

The logo for the Association of British HealthTech Industries (ABHI) features the letters 'ABHI' in a bold, sans-serif font. The 'A' is stylized with a white triangle cutout at its top-left corner. The letters are colored in a vibrant magenta.

ABHI

association of
**British HealthTech
Industries**

The background of the page is white, featuring two prominent magenta graphic elements: a thick diagonal line running from the top-left towards the bottom-right, and a large, stylized magenta arrow shape pointing upwards and to the right, positioned behind the main title.

CODE OF ETHICAL BUSINESS PRACTICE

www.abhi.org.uk

July 2019



CONTENTS

INTRODUCTION	2	PART 2: Disclosure Guidelines	46
Promoting an Ethical Industry	2	Preamble	47
Key Legislation	3	Chapter 1: Applicability of these Guidelines	48
Aims and Principles of the Code	4	Chapter 2: Disclosure Obligation	50
Interpreting the Code	6	Chapter 3: Form of Disclosure	51
Administering the Code	6		
Implementation and Transition Period	7	PART 3: Guidelines on Advertisements and Promotions addressed solely or primarily to Healthcare Professionals	53
Transition Period to phase out direct support for HCP attendance at Third Party Organised Educational Events and for HCP speakers at satellite symposia	7	Preamble	54
		Guidelines	55
PART 1: Guidelines on the Interactions with Healthcare Professionals and Healthcare Organisations	8	1. Scope of Guidelines	55
Chapter 1: General Criteria for Events	9	2. Accuracy and Substantiation of Claims and Information	55
1. Event Programme	9	3. Comparative Advertising	57
2. Event Location and Venue	10	4. Requests for Substantiating Data	57
3. Guests	11	5. Use of Published Data to Support Advertising	58
4. Reasonable Hospitality	11	6. No Disparagement	58
5. Travel	12	7. Non-Referreed Articles	58
6. Transparency	13	8. Off-Label Use	59
Chapter 2: Third Party Organised Educational Events	14	9. Quotations	59
1. Third Party Organised Educational Conferences	14	10. Material Commissioned by the Advertiser	59
2. Third Party Organised Procedure Training	16	11. Testimonials and Endorsements	59
3. Transition Period: Support of Individual Healthcare Professionals to Third Party Organised Educational Events	17	12. Reimbursement of Expenses for Providers of Testimonials or Endorsements	60
Chapter 3: Company Events	18	13. Effect of Background Collaboration or Sponsorship on Testimonials and Endorsements	61
1. General Principles	18	14. Annex 1: General Advertising Law and Codes	62
2. Product and Procedure Training and Education Events	19		
3. Sales, Promotional and Other Business Meetings	22	PART 4: Complaints Principles, Procedure & Panel Constitution	63
Chapter 4: Grants and Charitable Donations	23	Introduction	64
1. General Principles	23	Dispute Resolution Principles	65
2. Charitable Donations	25	Structure & Responsibilities	65
3. Educational Grants	26	Complaints Procedure	66
4. Research Grants	30	General Provisions	69
Chapter 5: Sponsored Posts	32		
Chapter 6: Arrangements with Consultants	33	PART 5: Glossary and Definitions	70
1. General Principles	33	PART 6: Annexes	75
2. Criteria for Genuine Consulting Arrangements	34	Annex I: CVS scope: When are CVS assessments required?	76
3. Remuneration and Fair Market Value	35	Annex II: Disclosure Guidelines Template Example	77
4. Disclosure and Transparency	35	Annex III: MedTech Europe Geographical Area	78
Chapter 7: Research	36	Annex IV: Verification Of The Use Of Funds	79
1. Member Company-Initiated Research	36	Annex V: Example of Disclosure Guidelines Methodology Note	80
2. Member Company Post-Market Product Evaluation	37	Annex VI: Direct support to HCP Participation in Events as of 1st January 2019	81
3. Third Party-Initiated Research	38	Annex VII: The Criteria Applicable to Third Party Organised Procedure Trainings	82
Chapter 8: Royalties	39		
Chapter 9: Educational Items and Gifts	41		
Chapter 10: Demonstration Products and Samples	43		
1. General Principles	43		
2. Demonstration Products (Demos)	44		
3. Samples	45		



INTRODUCTION

PROMOTING AN ETHICAL INDUSTRY

ABHI is the industry association for the health technology sector in the UK.

CODE

The Association of British HealthTech Industries (ABHI) supports the health technology community to provide products and services that help people live healthier lives. With over 275 members, ABHI's work is focused on showing the value of healthtech and encouraging a healthy environment for economic growth. ABHI help Members understand healthtech regulation and our work is underpinned by our Code of Ethical Business Practice, which all Members adhere to.

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

Furthermore, Member Companies must be mindful of the fact that they may be liable for the activities of third party intermediaries who interact with Healthcare Professionals or Healthcare Organisations in connection with the sale, promotion or other activity involving Member Companies' products. Accordingly, it is recommended that where such arrangements are entered into, the relevant contractual documentation impose obligations upon the third party (for example, third party sales & marketing intermediaries (SMIs), consultants, distributors, sales agents, marketing agents, brokers, commissionaire commercial agents and independent sales representatives) to comply with provisions set out in the Code or equivalent guidelines¹.

KEY LEGISLATION

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

- Safety, Quality and Performance Laws;
- Advertising and Promotion Laws;
- Data Protection Laws;
- Anti-corruption Laws;
- Environmental Health and Safety Laws;
- Competition Laws.

National and European Union (EU) competition legislation applies not only to Members in their business operations, but also to ABHI, each of the association's working groups and any sub-group within the association, irrespective of size and name. Liability under competition laws may be strict and a Member may become liable for the infringement of such laws by other Members of an association group in which it participates. Accordingly, Members must make every effort to observe UK and EU competition laws in all their interactions.

¹. For further details, please refer to the Eucomed/AdvaMed Third Party SMIs guidance

QUESTIONS AND ANSWERS

Q1: Is the Code applicable to activities of an Affiliate of a Member Company located outside the MedTech Europe Geographic Area? (Added in July 2019)

A1: With regards to activities of an Affiliate of a Member Company located outside of the MedTech Europe Geographic Area;

The Code is applicable:

- whenever they support an Event taking place in the MedTech Europe Geographic Area or
- whenever they interact with Healthcare Organisations located, or Healthcare Professionals registered or practising inside the MedTech Europe Geographic Area.

The Code is not applicable:

- whenever they support an Event taking place outside the MedTech Europe Geographic Area (for the avoidance of doubt and as stated in the above paragraph; except if they are supporting participation of Healthcare Professionals registered or practising inside the MedTech Europe Geographic Area to attend the Event) or
- interact with Healthcare Organisations located, or Healthcare Professionals registered or practising outside the MedTech Europe Geographic Area.

However, in the interest of increased transparency, it would always be preferable for the Affiliate of the Member Company based in the MedTech Europe Geographic Area to handle support for Healthcare Professionals attending Events held in the MedTech Europe Geographic Area.

AIMS AND PRINCIPLES OF THE CODE

The interaction between Members and Healthcare Professionals and Healthcare Organisations is an important feature in achieving ABHI's mission to make safe, innovative and reliable technology and Related Services available to more people. For example:

- **Advancement of Health Technologies**

The development of innovative medical devices, technologies and in vitro diagnostics and the improvement of existing products require collaboration between Member Companies and Healthcare Professionals and Healthcare Organisations. Innovation and creativity are essential to the development and evolution of health technologies and/or Related Services.

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

The safe and effective use of health technology and Related Services requires Member Companies to offer Healthcare Professionals and Healthcare Organisations appropriate instruction, education, training, service and technical support.

- **Research and Education**

Member Companies' support of *bona fide* medical research and education, serves to enhance Healthcare Professionals' clinical skills and thereby contribute to patient safety and increase access to new technologies and/or Related Services.

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

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?

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 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.*

CODE

- **The Principle of Image and Perception**

Member Companies should, at all times, consider the image and perception of the health technology industry that will be projected to the public when interacting with Healthcare Professionals and Healthcare Organisations.

- **The Principle of Separation**

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

- **The Principle of Transparency**

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

- **The Principle of Equivalence**

Where Healthcare Professionals are engaged by a Member Company to perform a service for or on behalf of a Member Company, the remuneration paid by the Member Company must be commensurate with, and represent a fair market value for, the services performed by the Healthcare Professional.

QUESTIONS AND ANSWERS

Q3: Must a Member Company require Employer Notification to be given whenever Company personnel meet HCPs at an HCO? (added in May 2017)

A3: No. Unless the Member Company's interaction with an HCP entails a transfer of value or raises a potential conflict of interest there is no requirement for Employer Notification. However, Member Companies must comply with any access requirements imposed by HCOs to visiting Member Company personnel.

CODE

• The Principle of Documentation

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

INTERPRETING THE CODE

The use of capital letters indicates that a word or expression is a defined term, the meaning of which is set out in the [Glossary](#).

Any phrase introduced by the terms: including, include, in particular, or any similar expression shall be interpreted as illustrative and shall not limit the sense of the words preceding those terms.

ADMINISTERING THE CODE

The Code operates within a procedural framework which includes procedures designed to provide an effective and efficient complaint-handling process, to ensure compliance with the Code. ABHI's complaints handling system is based on the principle that disputes are best resolved through mediation.

The Conference Vetting System¹ is an independently-managed system which reviews the compliance of Third Party Organised Educational Events with the Code.

¹ For scope of application of CVS please refer to: www.ethicalmedtech.eu

QUESTIONS AND ANSWERS

Q4: What is the Conference Vetting System (CVS) and, is CVS approval required for all Third Party Organised Educational Events before a Member Company can provide support to these events? (added in May 2017)

A4: *The Conference Vetting System (see the Glossary) has been established as the online, binding and centralised decision-making process to help Member Companies review the compliance of relevant Third Party Organised Educational Events with the Code. It is managed independently of the MedTech Europe Secretariat and Members and is under the supervision of the MedTech Europe Compliance Panel. CVS approval is only required for Third Party Organised Educational Events which fall within its scope, as provided [here](#). Where there is a CVS decision in relation to a specific Third Party Organised Educational Event, this decision is binding upon all Member Companies.*

Q4-bis: What is a Virtual Third Party Organised Educational Event ("Virtual Event") (added in July 2019)

A4-bis: *A [stand-alone] Virtual Third Party Organised Educational Event ("Virtual Event") consists of the filming of presentations, panel discussions or live clinical procedures (e.g. hands-on sessions, surgery simulations, live surgeries, etc.) and their broadcasting (whether immediate or deferred) to an audience which is not physically in attendance.*

A Virtual Event is delineated by the lack of Healthcare Professional ("HCP") attendees, as the only HCPs physically present at a Virtual Event are those involved in its creation, i.e. presentation. As a result, a Virtual Event will not be connected in any way with a physical Third Party Organised Educational Event.

Conversely, the filming of presentations, discussions, etc. made during a Third Party Organised Educational Event ("Broadcasted Event"), and its broadcasting to audiences not present at the physically attended Event—whether contemporaneously or after the Event—do not qualify as a Virtual Event.

For avoidance of doubt, Member Companies may provide financial and/ or in-kind support (e.g. Member Company products) to Virtual Events in accordance with the rules of the Chapter 2 of the Code.

Q4-ter: Are Virtual Events subject to the MedTech Europe Conference Vetting System (CVS)? (added in July 2019)

A4-ter: *Virtual Events are not subject to CVS. Third Party Organised Educational Events as well as their broadcasting, falling in the scope the MedTech Europe CVS, are subject to CVS. Both Virtual and Broadcasted Third Party Organised Educational Events are subject to the rules of the ABHI Code of Ethical Business Practice.*

IMPLEMENTATION AND TRANSITION PERIOD

This edition of the Code comes into force as follows:

- PART 4: The Complaints Procedure & Panel Constitution shall enter into force on 1 January 2017; and
- The balance of the Code i.e. Introduction, PART 1 and PART 2, shall enter into force on 1 January 2018.

For the avoidance of doubt, during the transposition period 1 January 2017 to 31 December 2017, no material or activity will be regarded as being in breach of the Code if it fails to comply with its provisions only because of requirements which this edition of the Code newly introduces.

TRANSITION PERIOD TO PHASE OUT DIRECT SUPPORT FOR HCP ATTENDANCE AT THIRD PARTY ORGANISED EDUCATIONAL EVENTS AND FOR HCP SPEAKERS AT SATELLITE SYMPOSIA

After the end of the Transition Period (see the [Glossary](#)) on 31 December 2018, Member Companies shall no longer provide financial or in-kind support directly to individual Healthcare Professionals to cover costs of their attendance at Third Party Organised Educational Events with the exception of Third Party Organised Procedure Training meetings or pursuant to a consulting agreement with a Healthcare Professional speaker engaged by a Member Company to speak at a satellite symposium. This means that support of individual Healthcare Professionals to attend Third Party Organised Educational Events (as provided for at [Chapter 2, Section 3](#)) shall no longer be permitted under the Code.

After the Transition Period, Member Companies may provide financial or in-kind support to Third Party Organised Educational Events only through Educational Grants or other types of funding in accordance with the rules of [Chapter 2: Third Party Organised Educational Events](#) and [Chapter 4: Grants and Charitable Donations](#).

Q5: What is the difference between the Transposition period and the Transition Period as defined in the [Glossary](#)? (added in May 2017)

A5: *Transposition means the process of incorporating the Code within the Member Company's own policy and procedures. This process must be completed by 1 January 2018.*

Transition Period means the period between 1 January 2017 and 31 December 2018 by the end of which Member Companies must have ceased all financial or in-kind direct support to Healthcare Professionals to attend Third Party Organised Educational Conferences. Any exceptions to this rule are outlined in the Code

Q5-bis: How does the Code apply to members with company structures that include different business units, e.g. medical devices, pharmaceuticals, research-only products? How can educational grants be applied in such organisational structures? (added in July 2019)

A5-bis: *The Code applies to all Member Companies regarding their interactions linked to Medical Technologies. Ensuring compliance with the Code may be more challenging for companies with structures 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 organisational set up. For example, if a member were to have Medical Devices or In Vitro Diagnostics marketed under or linked to their pharmaceutical business unit, the interactions with Healthcare Professionals and Healthcare Organisations in relation to these medical technologies would be governed by the Code irrespective of the business unit that pays for or manages the interaction. In this respect, the Member Company cannot circumvent the Code's requirements by using its pharmaceutical business/ affiliate to directly support a Healthcare Professional to attend a medical technology-related Third Party Organised Educational Conference as this would amount to a violation of the Code. For the avoidance of doubt, the Code will not apply to Member Companies' interactions linked exclusively to non-Medical Technology products or services such as medicinal products or research-only products, without any link to Medical Technology products. However, this does not mean that different business units can be used to circumvent Code requirements as explained above. In case an interaction or activity is linked in part to Medical Technology products, the Code shall apply.*

PART 1

**GUIDELINES ON THE INTERACTIONS
WITH HEALTHCARE PROFESSIONALS
AND HEALTHCARE ORGANISATIONS**



1

GENERAL CRITERIA FOR EVENTS

CODE

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

1. EVENT PROGRAMME

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

A Member Company shall not organise Events which include social, sporting and/or leisure activities or other forms of Entertainment, nor support such elements where

QUESTIONS AND ANSWERS

Q6: What is meant by "legitimate" or "genuine" as used in the definitions of 'Company Event' and 'Third Party Organised Educational Conferences'?

A6: *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.*

CODE

part of Third Party Organised Educational Events. For Third Party Organised Educational Events, Entertainment must be outside of the educational programme schedule and paid for separately by the Healthcare Professionals. Entertainment should not dominate or interfere with the overall scientific content of the programme and must be held during times that do not overlap with a scientific session. The Entertainment should not be the main attraction of the Third Party Organised Educational Event.

2. EVENT LOCATION AND VENUE

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

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

QUESTIONS AND ANSWERS

Q7: 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? (Amended in July 2018)

A7: *In principle, no. 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.

Q8: Under the Code, what is meant by "ease of access" in relation to Event location and venue?

A8: *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 connections, with associated reliable ground transportation infrastructure to the venue.*

Q9: Under the Code, how does the "season" impact evaluation of Event location? (Amended in July 2019)

A9: *Even assuming a location or venue meets all other applicable requirements under the Code, geographic locations renowned primarily as seasonal vacation or holiday destinations (for example, ski-, island-, or beach resorts) are still not appropriate locations during the season in question. For this purpose, in Europe, the ski season is considered to run from 20th December to 31st March and the summer season from 15th June to 15th September. Equivalent, seasonally adjusted dates apply in other regions of the world. Member Companies must not support or organise Events at these locations if they take place during those seasons, even if only in part.*

3. GUESTS

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

4. REASONABLE HOSPITALITY

Member Companies may provide reasonable hospitality to Healthcare Professionals in the context of Company Events and Third Party Organised Educational Events but any hospitality offered must be subordinate in time and focus to the Event purpose. Member Companies must in any event meet the requirements governing hospitality in the country where the Healthcare Professional carries on their profession and give due consideration to the requirements in the country where the Event is being hosted¹.

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

¹ In the UK, the NHS England document *Managing Conflicts of Interest in the NHS* (Publications Gateway Reference: 06419) sets the upper limit for meals and refreshments that may be accepted by NHS HCPs at £75. While this only directly applies to the NHS in England it should be taken as indicative of what is acceptable in the rest of the UK, including in relation to HCPs working in the non-NHS sector. Different limits may apply in other territories and Member Companies should comply with these as appropriate. Where no such limits apply, the UK figure may be taken as indicative of what is acceptable under the Code although in exceptional circumstances local considerations may allow the £75 limit to be exceeded.

Q10: What does the term "facilitate" mean where used in connection with the Guest expenses?

A10: *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.*

Q11: 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?

A11: *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.*

Q12: 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?

