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 meeting.

Q9 Can a member use a meeting venue outside Europe?

A9 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 meeting.

Q10 Are hotels suitable venues for member-sponsored meetings with Healthcare Professionals? *(Amended in December 2011)*

A10 Yes, hotels are suitable venues for member-sponsored meetings with Healthcare Professionals. The hotel selected should not become the main attraction of the event and members must consider at all times the image that may be conveyed to the public by their choice of hotel. The hotel should not normally be a top category or luxury hotel in the country in which it is located nor be renowned for its entertainment facilities. An important factor in selecting a hotel is its suitability for business meetings, including the availability of conference facilities.

The fact that a top category or luxury hotel downgrades itself to a lower category hotel in order to attract a conference or an event does not change the analysis. Perception of what is considered as an appropriate location by the industry, the public and government authorities overrides price considerations.

Q11 Provided that the location is appropriate, are top category or luxury hotels suitable venues for third-party conferences attended by Healthcare Professionals? *(Added in December 2011)*

A 11 In principle no. The hotel should not normally be a top category or luxury hotel in the country in which it is located nor be renowned for its entertainment or sporting facilities. The hotel should not become the main attraction of the event and members must consider at all times the image that may be conveyed to the public when supporting an event taking place in such a hotel. An important factor in considering the venue appropriateness is the suitability for business meetings, including the availability of conference facilities.

However, if a top category or luxury hotel is chosen by an independent third-party as the venue of their scientific conference, the following should be considered: Provided that the conference is a bona fide independent, educational or scientific event and the above-mentioned considerations carefully appraised, members can sponsor healthcare professionals to attend the conference (i.e. registration fees and reasonable travel) but cannot sponsor accommodation for healthcare professionals at such top category or luxury hotels, unless there are exceptional extenuating circumstances which can be adequately documented. Exceptional extenuating circumstances would be generally limited to healthcare professional health and security risks prevailing in the chosen location.

Q12 Can a member use a hotel that offers leisure facilities such as golf, or water sports for member-sponsored training and education?

A12 Many business hotels and conference centres provide leisure facilities and while it would not be reasonable to exclude these venues if otherwise appropriate, members must exercise caution. Members should arrange the meeting agenda such that Healthcare Professionals attending the meeting 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, members may not make such payments on behalf of the Healthcare Professionals.

Q13 Are cruise ships or golf clubs appropriate venues for member-sponsored training and education?

A13 No. Cruise ships, golf clubs or health spas and venues renowned for their entertainment facilities are not appropriate venues and should not be used.

Q14 Under the guidelines, what do the terms 'reasonable' and 'hospitality' mean?

A14 The guidelines seek to find a balance between the courteous and professional treatment of Healthcare Professionals by Eucomed members, with the desire to avoid even the appearance that hospitality may be used by members as a means to induce Healthcare Professionals to purchase, prescribe or recommend company products. Accordingly, members must assess what is 'reasonable' in any given situation and regional variations will apply. As a general guideline, 'reasonable' should be interpreted as the appropriate standard for the given location and must comply with the local laws, regulations and professional codes of conduct. If the meeting venue is a hotel which complies with the requirements of the guidelines, it would be acceptable for members to offer participants meals and accommodation at the same hotel.

The term 'hospitality' includes meals and accommodation. It is important that members differentiate between 'hospitality' which is permitted and 'entertainment' which is not. 'Entertainment' includes, but is not limited to, dancing or arrangements where live music is the main attraction, sight-seeing trips, theatre excursions, sporting events and other leisure arrangements.

Q15 Under the guidelines, what standard of air travel may a member provide a Healthcare Professional attending member-sponsored training?

A15 Members may provide only economy or standard class air travel to Healthcare Professionals unless the flight time is of a duration of greater than 5 hours; in which case, it is appropriate to consider premium economy or business class provided this is permitted under the national and local laws, regulations and professional codes of conduct of the country where the Healthcare Professional is licensed to practise.

