

Online notification of sanctions issued to medical device companies

Dicle Dođan and Fatma Sevde Tan, Gun + Partners

The Turkish Medicines and Medical Devices Agency has *announced* that sanctions for breaches of the provisions governing the online notification of scientific and educational meetings (Turkish language) shall be imposed automatically via the online system only.

Pursuant to Article 21 of the Regulation on the Sale, Advertisement and Promotion of Medical Devices and its relevant guidelines, for meetings (including the sponsorship of healthcare professionals) to be organised or supported by a medical device sales centres, the sales centre must make an initial notification at least 15 days prior to each meeting and a post-notification one month after the meetings. The notifications must be made electronically through the system established by the Medicines and Medical Devices Agency. Under Article 28 of the Regulation, in case of a breach of Article 21, the agency shall issue a warning. The repetition of the breach within one month upon the receipt of a sanction shall prohibit the company from organising or supporting any activity mentioned in Article 21 for three months. If there is a third breach of Article 21, a third sanction will be issued and the company will be prohibited from carrying out any of the activities as set out in Article 21 for one whole year.

The regulation had previously been silent on how the sanctions would be issued and notified to the relevant company. On 5 November 2018, the agency announced that any sanction imposed due to a breach of Article 21 would be notified to the company through the online system and that no further written official letter would be sent to the company regarding the matter.