A12: *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.*

CODE

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

Member Companies may not pay for or reimburse Healthcare Professionals' lodging expenses at top category or luxury hotels. For the avoidance of doubt, if the Event venue is a hotel which complies with the requirements of the Code, it would be acceptable for Member Companies to offer participants meals and accommodation at the same hotel. However, accommodation and/or other services provided to Healthcare Professionals should not cover a period of stay beyond the official duration of the Event.

5. TRAVEL

Member Companies may only pay or reimburse for reasonable and actual travel. Travel provided to Healthcare Professionals should not cover a period of stay beyond the official duration of the Event.

For air travel, in principle, this means that Member Companies can only pay or reimburse economy or standard class unless the flight time is of a duration of greater than 5 hours including connection flights, in which case business class can be considered. First class is never appropriate.

QUESTIONS AND ANSWERS

Q13: 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?

A13: *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.*

6. TRANSPARENCY

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

Q14: 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?

A14: *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.*

Q15: 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?

A15: *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.*

Q16: 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?

A16: *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.*

2

THIRD PARTY ORGANISED EDUCATIONAL EVENTS

CODE

Member Companies may provide financial and/or in-kind support (e.g. Member Company products) to Third Party Organised Educational Events in accordance with the rules of this Code. Such Events include:

- Third Party Organised Educational Conferences;
- and Third Party Organised Procedure Training meetings.

1. THIRD PARTY ORGANISED EDUCATIONAL CONFERENCES

Member Companies may support in cash and/or in-kind Third Party Organised Educational Conferences (see the [Glossary](#)) which comply with:

- [Chapter 1: General Criteria for Events](#);
- and where applicable, has approval via the [Conference Vetting System](#)¹ (see the [Glossary](#)).

¹ For scope of application of CVS please refer to: www.ethicalmedtech.eu

QUESTIONS AND ANSWERS

Q17: 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”? (Amended in July 2018)

A17: “In-kind support” can be provided to the Healthcare Organisation (HCO) and Member Companies should ensure that any such in-kind support does not, nor is perceived to, circumvent the prohibition of Member Companies providing direct financial support to identifiable Healthcare Professionals to attend Third Party Organised Educational Conferences. For example, after the Transition Period, 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. Examples of “in-kind support” which Member Companies may provide could include modest secretarial and/or logistical support to assist with meeting arrangements.

CODE

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

a. Educational Grants

Please refer to [Chapter 4: Grants and Charitable Donations](#) for guidance on Educational Grants.

b. Promotional Activity

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

c. Satellite Symposia

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

QUESTIONS AND ANSWERS

Q18: Please provide examples of appropriate booth activities which will be perceived as professional?

A18: *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.*

Q19: Can a Member Company, for example, be present via a satellite symposium or rent booth space at a Third Party Organised Educational Conference which was assessed as non-compliant by the Conference Vetting System (CVS)? (Amended in May 2017)

A19: *Please refer to [Annex I](#) for a detailed visualisation of the scope CVS and its impact on commercial activities.*

Q20: 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? (Amended in July 2018)

A20: *Member Companies must ensure all aspects of the arrangement comply with the Code, including entering into a consulting agreement with Healthcare Professionals engaged to speak at satellite symposia. The consulting agreements may provide for payments to be made in respect of travel and/or accommodation for the purpose of delivering the speaker services. Where payment of a registration fee is required in order for speakers to access satellite symposia, Member Companies may also pay for the registration fee.*

2. THIRD PARTY ORGANISED PROCEDURE TRAINING

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

- a. Financial support must comply with the criteria provided in [Chapter 1: General Criteria for Events](#). Member Companies may therefore pay travel, hospitality and the registration fee.
- b. Where applicable, the Third Party Organised Procedure Training has approval via the Conference Vetting System (see the [Glossary](#))¹.
- c. For financial support to Third Party Organised Procedure Training meetings Member Companies must apply the requirements governing conduct and attendance at such meetings in the country where the Healthcare Professional carries on their profession and give due consideration to the requirements in the country where the meeting is being hosted.

Q21: What are the main differences between Third Party Organised Educational Conferences and Procedure Trainings? (added in May 2017)

A21: *Both Third-Party Organised Educational Conferences (see the Glossary) and Third-Party Procedure Trainings (see the Glossary) are a type of Third Party Organised Educational Events. 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 Training is not subject to the phase out of direct support for the attendance of Healthcare Professionals. Nonetheless, for Third Party Organised Procedure Training the following three criteria shall apply:*

- *Programme: Unlike Third Party Organised Educational Conferences which are theoretical in nature, Third Party Organised Procedure Training consists of practical, hands-on training, generally involving more than one provider/ manufacturer/sponsor. This must be evident by the programme of 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 health 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 technologies are used on cadavers; skin models; synthetic bones; cath labs; etc.

- *Venue: Third Party Organised Procedure Training is typically organised in a clinical environment, as opposed to, e.g., a classroom setting.*

For the avoidance of doubt, 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 health technologies to be used on cadavers; skin models; synthetic bones; etc.

- *Stand-alone event: Third Party Organised Procedure Training must stand alone. Where the majority of the Training is not given in a clinical environment, for example, where the Training is organised in connection, 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.*

¹ For scope of application of CVS please refer to: www.ethicalmedtech.eu

3. TRANSITION PERIOD: SUPPORT OF INDIVIDUAL HEALTHCARE PROFESSIONALS TO THIRD PARTY ORGANISED EDUCATIONAL EVENTS

Member Companies may provide financial support directly to individual Healthcare Professionals to cover the costs of attendance at Third Party Organised Educational Events where this is permitted under national laws, regulations and professional codes of conduct. Such support shall be in accordance with the following rules:

- a. Financial support must comply with the criteria provided in [Chapter 1: General Criteria for Events](#). In addition Member Companies may pay the registration fee.
- b. Where applicable, the Third Party Organised Educational Event has approval via the Conference Vetting System¹ (see the [Glossary](#)).
- c. For financial support to Third Party Organised Educational Events Member Companies must apply the requirements governing conduct and attendance at such Third Party Organised Educational Event in the country where the Healthcare Professional carries on their profession and give due consideration to the requirements in the country where the meeting is being hosted.

¹ For scope of application of CVS please refer to: www.ethicalmedtech.eu

Q22: In the definition of Third Party Organised Procedure Training, what is meant by “Proctorship” and “Preceptorship”? Further, do Proctorships and Preceptorships require CVS approval before they can be provided and/or supported by a Member Company? (added in May 2017)

A22: For the purpose of the Code both Proctorship and Preceptorship are types of clinician-to-clinician trainings funded by a Member Company.

Proctorship is where the trainee clinician performs a procedure under the supervision of another clinician and where the trainee clinician has primary responsibility for the patient undergoing the procedure.

Preceptorship is where the supervising clinician oversees the procedural training of the trainee clinician and the trainee does not have primary responsibility for the patient undergoing the procedure.

Such Proctorships and Preceptorships normally take place on Healthcare Organisation 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.

3

COMPANY EVENTS

CODE

1. GENERAL PRINCIPLES

Member Companies may invite Healthcare Professionals to Company Events. Such events include, as defined in the [Glossary](#):

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

Company Events should comply with the principles mentioned in [Chapter 1: General Criteria for Events](#).

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

QUESTIONS AND ANSWERS

Q23: 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?

A23: 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.

2. PRODUCT AND PROCEDURE TRAINING AND COMPANY ORGANISED EDUCATION EVENTS

Where appropriate, in order to facilitate the safe and effective use of health technologies, therapies and/or services, Member Companies should make product and procedure training and education available to relevant Healthcare Professionals.

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

QUESTIONS AND ANSWERS

Q24: Can Member Companies directly support travel and/or accommodation or other expenses of individual Healthcare Professionals for attendance as delegates at Company Organised Events happening during or around a Third-Party Organised Educational Event? (Amended July 2019)

A24: No, as from 1st January 2019, Member Companies cannot directly support travel and/or accommodation or other expenses of individual Healthcare Professionals participating as delegates in Company Organised Events which take place during, around, or at the same time and in the same approximate location as a Third-Party Organised Event.

However, Company Organised Events, including fee-for-service arrangements like Advisory Boards and Clinical Investigator meetings, may be organised at or around a Third-Party Organised Educational Event for reasons of convenience and efficiency, given the attendance of Healthcare Professionals at that Third-Party Organised Educational Event. If such an event overlap occurs, the Member Company may only pay for the contractual remuneration and expenses agreed for the provision of the services by the Healthcare Professional at the Company Organised Education Event itself. Under no circumstances may a Member Company pay for incremental costs relating to the Healthcare Professional's attendance at the Third Party Organised Educational Event, such as registration costs, hospitality, additional travel or accommodation. Member Companies may provide flexibility in the Healthcare Professionals' travel arrangements—provided there is no additional or incremental cost involved (i.e. registration, hospitality, additional accommodation or travel). Moreover, the Healthcare Professionals must have an active role at such a Company Organised Event, rather than being mere passive attendees. [E.g. no support shall be provided by Member Companies to Healthcare Professionals attending a Company Organised Educational Event as a delegate or trainee where this is organised at or around a Third Party Organised Educational Event.]. Specific examples of support which can and cannot be provide include the following:

- For an advisory board or a clinical investigator meeting organised at or around a Third-Party Organised Educational Event:
 - the registration fee of the Healthcare Professional to the Third-Party Organised Educational Event shall in no circumstances be covered by the Member Company as this would not be related to the services to be provided.
 - the flight and accommodation costs can be covered pursuant to the services provided, with the flexibility caveat noted above.
- For a satellite symposium or a booth speaker engagement taking place during the Third-Party Organised Educational Event (i.e. as part of that Third-Party Organised Educational Event):
 - the Healthcare Professional's registration fee for the Third-Party Organised Educational Event may be covered only if the Healthcare Professional's access to the satellite symposium or booth at the Third-Party Organised Educational Event is conditional upon the payment of the registration fee.

Where this does apply, the registration fee must, where possible, be pro rata'd to the actual attendance required in order to deliver the required services. E.g. if the satellite symposium is held on a single day of the three-day event, and it is possible to choose a one-day registration, that option should be selected.

- the flight and accommodation costs can only be covered if the Healthcare Professional is not already benefiting from an educational grant covering his/her attendance at the event.

Q25: Under the Code, Chapter 3, Point 2, what is meant by "Company Organised Education Events"? (added in May 2017)

A25: A "Company Organised Education Event" is a Company Event as defined in the Glossary, whose objective is genuine and bona fide medical education, and the enhancement of professional skills. "Educational" or "education" means communicating information directly concerning or associated with the use of Member Companies' health technologies, e.g., information about disease states and the benefits of health technologies to certain patient populations. In all cases the information and/ or training must directly concern a Member Company's health technologies, therapies and/or Related Services.

This means that a Member Company must meet the following tests when organising such an Event in order to be compliant with the Code:

- a) The entire Event must comply with the criteria of Chapters 1 and 3;
- b) The programme must be rigorous from a scientific and/or educational point of view. This means that its content must include current scientific information of a nature and quality which is appropriate to the Healthcare Professionals who are attendees at the Event.
- c) The programme must be genuine and bona fide educational, and therefore cannot have a primary sales and marketing objective. This means that the education part must fill most of the programme.
- d) Information on the programme, clearly indicating the name of the Company organising the Event, should be made available sufficiently in advance in order for invited Healthcare Professionals to be able to make a reasoned judgment as to the rigor and quality of the programme, provided however that subsequent changes, deletions and additions to the programme are acceptable to the extent that such changes, deletions and additions are reasonable and do not significantly modify the quality or nature of the programme.
- e) The programme should in principle involve full days, with the majority of the morning and afternoon parts dedicated to scientific and/or educational sessions, unless the Event is a half day event, commences or ends on a midday or lasts less than half a day. Such half-day or less sessions are permissible, but there should not be any non-scientific or non-educational events or activities organised for the other part of the day. Furthermore, there should be no significant gaps in the programme which would permit Healthcare Professionals to engage in non-scientific or non-educational activities. For example, early morning sessions should not be followed by late afternoon or evening sessions with large blocks of free time in between.

Q26: Are cruise ships or golf clubs appropriate venues for Product and Procedure Training and Education Events?

A26: *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.*

Q27: What criteria should a Member Company apply when considering the country location of Product and Procedure Training and Education Events?

A27: *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.*

Q28: Can a Member Company use a meeting venue outside Europe?

A28: *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.*

Q29: 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. (Added July 2018)

A29: *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").*

3. SALES, PROMOTIONAL AND OTHER BUSINESS MEETINGS

Where it is appropriate, Member Companies may organise Sales, Promotional and Other Business Meetings where the objective is to discuss product and Related Services features and benefits, conduct contract negotiations, or discuss sales terms.

In addition to the principles laid down in the [Chapter 3, Section 1](#), Sales, Promotional and Other Business Meetings should also comply with the following more stringent requirements:

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



4 GRANTS AND CHARITABLE DONATIONS

CODE

1. GENERAL PRINCIPLES

- a. Grants and Charitable Donations (see the [Glossary](#)) shall not be contingent in any way on past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the Member Company's products or services. It is important that support of charitable and/or philanthropic programmes and activities by Member Companies is not viewed as a price concession, reward to favoured customers or as an inducement to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services.
- b. A Member Company shall not provide Grants or Charitable Donations to individual Healthcare Professionals. Grants and Charitable Donations must be provided directly to the qualifying organisation or entity,

QUESTIONS AND ANSWERS

CODE

as the case may be. Grants and Charitable Donations shall not be provided in response to requests made by Healthcare Professionals unless the Healthcare Professional is an employee or officer of the qualifying organisation or entity and submits the request in writing on behalf of the qualifying organisation or entity.

- c. The payment (or provision of other support) by way of any Grant or Charitable Donation shall always be made out in the name of the recipient organisation and shall be paid directly to the organisation. A Member Company shall not provide Grants or Charitable Donations in the name of any Healthcare Professional. In addition, all Grants and Charitable Donations shall identify the Member Company as the provider of the Grant or Charitable Donation.
- d. It must in all cases be lawful under applicable national laws and regulations for the Grant or Charitable Donation recipient to receive and benefit from the particular type of Grant/Charitable Donation.
- e. Member Companies shall implement an independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with the provision of a Grant or a Charitable Donation to a specific prospective recipient. This process shall include a documented, prior evaluation of any such associated risks and of the relevant information concerning the intended recipient organisation or entity.

QUESTIONS AND ANSWERS

Q30: Under the General Principles in Chapter 4. Grants and Charitable Donations, what is meant by an "independent decision-making/review process"?

A30: *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.*

Q31: 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?

A31: *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.

CODE

- f. All Grants and Charitable Donations must be appropriately documented by the Member Company. Moreover, Grants and Charitable Donations shall only be provided in response to a written request submitted by the requesting organisation or documented initiative from a Member Company containing sufficient information to permit an objective evaluation of the request to be carried out by the Member Company. No Grant or Charitable Donation shall be provided until a written agreement documenting the terms of this is signed by both parties.
- g. This section of the Code ([Chapter 4: Grants and Charitable Donations](#)) is not intended to address the legitimate practice by Member Companies of providing appropriate rebates, additional product and/or service offerings, including free of charge, or other comparable pricing incentive mechanisms ("value adds") which are included in competitive and transparent centralised purchasing arrangements, such as, for example, tenders.

2. CHARITABLE DONATIONS

Member Companies may make unrestricted Charitable Donations for genuinely charitable or other philanthropic purposes. "Unrestricted" in this context means that Member Companies shall have no control over the final use of funds (or other support) they provide as Charitable Donations beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes.

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

Restricted Charitable Donations to non-profit hospitals may be permissible in case of demonstrated Financial Hardship (see [Glossary](#)), when Charitable Donations serve exclusively the benefit of the patient, are limited in value, or explicitly permitted by applicable national laws.

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

QUESTIONS AND ANSWERS

Q32: What does "sufficient information" mean where used in connection with documentation of Grants and Charitable Donations?

A32: *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.*

Q33: Under the Code, can a Member Company make a Charitable Donation to support the general running of hospital or other Healthcare Organisation?

A33: *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.*

Q34: 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? (added in May 2017)

A34: *Under the Code it is not appropriate for a Member Company to apply conditions or restrictions to the final use of a Charitable Donation which go beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes. Member Companies may therefore impose general restrictions concerning the final use, 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 the earthquake in that country). However, Member Companies must take care that such general restrictions are not so specific that the Charitable Donation is no longer unrestricted. The Charitable Donation must not be misused or be perceived to influence through undue or improper advantages, purchasing decisions, nor should such Donation be contingent upon sales transactions or use or recommendation of Member Companies' products.*

3. EDUCATIONAL GRANTS

Member Companies may provide restricted Educational Grants (see the [Glossary](#)) for the advancement of genuine medical education. "Restricted" in this context means that Member Companies shall specify the intended purpose of the Educational Grant in the Grant agreement. A Member Company shall also ensure that the Educational Grant agreement with the recipient organisation includes rights to enable it to verify that the Grant is in fact used for the agreed intended purpose.

Member Companies shall document and publicly disclose all Educational Grants in accordance with the Code's Disclosure Guidelines, and publication shall commence no later than the end of the Transition Period.

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

QUESTIONS AND ANSWERS

Q35: 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?

A35: *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.*

Q36: 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?

A36: *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.*

Q37: Can a small sized Healthcare Organisation receive Educational Grants to support Healthcare Professionals participation at Third Party Organised Educational Events? (added in May 2017)

A37: *Yes, in principle. There are no size limits for Healthcare Organisations to receive Educational Grants; however, Member Companies must ensure that the final beneficiaries of the Educational Grant cannot be identified beforehand. For example, Healthcare Organisations 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.*

CODE

a. Support for Third Party Organised Educational Events:

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

- Comply with [Chapter 1. General Criteria for Events](#); and
- Where applicable, have approval via the Conference Vetting System¹ (see the [Glossary](#))

a.1. Support for HCP Participation at Third Party Organised Educational Events:

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

QUESTIONS AND ANSWERS

Q37-bis: 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? (Added July 2018).