Q16 What does the term "facilitate" mean where used in connection with the guest or spouse expenses?

A16 The term "facilitate" refers to the prior arrangement, organisation or booking of meals, travel or accommodation by a member on behalf of the spouse/guest of a Healthcare Professional participant. Such organisation or booking is not permitted unless the individual qualifies as a participant in their own right. If Healthcare Professionals attending product training wish to be accompanied by a spouse/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 spouse/guest's expenses.

Q17 In the event that a Healthcare Professional is accompanied by a spouse/guest at member-sponsored product training, may the spouse/guest be admitted to any member-related activity?

A17 It would not be appropriate for the spouse/guest of a Healthcare Professional to be invited to attend any of the member-related activities, including associated meals even when the Healthcare Professional has paid for the spouse/guest expenses. Any uninvited appearance by a spouse/guest should be strongly discouraged.

Q18 In connection with providing financial support to cover the cost of conference attendance by individual Healthcare Professionals, what are deemed to be reasonable travel, meals and accommodation?

A18 Members must assess what is reasonable in any given location and regional and country variations will apply. However, as with member-sponsored training, the hospitality provided by members at third party educational events should not be of such a level as to become the main attraction of the event. Accordingly, hotel accommodation should not normally be provided at top category or luxury hotels, air travel should be economy or standard class unless the duration of the flight extends beyond 5 hours (in which case premium economy or business class may be considered) and meals should be of a standard that Healthcare Professionals would routinely expect if they were paying for them out of their own pockets. A meal at the conference hotel with wine would normally be considered acceptable.

Q19 Is it appropriate for members to cover the full registration fee of third-party conferences where such fee covers the cost of a conference dinner and/or social or cultural activities?

A19 Members must not pay for the expenses which relate to the purely social or cultural aspects of the conference. Modest and incidental gatherings such as the welcome cocktail are appropriate and members may cover these expenses. Where the registration fee includes an element of entertainment members must request that these elements are separated in the registration fee and subsequently not pay for this element. If the conference organiser is unable to separate the entertainment costs from the registration fee, members should assess the image that may be projected to the public and reconsider supporting the event. For the avoidance of doubt, the conference dinner may be supported if it is expected that all delegates to the conference would normally attend and provided the dinner is otherwise in line with the requirements of the guidelines.

Q20 Please provide examples of the types of third party educational conferences that members may provide financial support to cover the attendance by individual Healthcare Professionals.

A20 Where permitted under national and local laws, members may provide reasonable financial support to cover the cost of attendance (e.g. registration fee, travel, meal and accommodation) by individual Healthcare Professionals at third party scientific events such as medical congresses and symposia, seminars, training courses and therapy-orientated training.

Q21 May a member provide financial support to cover the cost of conference attendance (including conference registration and reasonable travel, meals and accommodation) to HCPs who are conference faculty members?

A21 Yes, a member may provide financial support to individual HCP who are conference faculty members to cover the cost of the conference attendance. The principles set out in the guideline in Section III relating to the HCP sponsorship shall apply. Payment should generally be made to the conference organiser or the appropriate supplier/vendor or intermediary agency or alternatively members may reimburse the faculty members expenses against original invoices or receipts. Furthermore, in the interest of transparency, the faculty member should declare that he/she is the recipient of such sponsorship from a member company at the time he/she delivers a presentation at the conference.

Q22 Are members permitted to invite Healthcare Professionals to educational conferences, offering to cover their reasonable expenses or are members only permitted to support Healthcare Professional attendance at conferences in response to unsolicited requests from Healthcare Professionals?

