Dear Members,

The European compliance landscape in which the Medical Technology industry operates is changing rapidly. As our industry is becoming increasingly visible, we need to guard and promote our integrity.

The current model of direct sponsorship (see definition below) of passive attendance of Healthcare Professionals (HCPs) to third party organised conferences is a model which is questioned by judicial authorities, HCPs and more generally the public as it carries an inherent compliance risk of a unilateral benefit to HCPs. In parallel, we see that different countries are progressively introducing measures to regulate and limit industry relationships with HCPs.

After more than a year of careful consideration, listening to our members and stakeholders, and a thorough analysis of the implications of different ways forward, both the EDMA Executive Committee and the Eucomed Board believe that phasing out direct sponsorship while at the same time swiftly introducing stricter rules for indirect sponsorship (see definition below) is the best way forward for our industry in the long run.

The EDMA Executive Committee and the Eucomed Board are therefore recommending to their respective memberships to phase out direct sponsorship of Healthcare Professionals to third-party organised conferences over a three-year period with view to ending all such sponsorships by 1 January 2018.

In addition, stricter self-regulation of indirect sponsorship activities is already being developed by the responsible working groups with the recommendation to enter into force as soon as possible, and before 1 January 2018.

Other aspects of the relationship between industry and HCPs covered in the EDMA and Eucomed Codes of Business Practice are being reviewed and adapted to reflect the new compliance environment.

This will lead to a significant revision of the EDMA and Eucomed Codes of Business Practice, which will provide a set of minimum ethical standards and principles for the MedTech industry in Europe. The revised EDMA and Eucomed Codes will be jointly referred to as the MedTech Europe Code. The Codes, to which all EDMA and Eucomed members will be bound, will be proposed for adoption at the 2015 General Assembly of Eucomed and EDMA (November 2015).

Both the EDMA Executive Committee and the Eucomed Board have instructed the MedTech Europe Secretariat to immediately begin preparing for an effective implementation of this important change and to use the next 12 months to intensify its ongoing consultation with HCPs organisations, other healthcare partners as well as members (national associations and corporate members). The consultation process will focus particularly on alternative future models of continued education, to which the MedTech Industry remains committed and in which it will continue to be engaged.

In the next few weeks we will inform our external stakeholders of the above plan.

Jürgen Schulze, EDMA President
Rob Ten Hoedt, Eucomed Chairman

Serge Bernasconi, EDMA & Eucomed CEO
Key Definitions

**Direct sponsorship** of HCPs to attend as delegate medical education conferences refers to the direct payment by companies of some or all of the following: travel, lodging, 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** 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 that is more or less detailed but, in general, recipients of the grant determine independently which HCPs will be invited to attend.

**Healthcare Professionals (HCPs)** 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.
Questions & Answers

1. **Will all categories of Healthcare Professionals (HCPs) be ineligible for direct sponsorship?**

   Any HCP, falling in the definition above, who is a “passive” attendee/delegate at a third-party organised 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, may still be eligible for direct sponsorship under specific rules.

   It should however be noted that already currently, the recommended set up for support of faculty is to provide financial grants directly to the conference organiser to cover overall costs of attendance, reasonable honoraria, travel, meals and accommodation expenses.

2. **Will companies be permitted to directly sponsor HCPs for company events focused on product training?**

   Industry has a responsibility to train physicians 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.

3. **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. However, direct sponsorship of faculty will be permitted under specific rules.

4. **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, as MedTech Europe. 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).
5. **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 implement the new Code nationally and enforce it among their own members.

The three years phase out period will provide the opportunity to work with National Association to best make such transition.

6. **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.

7. **Under the new Codes, will it be permitted for a non-European affiliate of an EDMA or Eucomed member company 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 same Code and therefore may not provide direct sponsorship for “passive” HCP attendees of third-party organised educational conferences.

Given the complexity of this issue, however, the subject will be the topic for a recommendation by the Compliance Network during upcoming phase out period.

8. **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?**

We cannot impose our code 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.
9. 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 prosperity and that the implementation of the new Code will actually 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.

Once the new Codes are adopted, EDMA, Eucomed and MedTech Europe will actively communicate them to internal and external stakeholders.

10. Is such a change of Code legal from a competition law perspective?

We have engaged specialised external legal counsel to support EDMA, Eucomed and MedTech Europe in ensuring that all of our activities, including change to the Codes are compliant with competition law.

11. How will EDMA, Eucomed and MedTech Europe handle a member’s non-compliance with the Code?

Both EDMA and Eucomed currently have dispute resolution mechanisms in place, which include a range of sanctions. In the new EDMA, Eucomed and MedTech Europe Codes, such a mechanism will be common and independent.

12. 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.

13. 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 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.

14. Will the Eucomed Conference Vetting System remain operational?

The independent Conference Vetting System has proven to be a very useful mechanism for companies and other stakeholders in determining the appropriateness of providing direct
sponsorship for HCPs to attend third-party organised 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.

15. 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 maximum clarity.

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

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

17. Why has the MedTech industry chosen not to adopt 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 conferences both EDMA and Eucomed concluded that such a system does not effectively address the inherent compliance risk related to providing a unilateral benefit to HCPs. 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, that also cover other elements of the relationship between industry and HCPs, are currently being reviewed and will be adapted to reflect the new compliance environment.