A37-bis: *One of the guiding principles in the Code is that companies should not receive or be able to determine the names of the ultimate HCP beneficiaries and the inclusion of a criterion specifying an individual hospital or hospital department is not prohibited under the Code. However, companies should bear in mind that the smaller the hospital or department, the greater will be the risk that companies will be able to make such a determination making the use of such a criterion inappropriate under the Code. In addition, companies should be mindful of any proximate or ongoing tender proceedings with that specific hospital, as such tenders may raise additional red flags.*

Q38: 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?

A38: *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.*

Q38-bis: Can Member companies give criteria for HCOs and/or PCOs to allocate their Educational Funds? (Added July 2018)

A38-bis: *Yes, objective criteria for HCOs or PCOs to select HCPs to benefit from Educational funds may be given 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' speciality, 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.*

Q39: Is it appropriate for a Member Company that has provided an Educational Grant to support Healthcare Professional attendance at a Third-Party Organised Educational Event to receive the names of the Healthcare Professionals benefiting from the Educational Grant? (Added July 2018).

A39: *A Member Company should not proactively seek to receive the names of the healthcare Professionals benefiting from its Educational Grant. Generally, when a Third-Party Organised Educational Event is supported by more than one company, all companies should receive the same attendance list, from which it should not be possible to identify which Healthcare Professionals have benefited from a particular Member Company's Educational Grant.*

¹ For scope of application of CVS please refer to: www.ethicalmedtech.eu

CODE

a.2. Support for Third Party Organised Educational Events:

Where the prospective beneficiary of an Educational Grant is the organiser of the Third Party Organised Educational Event and is also a Healthcare Organisation, the recipient Healthcare Organisation shall be solely responsible for:

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

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

QUESTIONS AND ANSWERS

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

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

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

Q39-bis: Can a Member Company provide funds to a commercial organisation where the commercial organisation will be responsible for the management of the Educational Grant (i.e., selection of HCPs, arrangement of conference attendance, travel and accommodation) but is not the organiser of the event (or all of the events) in question? (Amended in July 2019)

A39-bis: *In principle yes, however Member Companies must bear in mind that certain compliance risks may arise from working with intermediary companies for the management of Educational Grants, and must also take all necessary actions to mitigate them. In particular, Member Companies must ensure that any company receiving funds for the management of Educational Grants manages those funds in accordance with the Code. To the extent the managing company will select particular HCPs to benefit from the grant, the Member Company must ensure that the managing company has the experience and expertise sufficient to make an appropriate selection. Additionally, Member Companies must include appropriate and specific compliance-related criteria in all contractual arrangements relating to management of Educational Grants, to ensure that the funds are used appropriately and in accordance with ethical standards and local rules and regulations. The contractual arrangements should include appropriate provisions to provide the Member Companies the right to monitor and audit the activity of the companies managing the Educational Grants. However, Member Companies may not provide an Educational Grant or Educational funds to a Third Party Travel Agency directly. For the avoidance of doubt, a Member Company may provide an Educational Grant to a Healthcare Organisation (HCO) or funds earmarked for education to a Professional Conference Organiser (PCO) which is structured so that payments for travel, accommodation [and registration] are remitted directly by the Member Company to a third party travel agency on behalf of the HCO / PCO, which is the recipient of the Educational Grant or the funds earmarked for education. In these circumstances the Member Company may choose to establish a tripartite contract, with the HCO/ PCO and the third party travel agency. Such a third party travel agency could in principle include a third party travel agency also used by the Member Company for its own internal travel arrangements provided this is not a Company-internal function or Company-owned entity. In any event, where a Member Company decides to use any such arrangement involving funding for, or payments to, a third party travel agency to arrange travel, accommodation [and/or registration] it is important that*

b. Scholarships and Fellowships

Member Companies may provide Educational Grants on a restricted basis in the form of Grants for Scholarships and Fellowships to support advancement of genuine medical education of Healthcare Professionals (see the [Glossary](#)). Only Healthcare Organisations where Healthcare Professionals are in training shall be eligible to request and/or receive such Educational Grants. A Member Company shall not provide Educational Grants to support Scholarships and Fellowships upon request of individual Healthcare Professionals. Similarly, the Member Company shall not have any involvement in any way in the selection of the HCPs who will benefit from the Educational Grant and this shall be reflected in the written Grant agreement between the Member Company and the recipient HCO.

QUESTIONS AND ANSWERS

the Member Company carries out appropriate, prior due diligence on a country-by-country and case-by-case basis in order to evaluate and mitigate the particular compliance risks and practicalities where such an arrangement is considered. Additionally, the Member Company must include in all of the contractual arrangements appropriate and specific compliance-related criteria and conditions for the HCO/PCO to outsource travel arrangements to a third party travel agency, which should include appropriate provisions to allow the monitoring and controlling of the activity of the third party travel agency.

Q40: 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?

A40: *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.*

Q41: 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? (modified in May 2017)

A41: *Member Companies may enter into a commercial sponsorship arrangement with a Professional Conference Organiser 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 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). In addition, 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 also 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 Events, where applicable, must have CVS approval and the Member Company shall publicly disclose such funding in accordance with the Code's Disclosure Guidelines.*

Q42: Can a Member Company pay for or reimburse travel costs to a Third Party Organised Educational Event for a Scholar or Fellow?

A42: *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*

c. Grants for Public Awareness Campaigns

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

4. RESEARCH GRANTS

Where permitted by national laws, regulations, national guidelines and professional codes of conduct, Member Companies may provide restricted Research Grants (see the [Glossary](#)) to support clearly defined third party-initiated research studies for clinical or non-clinical research programmes in therapeutic areas in which the Member Company is interested and/or involved. Research Grants may include in-kind or financial support for legitimate, study-related, documented expenses or services, and/or reasonable quantities of single-use and/or multiple-use free of charge product(s) for the limited duration of the research.

Member Companies providing Research Grants shall ensure that they do not influence the research. However, in order to ensure that Research Grants are provided on a "restricted" basis, Member Companies shall clarify

QUESTIONS AND ANSWERS

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.

Q43: Can Member Companies support professional training of Healthcare Professionals on general medical education topics, such as courses on health economics/health technology appraisal, good laboratory practices or similar topics that promote patient care? (Added in July 2018).

A43: *Member Companies can support genuine medical education for Healthcare Professionals on general healthcare-related topics through Educational Grants in accordance with Chapter 4 of the Code.*

Member Companies can also support genuine medical training on general healthcare-related topics through company-organised "Product and Procedure Training and Education Events" as long as the information directly concerns the Member Company's health technologies, therapies, and/or Related Services. The Event must be conducted in accordance with and meet the other requirements of Chapter 3, Section 2 of the Code.

Q44: 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?

A44: *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.*

Q44-bis: Can Member Companies support the participation of Poster or Abstract Presenters in Third Party Organised Educational Conferences? (Added in July 2019)

A44-bis: *Poster or Abstract Presenters at Third Party Organised Educational Conferences are not to be considered as Speakers, as defined in the Code ("Glossary"). As such, if Member Companies want to support their participation in the 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 Company Initiated or Third Party Initiated Research.*

However, if the support is included in a Research Agreement, Companies may only support attendance of Poster and Abstract presenters to Third Party Organised Educational Conferences provided the following considerations are met:

CODE

the intended research scope and purposes for which the Grant is requested and shall ensure that the written Grant agreement with the recipient organisation includes rights for the Member Company to verify that the Grant is applied solely for the agreed intended research use. Such verification may include a request for study-related documentation, such as a copy of the research protocol, a copy of the ethics committee and/or regulatory approvals or a copy of the study report upon completion or earlier termination of the research.

All requests for Research Grants from prospective Grant beneficiaries must be in writing and must detail, as a minimum, the type, nature and objectives of the research activity, the milestones and budget, the approximate duration of the research, and where applicable, the requirements for ethics committee, regulatory and/or other authorisations or approvals. A Member Company may give consideration to a request for a Research Grant prior to ethics committee approval for the specific research project but shall not take any final decision regarding the Grant request unless and until the research receives formal ethics committee approval.

Research Grant agreements shall include provisions relating to adverse event reporting where appropriate, and shall require full disclosure of the Member Company and of the Grant by the Grant recipient organisation and the lead-investigator in all oral or written presentations of the results.

For guidance on how Member Companies may undertake Member Company-initiated research please refer to [Chapter 7: Research: Member Company Initiated Research](#)

QUESTIONS AND ANSWERS

- *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 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 a direct relationship would be eligible to receive support for the dissemination of the research results).*

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.

5

SPONSORED POSTS

(Added in May 2017)

CODE

Safeguards are required to ensure that the deployment of sponsored posts does not cause a conflict of interest between the aims of the sponsoring Member Company and the aims of the Healthcare Organisation, particularly in relation to procurement and competition.

Where a Member Company sponsors part or all of the salary of a Healthcare Professional employed by a Healthcare Organisation, they must have due regard to national rules or relevant codes of practice that may apply. Sponsorship must be with the Healthcare Organisation not the HCP and must be in response to a request from the HCO through a formal and transparent procurement process. Written agreements should detail the circumstances under which the HCO may exit from the sponsorship arrangement if conflicts of interest which cannot be managed arise.

There should be written affirmation that the arrangements will have no effect on purchasing decisions or prescribing and dispensing habits and no pressure must be exerted on the sponsored HCP to favour the Member Company's products over any other. For the duration of the Sponsored Post, auditing arrangements should be established to ensure independence of product or service choice.

QUESTIONS AND ANSWERS

Q45: If part of the funds provided to a Healthcare Organisation for a Sponsored Post are intended to cover training and education of the sponsored Healthcare Professionals, is it necessary to declare these monies as part of the annual declaration of indirect sponsorship of HCP attendance at Third Party Organised Educational Events or Conferences?

A45: *If the funds are specifically linked to attendance at particular Third Party Educational Events or Conferences then this should be declared in the normal way as set out under the Part 2 Disclosure Guidelines in this document. If the funds are specified as being for general training and education needs of the sponsored HCP(s) and the decisions on how those funds are spent in this regard are under control of the Healthcare Organisation rather than the HCP(s) then it is not necessary to disclose under Part 2.*

6

ARRANGEMENTS WITH CONSULTANTS

CODE

1. GENERAL PRINCIPLES

Member Companies may engage Healthcare Professionals as consultants and advisors to provide *bona fide* consulting and other services, including but not limited to research, participation on advisory boards, presentations at Company Events and product development. Member Companies may pay Healthcare Professionals reasonable remuneration for performing these services. In all cases, consulting arrangements must be permitted under the laws and regulations of the country where the Healthcare Professional is licensed to practise and be consistent with applicable professional codes of conduct in that country.

The principles in this chapter are applicable to all consulting arrangements between Healthcare Professionals and Member Companies including where a consultant Healthcare Professional declines a fee for provision of their services.

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

QUESTIONS AND ANSWERS

CODE

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

2. CRITERIA FOR GENUINE CONSULTING ARRANGEMENTS

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

- a. Consulting arrangements must be entered into only where a legitimate business need for the services is identified in advance.
- b. The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need.
- c. Selection of consultants must be based on criteria directly related to the identified business need and the relevance of the consultant's qualifications, expertise and experience to address the identified need. The volume or value of business generated by a prospective consultant or the Healthcare Organisation where s/he performs her/his professional activity is not a relevant criterion.
- d. Consulting arrangements with Healthcare Professionals must be documented in a written agreement, signed by the parties in advance of the commencement of the services, which must specify the nature of the services to be provided and the basis for payment for those services.
- e. The hiring of the consultant must not be an inducement to purchase, lease, recommend, prescribe, use, supply or procure the Member Company's products or services.
- f. The remuneration for the services rendered must be reasonable and reflect the fair market value of the services provided.
- g. Member Companies must maintain records of the services, and associated work products, provided by the consultant Healthcare Professionals and of the use made of those services by the Member Company.
- h. The venue and other arrangements (e.g. hospitality, travel etc.) for Member Company meetings with consultants shall follow the rules for Events set out in [Chapter 1: General Criteria for Events](#).

QUESTIONS AND ANSWERS

3. REMUNERATION AND FAIR MARKET VALUE

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

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

4. DISCLOSURE AND TRANSPARENCY

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

Member Companies shall also include appropriate obligations on the consultant to ensure that the consultant's status as a consultant for the Member Company and his/her involvement in the research for, or the preparation of, material for scientific publication is disclosed at the time of any publication or presentation.

Q46: What is meant by fair market value (FMV) in the context of consulting arrangements?

A46: *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.*

Q47: How should Member Companies determine FMV for a service?

A47: *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.*



7 RESEARCH

CODE

1. MEMBER COMPANY-INITIATED RESEARCH

Where there is a legitimate business need to do so, Member Companies may initiate, conduct, manage and finance scientifically valid research to generate data, whether pre- or post-market. In this context, legitimate business needs for data include medical needs, including patient safety; research and development; scientific purposes (e.g. performance indicators, comparing objective scientific parameters); regulatory, including post-market surveillance (PMS) and post-market clinical 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.

QUESTIONS AND ANSWERS

CODE

Where a Member Company uses a Healthcare Professional as a consultant, for example to lead a study on the Member Company's behalf (i.e. act as Principal Investigator), the Member Company shall ensure that such consulting arrangements comply fully with [Chapter 6: Arrangements with Consultants](#).

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

Member Companies must ensure that their research activities comply with all applicable national laws, regulations and researchers' own professional codes of conduct, as well as with applicable Good Clinical Practice guidelines, if relevant.

In accordance with the Principles set out in the [Introduction: Aims and Principles of the Code](#), Member Companies shall also ensure appropriate clinical trial transparency in relation to their research activities and results. This shall include appropriate disclosure of information about Member Companies' clinical trials, for example in external public registries and peer-reviewed journals.

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

2. MEMBER COMPANY POST-MARKET PRODUCT EVALUATION

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

QUESTIONS AND ANSWERS

Q48: What is an example of an external public registry for clinical trial transparency?

A48: Examples of an external public register for clinical trial transparency are www.clinicaltrials.gov or www.who.org.

CODE

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

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

3. THIRD PARTY-INITIATED RESEARCH

Please refer to [Chapter 4: Grants and Charitable Donations: Research Grants](#).

QUESTIONS AND ANSWERS



8

ROYALTIES

CODE

Healthcare Professionals, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve products or health technologies. They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement.

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

QUESTIONS AND ANSWERS

CODE

obligations to comply with any applicable obligations to pay royalties which may arise under applicable laws and regulations in some countries.

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

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

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

QUESTIONS AND ANSWERS

9

EDUCATIONAL ITEMS AND GIFTS

CODE

Member Companies exceptionally may provide inexpensive educational items and/or gifts, in accordance with national laws, regulations and industry and professional codes of conduct of the country where the Healthcare Professional is licensed to practise¹. Member Companies may only provide such educational items and/or gifts in accordance of the following principles:

- a. Educational items and/or gifts may be provided but these must relate to the Healthcare Professional's practice, or benefit patients, or serve a genuine educational function.
- b. No educational items and/or gifts should be provided in response to requests made by Healthcare Professionals.
- c. Educational items and/or gifts must not be given in the form of cash or cash equivalents.
- d. Educational items and/or gifts must be modest in value, and can be branded or non-branded items.

¹ In the UK, the NHS England document *Managing Conflicts of Interest in the NHS* (Publications Gateway Reference: 06419) sets the limit for such items at £6. While this only directly applies to the NHS in England it should be taken as indicative of what is acceptable in the rest of the UK, including in relation to HCPs working in the non-NHS sector. Different limits may apply in other territories and Member Companies should comply with these as appropriate. Where no such limits apply, the UK figure may be taken as indicative of what is acceptable under the Code.

QUESTIONS AND ANSWERS

Q49: What are examples of items of modest value that are "related to the Healthcare Professional's practice or for the benefit of patients".

A49: 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.

CODE

- e. A Member Company may occasionally provide educational items of greater value to a Healthcare Organisation always provided that the item serves a genuine educational function for the Healthcare Professionals at that Healthcare Organisation and is of benefit to patients. Such items shall not be provided to Healthcare Professionals for their personal use. The item shall also be related to the therapeutic areas in which the Member Company is interested and/or involved. For higher value educational items, Member Companies must maintain appropriate records of their provision of such educational items to Healthcare Organisations. Such items should not be part of the Healthcare Organisation's normal overheads or routine costs of operation.
- f. Provision of educational items and/or gifts must not improperly reward, incentivise and/or encourage Healthcare Professionals to purchase, lease, recommend, prescribe, use, supply or procure the Member Company's products or services.

Prize draws and other competitions at Events are permissible if the prize awarded complies with [Chapter 9: Educational Items and Gifts](#). In addition, it must comply with national laws, regulations and industry and professional codes of conduct.

This Chapter is not intended to address the legitimate practice of providing appropriate Evaluation Products, Demonstration products or Samples. For guidance on how Member Companies may provide Evaluation Products, Demonstration products or Samples, please refer to [Chapter 7: Research](#) and [Chapter 10: Demonstration Products and Samples](#), as applicable.

QUESTIONS AND ANSWERS

Q50: 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?

A50: *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.*

Q51: 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?

A51: *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 9. Educational Items and Gifts as they neither relate to a Healthcare Professional's practice nor serve an educational function.*

Q52: Please provide examples of educational items of greater value that can be provided to Healthcare Organisations under the Code?

