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MedTech Europe Calls for the End of Direct Sponsorship



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Abstract: On October 15, 2014, the Executive Committee of the European Diagnostics Manufacturers Association (EDMA) and the Board of the European Medical Technology Industry Association (Eucomed) formally recommended to their members that they phase out "direct sponsorship" by January 1, 2018. "Direct sponsorship" refers to a company selecting and sponsoring a health care professional to attend a conference hosted by a third party (e.g., a CME seminar). This is a significant decision, as direct sponsorship is common in Europe. The decision signals a shift towards stricter controls on interactions between health care professionals and companies, to avoid even the appearance of impropriety. Additionally, the decision brings Eucomed and EDMA in line with their U.S. counterpart, AdvaMed, which does not support direct sponsorship by member companies. This article will briefly examine the evolution of direct sponsorship and the reasons behind Eucomed's decision to phase the practice out. The article will also examine: (1) the effects the decision will have on medical technology companies doing business in Europe and other markets; and (2) alternate ways for medical technology companies to support continuing education for health care professionals.

On October 15, 2014, MedTech Europe formally recommended that member companies phase out direct sponsorship of health care professionals (HCPs) by January 1, 2018.¹ MedTech Europe is an alliance founded by two trade associations—(1) the European Diagnostics Manufacturers Association (EDMA), which represents the interests of the medical in vitro diagnostics industry in Europe, and (2) the European Medical Technology Industry Association (Eucomed), which represents the medical device industry in Europe. The recommendation is the latest move in a global trend toward increased transparency in interactions between the medical technology industry and HCPs.

¹ Press Release, MedTech Europe, *European MedTech Industry Continues to Reinforce Its Codes of Ethical Business Practice* (Oct. 15, 2014), <http://www.medtecheurope.org/mediaroom/139/110/European-MedTech-industry-continues-to-reinforce-its-Codes-of-Ethical-Business-Practice?cntnt01template=detail-pr> (last visited Jan. 14, 2015).

Most HCPs keep their knowledge and skills current and satisfy some licensing requirements through continuing medical education (CME), and they often rely on companies in the industry to provide this education. Medical technology companies may provide continued education by hosting their own live events. Alternatively, companies may sponsor an HCP to attend an educational conference hosted by a third-party organizer.² These sponsorships may be direct or indirect. Direct sponsorship, which generally refers to a company selecting and sponsoring an HCP to attend a conference organized by a third party, is currently permissible under the MedTech Europe Code of Ethical Business Practice. Through direct sponsorship, companies may provide financial support to individual HCPs, limited to the conference registration fee and reasonable hospitality expenses. Indirect sponsorship, by contrast, refers to a company giving money to the third-party conference host to defray the overall cost of the conference for attendees (e.g., reducing or eliminating the tuition that would otherwise be paid). Under indirect sponsorship, the company-donor has no control over which particular HCPs receive the benefit of its contribution.

² Under MedTech Europe's recommendation, only HCPs who are passive attendees at third-party conferences will be ineligible for direct sponsorship. Active attendees, who will speak or present at the third-party conference, will not be subject to the prohibition, although they will be subject to other rules currently being developed. MedTech Europe, *Reinforcing the EDMA and Eucomed Codes of Ethical Business Practice: Questions & Answers*,

http://medtecheurope.org/uploads/Modules/Publications/20141015_hcp_sponsorship_qanda_website.pdf (last visited Jan. 14, 2015).

The financial link between continuing education for HCPs and industry participants is widely criticized for creating commercial bias.³ Dr. Robert Steinbrook, National Correspondent for the *New England Journal of Medicine*, has commented that “[c]ontinuing medical education has become so heavily dependent on support from pharmaceutical and medical device companies that the medical profession may have lost control over its own continuing education.”⁴ Stated simply, the concern is that an HCP who attends an educational conference on the industry participant’s dime may be tempted to recommend that industry participant’s product over a product manufactured by a non-sponsoring competitor. And, even if direct sponsorship does not actually carry that effect, the practice at least creates the appearance of potential impropriety.

