THE NEW MEDICAL DEVICE REGULATIONS –A SAFER SECTOR SUBJECT TO CLOSER SCRUTINY

The Medical Devices Regulation numbered 2017/745 (the "**MDR**") of the European Union (the "**EU**") became fully effective as of 26 May 2021. Given the substantial changes that the MDR brings, it is for sure that the medical devices sector will never be the same. In parallel with the changes brought by the MDR, Turkey's corresponding legislation has been amended with a view to harmonising the legislative framework of the country with that of the EU. The new Medical Device Regulation (the "**Regulation**") has been prepared in full compliance and mostly includes very similar provisions -if not identical- with the MDR. The Regulation was published in Turkish Official Gazette on 2 June 2021 with several dates of coming into force depending on the relevant provision.

The MDR and the Regulation (together, the "**New MDRs**") include more detailed and stricter requirements and responsibilities for those subject to the legislation than the current legislation, and expand the scope and classification of the in-scope products. This comes as no surprise given that as a result of the recent technological developments, the previous legislation had become obsolete in terms of meeting the need to ensure safety and effectiveness of the market, particularly in protecting the medical device users, and it had thus become necessary to amend the legislative framework to keep up with the necessities of the time.

Below are some significant changes offered by the New MDRs:

Expansion of the product scope. Products similar to medical devices in terms of functioning and risk profile that were not previously considered as medical products (e.g., contact lenses, cosmetic implant devices, liposuction equipment, lasers and brain stimulation equipment) have been included within the scope of the New MDRs under Annex XVI of the regulations, and are now treated as medical products. Thus, the provisions of the New MDRs are now applicable to such products as well. The common specifications which will apply to the products listed under Annex XVI that are yet to be concluded by the EU Commission will come into effect at the end of a six month period upon their publication date. The Turkish regulatory framework follows the EU in terms of adoption of the common specifications to be applicable to the medical products under Annex XVI as well.

Reclassification of products. As in the previous legislation, medical products are classified under four different risk categories in the New MDRs. There are however 22 different classification rules envisaged by the New MDRs as opposed to the previous legislation which included 18 of them. Accordingly, a number of products fall within the scope of a higher risk class than their previous respective classes, and thus will be under closer scrutiny. In this context for example, certain products are now subject to inspection of the relevant notified bodies, and EC certificate will need to be obtained for such product, when this was not previously the case. It is important for manufacturers of in-scope products to observe the new classification rules and to take measures such as updating the technical documentation or software programmes as necessary.

Regulatory compliance officer. According to the New MDRs, manufacturers must identify at least one person within their organisation that shall be responsible for regulatory compliance who must either (i) have a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognized by competent authorities concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical device or (ii) have four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Stricter market oversight. The New MDRs also aim to tighten the market surveillance. Under the new legislative framework, there will be more frequent unannounced audits and product sample checks as well as increased product testing procedures. The surveillance shall be conducted by the notified bodies that hold the necessary qualifications indicated under the New MDRs. In light of the qualifications provided by the New MDRs, it seems that the bodies that can conduct the surveillance under the previous legislation may no longer qualify. Therefore, it would be fair to expect new entrances in the market as well as the existing bodies to take actions to also qualify under the New MDRs.

Clinical research requirement. Pursuant to the New MDRs, clinical evaluation is set forth as part of general security and performance requirements of a medical device. As such, manufacturers are required to make clinical researches before placing a medical device on the market except for products, which are manufactured on-demand.

Registration to EUDAMED. EU Medical Device Database ("**EUDAMED**"), which is considered to be a user-friendly and easily-searchable electronic database is introduced by the New MDRs for purposes of ensuring a transparent market where the public will be adequately informed on the medical devices placed on the market and it is also aimed that individual traceability of each product shall be improved.

To conclude, with the New MDRs becoming fully effective, a stricter and more inclusive legislative framework is now in place. Market players would thus better closely follow the developments for a smooth tuning-in process until all click into place.