A22 Members are permitted to invite Healthcare Professionals to attend educational conferences provided the selection is based upon the training and educational requirements of the individual Healthcare Professional and is in no way tied to the Healthcare Professional's past or potential future use of the member's products or services. Members have to ensure that they comply with all national and local laws, regulations or professional codes of conduct with regards to transparency. In countries where specific provision is not made, Members must maintain appropriate transparency by giving prior written notification to the hospital administration, the HCP superior (or other designated competent authority) expressly offering the possibility to comment and/or oppose the invitation or to designate an alternative HCP recipient.

Q23 How does the Code apply where a member organises or sponsors an international meeting with Healthcare Professionals attending from various European countries?

A23 When organising or sponsoring international events, members must comply with the regulations on hospitality applicable to each Healthcare Professional in their respective countries and with the regulations in the country where the event takes place. Each Healthcare Professional remains subject to the regulations of his/her own country, irrespective of where the event takes place. In the case of conflict, the member is recommended to apply the stricter rule.

Q24 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 a conference?

A24 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 members may reimburse individual Healthcare Professional expenses retrospectively against original invoices or receipts.

Q25 May member companies offer to cover the travel and accommodation expenses of Healthcare Professionals for periods that extend beyond the duration of the congress or other training programme attended?

A25 Generally, travel and accommodation support given by member companies to Healthcare Professionals should be strictly tailored to the duration of the congress or educational event. However, where the travel expenses incurred are significantly reduced by the Healthcare Professional travelling at alternate times, the travel arrangements may be extended. Any accommodation expenses relating to the extended stay must be met the by Healthcare Professional.

Q26 May member companies organise the travel and accommodation arrangements of the spouse or other guest of a Healthcare Professional attending a third-party congress if the Healthcare Professional pays for the spouse or guest?

A26 No, unless that person qualifies as a proper delegate or participant at the meeting in their own right, it would not be appropriate for a member to organise the travel and/ or accommodation arrangements of the spouse or guest of a Healthcare Professional, irrespective of who pays. Such actions are open to misinterpretation.

Q27 Is it permissible under the Code for member companies to sponsor the attendance of individual Healthcare Professionals on courses of further education, for example, masters degree courses or modules of such courses?

A27 No, members may not sponsor individual Healthcare Professionals to attend courses of further education such as masters degree courses. Members may make educational grants available and provide such grants to the training institution but must have no role in the selection of the individual who will receive the grant.

Q28 Is it acceptable for members to subsidise or pay for the attendance of Healthcare Professionals at training or educational events organised by medical device industry associations or by professional associations or patient groups (in both cases with or without the involvement of third parties)? *(Updated in March 2011)*

A28 Yes, this is acceptable provided the Healthcare Professional is likely to obtain an objective benefit from such attendance and there is no overt commercial promotion. For example, meetings arranged for the purpose of training Healthcare Professionals on the guidelines or gaining a better understanding of the industry in general, would be acceptable.

Q29 Is it appropriate for members 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?

A29 Yes it is appropriate for members 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 guidelines in all respects. Accordingly, members should ensure that appropriate documentation is put in place, hotel accommodation is not normally provided at top category or luxury hotels, air travel is economy or standard class unless the duration of the flight extends beyond 5 hours (in which case premium economy or business class may be considered) and meals are of a standard that Healthcare Professionals would routinely expect if they were paying for them out of their own pocket.

Q30 What general criteria need to be fulfilled for arrangements with Healthcare Professionals that are engaged to provide genuine consultancy services?

A30 The criteria that should be adopted are as follows:

1. A legitimate business need is identified in advance;
2. The criteria for the selection of Healthcare Professionals are related to the identified need;
3. A written agreement specifying the services to be provided is in place before the service is rendered;
4. The compensation for the service rendered is reasonable and according to fair market value;
5. Members document the work products generated by the Healthcare Professionals; and
6. The arrangement is entered into without intention of using it as a means to induce the recommendation, purchase, prescription, supply or sale of medical products or services.

Q31 Under the guidelines, is it compulsory that a Healthcare Professional engaged as a consultant by a member obtains a written permission from the main Healthcare institution where the Healthcare Professional conducts his or her work to render services as a consultant for the member?

