Ethical MedTech Launch

Brussels, 4th July 2017



Agenda

Welcome & Introduction

Key Requirements of MedTech Europe Code, including CVS

- Key changes
- What we have been doing since 6 months
 - New guidance
 - CVS new criteria & features

New initiative – Ethical Charter

- Overview
- Process
- S Coffee break
- Interactive session (review of case-studies with Industry Panel)
- Networking Drinks & Official Launch of Ethical MedTech



Introduction



HCO & PCO Outreach & discussions





Reminder – Six biggest changes







Phasing out direct sponsorship

Transparency of educational grants

Common chapter on general criteria for events



New chapter on demonstration products and samples



Agreed definitions

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Common independent enforcement mechanism



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Code structure

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

Chapter 1: General Criteria for Events

Chapter 2: Third Party Organised Educational Events

Chapter 3: Company Events

Chapter 4: Grants and Charitable Donations

Chapter 5: Arrangements with Consultants

Chapter 6: Research

Chapter 7: Royalties

Chapter 8: Educational Items and Gifts

Chapter 9: Demonstration Products and Samples

PART 2: Disclosure Guidelines

PART 3: Procedural Framework

PART 4: Glossary and Definitions

PART 5: Annexes



Latest guidance Recent Q&As



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?

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.





(A6. Cont.)

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.



Recent Q&As

(A6. Cont.)

For reasons of perception, cruise ships or hotels with on-site casinos are under no circumstances compliant with the Code, either as an Event venue or for accommodation for Healthcare Professionals.





Q8: Under the Code, how does the "season" impact evaluation of Event location or venue?

A8: 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 December 20 - March 31 <u>and the summer season from June 1 - September 15</u>. 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.



Q23: Can Member Companies directly support travel and/or accommodation or other expenses of individual Healthcare Professionals for passive attendance at Company Organised Education Events, happening during or around a Third-Party Organised Event?

A23: No, as of 1 January 2018, Member Companies cannot directly support travel and/or accommodation or other expenses of HCPs passively participating at Company Organised Education Events which take place **during**, **around**, **or at the same time and in the same approximate location** as a Third-Party Organised Event.

Company Events, for example Advisory Boards; Clinical Investigator meetings; but not Sales, Promotional and Other Business Meetings, may be organised at or around a Third Party Organised Event for reasons of convenience, given the attendance of HCPs at that Third-Party Organised Event.

In such circumstances, the Member Company may only pay for the contractual remuneration and expenses agreed for the provision of the services by the HCP at the Company Organised Education Event. Under no circumstances may a Member Company pay for a registration fee, travel, accommodation or any other costs associated with the Third Party Organised Event.



Example of a case Q&A 23:

A Company can organise a Product Training meeting around a conference, but they will not be able to directly support the attendance of HCPs to the training (as they otherwise could).

If an HCP who is under a consultancy agreement with a company happens to be attending a conference, and to take advantage of the presence of the HCP at that location the company decides to organise an advisory board meeting there, they could only pay for the concepts specified in the consultancy agreement, and never for any additional costs associated to the Conference.



Q38: 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?

A38: 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.



(cont.)

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 that 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.



Procedural Framework – Dispute resolution mechanism

- Disputes are best resolved amicably and efficiently by conciliation, mediation or mutual settlement;
- Disputes are generally best handled by national panels subject to certain exceptions.

Independent Compliance Panel



Nancy Russotto (Chair)





David Horne



Conference Vetting System New features



What is the Conference Vetting System?

- A centralised decision-making system that reviews the compliance of third-party educational events with the MedTech Europe Code of Ethical Business Practice to determine the appropriateness for companies which are members of MedTech Europe and members of the national associations affiliated with MedTech Europe to financially support such events with educational grants or through commercial activities.
- CVS renders a binding decision for MedTech Europe and members of the national associations affiliated with MedTech Europe as well a Mecomed members (The medical devices, imaging and diagnostics trade association in the Middle East).
- The system operates independently of MedTech Europe to ensure objectivity in events assessments, under the supervision of the Compliance Panel.
- Separate website & visual identity: <u>www.ethicalmedtech.eu</u>.



www.ethicalmedtech.eu

- So No longer hosts only The Conference Vetting System.
- So Now hosts all MedTech Europe initiatives in ethics and compliance.



S New visual identity.





5 Years of CVS?



Submissions of Third Party Educational Events are mandatory

No MedTech Europe member can provide financial support to an event that hasn't been prior assessed by CVS.

