Sponsorship exemption for medical device simulation centres and cadaver centres for surgical training

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Introduction

The Regulation on the Sale, Advertisement and Promotion of Medical Devices was amended by a new regulatory measure published in the *Official Gazette* on September 22 2016. The amendments introduce new provisions regarding:

- the notification of changes to sales and promotion staff;
- where medical device sales centres can be opened; and
- exceptions to activities considered to be scientific and educational meetings.

The third provision will make significant changes to the medical device sector and has received the most attention from industry stakeholders.

Scientific and educational meetings

The Regulation on the Sale, Advertisement and Promotion of Medical Devices – which was published in 2014 by the Medicines and Medical Devices Agency, established under the Ministry of Health – regulates the sponsorship of healthcare professionals attending scientific or educational meetings by medical device companies. These rules and principles were adapted from already established pharmaceutical sector rules. As they involved practices taken from the pharmaceutical sector, some of the regulation's provisions, particularly those relating to scientific meetings, did not fully address the needs and realities of the medical device sector.

The regulation identifies two types of permissible meetings – namely, scientific meetings and educational meetings – and provides different rules of attendance and sponsorship for each one. While scientific and educational meetings are not defined in the regulation, an agency announcement defines the terms as follows:

- 'scientific meetings' are domestic or international congresses, symposia and conferences that aim to provide information on a scientific topic; and
- 'educational meetings' are educational meetings organised or supported by medical device companies, which include the promotion of medical devices.

Healthcare professionals who attend scientific meetings are subject to annual sponsorship quotas (the so-called '4-2-2 quota allocation') and medical device companies must notify the agency of each sponsorship. Healthcare professionals may receive a maximum of four sponsorships to attend scientific meetings per annum. Two sponsorship allowances can be used to participate in scientific meetings abroad and two sponsorships can be offered by the same medical device company. Companies can pay the transportation, accommodation or registration expenses of healthcare

professionals attending scientific meetings. Conversely, companies cannot pay for the transportation, accommodation or registration expenses of participants at educational meetings.

Although medical device companies must notify the agency of the participation of healthcare professionals in scientific or educational meetings, the main differences between these two categories are that:

- scientific meetings cannot involve content directly relating to product promotion; and
- support cannot be provided to healthcare professionals to cover their expenses for attending educational meetings.

Within the scope of the definitions provided above, the agency considered that the sponsorship of healthcare professionals to attend medical device company simulation centres constitutes support for participation in a scientific meeting. Therefore, the agency must be notified of such sponsorships and they must be deducted from the healthcare professional's sponsorship quota.

These restrictive rules had a major impact on Turkish affiliates of multinational medical device companies that established simulation centres in Turkey and existing centres abroad.

Due to the quota requirement, such companies had to restrict their support to healthcare professionals in this regard and, in some cases, went so far as being unable to organise modular training programmes at such centres.

Training activities

Under the recent changes to the regulation, training activities held in medical device simulation centres and cadaver centres for surgical training will no longer be categorised as scientific or educational meetings. Therefore, providing support to healthcare professionals for their attendance at a training event that a medical device company is organising or supporting in such centres is not bound by the quota and notification requirements.

However, the implementation of the rules is still under debate and could result in temporary uncertainty.

Although the relevant provision foresees that training activities in medical device simulation centres and cadaver centres for surgical training for healthcare professionals and technical personnel working in the field of medical devices at healthcare institutions and organisations will not be regarded as scientific and educational meetings, no clear definition of what constitutes a 'medical device simulation centre' or 'cadaver centre for surgical training' has been provided. Therefore, it is unclear whether this exemption will cover centres abroad or is intended strictly for those in Turkey. Further, it is unclear whether the Medicines and Medical Devices Agency will provide more detailed guidelines for such training.

As no explicit rule has been established for training abroad, it might be safe to interpret this provision as allowing such events to be held in local and international medical device simulation centres and cadaver centres for surgical training. However, during a meeting between the agency and industry associations, agency representatives stated that they interpreted the article as being valid only for events organised in medical device simulation centres and cadaver centres for surgical training in Turkey. Although the regulation does not clarify this matter, the agency may publish guidelines regulating this limitation.

As mentioned above, there is no specific rule regarding the establishment of medical device simulation centres. As a result, it is unclear whether a meeting room with a simulator device provided by a medical device company would be considered a simulation centre by the agency. By the spirit of the provision, it may be understood that a centre will not be mobile. This uncertainty may be resolved by practice or further guidelines.

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