New Turkish Medical Device Regulation Published and Aligned with EU Regulations

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Turkish Ministry of Health's preparations of the draft Medical Device Regulation ("*Draft Regulation*") which was announced on October 4, 2018[1] has come to an end and the finalized Medical Device Regulation ("*Regulation*")[2] has been published in the Official Gazette on June 2, 2021. The Regulation has similar content to that of the Draft Regulation, and it re-designs the rules pertaining to placement of medical devices in market, having been prepared in a manner to be fully in line with Regulation (EU) 2017/745 of the European Parliament which also has come into force recently. Along with the Regulation, "In Vitro Diagnostic Regulation" and "Communiqué on Annulment of Communiqué on Notified Bodies to Operate in Medical Device Sector" have also been published in the Official Gazette on the same day. Turkish Medicines and Medical Devices Agency ("*Agency*") is noted as the competent authority to enforce the Regulation.

The Regulation aims to ensure a high level of safety and protection for patient health, also rendering procedures pertaining to medical devices more transparent, trackable and predictable. As general principles, medical devices may be placed in the market and put into service only after meeting the relevant requirements pertaining to acquiring, installment, maintenance and evaluation of the device within the Regulation. The Agency is authorized to require additional information on devices from medical institutions, monitor their activities and decide to restrict manufacturing and use of relevant devices.

The Regulation also covers rules pertaining to providing distant services, indicating that a medical device that is used in distant diagnosis and treatment services through information society services (by also providing its definition), will also be subject to the rules and principles laid out in the Regulation, which includes submission of EU declaration of conformity and termination of the service provider, if required.

With regard to labels, user manual and advertisement of medical devices, the Regulation clearly prohibits use of misleading texts, names, trademarks, pictures, and figurative or other signs by (i) ascribing functions and properties to the device that the device does not possess, (ii) creating a false impression regarding any functions or properties related to treatment or diagnosis that the device does not have, (iii) failing to inform or misinforming the user or patient of a potential risk associated with the use of the device in line with its intended

[1] Please see https://www.mondaq.com/turkey/life-sciences-biotechnology-nanotechnology/769980/turkey-aligns-its-medical-device-regulation-with-the-eu-regulation for ELIG Gurkaynak's full article on the matter (last access: June 3, 2021)
[2] Please see https://www.resmigazete.gov.tr/eskiler/2021/06/20210602M1-2.pdf for the full text of the Guidelines in Turkish (last access: June 3, 2021)

purpose, and (iv) suggesting areas of use for the device other than the intended purposes for which a conformity assessment has been carried out, in relation to their intended purpose, safety and performance of the relevant medical device.

The Regulation stipulates that, medical devices that are in conformity with the harmonized standards which are prepared and accepted by one of European standardization institutions upon EU Commission's request, will be deemed to be in conformity with the Regulation and its requirements as well.

Obligations of parties within the supply chain of a medical device such as manufacturers, importers and distributors, have also become more detailed through the Regulation. Manufacturers are required to (i) prepare and regularly update the EU declaration of conformity, (ii) establish a risk-management system, (iii) conduct a clinical evaluation for tracking their devices that have been put into market, (iv) prepare and update the technical documentation of their devices, and (v) establish a quality-management system. They are also required to retain at least one person responsible for regulatory compliance within their organization. The Regulation sets out the specific qualifications this person must possess.

As for medical devices whose manufacturer is not a resident in Turkey or in an EU Member State, the Regulation foresees that such devices can only be placed in the market by the manufacturer's appointment of an authorized representative. The authorized representative must be appointed through a certificate of authority which should then be provided to the Agency.

The Agency will appoint and supervise a conformity evaluation institution as a notified body for the purposes of carrying out activities relating to conformity evaluation.

Concerning classification of medical devices, differing from the Draft Regulation, the Regulation includes and covers certain product groups that are not medical devices but possess similar qualities as medical devices in terms of risk profile, such as contact lenses, products to be used on human body through invasive means for the purposes of altering the anatomy or fixation of body parts, or equipment used in liposuction.

In the event of non-compliance with the relevant requirements, the Regulation indicates that Product Safety Law, Turkish Criminal Code and other relevant legislation will be applied in terms of sanctions to be imposed. As to the enforcement date of the Regulation, it is stipulated that aside from certain provisions, the Regulation has come into force as of May 26, 2021.

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First published by Mondaq on June 8, 2021