³ Dr. Ronald M. Cervero & Jiang He, *The Relationship between Commercial Support and Bias in Continuing Medical Education Activities: A Review of the Literature*, <http://tinyurl.com/lcya3my> (last visited Jan. 14, 2015).

⁴ Dr. Robert Steinbrook, *Financial Support of Continuing Medical Education*, <http://www.ohsu.edu/xd/about/services/integrity/coi/gifts/upload/Financial-Support-of-Continuing-Medical-Education.pdf> (last visited Jan. 14, 2015).

From Transparent to Taboo: The Evolution of Direct Sponsorship and MedTech Europe

When EDMA and Eucomed were first formed in 1979, direct sponsorship was not viewed as particularly problematic. Over time (and perhaps as a result of medical technology companies flourishing and expanding their revenue base), this sentiment has changed and direct sponsorship is increasingly viewed as a potentially improper way for companies to exert influence over HCPs. In 2012, one of the MedTech Europe associations, Eucomed, attempted to mitigate this appearance of impropriety in a white paper entitled “Transparency and Disclosure: Interactions between Industry and Healthcare Professionals (HCP).” In that paper, Eucomed recommended a set of “reasonable, minimum arrangements for a national framework for disclosures” relating to HCPs.⁵ In the context of direct sponsorship, Eucomed recommended that companies disclose the HCP’s name, institution, and location where the HCP practiced, and the financial value contributed in the form of conference fees and related hospitality expenses. Under Eucomed’s recommended framework, contributions falling below an unspecified threshold need not be disclosed. Eucomed did not suggest an outright prohibition on direct sponsorship at the time.

⁵ Eucomed Medical Technology, White Paper, *Transparency and Disclosure: Interactions between Industry and Healthcare Professionals (HCP)*, http://www.eucomed.org/uploads/Modules/Publications/20120920_transparency_position_final.pdf (last visited Jan. 14, 2015).

Serge Bernasconi, CEO of EDMA, Eucomed, and MedTech Europe, recently explained that, after more than a year of consulting with EDMA and Eucomed’s members and stakeholders, MedTech Europe has reached a different conclusion. After thoroughly analyzing the options, Bernasconi reports that both associations “believe that phasing out direct sponsorship while at the same time swiftly introducing stricter rules for indirect sponsorship is the best way forward for our industry to continue to reinforce our Codes.”⁶ Under MedTech Europe’s revised Code, members of each trade association are expected to phase out the direct sponsorship of HCPs by January 1, 2018. Along with its recommendation, MedTech Europe provided a set of Q&As intended to help guide the transition for its members.⁷

⁶ Press Release, MedTech Europe, *European MedTech Industry Continues to Reinforce Its Codes of Ethical Business Practice* (Oct. 15, 2014), <http://www.medtecheurope.org/mediaroom/139/110/European-MedTech-industry-continues-to-reinforce-its-Codes-of-Ethical-Business-Practice?cntnt01template=detail-pr> (last visited Nov. 8, 2014).

⁷ MedTech Europe, *Reinforcing the EDMA and Eucomed Codes of Ethical Business Practice: Questions & Answers*, http://medtecheurope.org/uploads/Modules/Publications/20141015_hcp_sponsorship_qanda_website.pdf (last visited Jan. 14, 2015).

In the United States, voluntary standards widely adopted by both the pharmaceutical and medical technology industries do not permit direct sponsorship. The trade association representing pharmaceutical companies in the United States, PhRMA, has long prohibited this form of direct financial support. Eucomed’s counterpart in the United States, AdvaMed (representing medical device companies in the United States), has not supported direct sponsorship of HCPs since at least 2004. Not only does MedTech Europe’s recommended phase-out mark a significant change for the European medical technology industry, but the recommendation also represents a bold first step by the medical technology industry abroad, which usually follows the pharmaceutical industry’s lead. Although the European Federation of Pharmaceutical Industries and Associations (EFPIA), which represents the pharmaceutical industry in Europe, has taken a firm stance in favor of transparency by requiring companies to publicly disclose their financial contributions to HCPs and health care organizations,⁸ the trade association still permits direct sponsorship. MedTech Europe seriously considered implementing a complete disclosure rule like EFPIA’s (*i.e.*, in lieu of prohibiting direct sponsorship), but ultimately determined that a ban on direct sponsorship would present less compliance risk.

