MedTech Europe's New Code of Ethical Business Practice

Perspectives on the rationale and implementation of new protocols for industry interaction in physician education and congress attendance in Europe.

What comprises the entities involved in Eucomed, the EDMA, and MedTech Europe?

MedTech Europe: MedTech Europe is an alliance of European medical technology industry associations. It currently has two members: the European Diagnostics Manufacturers Association (EDMA), representing the European in vitro diagnostic (IVD) industry, and the European Medical Technology Industry (Eucomed), representing the European medical devices industry. Our members are medical device and IVD companies, as well as national associations representing these two sectors in Europe.

What are the purpose and goals of these organizations?

MedTech Europe: Founded in October 2012, MedTech Europe's mission is to make innovative medical technology available to more people, without any government attachment, while assisting health care systems with the ability to move toward a sustainable path.

What is MedTech Europe working on?

MedTech Europe: We promote a balanced policy environment that helps the medical technology industry meet Europe's growing health care needs and expectations. We also promote the value of medical technology for Europe through our 5-year industry strategy, which focuses on value-based innovations that support more sustainable health care systems.

MedTech Europe uses economic research to show the benefits of medical technology. We organize many initiatives to expand the value we bring to Europe, and we bring stakeholders together to discuss trends, issues, and opportunities. Each year, we also organize the European MedTech Forum, the largest health and industry policy conference in Europe, to engage with stakeholders on common topics of interest.

What can you tell us about the code of ethics that was recently adopted in the European device industry?

MedTech Europe: Members of EDMA and of Eucomed—both members of MedTech Europe—adopted a common Code of Ethical Business Practice on December 2, 2015. The code was created as part of a continuous effort to reinforce the medical technology industry's ethical standards across Europe. The code will replace the EDMA and Eucomed Codes of Business Practice and will be known as the MedTech Europe Code of Ethical Business Practice.

How would you summarize the key changes?

MedTech Europe: The new MedTech Europe code regulates all aspects of the industry's relationship with health care professionals (HCPs) and health care organizations (HCOs), among others, such as company-organized events, arrangements with consultants, as well as research and financial support to medical education and demonstration of samples and products. The code also introduces a common, independent enforcement mechanism and a glossary of concepts (see *Summary of Changes and Provisions of Medtech Europe's Primary Code of Ethical Business Practice*).

One provision of the new code examines third-party organized events. Under the code, companies will no longer directly invite or sponsor HCPs to attend third-party organized events, also known as direct sponsorship. Such support will now be done only through educational grants to HCOs (eg, scientific societies, hospitals). HCOs will then choose the HCPs who will benefit from these grants.

The new code also introduces more stringent rules for educational grants provided by companies, also known as indirect sponsorship. Educational grants will have to be publicly disclosed and comply with specific requirements. The Conference Vetting System, which ensures the respect of the key principles of the new code in conferences, will continue to play a crucial role in this matter.

What is the enforcement mechanism for code violations?

MedTech Europe: The code introduces a common enforcement mechanism whereby members of MedTech Europe that do not comply can face audits by an independent three-member compliance panel. Sanctions range from publication of their infractions or exclusion from membership, depending on the severity of the fault.

How will these changes affect HCPs and medical education (in particular their travel, accommodation, and conference registration expenses)?

MedTech Europe: In accordance with the code, member companies may provide restricted educational grants for the advancement of genuine medical education. This means that member companies of MedTech Europe will specify the intended purpose of the educational grant in the grant agreement but will never choose or refer to individual HCPs in the educational grant agreement.

In accordance with the principles of documentation (written agreement) and separation (decision-making is not primarily sales-driven), HCOs will develop an independent methodology or process to select HCPs based on objective criteria.

The key aspect in the new MedTech Europe code provision is to introduce an "ethics wall" between the money provided by a member company and the selection of the individual HCPs who will be receiving it in the form of an educational grant.

To what degree were meeting organizers and medical societies consulted in fact finding and constructing the new code?

MedTech Europe: Since the decision to revise the EDMA and Eucomed codes was made, we have reached out to all key European medical societies, as well as other stakeholders, such as hospital representatives and conference organizers.