S Faster assessment route for Chartered organisations

- S Chartered organisation have the presumption of knowledge
 - Preliminary assessment of limited number of criteria

Sew system functionalities

- S Enhanced application form
- Onique Event ID throughout the process
 - Pre-Cleared events can be moved to regular submission => possibility to add file via the system
- G Communication box
- Appeal function



Segroupment of assessment criteria into 6 categories





- Introduction new color coding orange
 - S Provisional status event presenting non compliant criteria not showing as not compliant

CVS Event Calendar

🗧 Compliant 🗧 Correction notice 🗧 Non compliant 🗧 Provisionally compliant 🔳 To be reviewed 📄 Not assessed

- Inciple of perception
 - S Ex: Venue with in-house casino, regardless of nature of management, of whether or not the premise can be closed for the duration of the event will not be accepted under CVS.
- Solution New Q&A regarding seasonality, appropriateness of venue
- S Eligibility of events to be assessed
 - Sevents to which passive delegates are from at least two countries of the MedTech Geographic scope
 - Intent : Do organisers <u>aim</u> at having a pan-European/international attendance?





- What type of support for which type of event?
 - G Educational grants
 - S To support general running of the event
 - Includes funds to support HCPs
 - Includes funds to support Faculties
 - G Commercial Activities
 - Speakers consultanc
 - Sooths/advertising

			PRIOR CVS	SUBMISSION	
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WHICH TYPE OF SUPPORT CAN MEMBER COMPANIES PROVIDE TO WHICH THIRD PARTY ORGANISED EDUCATIONAL EVENTS?		NATIONAL Third Party Organised Educational Events attended by delegates which are local HCPs only)	INTERNATIONAL (Third Party Organised Educational Events attended by delegates coming from at least two countries of the MedTech Europe Geographic Area ^{1,2})	INTERNATIONAL (Third Party Organised Educational Events attended by delegates who are Healthcare Professionals registered and practising in the MedTech Europe Geographic Area ²)	INTERNATIONAL (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	Educational Grant to support the general running of a conference	2017 – Allowed ⁵ . 2018 – Allowed.	2017 – Allowed. Not subject to CVS decision 2018 – Subject to CVS decision	2017 – Allowed. Not subject to CVS decision 2018 – Allowed. Not subject to CVS decision	Out of scope of the application of the Code ⁶
PROVIDED TO SUPPORT A THIRD PARTY	Educational Grants that includes funds to support	2017 – Allowed.	2017 – Allowed. Not subject to CVS decision	2017 – Allowed. Not subject to CVS decision	NA



Ethical Charter Why? What? How?



Communication Process Overview





Ethical Charter – Mission



Certified Trusted Partners





New online platform: www.ethicalmedtech.org



LAUNCH DATE 4 JULY 2017

About Us Conference Vetting System Transparent MedTech Ethical Charter MedTech Codes

EthicalMedTech is a platform, supported by MedTech Europe, dedicated to ethics and compliance projects

in the MedTech industry.

Conference Vetting System

A unique initiative that assesses the conformity of third-party educational events with the MedTech Europe Code.

ACCESS

Transparent MedTech

A European centralised platform for MedTech companies to disclose publicly the financial support they provide to independent medical education.

ACCESS

Ethical Charter

A voluntary certification initiative to raise awareness of industry's ethical standards among third-parties organising Events and eventually facilitate industry's support to independent medical education.

ACCESS



Ethical Charter – Two pillars



Ethical Charter

A voluntary certification system showing third parties' commitment to comply with MedTech Europe's ethical standards when interacting with industry which will facilitate their support to independent medical education.



- Voluntary certification system displaying HCOs/PCOs' engagement to comply with MTE Code when organising educational conferences.
- The Ethical Charter provides a Trusted Partner logo valid for a duration of maximum two years, renewable. The logo will also provide a presumption of compliance for the Events which are eligible to be assessed under the CVS.



Ethical Charter – A walk through the online process





STEP 1 – *How to apply?*

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Ethical MedTech MedTech Europe compliance portal

About Us Conference Vetting System Transparent MedTech Ethical Charter National Associations' Codes Resources

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Application = Expression of Interest

🧐 GENERAL OVERVIEW – EL 🗙

Ethical MedTech MedTech Europe compliance portal

About Us Conference Vetting System Transparent MedTech Ethical Charter National Associations' Codes Resources

Ethical Charter

GENERAL OVERVIEW

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GENERAL OVERVIEW

ACCESS YOUR ACCOUNT

OBJECTIVE & SCOPE

EXPRESSION OF INTEREST

The MedTech Europe Code of Ethical Business Practice which came into force on 1 January 2017 regulates all aspects of the MedTech industry's relationships with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs). One important change introduced by the Code which will only be applicable as of 1 January 2018 is discontinuation of direct sponsorship of ICPs. As of that date, independent medical education has to be supported exclusively by means of Educational Grants. uch Educational Grants can be provided to Healthcare Organisations (HCOs) or Professional Congress Organisers (PCOs).

order to allow these organisations to demonstrate their commitment to the ethical standards included in the Code to the industry partners, MedTech Europe set up the Ethical Charter, which is a voluntary certification initiative.

Upon completion of a three-step process, the Ethical Charter provides to HCOs and PCOs a Trusted Partner logo valid for renewable periods of two years. Acquisition of the logo is a presumption of compliance, on which Events Organisers can capitalise to obtain quicker assessment of their Events eligible to be assessed under the Conference Vetting System.

