MedTech Europe Code of Ethical Business Practice

Summary

Background

- The MedTech Europe Code of Ethical Business Practice ("the Code") was adopted in December 2015 by the Members of EDMA and Eucomed (forming the MedTech Europe alliance representing the Medical Device and In-Vitro Diagnostics industries).

- Eucomed has been discussing the revision of its Code of Ethical Business Practices since 2011 and in particular industry's practice of engaging with Healthcare Professionals (HCPs) in view of a changing and increasingly more scrutinizing environment worldwide.

- EDMA and Eucomed decided in January 2014 to revise their respective codes of ethics and adopt a common code for Eucomed and EDMA members. This code will be referred to as the MedTech Europe (MTE) Code of Ethical Business Practice.

- Since 30 November 2016, after four years of successful alliance, EDMA and Eucomed members voted to dissolve their respective European associations and create a new MedTech Europe single entity, representing the medical technology sector in Europe, from diagnosis to cure. As a consequence, EDMA and Eucomed no longer exist.

What is at stake? Protecting industry's reputation

- **Compliance with existing laws is not sufficient to protect the integrity and reputation** of the industry.

- Regulators, other trade associations, HCP groups and companies **are taking action,** and the MedTech industry has been asked to take position.

- The relationship with Healthcare Professionals (HCPs) has many different components (e.g. product development, training), however **one aspect is harder to justify** from a public opinion perspective: the **support** by industry **of individual HCPs / customers to attend third-party organised congresses**.

- The European MedTech industry **strategy** is based on **a European, pro-active and stringent self-regulation.**

- The European MedTech Industry wishes to **establish its own set of rules and create a level playing field**, with common rules across the EU and all Members.

Key elements of the change

The Code covers all types of interactions between the MedTech industry and Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs), such as Research and Consulting Agreements, Samples, Gifts as well as support of HCPs to attend Product Trainings or Third-Party Organised Conferences. However, the most controversial aspect is the following:

1. [Phasing-out by 1 January 2018 of **direct sponsorship**](#) of HCPs attending Third-Party Organised Conferences as either delegates or Faculty[1].

2. [Introduction on 1 January 2017 of a controlled framework with stringent rules for **indirect sponsorship, i.e. Educational Grants**](#). The key elements of this framework are the following:

   - Grants can only be provided to legal entities, i.e. Healthcare Organisations (HCOs), not individuals.

   - Grants will need a written contract with the HCO, defining the grant's purpose, use and obligations of grant recipients.

   - Whilst companies will not be allowed to identify individual recipients of the grants, they will be allowed to define the type of recipients (e.g. young Romanian HCPs).

   - Grants will be made public on a European platform ("MedTech Transparency").

   - Conference will need to comply with the requirements laid out in the revised Code, and if applicable the [Conference Vetting System](#) (CVS).

   - Companies will need to have an internal process based on objective and transparent criteria to assess the grant request, including a decision process at "arm's length".
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   - The same principles apply to educational support provided to Professional Congress Organisers (PCOs) acting independently of HCOs.

What does this mean for HCOs and PCOs?

1. Since 1 January 2017, Corporate Members of MedTech Europe have transposed the new Code internally and have started to apply more stringent rules when providing financial support to HCOs and PCOs for the independent medical education of HCPs.

2. Outreach to medical societies, hospital organisations and Professional Congress Organisers (PCOs) is ongoing since April 2014 and aim at clarying any questions they may have on the new Code.

3. A new initiative will be launched in Q2 2017, the **Ethical Charter,** which aims at ensuring that PCO/HCO seeking financial support for their Third Party Educational Events from MedTech Europe Corporate Members are "Trusted Partners", i.e. are:

   - Knowledgeable of the provisions of MedTech Europe Code;
   - Organising their educational events in accordance with the Code's rules;
   - Applying the highest ethical standards in their interaction with industry.

Contact person

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[1] Financial support of faculty at satellite symposia is excluded of the scope.