A52: *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.*

10

DEMONSTRATION PRODUCTS AND SAMPLES



CODE

1. GENERAL PRINCIPLES

Member Companies may provide their own products as Demonstration Products and/or Samples (see the [Glossary](#)) at no charge in order to enable Healthcare Professionals and/or Healthcare Organisations (as applicable) to evaluate and/or familiarise themselves with the safe, effective and appropriate use and functionality of the product and/or Related Service and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

Demonstration Products and/or Samples may be either single- or multiple-use products. Member Companies may also provide products from another company in conjunction with the Member Company's own Demonstration Products

QUESTIONS AND ANSWERS

CODE

and/or Samples on an exceptional basis if those other company's products are required in order to properly and effectively demonstrate, evaluate or use the Member Company's products, e.g. computer hardware and software produced by a company other than the Member Company.

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

Member Companies shall in all cases maintain appropriate records in relation to the provision of Demonstration Products and/or Samples to Healthcare Professionals and/or Healthcare Organisations, for example recording proof of delivery for any Demonstration Products and/or Samples provided and receipt of return for multiple-use Demonstration Products and/or Samples. Member Companies shall clearly record in the Member Company's records as well as clearly disclose to Healthcare Professionals and/or Healthcare Organisations the no-charge basis and other conditions applicable for the supply of such Demonstration Products and/or Samples no later than the time of the supply. The disclosure to Healthcare Professionals and Healthcare Organisations shall be in writing.

This Chapter is limited to the provision of Demonstration Products and/or Samples and Related Service at no charge and is not intended to apply to provision of products or Related Service under any other arrangements, for example (but not limited to) provision within the framework for clinical trials and/or other research or commercial supplies by way of rebates or pricing incentives in a public procurement context.

2. DEMONSTRATION PRODUCTS (DEMOS)

Member Companies may provide examples of their products to Healthcare Professionals and/or Healthcare Organisations in the form of mock-ups (such as unsterilised single use products) that are used for Healthcare Professionals and patient awareness, education and training. For example, a Healthcare Professional may use a Demonstration Product to show a patient the type of technology which will be implanted in the patient or may use the Demo to train other Healthcare Professionals in the use of the product.

QUESTIONS AND ANSWERS

CODE

Demonstration Products are not intended for clinical use in any patient care nor are they intended for on-sale or other transfer. Member Companies shall clearly record in the Member Company's records as well as clearly disclose to Healthcare Professionals and/or Healthcare Organisations the no-charge basis and other conditions applicable for the supply of such Demonstration Products no later than the time of the supply. It is recommended that the disclosure to Healthcare Professionals and Healthcare Organisations be in writing.

3. SAMPLES

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

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

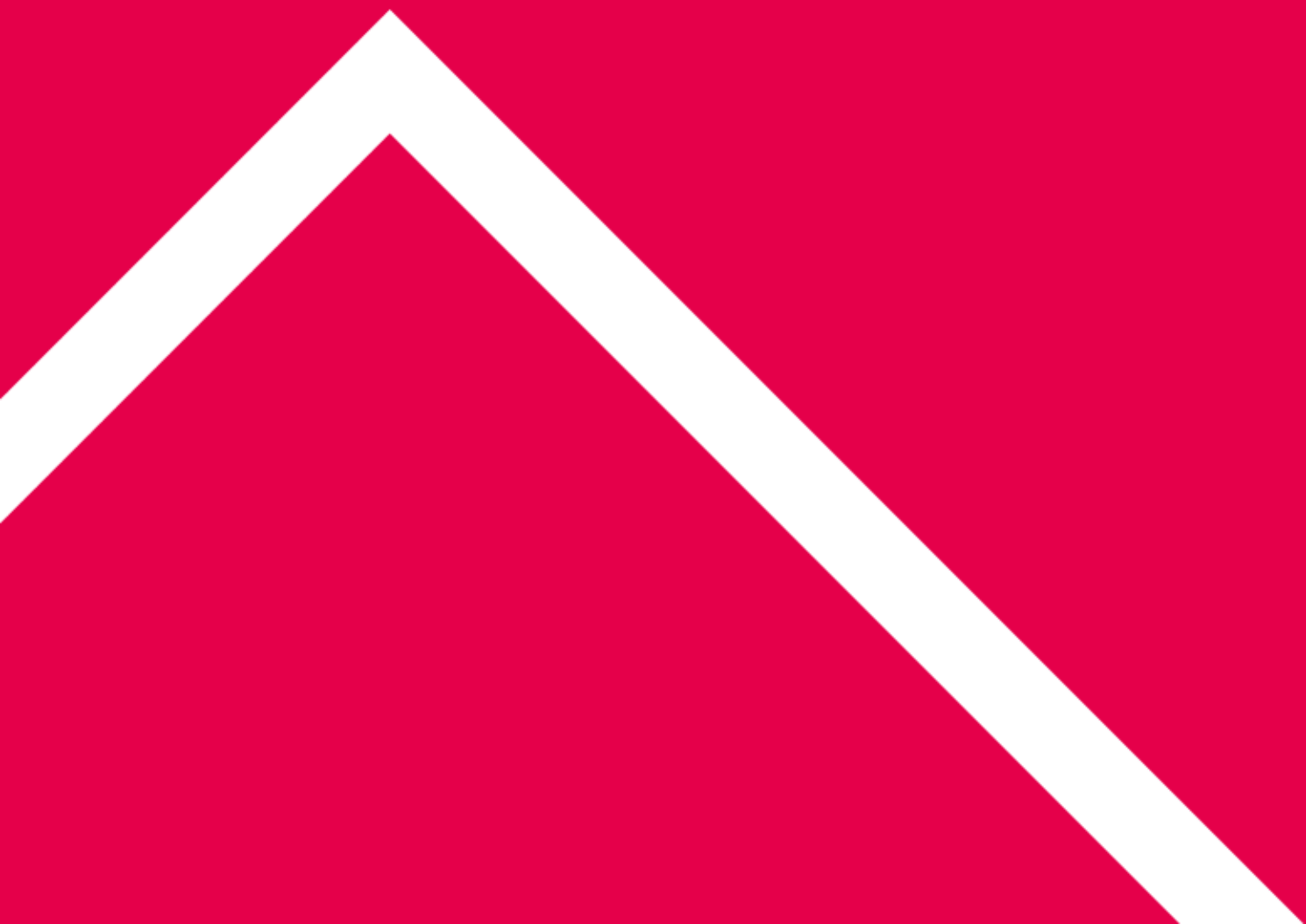
For Samples, which are multiple-use products, the specific length of time necessary for a Healthcare Professional to familiarise him/herself with the product will depend on the frequency of anticipated use; the duration of required training; the number of Healthcare Professionals who will need to acquire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

QUESTIONS AND ANSWERS

PART 2

DISCLOSURE GUIDELINES

Adopted by the ABHI in May 2017



PREAMBLE

Under the ABHI Code of Ethical Business Practice (the "Code"), Member Companies are not permitted to pay registration fees, travel or hospitality expenses directly to individual Healthcare Professionals for their participation in educational conferences organised by third-parties as of 1st January, 2019.

Medical Education may be supported through the provision of Educational Grants to Healthcare Organisations in compliance with the rules set out in the Code. To prevent abuses, specific safeguards when providing Educational Grants have been developed, including the obligation to disclose these Educational Grants.

Section 3 of Chapter 4 of the Code states that Member Companies shall document and publicly disclose all Educational Grants in accordance with these Disclosure Guidelines. These Disclosure Guidelines are therefore an integral part of the Code, and need to be interpreted as such.

For the avoidance of doubt, all funds provided by a Member Company for the advancement of genuine educational purposes to a Professional Conference Organiser ("PCO"), acting independently of any Healthcare Organisation, fall under the scope of these Disclosure Guidelines and are subject to the same conditions as Educational Grants. Whenever these Disclosure Guidelines refer to Healthcare Organisations, these shall also include Professional Conference Organisers. All capitalised concepts used in the Guidelines are concepts defined in the Code.

CHAPTER 1: APPLICABILITY OF THESE GUIDELINES

1. Scope

These Disclosure Guidelines apply to Member Companies in their interactions with Healthcare Organisations based or registered in the ABHI Europe Geographical Area.

Separate entities belonging to the same multinational company ("Affiliates") – which could be the parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation – shall be deemed to constitute a single company, and are as such committed to compliance with these Disclosure Guidelines.

Transfers of value that are not included in the definition of Educational Grants (as described in Chapter 4, Section 3 of the Code) and that consequently cannot be allocated to any of the categories set forth in Chapter 2, Section 2 Aggregate Disclosure are not within the scope of these Disclosure Guidelines.

2. Applicability of these Disclosure Guidelines

Member Companies need not report the same information twice due to being bound by national laws, regulations or professional codes imposing disclosure obligations regarding Educational Grants (as described in Chapter 4, section 3 of the Code) equivalent to the ones imposed by these Disclosure Guidelines.

Q1: Does the Disclosure Guideline's definition of "Affiliate" include legal entities belonging to the same parent Member Company but registered outside Europe?

A1: *Yes. Educational Grants made by Affiliates (parent companies are included in the definition of Affiliates to the effect of the Disclosure Guidelines) incorporated outside of MedTech Europe Geographical Area to Healthcare Organisations registered in Europe are within the scope of these Disclosure Guidelines. Any of the Affiliates registered in Europe can disclose these Educational Grants. Each Member Company can choose which Affiliate will report these Educational Grants made by Affiliates from outside the MedTech Europe Geographical Area.*

Q2: Are these Disclosure Guidelines applicable to third party intermediaries who interact with Healthcare Organisations in connection with the sale, promotion or other activity involving Member Companies' products?

A2: *No, these Disclosure Guidelines are not applicable to third parties such as third party sales & marketing intermediaries (SMIs), consultants, distributors, sales agents, marketing agents, brokers, commissionaire commercial agents and independent sales representatives (list not exhaustive). Nevertheless, it is recommended to document arrangements concluded between Member Companies and third party intermediaries in order to comply with the provisions set out in the Code.*

Q3: Where a national code already imposes disclosure obligations in a given country, where may Corporate Members disclose the Educational Grants?

A3: *Where a national code imposes disclosure obligations regarding Educational Grants (as regulated in Chapter 4, Section 3 of the Code) to the same extent as regulated by these Guidelines, Corporate Members, who are not a member of the National Association responsible for that national code, may choose either:*

- *To disclose only on the MedTech Europe platform; or*
- *To disclose on the national platform, if that possibility is provided for.*

Corporate Members who are bound by this national code may choose either:

- *To disclose only on the national platform or*

3. Applicability to Non-Member Companies

Non-member companies may implement these Disclosure Guidelines provided they are committed to ethical standards equivalent to those enshrined in the Code. Non-member companies may prove this commitment by signing up to the ABHI Code of Ethical Business Practice¹.

QUESTIONS AND ANSWERS

- To disclose both on the MedTech Europe platform and the national platform.

This selected option shall be included in the Methodology Note.

Q4: Who will decide if a national law, regulation or code imposes disclosure obligations regarding Educational Grants equivalent to the ones imposed by the Disclosure Guidelines?

A4: *The MedTech Europe Secretariat shall conduct a yearly assessment of the equivalence of national laws, regulations and/or professional codes imposing disclosure obligations with the MedTech Europe Transparency Obligations (as regulated in Chapter 4, Section 3 of the Code).*

Members can at any time submit any information or documentation they possess that could be relevant for this assessment to the Secretariat.

The MedTech Europe Secretariat shall submit its assessment to the MedTech Europe Transparency Task Force, who will analyse the proposal. If the MedTech Europe Transparency Task Force agrees with the proposal, it will be submitted for approval to the MedTech Europe Compliance Network. If the disclosure obligations imposed by a national law, regulation or professional code are deemed equivalent to the ones imposed by the Disclosure Guidelines, the assessment will be made public on the MedTech Europe Transparency website. This selected option shall be included in the Methodology Note.

¹ Non-members can sign up to the ABHI Code of Ethical Business Practice at abhicodeofpractice.org.uk

CHAPTER 2: DISCLOSURE OBLIGATION

1. General Obligation

Subject to the terms of these Disclosure Guidelines, each Member Company shall document and disclose all payments related to Educational Grants (as described in Chapter 4, section 3 of the Code) that it makes to a Healthcare Organisation based or registered in Europe, without limitation of value. The disclosure of Educational Grants provided by Affiliates of the Member Company described above, but which are not registered in the MedTech Europe Geographic Area shall be made by any of the Affiliates comprising said Member Company that are registered in the MedTech Europe Geographic Area.

2. Aggregate Disclosure

Educational Grants shall be disclosed on an aggregate basis. Each Affiliate of a Member Company shall disclose, for each clearly identifiable and separate recipient, the amounts paid as Educational Grants to such recipient in each Reporting Period¹ which can be reasonably allocated to one of the categories set out below. Such amounts will be aggregated on a category-by-category basis, but itemised disclosure shall be made available upon request by the Member Company, as deemed necessary, to (i) the relevant recipient, and/or (ii) the relevant authorities.

Member Companies shall disclose an aggregate amount related to any of the categories set forth below:

- a. Educational Grants to support Third Party Organised Events (including Support for HCP Participation at Third Party Organised Educational Events) and,
- b. Other Educational Grants to Healthcare Organisations (including Scholarships, Fellowships and/or Grants for Public Awareness Campaigns).

3. Optional Object Specification

If desired, Member Companies may indicate the object of the Educational Grants disclosed for one or both categories set forth in Chapter 2, Section 2 Aggregate Disclosure.

Q5: Which Affiliate should disclose a particular Educational Grant?

A5: *To facilitate the tracking of Educational Grants made to individual Healthcare Organisations, it is recommended that the Affiliate making the payment in relation to a particular Educational Grant is the one disclosing the Educational Grant, but this is an internal decision of each Member Company.*

A Member Company may choose to use internal arrangements of its choice to report the aggregated sum in relation to Educational Grants made by each legal entity composing the company (Affiliates) to a particular Healthcare Organisation during a disclosure period.

¹ Reporting Period means a full calendar year (starting on the 1st of January and ending in the 31st of December).

CODE

4. Methodology

Each Member Company shall create a note summarising the methodologies used by it in preparing the disclosures and identifying Educational Grants for each category described in Chapter 2, Section 2 Aggregate Disclosure. The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Educational Grants for purposes of these Disclosure Guidelines, as applicable. This Methodology Note shall be made available upon request by an interested party.

CHAPTER 3: FORM OF DISCLOSURE

1. Reporting Period

Disclosures shall be made on an annual basis and each Reporting Period shall cover a full calendar year.

2. Time of Disclosure

Disclosures shall be made by each Member Company within 6 months after the end of the relevant Reporting Period

3. Time of Publication

The disclosures shall be made public at the time of publication. The time of publication is the 31st August of the year of the relevant time of disclosure.

4. Template and Language of Disclosure

For consistency purposes, disclosures made pursuant to these Disclosure Guidelines shall be made in English using the template set forth in the Annex.

QUESTIONS AND ANSWERS

Q6: When should a Methodology Note be made available?

A6: Member Companies should create a comprehensive Methodology Note that would allow any Healthcare Organisation directly affected by a disclosure to understand how the amount disclosed was aggregated. The Methodology Note should therefore be made available upon specific request to Healthcare Organisations concerned about particular disclosure that directly affects them.

Q6-bis: (Added in July 2019) Are in-kind Educational Grants reportable under these Guidelines?

A6-bis: In-kind Educational Grants, or the provision of in-kind support for educational purposes, such as Samples or Demonstration Products do not need to be reported.

Q7: When will the first Reporting Period start?

A7: Chapter 4, Section 3 of the ABHI Code of Ethical Business Practice establishes that the first disclosure shall occur no later than the end of the Transition Period. The Transition Period ends on the 31st December 2018. As a consequence, the first Reporting Period is the calendar year 2018, starting on the 1st January 2018, and ending on 31st December 2018.

Q8: In what currency should the amounts payed be disclosed?

A8: Disclosed amounts should be in the currency used in the payment. In the event the aggregate amount includes Educational Grants made in different currencies, the reporting company may choose in which currency they wish to disclose the aggregate amount, and keep appropriate record of the exchange rate used to convert the different currencies. This information will then be included in their Methodology Note.

5. Disclosure Platform

Disclosures shall be made on the EthicalMedTech website¹ unless the Member Company is already bound by national laws, regulations or professional codes as regulated in Chapter 1, Section 2 Applicability of these Disclosure Guidelines. Member Companies will remain liable for the accuracy of the disclosed data. For the avoidance of doubt, MedTech Europe shall not be held liable for (i) maintaining, correcting, deleting the published data nor (ii) for the storage of data after the three years period of disclosure in the public domain.

6. Disclosures Retention and Modification

Member Companies shall be able to modify, delete or in any way alter their disclosures at any time before or after the time of publication.

The information disclosed shall remain in the public domain for 3 years after the time such information is first published.

7. Enquiries Regarding Reported Disclosures

Member Companies shall be able to modify, delete or in any way alter their disclosures at any time before or after the time of publication.

Member Companies shall make available to Healthcare Organizations upon request any data concerning their common contractual relations published in accordance with these Disclosure Guidelines at any time while the disclosed information remains in the public domain as stated in Chapter 3, Section 3 Time of Publication.

¹ www.ethicalmedtech.org

PART 3

**GUIDELINES ON ADVERTISEMENTS
AND PROMOTIONS ADDRESSED
SOLELY OR PRIMARILY TO
HEALTHCARE PROFESSIONALS**



PREAMBLE

Introduction

These Guidelines are published by ABHI because under current UK law and other advertising codes it is difficult to take legal action or to complain against a person or company who publishes misleading promotional material directed solely or primarily at Healthcare Professionals.

Consumer advertising is governed both by legislation (the main legal instruments being listed in Section 1) and by the codes of advertising practice issued by the Committee of Advertising Practice and the Broadcast Committee of Advertising Practice and administered by the Advertising Standards Authority. However, Advertising directed at Healthcare Professionals is not clearly caught by these provisions.

