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Feature Article

Changing the Rules Again

The MedTech Europe Code & Third-Party Educational Support

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ABSTRACT: Although the new code of conduct for member medical device and in-vitro diagnostic companies operating in the European marketplace has come into force the first day of this year, a grace period has been granted before new principles become effective. This article reviews the changes medical device and in-vitro diagnostic companies should consider implementing to adhere to the new principles for third-party educational support set forth by the MedTech Europe Code.

MedTech Europe Code of Ethical Business ("Code") will become effective on January 1, 2018. Now with only seven months left in the Transition Period, it is a good time to examine how medical device and in-vitro diagnostic companies have been preparing. While most of the standards and requirements are not new to Member Companies ("Companies"), the Code introduces several updates, which include:

- a 'fifth principle' of holding image and perception of the industry in high regard,
- new chapters with consolidated definition of events and demonstration products, and
- changes around the support of third-party educational conferences, which will be the focus of this article.

Although the constant need to adapt to regulatory change is nothing new to those operating within the compliance space, many would agree that transitioning everyday business operations to comply with new requirements is easier said than done. This article will summarize the key changes the Code requires around educational conference support and provide some insights and considerations for in-house ethics and compliance functions.

Background

MedTech Europe was born in 2012 out of an alliance between the European Diagnostic Manufacturers Association ("EDMA") and Eucomed, and currently represents both in-vitro diagnostic and medical device companies. Although not enforceable at the time, the MedTech Europe Code replaced the Eucomed Code of Ethical Business Practices and the EDMA Code of Ethics in 2016, with the intent to introduce the new trade association, and its mission. Rather than implementing the Code immediately, MedTech Europe took a more gradual approach to allow for companies to acclimate and prepare for the new changes. The ultimate goal was to have updated standards that would be enforceable by 2018.

Transition Period
- January 1, 2016 to December 31, 2017

With the two codes (EDMA and Eucomed) came two separate enforcement systems. Under the new combined

1 *FRA Life Sciences offers a broad set of services to help companies identify global compliance risks and develop practical, yet effective, solutions. http://www.forensicrisk.com*

Code, MedTech Europe formed an independent compliance panel that assisted Companies with complying with their obligations under the Code, and handles complaints as a 'first and last instance decision-maker'. This change of the compliance panel was immediately put into effect at the beginning of 2016, while the balance of the Code became effective at the beginning of 2017. Additionally, allowances for Companies to phase out the practice of direct sponsorship of individual health care professionals ("HCPs") to third-party educational conferences (discussed below), and for the opportunity to ask questions and gain a better understanding of how and what they needed to put into place to prepare for the changes was granted a further implementation extension until 2018.

What are the key updates Companies have been implementing this year?

At the end of the Transition Period in December of this year, the Code will be in full force, with the expectation that Companies will be following the new requirements put forth regarding educational conference support. As a result, enforcement by MedTech Europe is expected to begin promptly in 2018.

Below is a summary of the key changes facing Companies in 2018:

1. **Direct sponsorship for individual HCPs will cease.** Starting on January 1, 2018, companies operating in the European market will no longer be able to pay for an individual HCP to attend (e.g., registration fees) third-party organized educational events. While the prohibition of direct sponsorship has been an ongoing practice in the U.S. under the AdvaMed Code of Ethics on Interactions with U.S. HCPs,2 this will be new to many of the Companies operating in the EU. Up until now, providing financial support for HCPs in Europe to attend third-party educational conferences and events is a key part of the industry's daily business activities and the demonstration of the company's interest to further medical knowledge.
2. **Educational grants will be publically disclosed.** Under the Code, Companies will be required to gather data regarding educational grants payments for public disclosure, with the first reporting year to be 2017. The Code outlines that Affiliates (i.e., separate entities belonging to the same multi-national company, which are considered a single company) will be required to disclose educational grants support on an aggregate basis and include detail on who is receiving the grant, the amount of the grant, and categorize if the support was used for an educational event to support HCP participation and/or if its intended purpose was to help support fellowships, scholarships or public awareness campaigns. This includes the provision of obtaining consents and approval, as well as following the overall transparency principle put forth by the Code.
3. **Educational grants to third-party events are required to be vetted through the Conference Vetting System ("CVS"):** Managed and operated independently of MedTech Europe, this online decision-making tool has been developed to help Companies ensure that the standards of the third-party educational event are in compliance with the principles of the Code. CVS is under the supervision of the MedTech Europe Compliance Panel, who will oversee that the decision-making process is independent, impartial and does not pose a conflict of interest.

What does this mean for Companies?

Ban on direct sponsorship

Given that Companies will no longer be able to pay for registration fees, travel or hospitality expenses directly to individual HCPs to attend third-party organized educational conferences, restricted educational grants may be provided to conference sponsors to help off-set costs for participants, with the caveat that the conference sponsor will solely be responsible for selecting the participants. For U.S. multi-national companies, this change merely brings the EU in line with the U.S. For EU companies, this a drastic change.

2 The AdvaMed Code of Ethics on Interactions with U.S. HCPs allows for grants to the conference sponsor may be used to help reduce conference costs for medical students, fellows, residents or any other HCPs in training.

