Consultation on draft medical devices regulation

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On 4 October 2018, the Turkish Medicines and Medical Devices Agency published the *draft Regulation on Medical Devices* (Turkish language), which was drafted in parallel with the EU Medical Device Regulation (*(EU) 2017/745*). The draft regulation is currently open to public consultation until 16 November 2018 and may be amended before final publication.

One of the significant changes that the draft regulation will introduce for medical devices is the explicit regulation of processes for placing on the market, putting into service and distance sales. Devices that conform with the relevant harmonised standards shall be presumed to conform with the requirements of the Regulation, once adopted. Where the manufacturer of a device is not established in an EU member state or Turkey, the device may only be placed on the market if the manufacturer designates a sole authorised representative in Turkey.

The "Unique Device Identification" system and registration of devices and economic operators are also incorporated in the draft to allow the identification and facilitate the traceability of devices.

If adopted, the draft regulation will enter into force upon publication, although some of its provisions shall only enter into force as of 26 May 2020.