⁸ *Introducing the EFPIA Disclosure Code*,
http://transparency.efpia.eu/uploads/Modules/Documents/efpia_code_flier.pdf (last visited Jan. 14, 2015).

Filling the Gap: The Future of CME in Europe

Given that HCPs rely on industry participants to fund many CME opportunities, the phase-out of direct sponsorship may cause an education gap as HCPs seek alternative sources of funding for attending third-party educational conferences. While EDMA and Eucomed join in recommending a phase-out of direct sponsorship over a period of years, both organizations remain fully committed to supporting CME. MedTech Europe is currently consulting with HCP organizations regarding alternative models of CME and searching for ways to mitigate the impact that a phase-out of direct sponsorship could have on CME support. Anticipating member concern that non-member companies, not bound by the same ethical rules, will gain an advantage by continuing to directly sponsor HCPs, MedTech Europe promises over the next three years to provide ethical alternatives to direct sponsorship that will help its members to maintain relationships with HCPs.

EDMA and Eucomed members will likely fill the education gap caused by the elimination of direct sponsorship at least partly through the increased use of indirect sponsorship (*i.e.*, general funding from a company that the conference organizers can use to fund attendance by HCPs chosen by the organizers). In theory, indirect sponsorship should be able to fill the void entirely. Indeed, if companies that pay for direct sponsorship are motivated by a general desire to further the knowledge base of those in the medical profession, the exact mode of sponsorship (direct or indirect) should not matter.

But even indirect sponsorship has not escaped increased scrutiny. In addition to recommending the phase-out of direct sponsorship, EDMA and Eucomed are also recommending the introduction of stricter rules for indirect sponsorship. The associations caution that “[s]elf-regulation will be essential to mitigating the risks associated with indirect sponsorship,” and note that “[t]he MedTech Europe Code will provide clear, strict guidelines to ensure that the necessary safeguards are in place in member companies.”⁹ MedTech Europe also announced that industry working groups are actively working to develop stricter self-regulation measures for indirect sponsorship.

⁹ MedTech Europe, *Reinforcing the EDMA and Eucomed Codes of Ethical Business Practice: Questions & Answers*,
http://medtecheurope.org/uploads/Modules/Publications/20141015_hcp_sponsorship_qanda_website.pdf (last visited Jan. 14, 2015).

In the United States, where industry participants contribute over \$1 billion each year to third parties for the purpose of providing continuing education to HCPs, even indirect sponsorship is the subject of criticism. While industry participants may not be allowed to directly sponsor a particular HCP to attend a third-party educational conference, they still influence HCP education by choosing which CME providers and which conferences to support. Perhaps the self-regulation measures that MedTech Europe is currently developing will address these additional sources of potential bias and set an example for medical technology trade associations in the United States, and elsewhere, to follow.

Around the world, many are calling for even stricter controls over the relationship between industry and HCPs. Supporters of a complete ban on commercial sponsorship of CME generally argue that forcing HCPs to pay for their own continuing education would not only eliminate commercial bias in CME, but also improve the quality of the educational programs available because individual HCPs will pay only for the training they find most useful. Others suggest that industry participants should be allowed to contribute to a pooled education fund, but not to control which program their money will fund (*i.e.*, indirect sponsorship that is even more indirect).¹⁰ Regardless of where the relationship between HCPs and industry is headed, MedTech Europe's recommended phase-out of direct sponsorship will change how at least some HCPs meet their educational requirements in the near term. Since statistical data regarding the cost of direct sponsorship in Europe and the number of HCPs currently benefitting by the practice is scarce, the projected extent of the ban's impact is unclear.

