MEDICAL DEVICE INDUSTRY ANALYSIS

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Sukhanidhi
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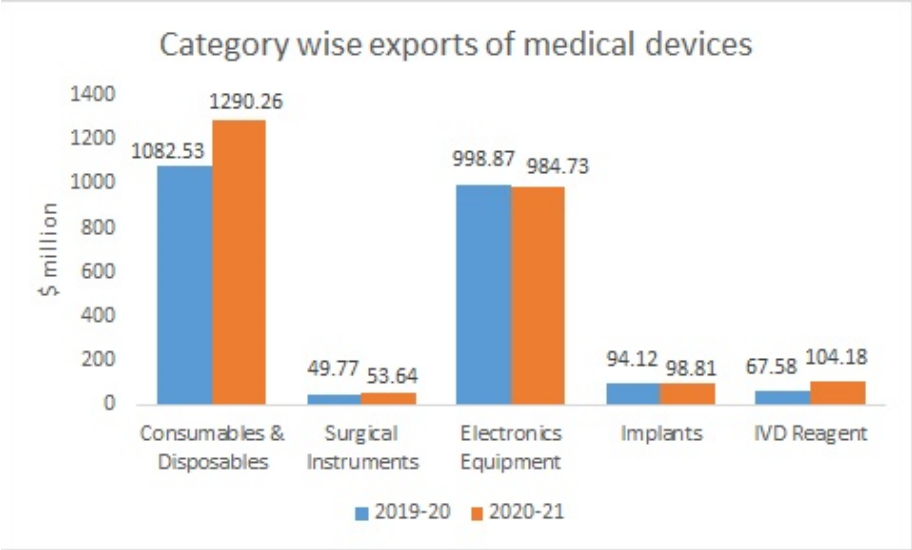
Medical device industry is a sunrise sector and has the potential of growing highest among all the sectors in the healthcare system. Various categories of devices starting from consumables to implantable medical devices are being manufactured in India. India is among the top five countries in the world manufacturing life-saving high risk medical devices but the cost of devices is about one-third of those manufactured by the other four countries like USA, Japan, Brazil and China. The Medical Device industry is highly capital intensive with a long gestation period and requires development/induction of new technologies. The sector also requires continuous training of healthcare system providers to adapt to new technologies. Most of the high technology and innovative products originate from a well-developed ecosystem and innovation cycle, which is yet to be fully developed in India.

The current market size of the medical devices sector in India is estimated to be $11 billion and its share in the global medical device market is estimated to be 1.5% and is an attractive export sector for U.S. firms, despite numerous market challenges. Importing nearly 80 percent of its medical devices, India remains highly dependent on foreign suppliers, particularly with respect to higher end equipment such as cancer diagnostics, medical imaging, ultrasonic scans, and polymerase chain reaction technologies. Imports are growing rapidly as world-class hospital groups such as Max, Hinduja Group, Fortis, and Apollo build high-end infrastructure and spur on India's medical tourism sector, which now contributes $2 billion to the Indian healthcare market. India faces a chronic shortage of healthcare infrastructure, especially in second and third tier cities and rural areas. There are six Medical devices manufacturing clusters – Gujarat / Maharashtra / Karnataka / Haryana / Andhra Pradesh & Telangana / Tamil Nadu.

Category wise exports of medical devices

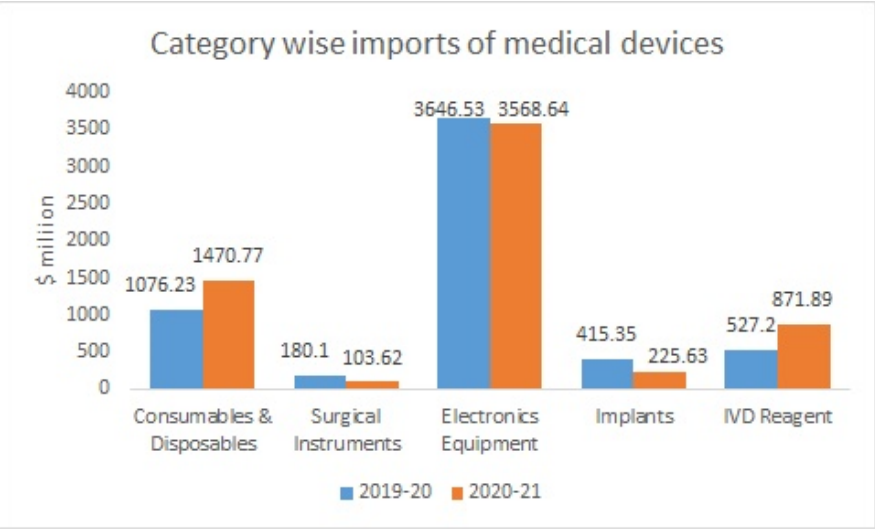
The overall exports of medical devices stood at $2531.62 million in 2020-21 as compared to $2292.87 million in 2019-20 i.e. up by 10.41%. Out of which, exports of Consumables & Disposables witnessed 19.19% to $1290.26 million in 2020-21 as against $1082.53 million in 2019-20. Surgical Instruments' exports stood at $53.64 million in 2020-21 as compared to $49.77 million during 2019-20. Exports of Electronics Equipment, Implants and IVD Reagent stood at $984.73 million, $98.81 million and $104.18 million respectively.

