TRADE & INDUSTRIAL POLICY STRATEGIES

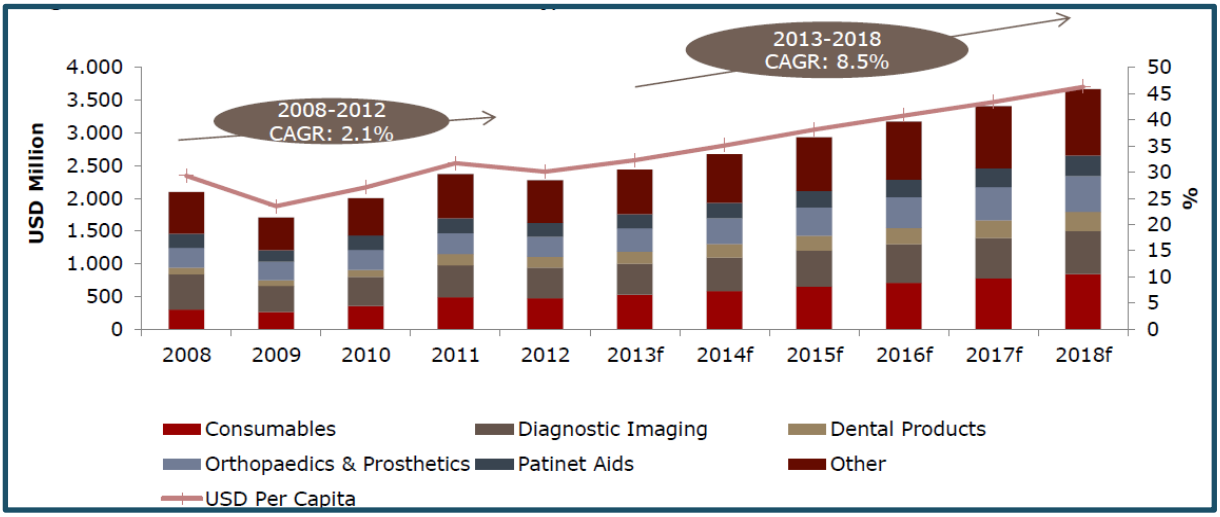
DRAFT OF THE SOUTH AFRICAN MEDICAL DEVICES MASTERPLAN – VALUE CHAIN 2024

ANNEXURE 4A: TURKEY CASE STUDY

Market Overview

As a large country, with a population of over 84 million, Turkey is a growing market for medical technologies and healthcare services.[1] The country's medical device market is one of the fastest developing and competitive markets in the world, and is ranked as the largest in the region of the Middle East and Africa and third in the Central and Eastern Europe region, with a value of US$2billion in 2020. Although the size of Turkey's medical device market has steadily increased over the years, it only accounts for 1% of the global medical device market. Graph 1 illustrates Turkey's medical device market between 2008 and 2018, according to contribution of various product categories. Between 2013 and 2018, Turkey's medical device market was forecast to grow by an annual growth rate of 8.5%, driven by the expansion of healthcare facilities and an increase in health expenditure. Between 2010 and 2020, Turkey's medical device market grew at an annual average growth rate of 17%.

Graph 1: Turkey's Medical Device Market, 2008 to 2018



Source: BMI Espicom. *Notes*: Other items include: Wheelchairs, ophthalmic instruments, anesthesia equipment, dialysis equipment, blood pressure monitors, endoscopy monitors and hospital furniture.

[1] International Trade Administration. Turkey – Country Commercial Guide. https://www.trade.gov/country-commercial-guides/turkey-medical-technologies-and-health-it

Within the medical devices sector, Turkey's Ministry of Health, which is responsible for the planning and implementation of healthcare policy, is the country's largest healthcare service provider. Based on data from the Turkish Statistics Institute's Health Expenditure 2020 report, Turkey's healthcare expenditure grew by 24.3% in 2020, with the public sector accounting for 79% of the country's healthcare related expenditure. Both the public and private sectors together spent US$2.4 billion on infrastructure investment in the healthcare sector.