Following individual discussions, and at the request of medical societies, we have also set up an advisory group on the future of medical education, where societies and industry get together and discuss how the change in support to HCPs can be managed in order to ensure an acceptable transition for societies. Along with this advisory group, we have continued bilateral discussions with all of the key European medical societies.

The new code is a clear message from the medical technology industry that we want to safeguard and protect our relationship with HCPs by adopting a clear and strict self-regulation. It will be a priority for us to work on the practical details of these changes with medical societies and HCPs to ensure they are properly implemented, as well as to define new models to support continuous and independent medical education.

When will these changes take effect?

MedTech Europe: Members of MedTech Europe will be required to start applying the new code by January 1, 2017, except for phasing out direct sponsorship, which will take effect on January 1, 2018. From that date, members must cease all financial or in kind direct support to HCPs linked to third-party organized educational events.

SUMMARY OF CHANGES AND PROVISIONS OF MEDTECH EUROPE'S PRIMARY CODE OF ETHICAL BUSINESS PRACTICE

The new common code, detailed in the following list, pushes forward clearer and more stringent self-regulations of the medical technology industry in Europe. It regulates all aspects of the industry's relationship with HCPs and HCOs, such as company-organized events, arrangements with consultants, research and financial support to medical education, among others.

- Common framework for both IVD and medical device industries
- Stricter rules for educational grants (ie, indirect sponsorship) which will, among others, be publicly disclosed
- Phasing out of direct sponsorship of HCPs to attend third-party organized conferences
- Addition of elements to the code that were previously in guidelines, including providing samples or demonstration products to hospitals and how to deal with royalties
- Common and independent enforcement mechanisms

What else can you tell us about alternative funding mechanisms such as indirect sponsorship? What is an example of acceptable indirect funding?

MedTech Europe: Indirect support through educational grants will become the primary way of continuing to support medical education. The main limitation to this system is that companies will not be able to narrow the object of the educational grant so much so that the beneficiaries of the grants become identifiable.

For example, if a medical society is organizing an educational conference, they may create several "educational grants packages" identifying a particular demographic that may need additional support to attend the conference. These demographics could consist of "surgeons younger than 35 years old" or "Belgian nurses." Companies could then choose to take on one of the packages and cover it through an educational grant. There are many other similar arrangements that are in principle compliance with the new code.

Will these changes affect the ability of the industry to directly sponsor HCPs outside of Europe (eg, Asia, Middle East, and Africa) to attend continuing medical education conferences in Europe?

MedTech Europe: Yes. Member companies of MedTech Europe will have to comply with the code as a minimum standard when at least one of the following criteria is met.

- Member companies interact with HCPs and HCOs registered or based in the MedTech Europe geographical area (countries in the European economic area, as well as countries where member associations are located) regardless of where the activity takes place
- The activity in question takes place in the MedTech Europe geographical area, regardless of where HCPs and HCOs are registered and practicing

What led MedTech Europe to make these changes?

MedTech Europe: First, the decision to adopt a common code was driven by the fact that both the EDMA and Eucomed current codes were established in 2007 and 2008, respectively, meaning both codes were quite dated. Having two codes also meant that each one had their own specificities, which created inconsistencies in the rules applied to the industry as a whole. With the deepening collaboration between EDMA and Eucomed, both organizations saw the need to align their codes.

In addition, the medical technology industry needs to collaborate closely with HCPs to develop new products and ensure safe and appropriate patient care. HCPs actively participate in the research to develop new technologies. The industry also liaises regularly with HCPs to ensure that technologies are updated.

This relationship is under scrutiny by regulators, the press, and the general public. Adherence to strict ethical rules is therefore crucial to us as an industry to protect our relationship with HCPs.

Inviting or directly supporting individual HCPs to attend a third-party organized educational event is perceived as creating a potential commercial bias. This, in turn, may affect the way the HCP uses or recommends a certain product, given the unilateral nature of the benefit given to them.

As an industry, we felt that publicly disclosing such support did not address the inherent conflict of interest of this direct sponsorship practice, which is why we have decided to phase out such support.

Where can interested parties obtain more information on the new code?

MedTech Europe: You can find more information on the MedTech Europe Code of Ethical Business Practice by visiting www.medtecheurope.org or by contacting our legal and compliance team at ethics@medtecheurope.org. ■