The intention of these Guidelines is to set out principles to be applied to Advertising directed solely or primarily at Healthcare Professionals. These principles will be part of the ABHI Code of Ethical Business Practice with which all ABHI Members agree to comply. The principles apply to all such Advertising issued by or on behalf of ABHI Members where it is directed at Healthcare Professionals in the UK. The principles set out in these Guidelines are, however, based upon the general principles contained in existing laws and codes of practice and are therefore generally applicable to all medical devices advertising. ABHI therefore encourages all persons advertising medical devices, not just ABHI Members, to ensure that Advertising published by them or on their behalf complies with these Guidelines.

Complaints that any ABHI Member has failed to comply with these Guidelines will be handled in accordance with the established Complaints Procedure set out in the ABHI Code of Ethical Business Practice Complaints Procedure and Panel Constitution, as amended from time to time.

Interpretation

The singular includes the plural.

Reference to any "commissioned" article, study or material is a reference to work done at the request or on behalf of an Advertiser, often in return for payment or some reward or other support. It may include the work of a journalist or opinion leader carried out directly or indirectly as a result of such request. However, reports on collected medical device clinical data (including reports on clinical investigations, as the expression is used in the Medical Devices Directives/Regulation) that are written by or at the direction of the clinical investigator ("investigator-initiated reports") shall not be considered to be "commissioned" whether or not payments have been made in respect of the investigators' services or expenses reimbursed or other in-kind support has been provided if they meet the conditions below. Equally, reports on collected medical device clinical data (including clinical investigations, as the expression is used in the Medical Devices Directives/Regulation) that are written by or at the direction of the Advertiser pursuant to an agreement to conduct the clinical data collection ("Advertiser-initiated reports") shall not be regarded as "commissioned", always provided that such investigator-initiated or Advertiser-initiated reports relate to clinical data collection and evaluation processes which are:

- a. performed according to scientifically valid standards;
- b. subjected to ethical review independent of the Advertiser, e.g. hospital ethics committee; and
- c. initiated and conducted for scientifically and/or medically legitimate purposes.

GUIDELINES

1. SCOPE OF GUIDELINES

- 1.1** These Guidelines apply to all Advertisements produced by or on behalf of Advertisers.

Advertising directed wholly or mainly at consumers, patients or others who are not Healthcare Professionals is not covered by these Guidelines. However, such advertising is subject to general UK advertising law as well as to the industry regulatory codes administered by the Advertising Standards Authority, and it should consequently comply with the law and with those rules.

ABHI and its Members encourage all persons advertising medical devices, not just ABHI Members, to ensure that advertising directed at non-Healthcare Professionals which is published by them or on their behalf complies with these Guidelines.

- 1.2** The following is a non-exhaustive list of the forms of Advertising that may be captured by these Guidelines:

- Advertisements in Healthcare Professional journals, brochures, leaflets, circulars, mailings, e-mails, text transmissions (including SMS and MMS), social media sites, fax transmissions, catalogues, follow-up literature and other electronic or printed material and/or verbal communications;
- detail aids and other printed material used by representatives;
- posters and other promotional media in public places at Healthcare Professional events, including moving images;
- video and DVD Advertisements intended solely or primarily for release or use at Healthcare Professional events;
- audio-cassettes, films, records, tapes, video recordings intended solely or primarily for release or use at Healthcare Professional events;
- Advertisements in non-broadcast electronic media, including but not limited to: online Advertisements (including banner or pop-up Advertisements and online video Advertisements); search listings; commercial classified Advertisements;

- Advertisements transmitted by Bluetooth; Advertisements distributed through web widgets and online sales promotions and prize promotions
- web-based data services;
- Advertisements in marketing databases containing Healthcare Professionals' contact information;
- Advertorials.

- 1.3** To comply with these Guidelines, Advertising must also comply with all other applicable laws and regulations. For example, Advertising that is in breach of the requirements of the Business Protection from Misleading Marketing Regulations 2008 will also be a breach of these Guidelines and therefore of the ABHI Code.

- 1.4** Advertising must be suitable for the intended audience and must conform to generally acceptable standards of good taste. It should respect the principles of fair competition generally accepted in business.

- 1.5** An Advertisement should be readily recognisable by the intended audience as an Advertisement and its commercial intent must be made clear if that is not obvious from the context.

2. ACCURACY AND SUBSTANTIATION OF CLAIMS AND INFORMATION

- 2.1** Information, claims and comparisons included in or as part of any Advertisement must be accurate, balanced, fair, objective and unambiguous and must be based on a fair evaluation of appropriate evidence and reflect that evidence clearly. They must not mislead the intended audience either directly or by implication, by distortion, exaggeration or undue emphasis. All reasonable efforts must be used to ensure that the substantiation for all information, claims and/or comparisons in an Advertisement is in accordance with an up to date evaluation of all the relevant clinical and scientific evidence.

Material used in or as part of any Advertisement must be sufficiently complete to enable the intended audience to form their own opinion of the therapeutic value of the device.

2.2 Different types of evidence are permissible to support claims in Advertisements. The evidence may include clinical data (which could be pre- or post-market data, including registry data); the results of a clinical investigation; laboratory data and testing, including in vitro test data; engineering data; and historical post-market experience.

All evidence must be relevant, balanced, comprehensive and credible and must in all cases be consistent with any specified device's CE marked Intended Purpose, as must the overall impression created by the Advertisement, including any graphics or artwork. Advertisers must in all cases hold documentary evidence (which includes equivalent recorded evidence, e.g. video) to substantiate all claims (direct or implied). This documentary evidence must be in existence before or at the time of the publication of the Advertisement.

2.3 Claims or comparisons made, or information included, in Advertisements must accurately reflect the balance of all relevant evidence. If justification for the content of an Advertisement relies on any selection from the available evidence, that selection must be fair and balanced so that the Advertisement does not mislead or give a false impression.

Evidence should be scientifically robust. If there is a significant division of scientific, medical or other expert opinion about any claims made in an Advertisement, those claims must not be presented as being generally agreed and it should be clear from the Advertisement that there is a division of opinion on the relevant matter.

Advertisers must make clear whether the evidence relied upon to substantiate claims used in an Advertisement is clinical or some other type of evidence or a combination. If the Advertisement includes claims that rely on a particular clinical investigation, that investigation must have been carried out to a standard equivalent to that required for clinical evaluation of a device under Annex X of Directive 93/42/EEC or Annex 7 of Directive 90/385/EEC or Annex XV of Regulation (EU) 2017/745, as applicable, as at the date of the Advertisement. Advertisers must not imply that claims are based upon peer-reviewed clinical investigation evidence where this is not the case as this will create a

misleading impression.

2.4 Testimonial evidence on its own is not sufficient substantiation for objective claims. However, provided the overall effect is not misleading, it may be sufficient to use testimonial evidence to justify subjective claims (for example based upon subjective perception) or opinions. Testimonial evidence must not be misleading and must illustrate typical examples only. (See also section 11.1 below.)

2.5 If engineering data or in vitro or other laboratory test data is used to substantiate claims made in Advertisements it must be directly relevant to, and significant for, the product being advertised. Particular care must be taken in extrapolating from such data to avoid any misleading impression as to the significance of the data.

2.6 Information and claims about side-effects used in or as part of any Advertisement must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no side-effects. The word 'safe' must not be used without qualification. Medical devices are all CE marked on a risk-benefit balance. No medical device is 100% safe and advertising claims should not create such an impression i.e. that the medical device is absolutely or completely safe as this is likely to be misleading.

2.7 Advertisements must encourage the appropriate use of a device (or Related Service) by presenting it objectively and without exaggerating its properties. Exaggerated or all-embracing claims must not be made, and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a device.

Any claim that a device (or a particular material, component comprised in a device or an active ingredient forming an integral part of that device) has some special merit, quality or property must be substantiated.

2.8 The word 'new' must not be used for more than twelve months from the date on which a device or an Intended Purpose of that device or any Related Service has been generally available in the UK in the form referred to in the Advertisement.

The claim that the medical device or Related Service (or new indication or feature) is "new" is no longer acceptable after the device or Related Service (or

new indication or feature) has been available for more than a year as this is no longer up-to-date and therefore misleading. While Advertising already in circulation need not be actively withdrawn, Advertisers should not continue to use these once the new device or Related Service (or new indication or feature) has been placed on the market in the UK for more than 12 months.

Where a device or Related Service (or new indication or feature) has been available in the UK in only one sector but subsequently becomes available in additional sectors (e.g. private healthcare sector availability is expanded to include NHS availability) it is still not possible to claim the device or Related Service (or new indication or feature) is "new" though it is allowable to refer to the fact that the device or Related Service (or new indication or feature) is "new to the NHS" provided the overall impression this creates is not misleading.

3. COMPARATIVE ADVERTISING

3.1 A comparison used in or as part of any Advertisement is only permitted if:

- it is not misleading;
- devices or services for the same needs or for the same Intended Purpose are compared;
- one or more material, relevant, substantiable and representative features are compared;
- no confusion is created between the device or service advertised and that of a competitor or between the Advertiser's trade marks, trade names, other distinguishing marks and those of a competitor;
- the trade marks, trade names, other distinguishing marks, products, services, activities or circumstances of a competitor are not discredited or denigrated;
- no unfair advantage is taken of the reputation of a trade mark, trade name or other distinguishing marks of a competitor; and
- the Advertiser's devices or services are not presented as imitations or replicas of goods or services bearing a competitor's trade mark or trade name.

3.2 Where comparative claims are made there should be clear evidence to support the claim bearing in mind the potential commercial impact of comparative claims. The intent of any comparison should be that it provides valuable, objective and accurate information comparing products and/or associated services for the benefit of Healthcare Professionals and their patients. It should not simply be a means of denigrating a competitor's product or Related Service.

3.3 Care must be taken not to mislead when expressing data as percentages. Patient numbers should be included whenever possible. Differences which do not reach statistical significance must not be presented in such a way as to mislead.

3.4 It is acceptable for a member to report on the outcomes of comparative testing of medical devices in an Advertisement provided:

- a. the devices have been subjected to the same and appropriate testing; and
- b. the outcomes are reported in a fair and balanced manner; and each outcome is referenced and consistent with the body of evidence.

3.5 It is acceptable to report on the outcomes of separate testing of medical devices in an Advertisement provided a qualifying statement is included to make clear that the substantiating data comes from separate studies.

3.6 Hanging comparisons whereby a device or Related Service is described as being better or stronger or such like without stating that with which the device is compared must not be made.

4. REQUESTS FOR SUBSTANTIATING DATA

4.1 If a bona fide request is made to an Advertiser to substantiate any information, claim or comparison used in or as part of any Advertisement, the enquiry must be acknowledged within ten working days of the date when the Advertiser has sufficient information to understand the nature of the enquiry or complaint. The initial response should where relevant indicate when a full response will be provided.

Unless section 4.2 applies, a full response together with relevant substantiating data must be provided within thirty working days of an adequately clear request being received.

A *bona fide* request means one received from an independent Healthcare Professional or from another person (including from companies) having a legitimate interest in the substantiation requested. However, there is no requirement to respond to fishing expeditions by competitors or others that are simply designed to obtain confidential or commercially sensitive information about the Advertiser's products or business.

There is no need to supply information relating to the validation of a device's explicit CE marked Intended Purpose or for claims that are expressly covered by the Intended Purpose of the device.

- 4.2 In justifying an Advertisement**, the Advertiser must be prepared to give relevant technical, clinical and scientific data. The Advertiser may be justified in requiring the person requesting substantiation of the Advertisement to enter into a confidentiality agreement in relation to information disclosed.

An Advertiser shall not be obliged to disclose confidential or commercially sensitive data or material directly to the person requesting it where such disclosure might cause financial harm or otherwise damage the business of the Advertiser. In such cases confidential disclosure to an independent mediator or expert or, (if a formal complaint is to be lodged under the Code) to the Panel, for consideration may be appropriate. Confidential disclosure of this type shall not be appropriate in cases where it is primarily the insufficiency of the Advertiser's substantiating data, which is likely to result in the financial harm or damage to the Advertiser's business.

5. USE OF PUBLISHED DATA TO SUPPORT ADVERTISING

- 5.1 When promotional material** used in or as part of any Advertisement refers to published studies, including clinical investigations, clear references must be given.
- 5.2 All artwork** used in or as part of any Advertisement including illustrations, graphs and tables must

conform to the letter and spirit of these Guidelines and of the CoBP. If artwork or data is taken from published studies a reference must be given. Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matters with which they deal, and must not be included unless they are relevant to the claims or comparisons being made.

If a graph or table is reproduced from a published study, it should not be altered unnecessarily. In any event, the way in which the material is used must not distort or give a false impression of the evidence published in that study and the Advertiser must clearly state that the material has been modified.

- 5.3 Advertisers** may use scientific peer-reviewed journals, clinical or otherwise, to substantiate claims made in an Advertisement. There may also be relevant data to be found in publications of patient data and case studies, whether or not it is published in a scientific journal. The key issues are the quality, relevance and overall credibility of the data when relied upon to support claims made in an Advertisement. (See also section 7.1 of these Guidelines).

6. NO DISPARAGEMENT

- 6.1 The products and activities** of other medical device companies must not be disparaged in an Advertisement.
- 6.2 Healthcare Professionals** and the clinical and scientific opinions of Healthcare Professionals must not be disparaged in any Advertisement.

7. NON-REFEREED ARTICLES

- 7.1 Journal** or other articles which have not been refereed are unlikely to be sufficiently robust to justify science-based claims about a device's safety or performance on their own. It also follows that reprints of such material must not be provided to Healthcare Professionals unsolicited.

However, if claims in an Advertisement are based upon subjective patient or consumer perceptions, it may be acceptable to use non-refereed articles to promote those specific aspects of a product.

8. OFF-LABEL USE

- 8.1 If Journal articles** discuss off-label use of a particular device, such discussion must not be used with the intention of promoting such off-label use. For example, the unsolicited supply of such materials to Healthcare Professionals would be an infringement of these Guidelines. However, it is permissible to supply such articles upon receipt of a *bona fide* unsolicited, written request from a Healthcare Professional. Care should be taken to record the written request and the response sent.

9. QUOTATIONS

- 9.1 Quotations** from medical and scientific literature or from personal communications must be accurate and must reflect the meaning of the author. The precise source of the quotation must be identified.
- 9.2 Quotations** relating to devices taken from public broadcasts, for example on radio and television, and from private occasions, such as medical conferences or symposia, must not be used without the formal permission of the speaker.
- 9.3 Where references** are made to medical and scientific literature or to personal communications these must accurately reflect the author's meaning.
- 9.4 All reasonable care** must be taken to avoid ascribing claims or views to authors when these no longer represent the current views of the authors concerned.

10. MATERIAL COMMISSIONED BY THE ADVERTISER

- 10.1 An article** or piece of information that is commissioned by or on behalf of the Advertiser must be clearly identified as such on its face and the Advertiser must also be clearly identified.

In line with the Introduction, Section 1.2 of these Guidelines, "commissioning" of an article in this context means the provision of any financial or other support or reward to the author for the purpose of producing the article. This includes the provision of any in-kind support, e.g. products, facilities, secretarial or administrative support by Advertisers.

However, reports on collected medical device clinical data (including reports on clinical investigations, as the expression is used in the Medical Devices Directives / Regulation) that are written by or at the direction of the clinical investigator ("investigator-initiated reports") shall not be considered to be "commissioned" whether or not payments have been made in respect of the investigators' services or expenses reimbursed or other in-kind support has been provided if they meet the conditions below. Equally, reports on collected medical device clinical data (including clinical investigations, as the expression is used in the Medical Devices Directives / Regulation) that are written by or at the direction of the Advertiser pursuant to an agreement to conduct the clinical data collection ("Advertiser-initiated reports") shall not be regarded as "commissioned", always provided that such investigator-initiated or Advertiser-initiated reports relate to clinical data collection and evaluation processes which are:

- a. performed according to scientifically valid standards;
- b. subjected to ethical review independent of the Advertiser, e.g. hospital ethics committee; and
- c. initiated and conducted for scientifically and/or medically legitimate purposes.

- 10.2 Where such** a commissioned article is used solely or primarily for the purpose of supporting a claim, including a comparative claim, the article cannot be the sole or primary evidence relied on to substantiate the claim – the claim must also be separately substantiated by other, additional evidence of sufficient quality and quantity to meet the standards specified in these Guidelines. Investigator-initiated or Advertiser-initiated reports which meet the conditions set out in the Preamble, Interpretation of these Guidelines may, however, provide independent substantiation for the safety or performance of a device or Related Service.

11. TESTIMONIALS AND ENDORSEMENTS

- 11.1 For testimonials** and/or endorsements (including but not limited to blogs) to be used in or in support of any Advertisement, the Advertiser must ensure that the testimonials or endorsements (whether from patients, suitably qualified Healthcare Professionals, celebrities or members of the public generally) whether written or spoken, are documented, genuine, not misleading and illustrate typical examples only, except where these are obviously fictitious.

In this context "typical" means something that is experienced by the great majority of patients or users, as applicable. If a testimonial or endorsement refers to a condition or situation experienced by only one or very few patients or users, this must be made clear. Also in this context "suitably qualified Healthcare Professionals" means persons who can provide suitable credentials evidencing relevant professional expertise or qualifications and accreditation by a professional or regulatory body that has systems for dealing with complaints and taking disciplinary action and has registration based on minimum standards for training and qualifications.

If a testimonial or endorsement which is used in Advertising is presented by a person other than the person originally providing the testimonial / endorsement – for example when presented by an actor or model – the effect must not mislead or otherwise distort the nature of the testimonial or endorsement. For example, Advertisers could include a suitable caption or other notice where an actor speaks the words of the actual provider of the testimonial to make the actual position clear.

Testimonials or endorsements must relate to the product being Advertised.