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MedTech Europe from diagnosis to cure

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Step 2 - Select/Add staff member(s)

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PARTICIPANT 1 STAFF MEMBER NAME			
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Email notifications to Leader & Participants

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Dear CLARISSE AILLET

Thanks for submitting the Expression of Interest on behalf of your organisation, and expressing your interest in the Ethical Charter. This notification email marks the official start of the registration process for your organisation.

Your Details Are: ORGANISATION: CA CONSULT FIRST NAME: CLARISSE FAMILY NAME: AILLET POSITION: CONSULTANT ORGANISATION ADDRESS: PERMEKE 21 - 1050 BRUSSELS - BELGIUM

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EMAIL: c.aillet@medtecheurope.org UNIQUE IDENTIFIER: #0002231 LOGIN: c.aillet@medtecheurope.org PASSWORD: cf567ab23d

A unique identifier and a unique user account have been automatically created for your organisation, with a login and a password. Please keep them carefully. The following users have been invited to join the Ethical Charter process. Each participant has received an email notification and is invited to access the online webinar and the online self-assessment

FIRST NAME: sofia FAMILY NAME: smith POSITION: consultant events EMAIL: clarisse aillet@hotmail.com

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The webinar and the self-assessment can be accessed through the links below or through the user account. **Online Webinar:** <u>http://ethical.dev.acw.website//ethical-charter/ethical-charter-login/webinsar</u>

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STEP 3 – Access the online webinar

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OPTION 1: FROM EMAIL NOTIFICATION – LINK TO WEBINAR

OPTION 2: FROM THE WEBSITE – ACCESS YOUR ACCOUNT SECTION



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G. J. ■ FRA 03/07/2017



Ethical Charter User Account





Ethical Charter User Account

Summary of Expression	n of interest	elcome, Clarisse!
Unique Identifi Submitted by Date 04/05/2017 Name Josh Smith Company Name Position Director	Email josh@company.com Phone +44 2040 505 393 Address 768 Hill Road, NW23 9HJ London, UK	Leader & Organisation details
Porticipont 1 Name Adam Kuroda Position Marketing Supervisor	Email josh@company.com Invitation status: Read Phone +44 2040 505 398 Self-Asessment Status: © Address 768 Hill Road, NW23 9Hj London, UK Self-Asessment Attempts: 1	Invitation Status and Self-Assessment
Participant 1 Name Adam Kuroda Position Marketing Supervisor	Email josh@company.com Invitation status: Read Phone +44 2040 505 393 Self-Asessment Status: Address 768 Hill Road, NW23 9HJ London, UK Self-Asessment Attempts: 1	Attempts have been added to the original copy
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Download Documents		This section will
Ethical Charter	Ethical Charter Logo [SUBMIT AN EVENT]	THIS SECTOR WILL



STEP 3 – online webinar & self-assessment





STEP 4 - User Account: Follow the progress





STEP 4 – Charter Signature & Logo delivery

AGREEMENT VALID 2 YEARS, unless major team turn-over (contact us!)

AGREEMENT NEEDS TO BE RENEWED (reminder sent via automatic email notification)



ORGANISATION NAME PUBLICLY DISPLAYED ON ETHICAL MEDTECH WEBSITE

Section Chartered Organisations (to be published soon)



Interactive session Case-studies discussion



Case Study I

- The European Society of Medicine (ESM), a Scientific Society based in London is planning a 5-day pan-European event to take place from Sunday 2 – Thursday 6 September 2018 at the Fira convention centre in Barcelona, Spain.
- It seeks to obtain financial support for both educational and commercial activities. For this purpose it is considering how to approach members of MedTech Europe in the light of the new rules introduced by the MedTech Europe Code of Ethical Business Practice.
- In the proposed packages ESM is offering to their industry partners, they include different benefits such as: booth spaces, placement in marketing material, complementary registrations for staff, support to HCP attendance as well as support to speakers in certain sessions.
- To build a more robust scientific programme, ESM is asking industry partners for speaker and KOL references.
- After the Event, one the industry partners is requesting the list of names of HCPs that benefitted from the support of the package they contracted on the basis that they need to perform a post-event verification of the use of the funds



Case Study II

- Some the started planning another educational event which will take place in Switzerland at the end of 2019.
- They are approached by a MedTech Europe member to co-brand such event and provide an Educational Grant that would support attendance of HCPs coming from Germany, France, Italy and Sweden.
- The Event will still be designed and driven by ESM, who has however outsourced the organisation of the Event to a local PCO whom will be the recipient of all industry financial support.
- The PCO is going to charge the ESM for the HCP travel and accomodation arrangements, and the ESM is asking for these costs to be covered in the offered packages.
- Later on, another industry partner interested in supporting the Event but who is only active in Italy approaches ESM to see if it would be possible to restrict their support to Italian HCPs, and more specifically, to those that practice medicine in their specific sector of interest.



FOR MORE INFORMATION

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MedTech Europe Legal & Compliance team