A31 Under the guidelines, written permission is not required. However, interaction between industry and Healthcare Professionals must be transparent and comply with national and local laws, regulations and professional codes of conduct. In countries where specific provision is not made, members shall nevertheless maintain appropriate transparency by giving prior written notification to the hospital administration or the Healthcare Professional's superior (or other locally-designated body), fully disclosing the purpose and scope of the engagement.

Q32 According to the guidelines, would it be permissible for members to organise entertainment or other social or leisure activities in association with meetings with Healthcare Professionals who are engaged as consultants by the member?

A32 No. Members should not provide or organise entertainment for Healthcare Professionals who are engaged as consultants by the member.

Q33 Is it appropriate for members to cover the cost of meals, travel or other hospitality expenses of the spouse or guest accompanying Healthcare Professionals at member-sponsored consultant meetings.

A33 No, it is not appropriate for members to pay for the meals, travel or accommodation of persons accompanying Healthcare Professional consultants at member-sponsored consultant meetings. Furthermore, members should not organise the travel or accommodation of such guests.

Q34 When a member contracts with a group of Healthcare Professionals for the development of intellectual property, is it appropriate for each Healthcare Professional pertaining to that group to receive financial compensation in respect of the co-developed medical devices prescribed or used by the other co-developer Healthcare Professionals?

A34 No. It is advisable that, the Healthcare Professionals who co-develop one or more medical devices under an appropriate contract with a member do not receive financial compensation in respect of the co-developed medical devices used or prescribed by the other co-developer Healthcare Professionals.

Q35 Please provide some examples of items of modest value that are "related to the Healthcare Professional's practice or for the benefit of patients".

A35 Mugs, 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 would be appropriate for use as gifts for Healthcare Professionals provided their value falls within the maximum value prescribed under national and local laws, regulations and industry and professional codes of conduct. 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.

Q36 Are prize draws and competitions appropriate forms of promoting medical devices?

A36 Prize draws and other competitions may be appropriate if the prize awarded complies with the guidelines on gifts and is in accordance with national and local laws, regulations and industry and professional codes of conduct.

Q37 What are regarded as cash equivalents?

A37 Items that have a specified cash value such as store vouchers, book tokens, music tokens or vouchers offering a discount or free gift are regarded as cash equivalents.

Q38 May a member provide a small gift to a Healthcare Professional upon significant life events such as a marriage, birth, birthday or death?

A38 The guidelines restrict the types of gifts 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 to determine the appropriateness of making a tasteful gift as a mark of respect.

Q39 May a member give gifts to staff of a Healthcare Professional who are not themselves Healthcare Professionals?

A39 Gifts given to the staff of a Healthcare Professional should be treated as though they were given to the Healthcare Professional and accordingly must comply with the provisions of the guidelines in all respects.

Q40 Where Healthcare Professionals engaged by members as consultants or speakers decline a professional fee for their services, would it be appropriate for the member to show its appreciation by giving the Healthcare Professional a small gift such as a bottle of wine or a bouquet of flowers? *(Added in March 2011)*

A40 No, it would not be acceptable for the member to make such a gift because to do so could be open to misinterpretation. Such gifts would not comply with Section V of the guidelines in that they do not relate to a Healthcare Professional's practice nor do they serve an educational function.

Q41 Can a member make a charitable donation to a non-profit organisation in the name of a Healthcare Professional?

A41 No. All contributions made with a member's funds must represent the member as the provider of the donation.

Q42 Can a member buy a stand or booth at a conference organised by a charity?

A42 Yes, but this activity would not be considered to be a charitable donation. It would be considered a legitimate commercial transaction as a normal part of marketing activity but members should consider the appropriateness of the location and the general circumstances of the event from the perspective of maintaining the reputation of industry.

