Turkey Amends Staffing and Location Rules for Medical Device Sales Centres

29 Nov 2016

The Turkish Medicine and Medical Device Institution has amended requirements for notifying the local health authority about staff changes for medical device sales and promotion support. Changes also apply to where medical device sales centres can be located, generally lifting certain restrictions acceptable locations.

The Regulation Amending the Regulation on Sale, Advertising and Promotion of Medical Devices ("**Amendment Regulation**") was published in Official Gazette number 29835 on 22 September 2016, entering into effect on the same date.

Notable amendments introduced by the Amendment Regulation include:

- Sales centres which have only one staffmember for sales and promotion support must now notify the Local Health Authority within five working days if that person is no longer working at the centre (due to resignation, dismissal or loss of qualifications). The deadline is 15 working days if the relevant staffmember has died. New personnel should be assigned to this position within one month.
- Education activities for health professionals and technical personnel working in the medical devices department of health institutions and organizations executed in simulation centres and cadaver study centres will no longer be considered scientific and educational activities.
- The scope of prohibited locations for sales centres is reduced and this restriction no longer applies to:
 - Clinics and laboratory diagnosis centres which merely provide examination and imaging services.
 - Pharmacies.
 - Optician centres.
 - Hearing aid centres.
 - Prosthesis and orthosis centres.
 - Dental prosthesis laboratories.
- Except for the above exemptions, medical device sales centres cannot be opened in the buildings (including its yard) and its extensions in which a health institution and organization is located. The restriction on establishing a sales centre in places zoned for healthcare which are owned by the serving health facility has now been removed.

Please see this link for full text of the Amendment Regulation (only available in Turkish)

Related Practices

• Employment and Labor

Related Attorneys

- DR. E. SEYF? MORO?LU, LL.M.
- BURCU GÜRAY

Moroglu Arseven | www.morogluarseven.com