The exceptions to this principle include support for individual HCPs to attend third-party organized procedural training meetings, or support for individual HCPs who are engaged as a consultant by the Company to speak at a satellite symposium. It should be noted that the provision of an educational grant must be restricted and reported for public disclosure. In effect, this requires a more detailed agreement between the Company and conference sponsor specifying the intended purpose of the grant and stricter close-out procedures (e.g., documentation of how the grant was in fact used), will be needed.

Transparency

The spirit of transparency is not a new concept for the health care environment and life science industry, especially in light of the U.S.'s Physicians Payments Sunshine Act, and the EU's European Federation of Pharmaceutical Industries and Associations ("EFPIA") code. The overall purpose of this principle is to provide visibility to the public around the financial relationships between HCPs and pharmaceutical and medical device companies.

Under the Code, as mentioned, the first reporting period for Companies will be for 2017, which will be made public in June 2018 (six months after the reporting period). After that it will occur on an annual basis for subsequent calendar years.

MedTech Europe has launched a new website (www.ethicalmedtech.com) where this information will be disclosed and will be made public at the end of August of the year of disclosure. Additionally, Companies will be required to develop a document, which the Code refers to as a 'Methodology Note', that summarizes the methods on how the amount disclosed was aggregated and to be available, if requested, by the recipient of the grant. To help Companies develop this document, MedTech Europe provided a template of the information that should be included within the Methodology Note.[3]

CVS

Starting in 2018, support for international conferences, both within and outside of the MedTech Europe geographic area, will require approval through CVS. This system is part of the Ethical MedTech platform, which publishes a calendar of conferences that displays online submissions made to CVS with the status of review to allow Companies to track their submissions. It should be noted that educational conference sponsors may also submit a request through CVS on behalf of the Company, if expressly outlined within the grant agreement between the two parties. This is a uniquely EU framework, but in some respects mirrors the accreditation process in the U.S. It helps prevent abuses.

Some Key Considerations:

As 2018 closes in, ethics and compliance functions are challenged with ensuring that the new requirements of the Code are integrated into their own codes of conduct and compliance expectations to effectively govern business. If not already completed, this is an opportunity for compliance functions to assess and review their current programs, while weaving in new practices to adhere to the new requirements. In short, this is the time to continually refine and strengthen compliance effectiveness.

For example, an up-tick of HCP and healthcare organization ("HCO") interactions to provide notification of the new principles around educational events undoubtedly will occur. The opportunity to monitor appropriate interactions presents itself – are the appropriate people delivering the message, per company standards? Have the materials being used been reviewed and approved and/or properly branded per the company materials policies? The Transition Period offers time to not only ease new practices into the organization, but to also pressure-test monitoring activities and overall adherence to the company's compliance expectation.

Another area worth a closer look is the company's third-party intermediary programs. Regulators are starting to focus on activities that companies execute to engage with third-parties, who are typically engaged to assist in the sales, marketing and/or distribution of company products. Since Companies are responsible for the activities of third-parties, third-party contracts will require updates to reflect the new obligations of the Code. Simply updating third-party agreements is not enough. This also is the time

3 *MedTech Europe Code of Ethical Business Practice - Annex III: Example of Disclosure Guidelines Methodology Note*

to take a closer look at how third-party intermediaries are managed. Therefore, a more thorough examination of third-party programs should take place including:

- Is company due diligence enough?
- Is the company currently engaging with the appropriate third-parties?
- Are these third-parties prepared to execute business in accordance with the Code principles? How can third-parties be monitored more effectively?

As mentioned previously, publically disclosing financial data is not new to the U.S. or the EU, however, few would argue that it's a seamless transition. Despite of the Sunshine Act and EFPIA disclosure guidelines, the inefficiencies of current systems and processes to capture HCP payment data are painfully clear to many companies. As companies started to collect data for the first reporting period, instances of 'I don't know what I don't know' started to become clear. For example, although one would assume to access the finance department's systems to collect payment data made to an HCP, basic questions started to arise including: how to uniquely identify each HCP, so that data can be entered accurately, how many systems track transfers of values, and will the company need to track transactions down in multiple systems. Considerations for updating and/or making updates to current systems can help facilitate a more streamlined process to capture the data moving forward.

Finally, MedTech Europe recognizes that the new standards around educational conference support are not going to be easy to adopt for many Companies, therefore they provide a library of resources, such as training guides, leaflets for discussions with customers, and even templates for companies to use for internal control documents (e.g., Methodology Note template), to name a few. The Code also clearly defines terminology and includes commonly asked questions within the document to help guide the reader in practical application of the principles. These templates and tools can be found on the MedTech Europe website, the Code itself, and within the Annex section of the Code.

Conclusion:

It is clear that as the regulatory landscape continues to evolve, companies will adapt and find ways to navigate through new requirements while meeting their business goals. The new standards for third-party educational support challenges companies to put forth further efforts to mitigate risks around wrongful conduct and corruption. Fortunately, there is still time for companies to take a look at current activities, assess what, if any, changes need to be made, and be ready for the January 1, 2018 enforcement date.

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