Approximately 6000 medical technology companies are operating in Turkey's healthcare market (Andra, 2016). The Action Plan and Strategic Document of the Turkish Medical Device Sector estimates there are around 1,000 medical device manufacturers (Kose and Cifter, 2018), and 2 300 importers in Turkey, mainly in İstanbul, Ankara, İzmir, Samsun, Adana and Konya (Presidency of The Republic of Turkey and Sistem Global, 2021). The medical devices products manufactured include a diverse offering of medical equipment such as medical and surgical instruments and appliances, waddling, gauze, bandages, medical disposables, syringes, needles and catheters, ophthalmic instruments, dental instruments, laboratory diagnostics and many others.

Most manufacturers are involved in the production of low-tech medical device products, while the high-tech products are mostly imported from leading countries such as the United States, Japan, China and the United Kingdom (Kose and Cifter, 2018). Approximately 85% of medical devices and supplies used in Turkey's healthcare sector are imported products, meaning that Turkey is a net importer in the medical devices and equipment market (Andra, 2016). The country imports advanced medical devices and equipment such as pre-screening and diagnostics devices, advanced point-of-care devices, surgical devices using robotics technology, cancer treatment devices and many others. With Turkey's medical industry being highly dependent on foreign imports, it suggests that domestic companies that manufacture using traditional technology, and produce low-value added products, are in a weak position against international companies that have adopted technology and innovation (Kilavuz and Erkekoglu, 2019). Table 1 summarises Turkey's production and trade, highlighting the trade deficit in the medical devices sector.

Table 1: Turkey's medical sector production and trade (US$ millions)

	2016	2017	2018 (estimate)	2019 (estimate)
Total local production	838	768	836	955
Total Exports	445	429	494	550
Total Imports	2 222	1 945	1 933	1 950
Imports from the US	445	398	386	351
Total Market Size*	2 620	2 284	2 275	2 355

Source: Kilavuz and Erkekoglu, 2019. *Note*:* Total market size is calculated as (total local production plus imports) minus exports.

That said, in its 10th Development Plan, the Turkish government highlighted the need to increase domestic production and export capabilities within the medical device and medical equipment industry. This has seen the number of firms in Turkey and the market share in this industry increase in terms of new production capacity.[2] In its 2017-2021 Action Plans, Turkey's Ministry of Health

[2] The following products are being manufactured: Operating tables and lamps, anesthesia devices, gynecological tables, surgical aspirators, oxygen delivery devices, X-ray devices, syringes, needles, elastic bandages, gauze and cotton steam and dry air sterilisers, blood retrieving seats, cushions, patient beds, dental units, dental repair materials, surgical instruments, drainage, stents, catheters and sondoles, medical gas systems, stone crushing devices, blood and blood products, removal

highlighted the following recommendations to ensure the development and competitiveness of its medical device industry:

- Product safety measures for imported medical devices should be increased.
- After-sales service responsibilities should be increased.
- By removing inventory of domestic medical devices and materials, dependence should be reduced.
- Organised industrial zones for medical devices should be established.
- A Medical Device Exporters' Association should be established.
- Increased international cooperation and transition to high technology medical devices in domestic production should be accelerated.
- Support for the establishment of accredited testing laboratories.

Key players in Turkey's medical devices industry

Leading global medical device producers have chosen Turkey for their regional headquarters and research and development (R&D) centres for their production facilities. Some of the major players in the medical devices market in Turkey are Siemens Healthineers, GE Healthcare, Boston Scientific Corp (Boston Scientific), Terumo, and Getinge AB (Getinge). Table 2 details the activities each company is involved in.

