



Main features of the new Fenin Code of Ethics

New Code of Ethics for the Spanish Healthcare Technology Sector transposing the provisions of the current “Code of Ethical Business Practice” of MedTech Europe

Background

On 21 December 2016, the general assembly of Fenin approved the new Code of Ethics for the Healthcare Technology Sector in Spain, transposing the current “Code of Ethical Business Practice” of MedTech Europe, the European association of the health technology industry.

The main objective of the new Code, which will come into force on 1 January 2018, is to ensure that certain relationships between companies associated to Fenin and healthcare professionals and/or healthcare organisations are based on criteria of transparency and independence and, in general, that they are carried out within the framework of an ethical conduct.

As may be noted, these objectives are no different from those pursued by the Fenin Code of Ethics currently in force. However, the new Code significantly changes the conditions that must be fulfilled in order for companies to engage in certain relationships and even prohibits healthcare professionals or healthcare organisations certain activities that are permitted under the current Code.

Sponsorship of third-party educational events

The new Code forbids Fenin members to directly sponsor healthcare professionals to attend educational events organised by third parties, unless the events relate to training on

clinical procedures and techniques. Thus, once the new Code comes into force, companies may not extend invitations to healthcare professionals for their attendance to this type of events and it will not be permitted for companies to bear the costs to be incurred by a specific professional for his/her attendance to such events.

The sole exception to this prohibition is for healthcare professionals participating as speakers at a satellite symposium. In such case, pursuant to a consultancy agreement with the speaker in question, companies may directly bear travel and accommodation costs, in addition to those corresponding to his/her registration at the event at which the symposium is taking place.

On the other hand, companies may continue to sponsor third-party events by making contributions to the organizer of the event; however, only when certain criteria are met, namely: (a) that the event, including the nature of the venue, is approved under the MedTech or Fenin events validation systems, (b) that the sponsorship is duly formalized in a contract; and (c) that the event organiser is solely responsible for the selection of attendees.

Transparency obligations

There has been an increase in the transparency obligations that companies associated to Fenin must comply with. In this regard, from 2018 onwards, each company associated to Fenin must publish, on an annual basis and via



publication on the MedTech website the grants for training and the support it has provided to third-party educational events during the previous year. This information must be published within the first six months of each year and must include, in addition to identifying the organisations and institutions receiving grant or support, the aggregate amount that has been paid to each entity.

Furthermore, the new Code also establishes that when a company covers the costs of a healthcare professional attending an event, whether organised by the company itself or a third-party, to receive training on clinical procedures or techniques, in addition to when a company signs a consultancy agreement with a healthcare professional, the company must previously notify the manager of the healthcare institution where the healthcare professional carries out his/her activity regarding the nature of the relationship with said professional.

Charitable donations

The situations in which companies associated to Fenin may make donations have been limited and the requirements that have been satisfied in order to carry out such donations increased. Thus, donations may only be made when charitable or philanthropic in nature, if the recipient is a non-profit entity and on the condition that the company making the donation does not control the final use of the funds donated.

In this regard, it is important to note that the new Code expressly forbids making donations, whether directly or through foundations or other entities, to support the general running of a hospital or another health organisation. The sole exception of this prohibition is the possibility of making donations of a limited value that solely benefit patients when the hospital

receiving the donation is undergoing a verifiable situation of financial hardship difficulties that adversely affect patient care.

Entry into force of the new Code

Although the new Code does not come into force until 1 January 2018, companies associated to Fenin must start adapting to certain provisions during 2017. For instance, in 2017, companies must gather information on grants and support offered throughout 2017, (as indicated in the transparency section above) as they will have to publish such information during the first six months of 2018, and refrain from entering into or renewing agreements that will remain in force after 2017 if their corresponding terms will be prohibited when the new Code comes into force.

Moreover, given that MedTech member companies must comply with the "Code of Ethical Business Practice" from 1 January 2017 onwards, Fenin members that are also MedTech members are subject to the MedTech Code, the contents of which are largely similar to the new Fenin Code from the aforementioned date.