If a testimonial or endorsement is used in or in support of any Advertisement, the Advertiser must hold signed and dated documentary evidence, including contact details, for the provider of the testimonial or endorsement in question. The Advertiser must also ensure that he has the consent of the person providing the testimonial or endorsement both to use it in connection with Advertising and (if necessary) to disclose it in connection with the substantiation of any claim.

Testimonials or endorsements taken from published articles should be treated in the same way as quotations (Section 9 above) and in accordance with any other relevant provisions in these Guidelines.

12. REIMBURSEMENT OF EXPENSES FOR PROVIDERS OF TESTIMONIALS OR ENDORSEMENTS

12.1 Any payment made to a person providing a testimonial statement or endorsement (or any other in-kind benefit or advantage provided) must not be an inducement or reward for giving that statement. Similarly, no testimonial or endorsement (including any blog) by any person should be used in or to support Advertising if the provider of the testimonial or endorsement has been paid directly or indirectly (including via in-kind benefits or advantages) on behalf of the Advertiser to endorse the device or Related Service or to provide the testimonial.

Reimbursement of reasonable and proportionate expenses either by or on behalf of an Advertiser, where the expenses have been incurred by an individual or a company providing a testimonial or an endorsement for use in or in support of Advertising, is permitted always provided such reimbursement:

- a. is limited to out-of-pocket expenses reasonably incurred by the provider of the testimonial or endorsement in connection with its provision (e.g. reasonable travel costs to reach the filming location provided the location chosen and the mode of travel do not themselves constitute an inducement or reward for providing the testimonial / endorsement); and
- b. is either paid to a third party travel agent / vendor to organise the travel / accommodation or only reimbursed to the testimonial / endorsement provider against original invoices or receipts; and
- c. is kept entirely separate from any payments or other arrangements relating to any background collaboration or sponsorship activities so that the reimbursement is not, and does not appear to be, a payment made in connection with, or as part of a broader scheme of, paid collaboration or sponsorship between the provider of the testimonial / endorsement and the Advertiser (or any person or organisation connected to him); and
- d. specifically in the case of Healthcare Professionals, such reimbursement is only paid in circumstances where the reimbursement payment does not in any way amount to a

payment (i.e. as an inducement or reward) for the testimonial or endorsement to be provided as a service by the Healthcare Professional (nor does it have the appearance of being such a payment).

12.2 There should be a written agreement (e.g. letter agreement) signed and dated by or on behalf of both the Advertiser and the provider of the testimonial / endorsement setting out which expenses will be reimbursed and the mechanism of reimbursement (as well as also meeting the other requirements stated at sections 11 and 12.1 above). Expenses should only be reimbursed to the testimonial / endorsement provider by or on behalf of the Advertiser against original invoices or receipts.

If the provider of the testimonial / endorsement is a Healthcare Professional, the written agreement must also comply with the requirements of [Part 1, Chapter 6](#) of the ABHI Code (Arrangements with Consultants).

It is important that any reimbursement of out-of-pocket expenses should not be, or appear to be, a contrived payment for a testimonial or endorsement. No payment is permitted simply to obtain the testimonial / endorsement of a Healthcare Professional or any other person, and the written agreement must make this clear.

13. EFFECT OF BACKGROUND COLLABORATION OR SPONSORSHIP ON TESTIMONIALS AND ENDORSEMENTS

13.1 Advertisers may use testimonials or endorsements of a device or a Related Service by patients, celebrities, suitably qualified Healthcare Professionals or members of the public in, or in support of, Advertising where there is background collaboration or sponsorship by or on behalf of the Advertiser only if:

- a. the background collaboration with or sponsorship by the Advertiser of the individual or company providing the testimonial or endorsement is made clear in the Advertisement; and

- b. the testimonial or endorsement meets the requirements for testimonials and endorsements contained in these Guidelines (see Sections 11 and 12).

“Background collaboration or sponsorship” in this context means any relationship or arrangement(s) (including for example consultancy arrangements or any other type of service provision) between the provider of the testimonial or the endorsement and the Advertiser (or its representatives or affiliates) which is not connected with the provision of the testimonial or the endorsement, irrespective of whether such relationship or arrangement involves any payments (or any other in-kind benefit or advantage) or not.

Examples of background collaboration or sponsorship could include arrangements for research, participation on advisory boards or product development.

Reports of clinical investigations shall not be regarded as testimonials or endorsements of a product or Related Service. Rather, they may provide independent substantiation for the safety or performance of a device or Related Service.

Statements made of his/her own volition by a Healthcare Professional (including but not limited to off-the-cuff statements) shall not be treated as testimonials or endorsements even if they have been made at an occasion (such as a conference or meeting) where the meeting organiser is directly or indirectly supported by the Advertiser, always provided such support is incidental to the statement made. If the Advertiser subsequently wishes to use such a statement in or in support of Advertising the Advertiser must ensure all the requirements of these Guidelines regarding testimonials or endorsements (see under sections 11 and 12) are met.

13.2 When Advertisers enter into written agreements covering potential background collaboration or sponsorship activities, Advertisers should anticipate the possibility that the party providing the services under the relevant agreement may at some future time provide a testimonial or endorsement in relation to a device or a Related Service. Advertisers should therefore include provisions in such agreements to cover this eventuality (specifically points (i) and (ii) below) in order to ensure that they will be able to meet the requirements in these Guidelines relating to transparency of background collaboration and sponsorship and use of testimonials and endorsements generally. Such agreements should

therefore include written agreement by the potential future testimonial / endorsement provider to:

- a. disclose clearly and conspicuously in any testimonial / endorsement any background collaboration with, or sponsorship by or on behalf of, the Advertiser; and
- b. promptly withdraw, or revise and re-publish any testimonial / endorsement at the Advertiser's reasonable request where the request is made on objective grounds of ensuring safety and effective use within the Intended Purpose of the device or Related Service.

Such agreements should be in writing and signed and dated by both the Advertiser and the potential provider of the testimonial / endorsement.

14. ANNEX 1 GENERAL ADVERTISING LAW AND CODES

The Business Protection from Misleading Marketing Regulations 2008

The Consumer Protection from Unfair Trading Regulations 2008

The UK Code of Non-Broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code)

The UK Code of Broadcast Advertising (BCAP Code)

PART 4

COMPLAINTS PROCEDURE AND PANEL CONSTITUTION



INTRODUCTION

A Code of Ethical Business Practice ("Code") has been adopted by the Association of British Healthcare Industries ("ABHI") to set standards for ethical behaviour and to govern ethical promotion and sales practices in the medical devices industry in the UK ("the Industry"). The Code is administered by the ABHI secretariat in conjunction with the "Chairman" of the Complaints Adjudication Panel, "Panel", which comprises a number of individuals with relevant industry and/or other experience. Compliance with the Code and with this Procedure is mandatory for members of ABHI and companies which (although not members) (together "Applicable Companies") have agreed to comply with the Code and this Procedure and accept the jurisdiction of the Panel. "Complaints" made under the Code include direct complaints, as well as indirect complaints made to MedTech Europe and referred to ABHI for adjudication, and may also include issues raised in the media or otherwise that fall within the remit of the Code.

The Panel is not an investigatory body as such. It asks the company whose activities are the subject of a complaint ("respondent") for a complete response and may ask the parties to a case for further information in order to clarify the issues. The company or individual making the complaint ("complainant") has the burden of proving their complaint on the balance of probabilities.

Any company wishing to make a complaint against an Applicable Company utilising this Complaints Procedure must initially attempt to reconcile any dispute with that company through conciliation or mediation procedures or mutual settlement. Any individual wishing to make a complaint against an Applicable Company utilising this Complaints Procedure must initially attempt to resolve the complaint utilising that company's internal or external whistleblowing and/or dispute resolution procedures. If, in either case, this does not prove possible then complaints are initially considered by the Chairman who will determine, if appropriate in consultation with the complainant and/or respondent, whether there is a case to answer.

Anonymous complaints (where the complainant does not disclose their identity to the Panel or Chairman) may be accepted in exceptional circumstances at the discretion of the Chairman, however the weight to be attached to any evidence may be adversely affected if the source is anonymous, and thus in many instances it will not be possible for such a complaint to proceed.

Confidential complaints (where the complainant does not disclose their identity to the Panel or Chairman but requests (whether at the outset or during the course of the complaint) that their identity remains confidential) are not encouraged but may be accepted at the discretion of the Chairman, however the ability of the respondent to respond properly to information or matters put to them and therefore the Panel's ability to adjudicate properly on any particular complaint may be adversely affected if the identity of the complainant is kept confidential, and therefore in certain instances it will also not be possible for such a complaint to proceed. Confidential complaints will not be accepted from Applicable Companies.

Reports on cases that are subject to a Panel decision are published and are available on request and on the ABHI Code of Ethical Business Practice website www.abhicodeofpractice.org.uk. Information on cases that are resolved through mediation are published in a summary report although the names of the companies or individuals involved will not be disclosed.

Complaints about the conduct of any Applicable Company under the Code should be submitted to:

Telephone: +44 (0)20 7960 4360,

E-mail: complaints@abhi.org.uk.

DISPUTE RESOLUTION PRINCIPLES

General framework

The procedures set out below are intended to provide an effective and efficient complaint-handling process, the object of which is to ensure compliance with the Code. It is based on principles of proportionality, speed, due process, fairness and transparency.

Applicability of the Code

Member Companies must comply with the Code as a minimum standard when:

- a. Member Companies interact with Healthcare Professionals and Healthcare Organisations registered and practising in the UK irrespective of where the activity takes place; and/or
- b. Activities take place in MedTech Europe Geographic Area, irrespective of where Healthcare Professionals and Healthcare Organisations are registered and practicing.

MedTech Europe Geographic Area includes the countries in the European Economic Area as well as those countries where MedTech Europe Member Associations are located.

STRUCTURE AND RESPONSIBILITIES

1. The Panel

- 1.1 **The Panel** is responsible for resolving complaints made under the Code. It may also assist in arranging for conciliation and/or mediation between companies when requested to do so.
- 1.2 **The Panel** and Chairman report to the ABHI Board in respect of their activities and the operation and administration of this Complaints Procedure.

2. The Panel – Constitution and Procedure

- 2.1 **The members** of the Panel and the Chairman and Vice-Chairman shall be appointed yearly by the ABHI Board. The Panel shall comprise individuals with a background in the industry and who have relevant expertise for assessing Complaints under the Code. The names of the members of the Panel shall be published on the ABHI website. There is no limit on the length of time that the Chairman, Vice-Chairman or other members of the Panel may serve in those capacities.

2.2 **In the event** that a Complaint cannot be resolved through mediation by the Secretariat, Chairman and such members of the Panel who may be enlisted for this mediation, the Complaint shall be referred to the Panel for formal adjudication. Each individual Panel appointed to consider any particular complaint shall, so far as possible, comprise of an appropriate cross-section of Panel members and shall be appointed by the Chairman from the wider list of Panel members referred to. The Chairman shall ensure that a Panel contains as far as possible individuals with expertise in relevant areas, e.g. legal, ethical compliance, advertising and promotion, scientific, business, as appropriate. Each individual Panel shall comprise of a minimum of the Chairman and three further Panel members and decisions shall be made by majority voting. The Chairman, and in his absence, the Vice-Chairman, acts as Chairman of the Panel and has both an original and a casting vote.

2.3 **Rulings** are made on the basis that a complainant has the burden of proving their complaint on the balance of probabilities.

2.4 **In advance** of their appointment to an individual Panel to consider any particular complaint, all Panel members involved shall sign an agreed form statement of independence confirming that they have no conflict of interest in adjudicating on the particular complaint.

2.5 **The Panel** may obtain expert assistance in any field. Expert advisers who are consulted may be invited to attend a meeting of the Panel, but have no voting rights. Each such expert shall also be required to confirm that they have no conflict of interest in providing expert assistance on any particular case.

2.6 **Subject to** paragraphs 2.7 and 2.8 below, any decision of the Panel shall be final, and there shall be no appeals procedure against any Panel rulings.

2.7 **At any time** during a complaint handling process the Chairman or the Panel shall be entitled to refer questions of interpretation of the Code in writing to the MedTech Europe Compliance Panel. The MedTech Europe Compliance Panel may at its discretion either decline to entertain the matter if it is felt that no question of principle is at issue or accept the interpretation referral, and review and provide guidance on the interpretation of the Code.

Where such a request has been made, the Chairman and the Panel shall be obliged to follow and apply any such guidance provided by

MedTech Europe unless so doing would conflict with UK law. For the avoidance of doubt MedTech Europe shall not rule on the merits or facts of any particular complaint but only on questions of interpretation of the Code.

- 2.8 This Procedure** shall not preclude complainants from having recourse to courts or other tribunals to seek resolution of complaints and any complaints made under the Code and this Procedure should not be initiated or should be suspended in case of initiation of formal civil court proceedings with respect to the same subject matter. Where a governmental or regulatory investigation or criminal proceedings are either initiated or threatened against an Applicable Company with respect to the same subject matter, that company shall notify the Chairman of the same in confidence, who shall then have the discretion whether or not to suspend any relevant proceedings under this Procedure.
- 2.9 For the avoidance** of doubt, all companies or individuals that wish to utilise this Complaints Procedure to submit a Complaint, and all Applicable Companies that have agreed to submit to the jurisdiction of the Panel in respect of a Complaint, shall not, save in respect of fraud, fraudulent misrepresentation, manifest error or gross negligence by the Panel (or a member thereof) in arriving at a Panel ruling, commence legal proceedings or any analogous contentious or complaint proceedings against ABHI, the Panel, or any Panel member, in respect of any loss or damage they may suffer as a consequence of any such Panel ruling.

COMPLAINTS PROCEDURE

3. Action on Complaints

- 3.1 Prior** to lodging a formal complaint against an Applicable Company under this Procedure, any company wishing to make a complaint against an Applicable Company shall first attempt a genuine mediation with that company in an attempt to reach an amicable solution. For complaints between Applicable Companies, such genuine attempt at mediation shall be a pre-condition before a complaint can be made utilising this Procedure and any such complainant shall adduce sufficient evidence to the Panel to prove such genuine attempts at mediation have been made. Any individual wishing to make a complaint against an Applicable Company utilising this Complaints Procedure must initially attempt to

resolve the complaint utilising that company's internal or external whistleblowing and/or dispute resolution procedures. If, in either case, no amicable resolution of the complaint can be reached through such means within a reasonable timeframe however, the complainant shall be entitled to pursue the matter further directly via this Procedure.

- 3.2 Any individual** or company making a complaint under this Procedure that is not an Applicable Company shall be required (in the case of a company for a minimum of 18 months, and in the case of an individual for the duration of the Procedure) to undertake to abide by the provisions of the Code and of this Procedure as a pre-condition before a complaint can be made utilising this Procedure.
- 3.3 If a complaint** is received about a company other than an Applicable Company, such company will be invited to agree to comply with the Code and accept the jurisdiction of the Panel. In the absence of such agreement however, the complaint will not be accepted for adjudication using this Procedure. Notwithstanding the foregoing, where a complaint is brought in respect of activities undertaken or instigated by an Applicable Company's parent or other affiliated company which is not itself an Applicable Company, the Applicable Company will be deemed as the respondent company for the purposes of this Procedure and the complaint will proceed accordingly.
- 3.4 When** the Chairman receives information from which it appears that an Applicable Company may have contravened the Code, the Chairman shall undertake an initial review of the complaint and will determine (if appropriate, in consultation with the complainant and/or respondent) whether there is a *prima facie* case to answer.
- 3.5 If, in the view** of the Chairman, a complaint does not show that there may have been a *prima facie* breach of the Code, the complainant shall be so advised. If the complainant does not accept that view, the following paragraphs of this Section 3 shall apply.
- 3.6 In the event** that the Chairman determines that there is either a *prima facie* case to answer, or (pursuant to paragraph 3.5) the complainant insists that the complaint is referred to the Panel for adjudication, then the Chairman shall write to the managing director or chief executive or equivalent of the Applicable Company against whom the complaint has been made requesting that it provide a complete response to the matters of complaint.

3.7 The respondent company shall provide such a response in writing to the Chairman within 10 working days. If no such response is provided by the respondent company within these timescales then, save as otherwise provided in paragraph 7, the Panel shall make its adjudication on the basis of the information provided by the complainant only. Following receipt by the Chairman of the respondent company's response, the case shall be referred to the Panel to determine whether or not there has been a breach of the Code.

3.8 To assist companies in ensuring that a complete response is submitted, the Chairman may suggest relevant supporting material to be supplied, although it is the responsibility of the respondent to ensure that a full response is submitted.

3.9 In addition, the Chairman may request (whether at the suggestion of the complainant or respondent or at the behest of the Panel) such further clarifications or documents from either the complainant or respondent within such reasonable timescales as he shall deem prudent and necessary to assist the Panel in making its determination.

3.10 As an alternative to proceeding directly to the Panel, the Chairman may offer to facilitate a time-limited mediation between the parties. Such mediation shall normally be limited to six working weeks but may be extended at the Chairman's discretion. Both parties shall make every effort to ensure that relevant personnel are available to participate in the process as and when they are required.

The parties shall agree at the outset to the terms of mediation and that the costs incurred in running the process shall be divided equally between them. Only Applicable Companies shall be liable for mediation costs.

3.11 If the complainant is not an Applicable Company, the Chairman may suggest the paragraphs of the Code to be addressed, however when the complaint is from an Applicable Company, the complaint must be signed or authorised in writing by the company's managing director or chief executive or equivalent and must state those paragraphs of the Code which are alleged to have been breached.

3.12 Unless the information is disclosed in the complaint, any complainant other than an Applicable Company will be asked to confirm in writing whether or not they have any commercial, financial or other interest in the matter of

complaint or in the company concerned, such as whether the complainant is an employee or ex-employee, a consultant or ex-consultant. Adjudication of a complaint without this written confirmation will not be permitted to proceed. Such interests will be disclosed to the respondent company and will normally be included in the case report.

