Turkish Medicines and Medical Devices Agency Announces Draft Regulation on Sales, Advertising and Promotion of Medical Devices

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The Turkish Medicines and Medical Devices Agency ("*Agency*") announced[1] the Draft Regulation on Sales, Advertising and Promotion of Medical Devices ("*Draft Regulation*") on May 9, 2019. The Draft Regulation will replace the Regulation on Sales, Advertising and Promotion of Medical Devices ("*Regulation*") currently in force. Through the announcement, the Agency expressed that the Regulation requires an amendment as a result of practical matters presented during the implementation of the Regulation and the current needs of the sector. The Agency has invited suggestions and comments from concerned parties until close of business on June 9, 2019, by post or through the Agency's official e-mail address.

One of the amendments the Draft Regulation introduces relates to a slight change in the procedure in the application for obtaining the authorization certificate and work permit for medical device sales centers. Both the Regulation and the Draft Regulation provide that the applicant will be notified in writing if the application documentation is incomplete. However, the Draft Regulation foresees the application will be rejected, in the event the applicant does not confirm completion of the documentation within forty five (45) days as of the notification, or if the second examination conducted by the local health authority following the applicant's confirmation demonstrates that the documentation is still incomplete.

Throughout the following provisions, there are several amendments relating to the physical and legal requirements of the infrastructure and personnel of medical device sales centers. For instance, sales centers are now required to be at least twenty five (25) square meters in size. Sales centers are now also able to provide sponsorship to scientific meetings, training activities, cadaver trainings, simulation trainings and online meetings which are scientifically or technically declared to be in relation with medical devices. Moreover, sales centers are not required to notify the Agency for researcher meetings of multi-centered domestic and international clinical researches that they are sponsoring. The audit intervals of sales centers have also been increased to at least once a year within the Draft Regulation, which is currently "every other year" as per the Regulation. Lastly, the Draft Regulation introduces a new standard where the authorization certificates of sales centers will be terminated indefinitely, as a result of their change of location.

One of the most critical amendments within the Draft Regulation could be the significant developments regarding advertising and promotion regulations. Both activities now include

[1] Please see https://www.titck.gov.tr/duyuru/tibbi-cihaz-satis-reklam-tanitim-yonetmelik-taslagi-09052019093043 for the full text of the announcement in Turkish (*last access: May 23, 2019*)

highly similar and even some identical provisions with the rules and principles laid out in Consumer Protection Law No. 6502 and Commercial Advertising and Unfair Commercial Practices Regulation ("*Advertising Regulation*"). The Draft Regulation introduces the most fundamental principles of the legislation with regard to advertising of medical devices, prohibiting commercial advertising by way of "*misleading consumers or taking advantage of their lack of knowledge, risking their security, promoting violence or crime, deranging public health, taking advantage of children and the disabled*" and "*using inaccurate, misleading, exaggerated or uncorroborated information*". On top of this, in line with the Advertising Regulation, the Draft Regulation now includes the definition of surreptitious advertising, as well as the prohibition of surreptitious advertising of medical devices. The related provision is identical to that of the Advertising Regulation, which goes along the lines, "*including or promoting trade names or company names within articles, news, broadcasts or programs for the purposes of advertising, by way of using names, trademarks, logos or other distinctive shapes or expressions pertaining to the products or services, without explicitly disclosing or clearly expressing that it is an advertisement*".

Provisions relating to free samples appear to have been removed from the Draft Regulation and have been incorporated into the provisions under "*donations*". We may expect that the Agency will provide the details and additional rules relating to free samples through secondary guidelines.

The Draft Regulation also significantly extends the provisions regarding administrative penalties and provides a more detailed list of potential violations.

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