Table 2: Main medical device manufacturers in Turkey

NAME	WHAT THEY DO
Siemens Healthineers	Subsidiary of Siemens AG. This medical technology company designs, develops, and distributes diagnostic imaging systems, clinical and workflow systems and solutions, and systems for minimally invasive procedures. Siemens Healthineers is headquartered in Erlangen, Germany. In Turkey, it operates from Esentepe, Istanbul.
GE Healthcare	Manufactures and sells medical imaging devices for diagnosis, as well as other medical devices. GE Healthcare is headquartered in Chicago, Illinois, US. In Turkey, it operates from Şişli, Istanbul.
Boston Scientific Corp (Boston Scientific)	This medical technology company develops, manufactures, and commercialises devices for a range of interventional medical specialties. The company offers products in the areas of electrophysiology and gastroenterology, among others. Boston Scientific is headquartered in Massachusetts, US. In Turkey, it operates from Uskudar, Istanbul.
Terumo	Manufacture and sales of medical products and equipment, including pharmaceuticals, blood bags, disposable medical devices, cardiovascular systems, vascular grafts, peritoneal dialysis, blood glucose monitoring system, medical electronic, and digital thermometers.
Getinge AB (Getinge)	A medical technology company specialising in providing equipment, systems, operating rooms, intensive-care units to the healthcare and the life science industries.

kits, orthopedic prostheses, orthopedic repair devices, medical masks, surgical gloves, blood storage cabinets, bio carriers, defibrillator, serum sets, stainless steel products.

Source: Compiled by author using information from https://www.globaldata.com/store/report/turkey-healthcare-regulatory-and-reimbursement-analysis/

Apart from these leading manufacturers, other key stakeholders and their role in Turkey's medical devices are presented in Table 3.

Table 3: Major stakeholders in Turkey's medical devices sector

NAME	WHAT THEY DO
The Ministry of Health of Turkey (MoH)	Turkey's MoH, founded in 1920, is the largest healthcare provider and the entity responsible for the provision of healthcare services. It determines the requirements for the design, manufacturing, supply, classification and supervision of medical devices.
The Turkish Medicines and Medical Devices Agency	Regulates, supervises and controls pharmaceuticals, medical devices, traditional herbal and supportive products, advanced therapeutic medical devices and cosmetic products in Turkey
The Turkish Drug and Medical Device Institute	The Turkish Drug and Medical Device Institute provides permission for and oversees clinical trials concerning medical devices. It is also responsible for certifying that a device manufacturer has taken steps to ensure compliance with the regulations.
Turkish Standards Institute (TSE)	TSE makes conformity assessments for CE marks demonstrating conformity of products to European standards
Social Security Institute	The Social Security Institute is responsible for financing the MoH and university hospitals for the procurement of medical devices.
The Health Industry Employers' Association of Turkey	The Health Industry Employers' Association is an association of companies operating in the medical devices sector. It represents companies active in the sector in the government's policymaking processes.
The Healthcare Products Manufacturers and Representatives Association	The Healthcare Products Manufacturers and Representatives Association was founded in 1993 by 14 companies active in the medical equipment sector. It strives to set high-level standards for commercial relations and promotes professionalism in the sector.
Federation of Medical Device Manufacturers and Suppliers Association (TÜMDEF)	TÜMDEF was established in 2004 and works to increase cooperation, industry standards and the adoption of new technology within the Turkish medical devices sector.

Source: Compiled by author using information from
Investment Support and Promotion Agency in Turkey, 2023.

Government's view of the medical devices industry

Turkey's public sector is the main contributor in the medical devices industry; therefore its views and perspective are important when it comes to understanding the dynamics of the sector in terms of emerging and expected trends. The Turkish government's strategy for the medical devices industry is centred around the government's localisation policy programme, which is targeted towards reducing the country's level of import dependence, and at the same time increasing local production capacity (Yalçın, 2023). Support measures to ensure the success of this strategy have included increased investment in healthcare infrastructure and services, promotion of medical tourism and alignment of regulatory polices with international standards.

