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Turkish Medicines and Medical Devices Agency Published the Industry Report on Medical Devices

On April 4, 2024, the Industry Report on Medical Devices, prepared by the Turkish Medicines and Medical Devices Agency ("Agency") to present the current state of the market together with recent developments in the medical device industry, was published on the Agency's website.

The Industry Report on Medical Devices includes assessments of global developments in the medical device industry, statistical information on the Turkish market, and explanations of the current activities of the Agency.

In the chart on health expenditures in Turkey between 2012 and 2022, prepared with the data obtained by the Turkish Statistical Institute in the Industry Report on Medical Devices, it is stated that health expenditures were approximately TRY 354 billion in 2021 and that spending increased by 71.5% in 2022, exceeding TRY 606 billion. It is observed that, similar to global trends, there is a continuous increase in all indicators of health expenditures in our country. In Turkey, the largest share of medical device purchases belongs to the public sector, and most of these purchases are made by the General Directorate of Public Hospitals of Turkey.

The Industry Report on Medical Devices also includes market distribution data prepared by Fitch Solutions, which is generating insights, data, and analyses in ever-changing markets in 2022. According to the data, medical devices in the Turkish market are categorized as consumables (26%), diagnostic imaging (18%), orthotics and prosthetics (9%), patient aid products (hearing aids, respiratory devices, pacemakers, etc.) (10%), dental supplies (8%), and other devices (29%). The value of the Turkish medical device market exceeded USD 2.5 billion in 2021 and is expected to reach USD 2.6 billion by 2026. However, it is noted that the market predominantly comprises imported products, and the majority of domestically produced devices are of low to medium technology. Analysis of the data from 2017 to 2023 shows that medical device exports' growth momentum is higher than imports.

The Industry Report on Medical Devices summarizes the investment incentives to increase Turkey's competitiveness against other countries in the medical device sector. Notably, the investment incentive system established under the "Decision on State Aids in Investments" numbered 2012/3305 was introduced to increase R&D investments. According to January 2024 data from the Ministry of Industry and Technology, TRY 4.2 million in investment incentives were granted in 2023, and 2.170 people were employed



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in the sector. However, it was pointed out that compared to OECD countries, R&D expenditures in our country are low, and various policies should be developed to increase this amount.

In addition to these general statements about the medical device market, the sectoral activities of the Agency have also been included. Within this scope, the legislative efforts to harmonize the medical device legislation with the European Union legislation, the publication of the Medical Devices Regulation, and the transition process of the In Vitro Diagnostic Medical Devices Regulation have been explained. Within the legislative framework, seven notified bodies have been appointed in Turkey. Regarding Product Tracking System ("UTS") registration activities, it is stated that 478,246 medical devices, constituting 92% of the 517,944 registered products, have been certified by domestic notified bodies authorized by the Agency. It is determined that the majority of the products manufactured and certified in Turkey belong to Class IIa Device and Class IIb Device risk classes. In 2023, the Agency responded to 235 product risk class assessment applications.

Statistical data related to clinical research indicate that the number of medical device clinical trial applications, which was 185 in 2021, has shown an increasing trend to 204 in 2022 and 240 in 2023. Corresponding to the increase in the number of products registered in the UTS, the total number of products inspected as part of market surveillance and inspection activities reached 4,142 in 2023, while the number of adverse event reports rose to 2,746.

The Regulatory Calendar for Implementation attached to the Industry Report on Medical Devices includes the upcoming deadlines for obligations to be complied with by the Medical Device Regulation and other legislation in May 2024 and beyond. In parallel with the dynamics of the sector, it is possible to say that there will be intensive legislative updates and studies in the coming years. In addition to the need to update the legislation under the mandate of the Agency, sector stakeholders also expect the rules regarding the reimbursement processes at the Social Security Institution to be revised.