

Reinforcing the EDMA and Eucomed Codes of Ethical Business Practice

Key Definitions

Healthcare Professionals

Healthcare Professionals are individuals (clinical or non-clinical, including but not limited to, physicians, nurses, technicians, biologists and research co-ordinators) or entities (such as hospitals or group purchasing bodies) that directly or indirectly purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe members' medical technologies.

Direct Sponsorship

Direct sponsorship of HCPs to attend as delegate third-party organised medical educational conferences refers to the payment by companies of some or all of the following: travel, lodging, and/or conference registration fees. These costs are either reimbursed to the HCP or paid directly by the company via the purchase of travel tickets, payment of hotel expenses and/or of the registration fee to the conference organiser.

Indirect Sponsorship

Indirect sponsorship functions, for the most part, via grants to medical societies, hospitals, conference organisers or, much less frequently, to governmental bodies who then allocate the funds to pay certain expenses of HCPs to attend third-party medical education conferences. The relationship between the granting company and the recipient of the funds is governed by a contract but generally speaking, recipients of the grant determine independently which HCPs will be invited to attend.

Active conference attendee

Active conference attendees, often called "faculty", are those HCPs who speak, present or serve another specific function at a third-party organised medical educational conference.

Passive conference attendee

A passive attendee is someone who is not faculty, and therefore does not have a specific active role at a third-party organised medical educational conference.

Questions & Answers (updated 15 October 2014)

1. What are “Codes of Ethical Business Practice” and why have EDMA and Eucomed decided to reinforce theirs?

For medical technology companies, interacting with Healthcare Professionals (HCPs) is a key component of their day-to-day activities. HCPs are an integral part of the R&D process and a source of innovation and creativity during the development of medical devices. HCPs are also the prime users of technologies and play an instrumental role in their successful adoption throughout Europe and beyond. Companies are also required to provide HCPs with appropriate instruction, education, training, service and technical support to ensure delivery of modern, safe and effective medical technology and care to patients.

The Eucomed and EDMA Codes of Ethical Business Practice (often referred to simply as the “Codes”) are intended to provide the minimum ethical standards for the medical technology industry’s interactions with HCPs. All Eucomed and EDMA members must adhere to the Codes as a condition of association membership.

EDMA and Eucomed strive to continuously reinforce and improve their Codes to account for the rapidly changing legal and compliance landscape in which the MedTech industry operates. EDMA and Eucomed are committed to adopting Codes which will set up-to-date and high ethical standards for industry-HCP relationships.

2. What have the EDMA Executive Committee and Eucomed Board recommended as part of the review of their respective Codes?

The EDMA Executive Committee and the Eucomed Board are recommending to their respective memberships a phase out of direct sponsorship of passive attendance of healthcare professionals (HCPs) to third-party organised conferences by 1 January 2018 as part of a continuous effort to reinforce their Codes of Ethical Business Practice.

Additionally and of equal importance, stricter self-regulation of *indirect sponsorship* activities are also currently being developed. The EDMA Executive Committee and the Eucomed Board are also recommending that these new rules on indirect sponsorship enter into force as soon as possible.

3. When could these recommendations potentially be adopted?

The revised Codes will be proposed for adoption at the General Assemblies of Eucomed, EDMA and MedTech Europe in November 2015.

4. What do you mean by the “MedTech Europe Code of Ethical Business Practice?”

In 2012, EDMA and Eucomed joined forces to create MedTech Europe, an alliance of the two organisations which in the future may also include other medical technology industry associations.

EDMA and Eucomed collaborate closely on ethics and compliance issues and have therefore decided that their revised Codes will jointly be referred to as the MedTech Europe Code of Ethical Business Practice.

5. If the recommendations are adopted, will the MedTech industry continue to support the continuing medical education of HCPs?

EDMA, Eucomed and MedTech Europe remain fully committed to supporting continuing medical education (CME) for HCPs. The associations have already begun and will intensify a comprehensive consultation process with HCP organisations and other relevant stakeholders at European and national levels to discuss alternative models of CME and alleviate the potential impact that the recommendation may have on CME support.

6. If the recommendations are adopted, will all Healthcare Professionals (HCPs) be ineligible for direct sponsorship?

Any HCP, falling under the above definition, who is a “passive” attendee/delegate at a third-party organised medical educational conference, will be ineligible to receive direct sponsorship. A passive attendee is someone who is not faculty, and therefore does not have a specific active role at a conference.

Active attendees, often called “faculty”, are those HCPs who will speak, present or serve another specific function at a third-party organised conference. Active attendees may still be eligible for direct sponsorship under specific rules. A recommendation is currently being developed on this topic.

7. If the recommendations are adopted, will companies be permitted to directly sponsor HCPs for company events focused on product training?

Industry has a responsibility to train healthcare professionals on the use of their products and relevant surgical procedures in order to ensure maximum safety for patients. As such, industry will continue to directly sponsor HCPs for these purposes in compliance with very strict criteria which is already included in the Code and which will be reinforced in the new Code.

8. If the recommendations are adopted, will companies be permitted to directly sponsor HCP attendance to satellite symposia (i.e. company events organised on the margins of third-party organised conferences)?

No, direct sponsorship will not be allowed for these satellite symposia.

9. If the recommendations are adopted, will all members of EDMA and Eucomed have to abide by the revised EDMA and Eucomed Codes of Ethical Business Practice (jointly referred to as the MedTech Europe Code of Ethical Business Practice)?

