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Turkey Aligns its Medical Device Regulation with the EU Regulation

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In May 2017, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices ("**EU Regulation**") entered into force, stipulating a transition period for medical device manufacturers to comply with the EU Regulation by May 2020.[1] As the title of the EU Regulation suggests,[2] it lays down enhanced rules on medical devices, manufacturers, distributors, importers, and notified bodies. For any medical device to be put into and sold on the market, full compliance with the EU Regulation is required. The EU Regulation introduces and addresses several new principles and renders procedures pertaining to medical devices more transparent, trackable and predictable. These changes aim to ensure a high level of safety and protection for patient health and for the users within this industry, also taking into consideration the technological evolution and developments in this field.

In Turkey, the Medical Device Regulation, which is based on the Council Directives 90/385/EEC and 93/42/EEC and which entered into force on June 7, 2011, is currently still in force and effect. Recently, a draft Medical Device Regulation ("**Draft Regulation**") has been prepared and announced by the Turkish Ministry of Health, with the intention and purpose of harmonizing and aligning the Turkish regulatory framework for medical devices with the new EU regulations.[3]

The Draft Regulation contains requirements that are in parallel (indeed, almost identical) to those put forth by the EU Regulation, while also addressing a few local issues and principles that are specific to Turkey. A translated version of the EU Regulation was first published on the official website of the Turkish Medicines and Medical Devices Agency ("**Agency**"), the authorized body for the enforcement of the Draft Regulation, and was opened to public comment in order to receive and gather opinions from interested parties. Subsequently, the Draft Regulation was published on the Agency's official website, requiring interested parties to convey their ideas, suggestions and comments to the Agency by November 16, 2018.

In this regard, it is safe to say that the Draft Regulation contains very similar regulations—even direct translations—to those set out in the EU Regulation. Accordingly, certain significant changes that have been introduced through the Draft Regulation are summarized below:

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[1] Please see http://data.europa.eu/eli/reg/2017/745/oj for the EU Regulation.
[2] The full title of the EU Regulation is "Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC."
[3] Please see http://titck.gov.tr/duyuru/3390 for the announcement and the draft regulation.

- Addressing a critical issue, the Draft Regulation clearly prohibits labels, usage instructions and advertisements relating to a device's intended purpose, safety and performance from including 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 the user or patient of a potential risk associated with the use of the device in line with its intended purpose, and (iv) suggesting areas of use for the device other than those specified to form part of the intended purpose for which a conformity assessment has been carried out.

- Another significant change introduced by the Draft Regulation pertains to the obligations of manufacturers, importers and distributors, as the current Medical Device Regulation (which is still in effect) contains several provisions with respect to manufacturers' obligations under a number of articles, but little to no regulation with respect to those of importers and distributors. In this regard, the obligations of manufacturers, importers and distributors are increased and become more detailed through the Draft Regulation. In this context, manufacturers are required to prepare and to regularly update the EU declaration of conformity. They are also required to fulfill their obligations with respect to (i) establishing a risk-management system, (ii) conducting a clinical evaluation for tracking their devices that have been put into market, (iii) preparing and updating the technical documentation of their devices, and (iv) establishing a quality-management system. Manufacturers must retain and have available at least one person within their organization who will be responsible for regulatory compliance, and who must possess specific qualifications. In the event that the manufacturer of a device does not reside in Turkey or in an EU Member State, the device may only be put into market by the authorized representative of the manufacturer. Increased and enhanced responsibilities have also been placed upon the importers and distributors of medical devices.

- The Draft Regulation also comprises several changes in relation to the medical devices. While the product classifications remain the same, certain new procedures have been introduced with respect to the registration of the devices. The current Medical Device Regulation simply requires the Ministry of Health to ensure the local registration and evaluation of certain information pertaining to devices, whereas the Draft Regulation, parallel to the EU Regulation, introduces international registry systems, such as the Unique Device Identification (UDI) and EUDAMED schemes, on top of the local registration requirement.

- The Draft Regulation also addresses issues relating to confidentiality and data protection, and requires the protection of personal data, commercially confidential and sensitive information, and information obtained during inspections, investigations, or audits.

As the notified bodies (which are currently authorized to grant the conformity certificate for medical devices to manufacturers) will also be required to meet and fulfill additional specifications in order to obtain their licenses and to continue operating, the Draft Communiqué on Notified Bodies Operating in the Medical Device Sector ("**Draft Communiqué**") has been prepared and published on the Agency's official website as well.[4] The announcement of the Draft Communiqué also includes a comparison chart with the relevant articles of the EU Regulation, indicating that the Draft Communiqué has been prepared based on the EU Regulation.

The publication and enforcement dates of the Draft Regulation and the Draft Communiqué have yet to be announced. However, in light of the extensive similarity between the Draft Regulation and the EU Regulation, and considering that the EU Regulation provides a transition period of three years, we might reasonably anticipate that the Draft Regulation will stipulate a similar transition period for compliance after entering into legal force.

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[4] Please see http://titck.gov.tr/duyuru/3295 for the announcement and the draft.