3.13 When an Applicable Company advises the Chairman or Panel that it may have breached the Code, the Chairman shall treat the matter as a complaint if it relates to a potential breach of the Code or if the company fails to take appropriate action to address the matter. The company's response is invited and the procedure set out in this Section 3 shall be followed.

4. Complaints Arising from Media Criticism

4.1 If it appears to the Chairman from media reports that an Applicable Company may have breached the Code, the Chairman may at his discretion treat such reports as a complaint if it relates to a potential breach of the Code or if the company fails to take appropriate action to address the matter. The company's response is invited and the procedure set out in Section 3 shall be followed.

4.2 The author or editor (as applicable) of the relevant media report may be asked if they want to be involved in the case and whether they have any additional information to submit. If the editor or author declines involvement, this is stated in the case report.

4.3 A published letter from which it appears that an Applicable Company may have breached the Code may also at the discretion of the Chairman be treated as a complaint. The procedure set out in Paragraph 4.1 above shall be followed.

5. Panel Rulings

5.1 Where the Panel rules that there is a breach of the Code, the Panel shall advise the complainant and the respondent of such in writing and give their reasons for the decision.

5.2 The respondent company has ten working days to provide a written undertaking that the activity in question (if not already discontinued) will cease forthwith and that all possible steps will be taken to avoid a similar breach of the Code in the future. This undertaking must be signed by the managing director or chief executive or equivalent of the company and must be accompanied by details of the actions taken by the company to implement the undertaking, including dates and timings and training undertaken.

- 5.3 In extenuating circumstances**, an extension in the time allowed in which to respond may be granted at the discretion of the Chairman in accordance with paragraph 7.
- 5.4 The respondent** company must also pay within twenty working days an administrative charge based on the cost of convening the Panel and dealing with the complaint as determined by the Chairman.
- 5.5 Where the Panel** rules that there is no breach of the Code, the Panel shall advise the complainant and the respondent of such in writing and give their reasons for the decision. Where the complaint is from an Applicable Company, the complainant must pay within twenty working days an administrative charge based on the cost of convening the Panel and dealing with the complaint as determined by the Chairman.
- 5.6 In addition** to the foregoing, the Panel may impose additional or alternative sanctions on either of the respondent company (in the event of its breach of the Code) or complainant company (in the event of no breach of the Code) as appropriate in respect of any particular complaint. In particular, the Panel may:
- a. Require the relevant company to publish any communication required by the Panel, including but not limited to explanatory information or statements of future intent or policy;
 - b. Issue a formal reprimand;
 - c. Recommend to the ABHI Board to suspend the offender from membership of ABHI for a specified period and impose conditions on readmission;
 - d. Recommend to the ABHI Board to expel the offender from ABHI;
 - e. Set time-limits for compliance with any sanction imposed or order made by the Panel in addition to those specified in paragraphs 5.1 to 5.5 above;
 - f. Order that either party pay the costs of the Panel, in whole or part, having regard to a standard scale published by ABHI and any other matters considered appropriate;
 - g. Provide for further sanctions in the event of further breaches of or non-compliance with the Code or any order, sanction or requirement of the Panel (including time limits), with or without the right to make further representations before such further sanctions are to take effect.

6. Case Reports

- 6.1 At the conclusion** of any case under the Code, the Panel shall advise the complainant and the respondent of the outcome and a report shall be published summarising the details of the case.
- 6.2 In a case** where the complaint was initiated by an individual, other than in those circumstances where an anonymous or confidential complaint is accepted for adjudication, that individual shall be named in the report.
- 6.3 In a case** where the complaint was initiated by a company or by an organisation or official body, that company or organisation or official body shall be named in the report. The respondent company and the product(s) concerned will usually be named in the report unless the Chairman in his discretion deems this inappropriate. Any information given must not, however, be such as to identify any individual person within such company, organisation or official body.
- 6.4 Where expert** assistance has been obtained by the Panel, the report will include the name and qualifications of the expert concerned.
- 6.5 Where guidance** has been sought from MedTech Europe, the question raised by the Chairman or the Panel and the guidance received from MedTech Europe shall be included in the report.
- 6.6 Where a company** has been required to issue a statement of its corrective actions, the report will reproduce its text and provide details of how the corrective actions statement was disseminated.
- 6.7 A copy** of the report on a case is made available to both the complainant and the respondent company prior to publication. Any amendments to the report suggested by these parties are considered by the Chairman, consulting with the other party where appropriate. The Chairman's decision is final.
- 6.8 Full case reports** will appear on a specified section of the ABHI Code of Ethical Business Practice website. Access to the relevant section of the relevant ABHI website referring to cases or decisions is unrestricted.

GENERAL PROVISIONS

7 Amendments to Time Periods

- 7.1 The Chairman shall**, in extenuating circumstances and at his discretion, be entitled to grant any party to this Procedure an extension in time or amend any timescales specified in this Procedure to the extent that to do so would be fair and reasonable in the circumstances.

8. Withdrawal of Complaints

- 8.1 A complaint** may be withdrawn by a complainant with the consent of the respondent company up until such time as the respondent company's comments on the complaint have been received by the Chairman, but not thereafter. In either case, the complainant shall pay an appropriate administrative charge.

9. Charges

- 9.1 The administrative** charges referred to in Paragraphs 5.4, 5.5 and 8.1 above are determined by the Chairman based on the costs of formally convening the Panel and in dealing with the complaint.
- 9.2 Administrative charges** are payable only by Applicable Companies, and these companies are liable for such charges whether they are members of the ABHI or not.
- 9.3 Where two or more** companies are ruled in breach of the Code in relation to a matter involving a joint activity, each company shall be separately liable to pay any administrative charge which is payable.
- 9.4 Failure to pay** any of the administrative charges provided for by this paragraph must be reported by the Chairman or the Panel to the ABHI Board. In such circumstances, the Panel shall be entitled to impose or recommend such further sanctions as it deems appropriate, including (but not limited to) those referred to in paragraph 5.6.

10. Anonymity and Confidentiality

- 10.1 Any complainant** or respondent shall be entitled to request that any document or information provided to the Panel or Chairman pursuant to this Procedure is not disclosed further on the grounds of confidentiality, in particular to either the complainant or respondent as the case may be or in any case report. The Chairman shall decide in his discretion whether to grant such request, in particular taking in to account the ability of either the complainant or the respondent to respond

properly to information or matters put to them if such documents or information is excluded and therefore the Panel's ability to properly adjudicate on any particular complaint. The Chairman's decision on this issue shall be final.

- 10.2 Anonymous complaints** (where the complainant does not disclose their identity to the Panel or Chairman) may be accepted in exceptional circumstances at the discretion of the Chairman, however the weight to be attached to any evidence may be adversely affected if the source is anonymous, and thus in many instances it will not be possible for such a complaint to proceed.

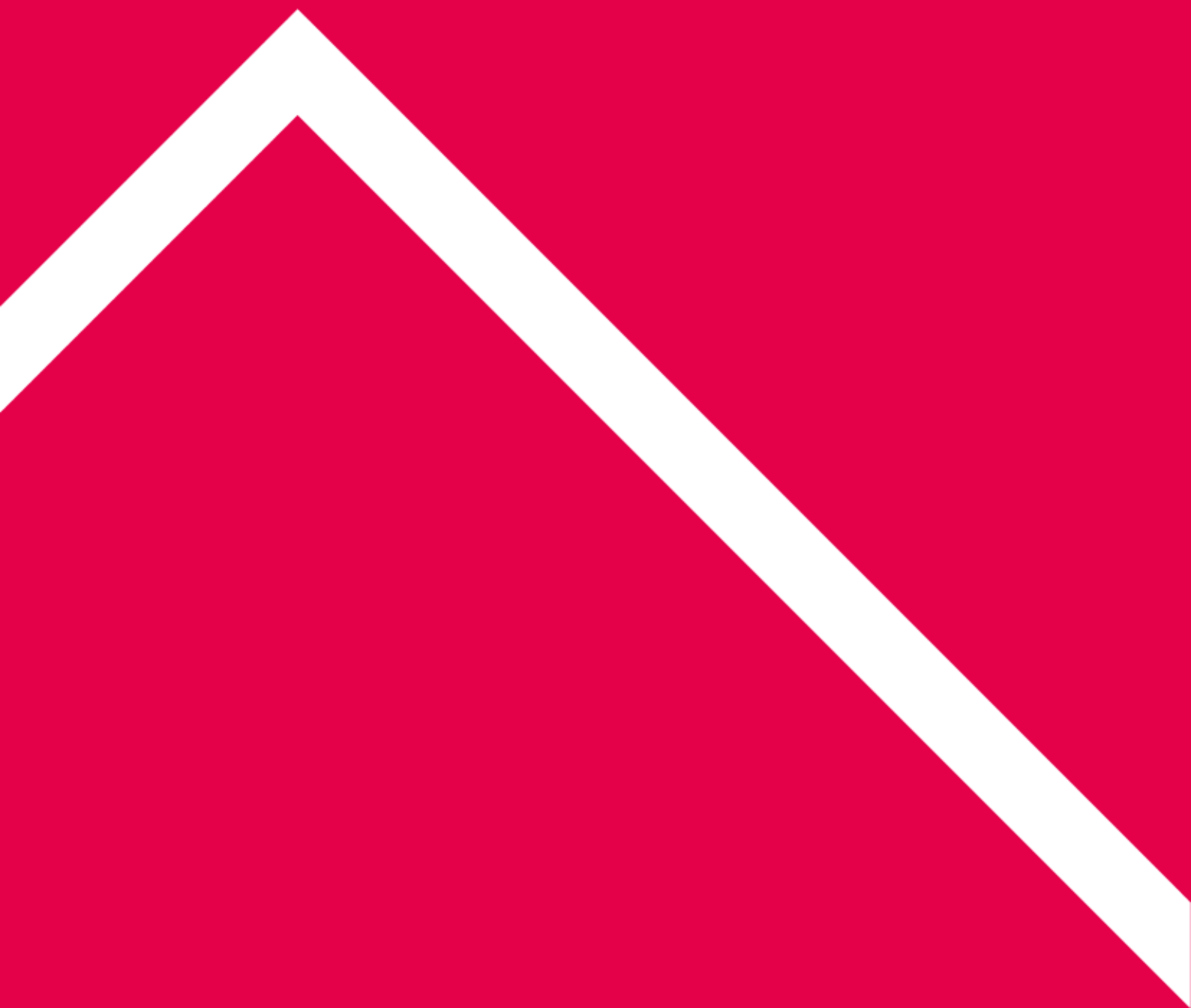
- 10.3 Confidential complaints** (where the complainant does disclose their identity to the Panel or Chairman but requests (whether at the outset or during the course of the complaint) that their identity remains confidential) are not encouraged but may be accepted at the discretion of the Chairman, however the ability of the respondent to respond properly to information or matters put to them and therefore the Panel's ability to adjudicate properly on any particular complaint may be adversely affected if the identity of the complainant is kept confidential, and therefore in certain instances it will also not be possible for such a complaint to proceed. Confidential complaints will not be accepted from Applicable Companies.

11. Amendments to the Code of Ethical Business Practice and Complaints Procedure

- 11.1 The Code** and this Procedure may be amended by a simple majority of those present and voting at the ABHI Board.
- 11.2 The Panel** may, in the light of their experience, make recommendations for amendment of the Code and this Procedure.

PART 5

GLOSSARY AND
DEFINITIONS



ABHI: Association of British HealthTech Industries

Advertiser: the ABHI Member by or on behalf of whom an Advertisement is placed and/or the ABHI Member supplying the relevant product or Related Service if he has approved the Advertisement or the Advertisement has been approved or placed by the Member's affiliated company which is not a Member of ABHI.

The ABHI Member shall be treated as the Advertiser where the ABHI Member, or the Member's affiliated company which is not a Member of ABHI, has approved Advertisements placed by a third party distributor or other service provider.

Advertisement or Advertising: any marketing communication or Advertorial issued by or on behalf of an Advertiser in whatever form (including but not limited to verbal communications) and through whatever media (including the world wide web) that is intended wholly or mainly to influence Healthcare Professionals or Healthcare Organisations directly or indirectly in (i) their choice of medical devices (or Related Services) to be purchased, leased, used or supplied for use by, or in connection with the treatment of, human patients or in (ii) any recommendation that they make to others about such purchase, lease, use or supply.

An example of Advertising intended to influence Healthcare Professionals or Healthcare Organisations indirectly would be information provided by or on behalf of an Advertiser to journalists working for publications which are directed primarily at Healthcare Professionals or Healthcare Organisations.

For the avoidance of doubt product labelling, packaging and instructions for use shall not in the ordinary course be treated as Advertising for the purpose of these Guidelines.

Advertorial: any communication, feature, announcement or promotion in a form that resembles independent editorial comment published by or on behalf of an ABHI Member, the content of which is controlled by the Advertiser, not the publisher, irrespective whether it is disseminated in return for a payment or other reciprocal arrangement, or free of charge.

Applicable Company: a member of ABHI or an organisation that has undertaken to comply with the provisions of the ABHI Code of Ethical Business Practice.

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

CoBP or Code: the code of ethical business practice published by ABHI as amended from time to time.

Company Events: means activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of Member Companies to fulfil a legitimate, documented business need of the Member Company, including but not limited to a legitimate business need to interact with customers including Healthcare Professionals and/or Healthcare Organisations.

Conference Vetting System (CVS): means the centralised decision-making process which reviews the compliance of Third Party Organised Educational Events with the Code and which is managed independently of ABHI under the supervision of the MedTech Europe Compliance Panel. For more information see: www.ethicalmedtech.eu

Disclosure Guidelines: means the Code provisions setting out the public disclosure requirements under the Code.

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

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

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

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

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

Evaluation Products: means either single-use or multiple-use products and/or equipment provided free of charge to a Healthcare Organisation by or on behalf of a Member Company for purposes of obtaining defined, evaluative user feedback over a defined period of use when used within the scope of their Intended Purpose, as per the authorisation in the country where the supply occurs. Evaluation Products do not include the following:

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

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

Faculty: means a podium speaker, moderator and/or chair, who presents during a Third Party Organised Educational Event. Poster- and abstract-presenters are not considered

to be Faculty.

Financial Hardship: means in relation to a Healthcare Organisation extreme and unavoidable financial distress resulting from matters outside the Healthcare Organisation's control where the Healthcare Organisation is unable to operate and where patient care is consequently jeopardised. Financial distress resulting in whole or in part from mismanagement of the Healthcare Organisation's funds or other matters within its control is not considered to be financial hardship. Financial Hardship must be documented and objectively substantiated.

Grants: means either an Educational Grant or a Research Grant, or both.

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

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

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

Intended Purpose: the use for which the device is intended according to the data supplied by the manufacturer on the label, in the instructions or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation (Medical Devices Regulation (EU) 2017/745).

Members: means all full and associate corporate members ("Member Companies") of ABHI as well as association members of ABHI ("Member Associations"), as defined in the ABHI statutes, as applicable and as amended from time to time.

Professional Conference Organiser (PCO): a for-profit company or organisation which specialises in the management of congresses, conferences, seminars and similar events.

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

- The safe and effective use of health technologies, therapies and/or Related Services, and/or
- The safe and effective performance of clinical procedures, and/or
- Related disease areas.

In all cases the information and/or training directly concern a Member Company's health technologies, therapies and/or Related Services.

Related Service: in relation to a medical device, a Related Service means an activity necessary to make the device available for use. This may include specialist installation services; repair and maintenance services; or end-of-use services such as specialist disposal of the device.

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

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

Samples: means single-use or multiple-use products provided free of charge by or on behalf of a Member Company to HCOs or HCPs who are equipped and qualified to use them in order to enable HCPs to familiarise

themselves with the products in clinical use. Samples do not include the following:

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

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

Sponsored Posts: Sponsored posts are positions within a Healthcare Organisation that are funded, in whole or in part, by a Member Company. Sponsored posts can offer benefits to the delivery of care, providing expertise, extra capacity and capability that might not otherwise be provided if funding was to be found from within the Healthcare Organisation's budget.

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

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

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

- Specific therapeutic, diagnostic or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of health technologies); and
- Practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment.

For the avoidance of doubt, proctorship and preceptorship are not considered to constitute Third Party Organised Procedure Training.

Transition Period: means the period from 1 January 2017 up to and including 31 December 2018, following which Member Companies shall no longer provide financial or in-kind support direct to Healthcare Professionals to cover costs of their attendance at Third Party Organised Educational Events with the exception of Third Party Organised Procedure Training meetings or pursuant to a consulting agreement with a Healthcare Professional speaker engaged by a Member Company to speak at a satellite symposium.

PART 6

ANNEXES



ANNEX I [AMENDED IN JULY 2019]

CVS SCOPE: WHEN ARE CVS ASSESSMENTS REQUIRED?

