MedTech Europe
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MedTech Europe Code of Ethical Business Practice

March 2022

What are the main changes?

Overview of the 2022 changes

General clean-up, re-organization, look & feel

No more reference to “gifts” – only “Promotional Items”

New chapter on Distributors

Clarification between Education Grants & commercial sponsorships

New guidance in Annex for in-kind Grants

New definitions in Glossary

Virtual Events

Addition of “collaborative research”

Consulting Arrangements applicable to HCOs & HCPs

New chapters consolidating the scope and governance rules of the Code

General clean-up

- Provided more context to some Chapters to add clarity. For example, the introduction of Chapter 1 was expanded to specify what can be done for each type of Event.
- Many Q&As were moved into the text of the Code
- Definitions from Q&As were moved to the Glossary
- The text of several Q&As was modified for clarity
- References were added to several standalone guidance documents (i.e., Patient Organisation Guidance, Placement of Equipment Guidance)
- The concepts of ‘restricted Educational Grants’ and ‘unrestricted Charitable Donations’ were removed. The rules are still the same regarding what can and can’t be done, but the names were removed to avoid confusion
- Old references were removed
- Renumeration of Q&As

Substance

- New Q&A specifying that Virtual Events are not affected by minimum duration of Events
- Virtual Events are now referenced in several areas of the Code, when relevant, if the rules are different for Virtual Events than for in-person ones. The rules have not changed, they are taken from the existing Virtual Events Guidance
- New Q&A on the difference Educational Grants and commercial sponsorships
- Chapter 5 on Consulting Arrangements is now also applicable to HCOs to avoid loopholes
- New Section in Chapter 6 on Collaborative research and a new Annex on the roles of the different parties in this type of research
- ‘Gifts’ renamed to ‘promotional items’ as they are the only acceptable gifts
- New Chapter on Distributors which consolidates all existing guidance and rules around them. The only change is a reinforcement of the obligation to contractually bind TPIs to the rules of the Code whenever possible
- Several new definitions were added to the Glossary
- New Annex on how to value in-kind Educational Grants for the purpose of disclosing them in TransparentMedTech

New design & layout

Chapter 1: General Criteria for Events

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 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:

- 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.
- The Event location and venue should be centrally located when regard is given to the place of residence of the majority of invited participants.
- The need for ease of access for attendees.
- 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.
- 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.

Q5 What is meant by "legitimate" or "genuine" as used in the definitions of 'Company Event' and 'Third Party Organised Educational Conferences'?

A5 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.

Q6 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 June 2017)

A6 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. Where an exception is considered, the Event's promotional material should not feature the on-site leisure aspects of the conference venue as a key attraction and the Event's agenda should be arranged in such a way that attending Healthcare Professionals would not be free to make use of the leisure and sporting facilities during any significant part of a normal working day. Further, where hotels require additional payment to use the leisure or sporting facilities, Member Companies may not make such payments on behalf of the Healthcare Professionals.

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Definitions are aligned and in the Glossary of the new Code

MEDTECH EUROPE – CODE OF ETHICAL BUSINESS PRACTICE

- **Charitable Donations**: means provision of cash, equipment, Member 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 to bona fide charities or other non-profit entities or bodies whose main objects are genuine charitable or philanthropic purposes.
- **Clinical Research**: a type of research that studies tests and treatments and evaluates their effects on human health outcomes. This includes clinical investigations or interventional and non-interventional clinical performance studies where people volunteer to take part in order to test medical interventions including drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments and preventive care.
- **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 MedTech Europe under the supervision of the MedTech Europe Compliance Panel. For more information see: http://www.ethicalmedtech.eu.

For more information on the 2022 Code

Material	Audience	Channel
Crosswalk	Internal (ECC + NAC)	Sharepoint & ethicalmedtech
One pager	Internal & external (e.g., HCO & PCOs; GMTA members; pharma)	MTE website
PowerPoint	Internal (ECC + NAC)	Sharepoint
Full training material	Internal (ECC + NAC)	Sharepoint
Recorded training session (Q2)	Internal (ECC + NAC)	Sharepoint
Press release (28 March)	General public	MTE website
Clean Code version	ALL	MTE website
Podcast (Q2 or Q3)	ALL	MTE website
Q&A document	Internal & external	Sharepoint & ethicalmedtech

Changes per Chapter

Chapter 1: General Criteria for Event

Changes

- More granularity was given to the introduction to make it more clear regarding what is and what isn't allowed in each type of event
- Ex Q&A 5 was moved into the text of the Code
- New Q&A 5 about duration requirements for virtual events was added
- In Sections 4 and 5, a clarification that hospitality and travel can be arranged around (i.e, slightly before of after) a Third Party Event to accommodate for attendance at Company Organised Events happing around them was added (This is currently allowed in chapter 3, change was introduced to avoid perception of contradiction)