Yes, the recommendation to phase out direct sponsorship has been taken jointly by the EDMA Executive Committee and the Eucomed Board. If agreed by the General Assemblies of both organisations in November 2015, all members of EDMA and Eucomed will be bound by their respective revised Codes (jointly referred to as the MedTech Europe Code of Ethical Business Practice), which will then have to be transposed by members within their own organisations.

10. If the recommendations are adopted, will National Association members of both EDMA and Eucomed and their respective members also be bound by the new Code?

National Association members have also agreed to the EDMA and/or Eucomed Codes as a condition of membership. National Association members will therefore have to transpose the new Code nationally and enforce it among their own members.

The recommended three-year phase out period will provide the opportunity for EDMA and Eucomed to work closely with their members to develop best practices and ensure a smooth transition.

11. If the recommendations are adopted, what will be the geographical scope of the revised EDMA and Eucomed Codes (jointly referred to as the MedTech Europe Code of Ethical Business Practice)?

As all members of Eucomed and EDMA, including Associate members, must commit to upholding their respective Codes as a condition of membership, the scope will include all territories in which Eucomed and EDMA have National or Regional association members and Associate members.

A comprehensive list of countries covered by our network of National Associations and Associate members will be provided.

12. If the recommendations are adopted, will a non-European affiliate of an EDMA or Eucomed member company be permitted to provide direct sponsorship to a European HCP for a conference held outside the geographical scope?

Affiliates of any member company are bound by the Code, which applies to interactions with any European HCP practicing in Europe. Affiliates would therefore not be permitted to provide direct sponsorship for “passive” HCP attendees of third-party organised medical educational conferences.

13. Eucomed and EDMA have less than 200 corporate members: How will they govern the thousands of MedTech companies that are not members of Eucomed, EDMA or a National Association?

Eucomed and EDMA cannot impose their Codes on companies that are non-members. We must lead by example and strongly urge non-member companies across the industry to consider the need to adapt their practices given the rapidly changing compliance landscape and the need to uphold the reputation of the industry.

We will also continue our practice of providing advice to non-members seeking to understand our Codes and how to implement them within their companies.

14. Will non-members of Eucomed and EDMA gain an advantage over member companies, because they are not bound by the same rules?

We believe that ethical business practices are a fundamental of long term business sustainability and that the implementation of the new Code will create a more level playing field across the MedTech industry.

Over the next three years, we also plan to elaborate good alternatives to direct sponsorship ensuring that our industry's essential relationship with HCPs endures.

15. How will EDMA and Eucomed enforce their new code?

Both EDMA and Eucomed currently have dispute resolution mechanisms in place, which include a range of sanctions. This is also the case with most National Association members. In the new EDMA, Eucomed and MedTech Europe Codes, such a mechanism will be common and independent.

16. Do EDMA and Eucomed run the risk of losing members who do not want to apply the Code?

Some members may decide to withdraw their membership from EDMA or Eucomed. We will of course be ready to help them understand the benefits of implementing the Code as well as the many other benefits they gain in being part of either EDMA and/or Eucomed.

17. In countries where legislation has imposed a form of transparency, which will take precedence: the national legislation or the MedTech Europe Code?

The MedTech Europe Code underlines that compliance with all applicable laws and regulations is a pre-requisite. The Code will serve as the minimum standard across Europe and in some countries may be even more stringent than national legislation. We will work with national associations and companies to assist when questions arise about the implementation of the Code vs their national legislation.

18. Will the Eucomed Conference Vetting System remain operational if the revisions to the Code are adopted?

The independent Conference Vetting System has proven to be a very useful mechanism for Eucomed member companies and other stakeholders in determining the appropriateness of providing direct sponsorship to HCPs attending third-party organised medical educational conferences, allowing them to self-regulate in a clear and transparent way.

The Conference Vetting System will remain operational at least until the phase out of direct sponsorship is complete. Over the next 12 months, we will also discuss what future role the system might have under the revised EDMA, Eucomed and MedTech Europe Codes.

19. Will companies be permitted to self-regulate regarding other items such as gifts and hospitality (e.g. meals) for HCPs?

The Eucomed and EDMA Codes currently strictly regulate appropriate gifts and hospitality. These provisions will be revised under the revised Codes to ensure appropriateness and maximum clarity.

20. Indirect sponsorship also entails compliance risks, how will you mitigate those?

Self-regulation will be essential to mitigating the risks associated with indirect sponsorship. The MedTech Europe Code will provide clear, strict guidelines to ensure that the necessary safeguards are in place in member companies.

21. Why has the MedTech industry chosen not to recommend a “full disclosure” option similar to the one implemented by EFPIA, the European pharmaceutical association?

The option of “full disclosure”, as adopted by EFPIA, has been given serious consideration by both the EDMA Executive Committee and the Eucomed Board. However, specifically for the direct sponsorship of HCPs to third-party medical educational conferences, both the EDMA Executive Committee and the Eucomed Board have concluded that such a system may not be the most effective way to address the inherent compliance risk related to providing a benefit to HCPs when supporting them directly to conferences. Both EDMA and Eucomed hold the opinion that the progressive phasing out of direct sponsorship is a more effective approach.

The EDMA and Eucomed Codes of Business Practice, which also cover other elements of the relationship between industry and HCPs, are currently being reviewed and will be adapted to reflect the changing legal and compliance environment.