		PRIOR CVS SUBMISSION			
		IN MEDTECH EUROPE GEOGRAPHIC AREA		OUTSIDE MEDTECH EUROPE GEOGRAPHIC AREA	
WHICH TYPE OF SUPPORT CAN MEMBER COMPANIES PROVIDE TO WHICH THIRD PARTY ORGANISED EDUCATIONAL EVENTS?		<u>NATIONAL</u> Third Party Organised Educational Events attended by delegates which are local HCPs only)	<u>INTERNATIONAL</u> (Third Party Organised Educational Events attended by delegates coming from at least two countries of the MedTech Europe Geographic Area ^{1,2})	<u>INTERNATIONAL</u> (Third Party Organised Educational Events attended by delegates who are Healthcare Professionals registered and practising in the MedTech Europe Geographic Area ³)	<u>INTERNATIONAL</u> (Third Party Organised Educational Events to which no Healthcare Professionals registered and practicing in the MedTech Europe Geographic Area attend, neither as speakers or delegates)
EDUCATIONAL GRANTS ⁴ PROVIDED TO SUPPORT A THIRD PARTY ORGANISED CONFERENCE	Educational Grant to support the general running of a conference	Allowed ⁵	Subject to CVS decision	Allowed. Not subject to CVS decision	Out of scope of the application of the Code ⁶
	Educational Grants that includes funds to support HCP attendance to the conference	Allowed.	Subject to CVS decision	Allowed. Not subject to CVS decision	N/A
	Educational Grants that includes funds to support Faculty	Allowed.	Subject to CVS decision	Allowed. Not subject to CVS decision	N/A
COMMERCIAL ACTIVITIES	Consultancy agreement for speakers in satellite symposia	Allowed.	Subject to CVS decision	Allowed. Not subject to CVS decision	N/A
	Booths/advertising	Allowed.	Subject to CVS decision	Allowed. Not subject to CVS decision	Out of scope of the application of the Code
DIRECT SPONSORSHIP OF HCPs REGISTERED AND PRACTISING IN THE MEDTECH EUROPE GEOGRAPHIC AREA	Direct sponsorship of HCPs as delegates (passive participation)	Not allowed ⁷	Not allowed ⁷	Not allowed ⁷	N/A
	Direct sponsorship of HCPs as Faculty (active participation)	Not allowed ⁷	Not allowed ⁷	Not allowed ⁷	N/A

1. MedTech Europe Geographic Area includes the countries in the European Economic Area (EEA), as well as those other countries where Member Associations are located.

2. Formerly referred to as "Cross-border Events".

3. For avoidance of doubt, in 2019, this category of "Third Party Organised Educational Events attended by delegates who are Healthcare Professionals registered and practicing in the MedTech Europe Geographic Area" has to be understood as covering only Healthcare Professionals from the MedTech Europe Geographic Area benefiting from an Educational Grant.

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

5. Allowed means no CVS decision is required but the provisions of the ABHI Code of Ethical Business Practice and national laws and regulations still apply.

6. Out of scope: Means the Code does not apply given that the situation does neither involve a Member Company interacting with an HCP or HCO registered and practicing in the MedTech Europe Geographic Area nor does the activity take place in the MedTech Europe Geographic Area.

7. Please note direct support for attendance of HCPs to Third Party Organised Procedure Training meetings is allowed provided it complies with the requirements of the Code.

ANNEX II (ADDED IN MAY 2017)

DISCLOSURE GUIDELINES TEMPLATE EXAMPLE*

TEMPLATE								
Full HCO Name	HCOs: city where registered	Country of Principal Practice / Activity	Registered Address	Unique country local identifier	A. Educational Grants to Support Third Party Organised Events /or to Support HCP Participation at Third Party Organised Educational Events)	Object (Optional)	B. Other Educational Grants to HCOs (including Scholarships, Fellowships and Grants for Public Awareness Campaigns).	Object (Optional)
HCO/PCO 1					Yearly amount	Optional	Yearly amount	Optional
HCO/PCO 2					Yearly amount	Optional	Yearly amount	Optional
etc.					Yearly amount	Optional	Yearly amount	Optional

*Please note that this template is for illustrative purposes only. The template to be used for reporting purposes will be available in the [TransparentMedTech website](#).

Q: What is a "unique country local identifier"?

A: It refers to a specific, unique and sustainable reference to identify Healthcare Organisations. Reporting companies will use the Healthcare Organisation's VAT as unique country local identifier by default. In those countries where Healthcare Organisations do not necessarily have a VAT number, another identifier, unique for this Healthcare Organisation and common for all reporting companies will be provided.

ANNEX III (ADDED IN MAY 2017)

MEDTECH EUROPE GEOGRAPHICAL AREA



The MedTech Europe Geographic Area currently includes:

a) countries with National Associations:

- Austria
- Belgium
- Bulgaria
- Czech Republic
- Denmark
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- The Netherlands
- Norway
- Poland
- Portugal
- Romania
- Russia
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Turkey
- The United Kingdom
- the countries where Mecomed is active

b) countries party to the European Economic Area agreement without a MedTech Europe National Association:

- Croatia
- Cyprus
- Estonia
- Iceland
- Latvia
- Liechtenstein
- Lithuania
- Luxembourg
- Malta

c) countries where Mecomed is active

- Algeria
- Bahrain
- Egypt
- Iran
- Iraq
- Jordan
- Kuwait
- Lebanon
- Libya
- Mauritania
- Morocco
- Oman
- Pakistan
- Qatar
- Saudi Arabia
- Sudan
- Syria
- Tunisia
- UAE
- Yemen

Please note that countries covered by Mecomed, the Middle East Medical Devices and Diagnostics association, are not currently under the scope of the Disclosure Guidelines.

ANNEX IV (ADDED IN JULY 2018)

VERIFICATION OF THE USE OF FUNDS

How can a Member Company verify that the Educational Grant is in fact used for the intended purpose as agreed in the Educational Grant agreement?

A Member Company should set up an internal verification process for the purpose of ensuring that the funds provided through an Educational Grant are used for the agreed intended purpose. For example, such a process could include verification of every single Grant provided by a Member Company or periodic verification of a selected sample of Grants, after the Event takes place or before any subsequent application for an Educational Grant.

Examples of the documents requested by a Member Company for verification purposes could include, but are not limited to, the following:

Grant to support Healthcare Professionals' attendance at the Third Party Organised Educational Event:

- Attendance proof (e.g. hotel check-out form, signed attendance list, a digital certificate issued by the Event organiser etc.)
- Travel proof (e.g. flight/train tickets)
- Copy of the receipts of taxi fares, meals etc.
- Where allowed, pictures of the Event.

Grant to support the costs related to organisation of the Third Party Organised Educational Event:

- Budget breakdown listing the general expenses of the Event
- Accounting records, copies of invoices, receipts
- Verifications performed by company staff on-site during the Event.
- Written confirmation from the Event Organiser that the funds were spent as intended
- Documentation of the speaker's presentation (e.g. slides)

Grant provided in the form of a Scholarship or Fellowship:

- Activity records of the educational programme
- Certification of enrolment from the institution or professor in charge
- Progress report by or of the beneficiary

If a Grant recipient fails to provide the requesting Member Company with the documents or if a Member Company determines that the Grant funds were not used as provided in the Grant agreement, the Member Company:

- Should take this into account when assessing any future funding request from the same Healthcare Organisation.
- May consider requesting MedTech Europe to withdraw the right to use the Logo, if the HCO/PCO is an MTE "Chartered Organisation" under the Ethical Charter (<https://www.ethicalmedtech.eu/ethical-charter/general-overview/>)

ANNEX V (ADDED IN MAY 2017)

EXAMPLE OF DISCLOSURE GUIDELINES METHODOLOGY NOTE

STRUCTURE

- 1 Introduction
- 2 Executive summary of the methodologies used for disclosure purposes and countries specificities
- 3 Definitions
 - Recipients
 - Types of Educational Grants
- 4 Disclosure scope and timelines
- 5 Disclosures in case of partial performance or cancellation
- 6 Cross-border activities
- 7 Specific considerations:
 - Multi-year agreements
 - Consent management (please note that some jurisdictions may require the legal entity's consent for publication of data)
 - Consent collection
 - Management of recipient consent withdrawal
 - Management of recipient's request
 - Partial consent
- 8 Disclosure Form
 - Date of submission
 - Currency in case of aggregated payments made in different currencies
 - VAT included or excluded and any other tax aspects
- 9 Disclosure financial data and amount of Educational Grants provided
- 10 Calculation rules

Disclaimer: This Methodology note is provided as a template to support Member Companies in the implementation of these Disclosure Guidelines. Any other template may be equally valid provided it complies with the general requirements set out in Section 2.4 Methodology.

ANNEX VI (ADDED IN JULY 2018)

DIRECT SUPPORT TO HCP PARTICIPATION IN EVENTS AS OF 1ST JANUARY 2019

		Direct Support for HCP attendance(+)		
Event	Setting	Faculty/speaker(s)	Delegates	
Third Party Organised Educational Conference	Main Event / Independent Scientific Program	Not allowed	Not allowed	
	Satellite Symposium	Allowed (through a consulting agreement)	Not allowed	
	Booth	Allowed (through a consulting agreement)	Not allowed	
Third Party Organised Procedure Training meeting* *Criteria to distinguish a Third Party Organised Procedure Training meeting can be found in Q&A 21		Allowed	Allowed	
Company Events	Product and Procedure Training and Education Event	NOT taking place around or at the same time as a Third Party Organised Educational Event	Allowed	
		Taking place around or at the same time as a Third Party Organised Educational Event	Not allowed	
	Sales, Promotional and Other Business Meeting	NOT taking place around or at the same time as a Third Party Organised Educational Event	Allowed (through a consulting agreement)	Not allowed (except for the demonstration of non-portable equipment)
		Taking place around or at the same time as a Third Party Organised Educational Event	Allowed	Not allowed

DESCRIPTION

Delegate: "Delegate" is any Healthcare Professional who is attending passively a Company Event or a Third Party Organised Event (TPOE) and cannot be considered as "Faculty".

For avoidance of doubt, poster- and abstract-presenters are considered to be Delegates.

Satellite Symposium: Common elements of Satellite Symposia are:

- It takes place at a TPOE and it is part of the TPOE official programme (i.e. not focused on marketing specific products);
- The Company is responsible for the content subject to review by the Organiser where required;
- It is open to any delegate, not only to selected individuals;
- It has Company branding and the Company can promote the Satellite Symposia to customers.

Speaker/Faculty: "Faculty/speaker" in this chart is someone who is considered as speaker, for example someone who gives a presentation whether in a Company Event or a TPOE; is moderating/chairing a session and therefore needs to prepare ahead of the presentation/moderation.

GUIDANCE

Speaker/Faculty: In order to determine whether an event is a TPOE or a Company Event, the following aspects should be taken into account:

- Open events (not only Company's customers) are typical of TPOE, and in this case, it is a Third Party that chooses HCPs attending;
- Who is primary initiator of the Event: How much is the Third-Party vs. the Company involved, who is driving the agenda?
- CME accreditation is an TPOE indication;
- TPOE are generally broader than one or few products;
- Single-sponsored events are often Company Events.

ANNEX VII (ADDED IN JULY 2019)

THE CRITERIA APPLICABLE TO THIRD PARTY ORGANISED PROCEDURE TRAININGS

Third Party Organised Procedure Training, as defined in the Glossary of the the ABHI Code of Ethical Business Practice ("the Code") means a type of Third Party Organised Educational Event that is primarily intended to provide HCPs with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:

- Specific therapeutic, diagnostic or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of medical technologies); and
- Practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment.

Chapter 2 of the Code provides that Member Companies may support Third Party Organised Procedure Trainings ("TPPT") either:

- via Educational Grants (in accordance with Chapter 4: Charitable Donations and Grants); OR
- by providing financial support directly to individual Healthcare Professionals ("HCP") to cover the cost of attendance at Third Party Organised Procedure Training sessions.

This exception is to be narrowly interpreted.

For cross-border and international Third Party Organised Events, it is the CVS Compliance Officers whose responsibility it is to determine whether or not a conference meets the criteria to be qualified as a Third Party Organised Procedure Training. In case the Event does not meet the TPPT criteria, it will be re-qualified as a Third Party Organised Educational Conference.

CRITERIA FOR TPPT DETERMINATION

1. Programme:

Practical and hands-on activities must comprise the majority of the programme of TPPTs (unlike Third-Party Organised Educational Conferences which are theoretical in nature). TPPTs are often referred to as "courses", rather than "conferences" or "seminars". Examples may include courses aimed at acquiring or improving the HCP's skills in minimally invasive surgery, orthopaedic trauma surgery, or the implantation of cardiac rhythm devices, etc.

The programme must be focused on acquiring specific medical skills relevant to certain medical procedures as opposed to products, or medical technologies. The programme must include practical sessions.

In order to be considered a TPPT, the practical sessions must in all cases represent more than 50% of the full programme and hands-on sessions must represent at least one-third of the full programme. These requirements must be clearly indicated in the TPPT programme.

The following will be considered as examples of practical sessions:

- Hands-on sessions in which all attendees to the TPPT participate actively. In these sessions, attendees perform specific procedures on settings and environments appropriate for the practice of the relevant procedure. Examples of hands-on sessions may include surgery simulations where the technologies relevant to the specialty are practiced on cadavers, skin models, synthetic bones, cath labs; etc. To ensure that attendants are able to fully benefit from the active aspects of hands-on sessions, no "station" (model, cadaver, table, etc.) can in principle have more than four participants. For ethical considerations, when human cadavers are used, up to eight participants may share a "station".
- Streaming (e.g. video, 3D-rendering software, augmented reality) or demonstrations of live surgeries.
- Case study sessions when the trainees learn about procedure preparations and best practices from specialty expert(s). These sessions must be interactive and based on pictures, videos, animations, 3D rendering software, augmented reality, etc.

2. Venue:

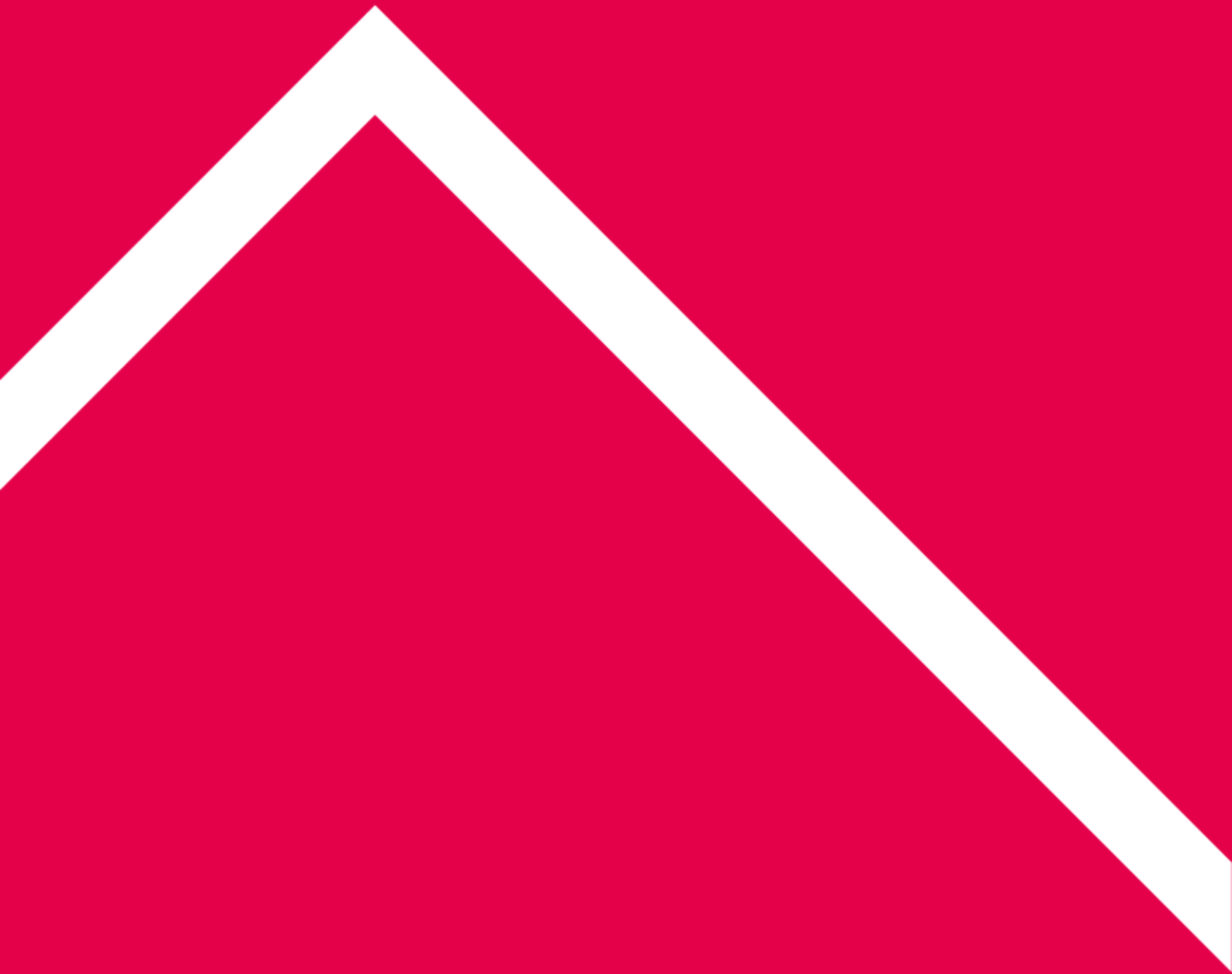
TPPTs' hands-on sessions are typically organised in either a clinical environment or in places suitable for medical procedures. Examples of a clinical environment include hospitals or clinics, where medical treatment on real patients is given (e.g. operating room, cath lab). Examples of simulation settings include conference or meeting rooms which are appropriately equipped with relevant simulation devices/systems, or experimental laboratories suitable for training on cadavers, skin models, synthetic bones, live animals in accordance to applicable regulations and ethical rules, etc.

3. Stand-alone event:

TPPTs must be stand-alone. Where the majority of the training is not given in a clinical environment, for example where the training is organised in connection with, adjacent to, or at the same time as a larger Third-Party Organised Educational Conference, that training will not qualify as a TPPT as defined in the Code.

4. Size:

Given the essential practical and hands-on element of a TPPT and given the fact that Member Companies would know the identity of the HCPs participating in the course, the size of such training is usually relatively small. However, provided that the above criteria are met, size may not be a determining factor.





ABHI

association of

**British HealthTech
Industries**

www.abhicodeofpractice.org.uk