Changes

- Q&A 12 was deleted as it is redundant with the previous addition
- Ex Q&A 13 was merged into the Code
- Minor language clarifications were made in ex Q&A 14
- New Section 7 introducing virtual events was added

Chapter 2: Third Party Organised Educational Events

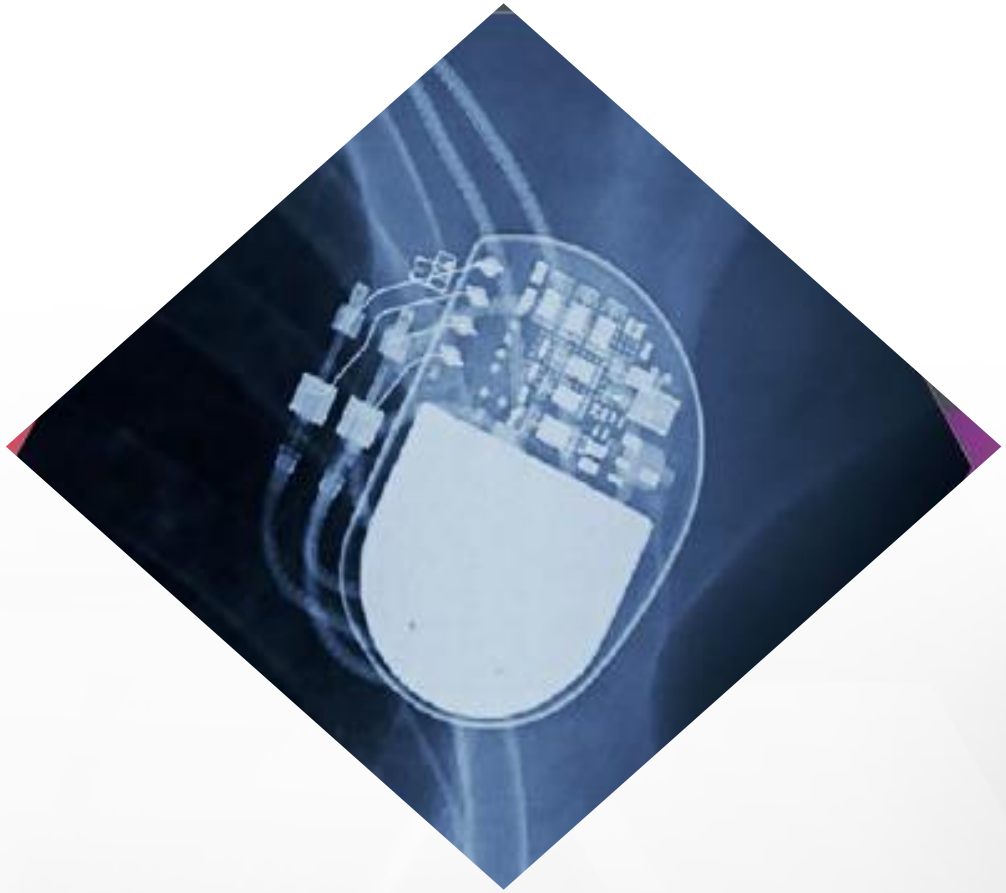
Changes

- The definitions of proctorship and preceptorship were moved to the Glossary. The part on CVS was left in ex Q&A 21
- The language in the answer of ex Q&A21bis was changed to make it easier to read. The principle has not changed.
- An additional bullet point was added to Section 2 (Third Party Procedure Trainings) to clarify that the hands-on part of these events cannot be made virtual, otherwise they cease to be considered as such. This is in line with the current guidance on Virtual Events.

Chapter 3: Company Events

Changes

- Ex Q&A 22 was merged into the text of the Code
- Title of Section 2 changed from "… and Education Events" to "… and Educational Events"
- Ex Q&A 23 moved to the text of the Code, in its own Section (Section 3)
- Ex Q&A24 was moved to the text of the Code, in its own subsection 2.1



Chapter 4: Grants and Charitable Donations

Changes

- A mention about the MTE Patient Organisation guidelines at the beginning of the Chapter was added
- A warning about the risk of providing repeated grants was added to letter b
- Ex letter d was moved to the text of new letter f
- The substantive part of ex Q&A 29 was moved to text in letter e. The examples were left in the QA (now 26)

Changes

- Ex Q&A 30 was moved to the text of the Code (now letter f)
- Ex Q&A 31 was moved to the text of letter g (ex letter f)
- The concept of “unrestricted” in Section 2 (charitable donations) was deleted. What “unrestricted” means and its implications on what companies can (or rather can’t) do is left in the text, but this concept was only used in this Section and was creating internal and external confusion.
- Ex Q&A 35 was moved to the text of the Code (now letter a of Section 2)