¹⁰ Dr. Jerry Avorn & Dr. Niteesh K. Choudhry, *Controversies in Cardiovascular Medicine, Funding for Medical Education: Maintaining a Healthy Separation from Industry*,
<http://circ.ahajournals.org/content/121/20/2228.full#ref-5> (last visited Jan. 14, 2015).

Toward a Global Code of Ethics for Medical Technology Companies

While MedTech Europe's recommendation to phase out direct sponsorship might upset some HCPs who may bear the higher cost of continuing education, the change may actually bring harmony to compliance codes for medical technology companies that operate globally. In light of a similar position on direct sponsorship taken by other medical technology trade associations, like AdvaMed, the recommendation by MedTech Europe brings the medical technology industry one step closer to a global code of business ethics. In today's global medical technology marketplace, a global code can be less confusing and easier to enforce.

Still, some obstacles remain. Not all countries have opted to eliminate direct sponsorship of HCPs by industry participants. For example, MEDEC, representing the Canadian medical technology industry, continues to allow its member companies to provide direct support to HCPs in the form of reasonable expenses for travel, meals, lodging, and conference registration fees. Furthermore, medical technology trade associations in some regions—Latin America, Africa, and the Middle East, for example—have been slower to adopt a transparency directive, let alone a complete prohibition

on direct sponsorship.¹¹ At the very least, ethically-minded companies may default to a rule that direct sponsorship is not allowed, unless it is expressly permitted by local law or the governing trade association's code of ethics. And given the scrutiny associated with direct sponsorship, even if permitted by local law or the relevant code of ethics, companies may want to consider taking the additional step to require approval from a senior Legal or Compliance employee prior to offering or making a direct sponsorship.

¹¹ Porzio Life Sciences, White Paper, *The Ongoing Global Transformation in Life Sciences Transparency*, <http://www.porzio Lifesciences.com/About-Us/Recent-Articles/The-Ongoing-Global-Transformation-in-Life-Sciences.aspx> (last visited Jan. 14, 2015).

Further, while some medical technology trade associations agree about how to handle direct sponsorship, their codes diverge with respect to their treatment of gifts. For example, the AdvaMed Code permits occasional gifts that either (1) benefit patients, or (2) have genuine educational value, while the less-restrictive Eucomed Code (and the MEDEC Code) allows for modest, non-educational gifts to HCPs which may even bear the company's brand. While MedTech Europe's recent announcement did not identify a change in the member organizations' stances on gifts, the questions and answers published shortly thereafter reveal that 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."¹²

¹² MedTech Europe, *Reinforcing the EDMA and Eucomed Codes of Ethical Business Practice: Questions & Answers*, http://medtecheurope.org/uploads/Modules/Publications/20141015_hcp_sponsorship_qanda_website.pdf (last visited Jan. 14, 2015).

Conclusion

MedTech Europe's recommendation to its members to eliminate direct sponsorship by January 1, 2018 is a significant decision that reflects a marked change in direction for the European medical technology industry. The decision signals a shift toward stricter controls on interactions between HCPs and industry participants, designed to avoid even the appearance of impropriety. Although the focus of the recommendation is on eliminating direct sponsorship, the accompanying Q&As suggest that the effort is more comprehensive. Over the next three years, both HCPs and industry participants will need to increase efforts to create vehicles and funding for indirect sponsorship. MedTech Europe and member companies will have to grapple with how best to allow companies to receive some sort of recognition for their contributions, while maintaining a layer of separation between the HCPs and company-donors. For example, MedTech Europe and its members may decide that all sponsors contribute to a pooled fund without any earmarks or special designations. This way, there will be no direct link between the companies and specific benefits conferred upon HCP-participants. In turn, company-donors may receive recognition through a banner or other mode of advertisement.

While the ultimate impact of MedTech Europe's recommendation on the relationship between HCPs and industry participants is unknown, companies should take heed by paying closer attention to their interactions with HCPs to ensure they are ethical, accurately recorded, and disclosed where appropriate.

EDMA and Eucomed members will vote to adopt the revised MedTech Europe Code of Ethical Business Practice in November 2015.

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