Q43 Under the guidelines, may a member make a charitable donation such as the purchase of a table of dinner invitations at a fundraising dinner?

A43 Yes, charitable donations made by members 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 charity or other eligible entity. However, the member should not invite Healthcare Professionals to attend the event at the member's expense. The member may use some or all of its ticket allotment for its own employees and return any unused portion to the sponsoring organisation for use as the sponsoring organisation sees fit. Furthermore, the member 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's table.

Q44 Is it permissible for a member to make a donation to a Healthcare Professional's designated charity in instances where the Healthcare Professional has requested the member to do so in lieu of receiving a professional fee for the provision of consultancy or speaking services to the member? *(Added in March 2011)*

A44 No, it would not be appropriate for the member to agree to such a request. Charitable donations to an organisation shall not be made in response to requests from Healthcare Professionals irrespective of the underlying reasons.

Q45 Can a member pay a research grant to a Healthcare Professional for a clinical study where the member is named as the sponsor of the study?

A45 No. Clinical investigators participating in a member-sponsored study are regarded as providing a consultancy service and arrangements should follow Section V Arrangements with Consultants.

Q46 Under the guidelines, may members make educational grants to appropriate institutions to cover the cost of books or other educational materials or make a contribution to cover a proportion of a tuition fee? *(Added in March 2011)*

A46 Yes, members may provide educational grants to organisations or entities entitled to receive them for the purpose of purchasing educational materials. Members may also provide support for modules of a course or other components of the total cost of tuition under an educational grant. However, a Member shall not designate or recommend the HCP(s) who will use the materials or attend courses.

Q47 Do the guidelines apply to requests for educational support made by medical institutions and group purchasing bodies in the context of public tender offerings.

A47 No. Such requests and the subsequent financial support made are not considered to be "educational grants" for the purpose of these guidelines. Such arrangements are commercial in nature and not philanthropic and should be documented in a written commercial agreement in accordance with normal business practice.

Q48 How is Eucomed's Code of Ethical Business Practice to be applied to collection of post-market data? *(Added in December 2011)*

A48 Any and all collection of data must comply with the guidelines. Particular care is required where data is collected on a voluntary basis - such as through clinical registries after a product has been placed on the market (i.e. other than clinical trials or post-market data collection which are required by national law and/or regulatory agencies).

The most important consideration for post-market data collection is that they are performed for **exclusively legitimate purposes**. Examples of legitimate purposes include medical need, including patient safety; research & development; scientific purposes (e.g. performance indicators, comparing objective scientific parameters); regulatory, including post-market surveillance (PMS) and post-market clinical follow up (PMCF), vigilance, safety, or reimbursement and health economic, including clinical and cost-effectiveness and outcomes data relevant to health technology assessments (HTA) and reimbursement decision-making.

Members may not provide **improper inducement** of any participants. The choice of participating Healthcare Professionals should therefore be driven by clinical or medical functions, and not by sales and marketing teams. Members must be vigilant to avoid even the perception that participation in data collection is contingent upon past, present or potential future use of the member's products or services.

As with all interactions with Healthcare Professionals, the four **principles** in the Preamble of the guidelines apply and therefore, in addition to the principle of separation already mentioned in the previous paragraph:
(a) any remuneration paid must represent a fair market value of the services performed;
(b) the purpose and scope of the data collection must be transparent and fully disclosed to the appropriate individuals/institutions;
(c) all elements of the data collection must be documented (including but not limited to the written agreement with the appropriate institution conducting the data collection, setting out, inter alia, the purpose of the data collection, careful and complete records of services actually performed, patient consent forms (where required).

More generally, members must ensure that collection of data complies with all relevant national and local laws and regulations, including participants' own professional codes of conduct, and the involvement (if required) of Ethics Committees. In addition, Medical Device, Data Protection and Tax rules, and the **Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects** must be complied with (and therefore members should obtain, where required, **prior written patient consent)**.

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