Changes

- The concept of “restricted” in section 3 was deleted (Educational Grants). What “restricted” means and its implications on what companies can (or rather can’t) do is left in the text, but this concept was only used in this Section and was creating internal and external confusion
- The answer of ex Q&A 33 was modified to avoid apparent contradiction
- New paragraph was added in Section 3, point 1) clarifying for the avoidance of doubt that Educational Grants to support HCP attendance to Third Party Events can cover travel, accommodation and hospitality

Changes

- Ex Q&A 38 was moved to the text of Section 3, letter a) point 1)
- New Q&A X on the difference between Educational Grants and commercial sponsorships was added
- Ex Q&A 38bis was moved to the text of the Code as new point 3) of Section 3, letter a).
- The answer of ex Q&A 37bis was amended to clarify that one criterion can be specific hospitals, provided the criteria do not then become so narrow that the recipients become identifiable

Changes

- Ex Q&A 41 was moved to the text of letter b) of Section 3 (scholarships and fellowships)
- Ex Q&A 42 was moved to the text of the Code as new letter c) of Section 3
- Section 4 (including ex Q&A 43bis) was moved to Chapter 6
- Ex Q&A 43 was moved to the text of letter d) (Grants for Public Awareness Campaigns)

Chapter 5: Consulting Arrangements

Changes

- The name of the Chapter was changed to Consulting Arrangements
- HCOs were added to the scope of the Chapter, and relevant part amended to reflect the change
- Language was added at the end of Section 1 to clarify that the decision to select a specific consultant cannot be sales driven, but that sales can be involved provided there are checks in place

Changes

- Clarified that the legitimate business need has to be identified prior engaging the consultant
- Some examples of criteria were added that can be used when selecting consultants
- The term “payment” was substituted by “compensation” across the Chapter

Changes

- A conflict of interest reminder was added to the criteria
- For the avoidance of doubt it was clarified that services and work products must be documented, and examples of what this documentation can be should be provided
- The definition of Fair Market Value was moved from ex Q&A 44 to the Glossary
- Ex Q&A 45 was moved to the text of the Code in Section 3

Chapter 6: Research

Changes

- An introduction was added to the Chapter
- A couple of additional examples of research consultancy services related to research were added
- An obligation to impose certain contractual obligations on CROs was added
- A couple of small language clarifications in Section 2 were added

Changes

- The Research Grants Section was moved from Chapter 4 to Chapter 6
  - Added “unduly” as in “do not unduly influence the research”.
  - Changed the last part to allow for grants to be provided before ethics committee approval provided it is legal in the jurisdiction at hand
- Ex Q&A 43bis was moved to Chapter 6
- A brand new section on Collaborative research was created
- Q&A X was added to Section 4.

Chapter 7: Royalties

No Changes

Chapter 8: Educational Items and Promotional Items

Changes

- “Gifts” were renamed to “Promotional items” without any change in the substance, but to avoid confusion a small introduction was added noting that gifts are prohibited, but that promotional and educational items might be provided
- Ex Q&A 48 was moved to the text of the Code as letter e) of Chapter 8
- Added new letter h) specifying that the educational/promotional item must not be intended mainly for personal use, reinforcing the idea that the item must be at least in pat for the benefit of the patient, although the HCP can use it personally if applicable (a pen, a notepad…)

Chapter 9: Demonstration Products and Samples

Changes

- Added a small remark at the end of Section 1 noting that the chapter is not intended to cover what is normally referred to as capital equipment, and a footnote was added mentioning the exiting MTE guidance on capital equipment for reference

New Chapter

Chapter 10: Third Party Intermediaries

New chapter on distributors

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 and/or services.

Accordingly, where such arrangements are entered into, and provided local laws and regulations allow it, Member Companies shall ensure that the relevant contractual documentation imposes obligations upon the Third Party Intermediary to comply with provisions set out in the Code and other applicable guidelines, as well as appropriate oversight to ensure this is duly implemented.

Risk Assessment

Member Companies should evaluate the risk profile for proposed and utilised Third Party Intermediary arrangements, including, for example, assessing:

- Risk in the relevant country, as well as specific risk profiles of planned or utilised Third Party Intermediaries;
- Information concerning local market legal and ethics requirements;
- Information from the Third Party Intermediaries for potentially unusual arrangements ; and
- Information available from public sources or employees for potential risks associated with the Third Party Intermediaries.

⇒ *N.B.:* No substantial changes, which came from the Eucomed/AdvaMed Third Party SMIs guidance

MedTech Europe Code of Ethical Business Practice Part 2:

Complaint handling and dispute resolution

Changes

- The procedural aspects of the Procedural Framework were left in this Section
- References to referral for questions of interpretation from national panels to the Compliance Panel were deleted
- Several provisions of no practical application were deleted

MedTech Europe Code of Ethical Business Practice Part 3:

Glossary and Definitions

Changes

The Q&A in Annex II was moved to the Disclosure Guidelines as Q&A 7, the Q&As were renumbered after that one

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