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Turkey Publishes a Draft Regulation to Address the Problems in relation to the Regulation on Sales, Advertising and Promotion of Medical Devices

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Turkey has published a draft regulation ("**Draft**") to amend the legislation due to the problems encountered in the application of the Regulation on Sales, Advertising and Promotion of Medical Devices published in the Official Gazette number 29001 on 5 May 2014. The Draft aims to regulate the procedures and principles related to placement on the market, advertising and publicity activities for medical devices. Through the announcement, it is 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 will receive suggestions and comments from parties until close of business on June 9, 2019 through the official e-mail address.

The major changes in the Draft are as follows:

- The following devices cannot be placed on the market or traded addressing the consumers through sales either remotely or directly:
    - Devices only sold and applied in hearing aid centers, bespoke prosthetics, and orthotic centers or optician facilities
    - Devices intended to be used exclusively by healthcare professionals.

With this provision, it is once again underlined that contact lenses and prescription glasses cannot be sold on the internet.

- Devices that are intended to be used exclusively by healthcare professionals, except for the devices used in the application of medicines, may not be sold at the pharmacies. Other devices are allowed to be sold without any authorization or permit.
- A managing director should constantly be present at the sales center. The director must have been graduated from an educational program given at the minimum undergraduate level and must have received a certificate from the training program organized by the higher education institutions. Bachelor's, master's or doctoral degrees received from higher education institutions abroad are considered appropriate only if they are accepted by the Council of Higher Education in terms of recognition and equivalence.
- The medical device sales center should establish and maintain the infrastructure required for the storage of the devices under the conditions stipulated by the manufacturer and meeting the international standards.

Please see this link for full text of the Draft (only available in Turkish).

Related Practices

- Product Liability and Consumer Protection

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