

## Amendments on the Medical Device Sale, Advertising, and Promotion Regulation

9 Oct 2020

Turkish Pharmaceuticals and Medical Devices Agency ("**Agency**") has issued Medical Devices Regulation Amending the Regulation on Sale, Advertising and Promotion ("**Amendment Regulation**") on Official Gazette number 31232 dated 2 September 2020. The Amendment Regulation mainly focusing on advertising and promotional activities, amends the principles and procedures relating to the activities stipulated under the Medical Device Sale, Advertising and Promotion Regulation ("**Regulation**").

Prominent changes brought with the Amendment Regulation are as follows:

- Dental prosthesis laboratories were excluded from the scope of the Regulation, while transactions pertaining to the activities of medical devices placed on the market through these laboratories were kept within the scope of the Regulation.
- If a sales center is located in a free zone, technocity or organized industrial zone, a document proving its operation in such place or a pharmaceutical wholesaler license issued by the Authority will be deemed necessary if the applicant is a pharmaceutical warehouse.
- Sales centers placing or keeping their products on the market are now obliged to enter into Authority's registration and information management system, keep their information up-to-date, and ensure their traceability with the product tracking system called single action notification.
- Devices that are sold, adapted or implemented in the below-listed places are prohibited to be directly advertised to the customers:
  - in hearing aid centers,
  - bespoke prosthesis and orthosis centers
  - in optician's establishments or dental prosthesis centers,

Furthermore, devices whose use or application are reserved for healthcare professionals or require application in medical device sales centers are also fell within this scope.

- Products other than those listed above can be promoted online where the device is sold, with a few exceptions specified in the Amendment Regulation.
- Those who fail to comply with promotion regulations in terms of these products will be warned, and sales activities of those who do not take necessary measures in three days upon warning will be temporarily suspended for 15 days.
- The scope of the ban on door-to-door and online sales of medical devices was expanded. Offering products to consumers outside of the workplace, such as in places where the consumer maintains their home or business life, by single or multi-layered sales methods, is also explicitly prohibited.
- In terms of sales offices whose transfer and transactions were determined without notification, the practice of indefinite closure was removed with the Regulation and the authorization certificate was canceled. Therefore, with this amendment, it is now possible for the sales office to continue its activities, provided that the authorization certificate is applied again.

- The notification period has been extended to 10 days, In addition, in the event that the responsible manager and promotion staff are dismissed or passed away, their notification period has been extended to 10 days from the occurrence of the situation or 20 days after the person's death. Following the notification, the appointment of the new responsible manager must be made within 30 days and the sales promotion person within 60 days. If the appointment is not made within this period, a temporary suspension will occur. However, it was resolved that if the appointment is not made at the end of the given period, the authorization certificate would be canceled.
- Within the scope, in case the authorization certificate is canceled for the second time, the authorization certificate cannot be issued for one year for the same person. If a third cancellation happens, this period increases to two years.
- Besides, the Regulation was updated by giving Turkey's Ministry of Health the authority to make exceptions regarding the sales points of medical devices for protection purposes in order to facilitate public access in cases of epidemics, pandemics, and similar situations.

The full text of the Amendment Regulation published in the Official Gazette dated 2 September 2020 and numbered 31232 is available at this [link](#) (only available in Turkish).

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