Turkish Medicines and Medical Devices Agency (“Agency”) recently published draft regulations for consultation in the field of medical devices. The drafts are important in terms of meeting with current market needs and harmonizing with EU legislation.

The first draft regulation is the Regulation on Medical Devices which was drafted in parallel with the EU Medical Device Regulation (EU/2017/745). The significant changes are the explicit regulation of processes for placing on the market, putting into service and distance sales and the broadened definition of medical device. Given that the draft regulation has not been put into effect yet, it is apparent that the transition period in Turkey will not be in parallel to the EU transition calendar. The delay is expected to create confusion in terms of registration and placing of the products on the market.

The most recent draft regulation which was published by the Agency on 9 May 2019 is the Regulation on Sales, Advertisement and Promotion of Medical Devices. The revisions proposed in the draft are due to the emergence of current market needs and problems while exercising the existing regulation. One of the significant changes is the prohibition of direct and distance sale of some devices to consumers.

The consultation period for both draft regulations are over but none of them are published and put into effect. The industry expects clear guidelines and transition periods in case the publication of both regulations are delayed.