Based on the President's Annual Program for 2022, which provides strategic guidance on specific programmes that the government set as high priority for different sectors, the following objectives are highlighted as critical for the growth of Turkey's medical devices industry:

1. Establishing an accredited centre of excellence to provide analysis, verification, testing and measurement services in the areas of medical device research and development, preclinical studies, prototype development, manufacturing and post-production processes.
2. Organising programmes and events on incentives and intellectual property rights to accelerate the commercialisation process, especially for university researchers.
3. Developing an infrastructure for the production of chemical, plant, biological and radiopharmaceutical (nuclear) raw materials.
4. Developing infrastructure and skills to strengthen R&D activities for biotechnological medicines.
5. Establishing preclinical research centres, which hold an internationally recognised certificate of good laboratory practice, to conduct R&D studies on medicinal products and medical devices prior to clinical trials.
6. In order to increase the share of international funding (e.g. EU funds and NIH funds) in clinical research, memberships in international networks are sought to increase Turkey's visibility at the international level
7. Ensure the decentralisation of the policy on vaccines, drugs, protective equipment and medical devices

These objectives, as set in the programme, are all geared towards increasing the local share in the development and manufacturing phase of medical devices, which will generate more income and employment .

Latest Trend in Regulation: Full Harmonisation with EU Legislation

Although Turkey is not a member state of the European Union (EU), it has managed to align its regulatory framework for medical devices manufacturers with that of the EU.[3] In June 2021, Turkey published two new regulations the first being the Medical Devices Regulation (MDR) and the second which is the Medical Devices In Vitro Diagnostic Regulation. Together, these regulations are fully harmonised with the EU legislation, with the aim of ensuring high standard levels in terms of safety of patients and end users and the quality of medical devices on the market. Additionally, the harmonisation will also ensure that the medical devices market is transparent, robust and sustainable (Yalçın, 2023).

Stakeholders in Turkey's medical devices industry, namely manufacturers, authorised representatives and importing companies are required to register on the European Database on Medical Devices (EUDAMED) as a means of increasing transparency and enabling traceability in the medical devices industry. This means that for manufacturing companies, registration of all medical devices must be done before the product is sold on the market. The following text box provides a summary of regulatory requirements in Turkey's medical device sector based on information from Johner Institute.

Summary of Turkey's Medical Device Regulatory framework

[3] Johner Institute. Medical Device Regulation. https://www.johner-institute.com/articles/regulatory-affairs/medical-devices-turkey/

While not an EU Member State, Turkey has aligned its regulatory framework for medical device manufacturers with that of the European Union.

- General: Customs Union
  - While Turkey is a de facto third country for the EU, the Customs Union between Turkey and the EU greatly facilitates the movement of commercial goods. As part of this agreement, Turkey has aligned its commercial law with EU law.
- Specifically: Medical devices
  - This is also true for medical device law. Turkey had already harmonized the EU medical device directives (Medical Device Directive (MDD), In Vitro Diagnostic Medical Device Directive (IVDD), Active Implantable Medical Device Directive (AIMDD)). In the meantime, the Turkish Medicines and Medical Device Agency has reconciled Turkish medical device and IVD regulations with the EU framework (Medical Device Regulation (MDR), In Vitro Diagnostic Medical Device Regulation (IVDR)).
- Harmonised requirements and CE marking
  - Since Turkey has aligned its legal framework with that of the European Union, devices which have successfully passed conformity assessment in Europe and bear a CE mark also meet the Turkish requirements, that is medical devices with a Conformité Européene (CE) mark may also be sold in Turkey – within the restrictions outlined below. No other conformity assessment is required.
- No additional authorised representatives
  - In a notice to stakeholders, the EU Commission has made it clear that EU manufacturers are not required to have an authorised representative in Turkey and, by extension, Turkish manufacturers do not require an authorised representative in the EU either.
  - Moreover, manufacturers from third countries intending to supply both markets only need to appoint one authorised representative, either in Turkey or in the EU.
- Other
  - The Customs Union eliminates customs restrictions. After the transition periods, device registration and vigilance notifications in EUDAMED will also suffice. Manufacturers are no longer required to use the Turkish database for these aspects.

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