

TITCK Updates the Guideline regarding the Regulation on the Sale, Advertising and Promotion of Medical Devices

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Turkish Medicine and Medical Devices Office ("**TITCK**") has updated Guideline ("**Guideline**") regarding the Regulation on the Sale, Advertising and Promotion of Medical Devices ("**Regulation**") on 20 October 2020 and introduced new provisions regarding the process of examination of the candidates and providing of compliance certificates of applicants which are sent by e-mail shall be provided through e-government gateway application.

The Guideline regulates the procedures and principles to be applied pursuant to Regulation, within the scope of real or legal persons' applications to get authorization as medical device sales centers, relevant trainings and examinations, and compliance certificates to be given as a result.

Pursuant to previous Guideline on Sale, Advertising and Promotion of Medical Devices which was entered into force on 27 February 2017 ("**Previous Guideline**"), a letter of undertaking, claiming the medical devices to be sold and promoted in sales centers to be recorded in the registration and the information system determined by the Institution, was required to be submitted to the relevant directorate along with the application petition. This letter is exempt from the obligations of applicants as per the updated Guideline dated 20 October 2020.

Furthermore, according to the Previous Guideline; real or legal persons', who are applied to be authorized as medical device sales centers and determined as in compliance with the guideline, were obliged to hang the compliance certificates given by the directorate in the sales center as visible. This is now excluded with the updated Guideline. Similarly, obligation of hanging the employment certificate issued for managing director that would work in medical device sales center as visible in sales center is also excluded pursuant to the updated Guideline.

While the training programs organized by the Institution were envisaged to be carried out sufficiently, the updated Guideline has revised the subject as the training programs shall be organized as at least once in a month. Additionally, the Guideline has also regulated that applications of those who apply to the trainings yet fail to participate shall be canceled.

Regarding the examination held after the training programs, according to the Previous Guideline, the candidates who failed the exam had the right to take the make-up examination for two times, while the updated Guide allows those candidates to take the next exam only. In this case, with the updated Guideline, it has been decided not to organize make-up examinations. While the results of the examinations were announced by the authorized institution themselves previously, with the updated Guideline the candidates will now be notified of the results through e-mail or a direct text message.

The most important update is that the candidates who have been eligible to obtain the qualification certificate previously were required to add the appropriate application petition on www.titck.gov.tr, while with the updated Guideline, the candidates will now make their application by uploading the qualification certificate through the e-government gateway portal. In addition, while there was no time limit for the payment of the qualification certificate fee, with the updated Guideline related fee must be deposited within 15 days following the application made through e-Government gateway, otherwise the candidates must once again make an application through e-government gateway. Following the payment of the cited fee, the qualification certificate directly sent to the Provincial Health Directorates where the candidates reside has been updated with the updated guideline that the candidates will print

out the certificate through e-Government gateway and the document will not be sent physically.

The full text of the updated Guideline updated on 20 October 2020 is available at this [link](#). (only available in Turkish)

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