Exports of medical devices is likely to increase in coming time as in order to promote exports of medical devices from India, the Union Ministry of Commerce and Industry has decided to set up an Export Promotion Council for Medical Devices (EPCMD). The setting up of the export promotion council will help bring in coordinated inter ministerial policy measures for unleashing the huge export potential and investment potential of over Rs 80,000 crore for manufacturing medical devices for the global market.



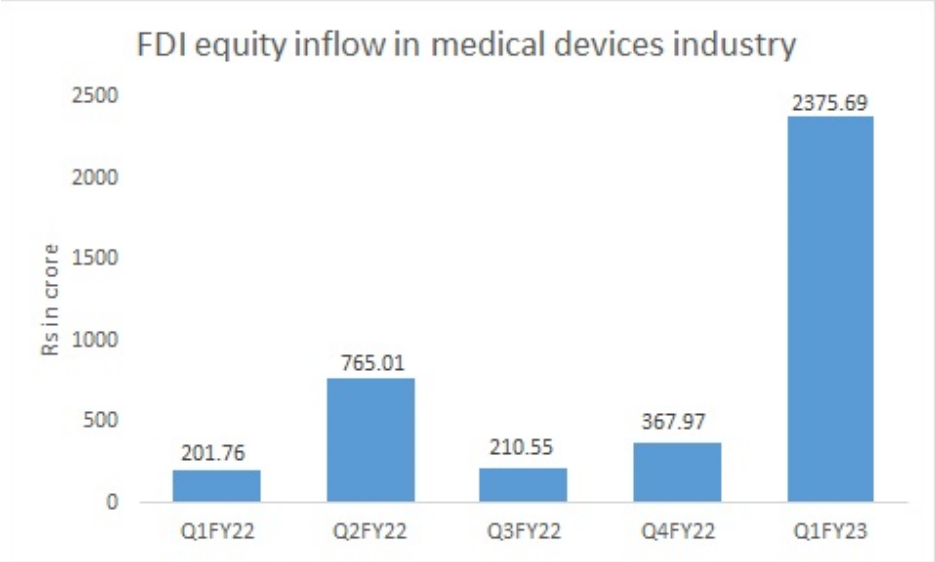
Category wise imports of medical devices

India imported $6240.55 million worth of medical devices in 2020-21 as compared to $5845.41 million in 2019-20, i.e. up by 6.76%. Among the six major categories of medical devices like Consumables & Disposables, Surgical Instruments, Electronics Equipment, Implants and IVD Reagent that are imported, the growth has been the highest in the 'electronics and equipment' category. India's top five medical device import sources -- China, USA, Germany, Singapore and Japan – together account for $3518.26 million. The pandemic has pushed India to increase its import of medical ventilators, Extracorporeal membrane oxygenation (ECMO), Continuous Positive Airway Pressure (CPAP) units, Continuous Positive Airway Pressure (CPAP) units, Oxygen concentrators, Oxygen humidifiers for oxygen therapy applications, Oxygen delivery devices to supply oxygen.



FDI in medical devices industry

In order to attract investments in this sector, the Government has allowed 100% foreign direct investments (FDI) in medical devices sector. In Q1FY23, FDI equity inflow in medical equipment sector stood at Rs 2375.69 crore as compared to Rs 367.97 crore during Q4FY22, i.e witnessed over 6- fold jump. Foreign direct investments in Q1FY22 stood at Rs 201.76 crore. The Indian medical devices sector's contribution has become even more prominent in COVID-19 pandemic as India supported the global battle against COVID-19 pandemic through the production of medical devices & diagnostic kits, e.g., Ventilators, RT-PCR kits, IR Thermometers, PPE Kits & N-95 masks. Favorable policies boosting domestic manufacturing drive investments from foreign investors.



Rising frequency of chronic diseases to boost demand for medical devices

There is a growing prevalence of chronic disorders, including diabetes, cancer, and other infectious diseases, owing to the adoption of sedentary lifestyles and other factors. Also, healthcare agencies of various countries are focusing on increasing the diagnosis and treatment rates through the growing number of awareness programs. With the rising prevalence and awareness of such conditions among the population, the patient population requiring diagnostic procedures and tests is also increasing. Also, a rapid rise in the geriatric population is increasing the demand for ophthalmic and orthopedic procedures due to increasing incidence of impaired vision and joint fractures in the elderly population. Due to increasing economic burden and rising population aged above 60, there is a paradigm shift of preference toward home healthcare services among the population. Additionally, with increasing efforts of key players and healthcare agencies to develop and launch new and easy-to-use medical equipment, such as portable and wearable devices for the treatment of chronic diseases, the adoption of home healthcare services is rapidly rising.

How 5G is transforming medical device industry?

The medical device industry has made significant strides in developing wearable devices fitted with wireless technologies, sensors, built-in GPS, and smartphone compatibility. For instance, Fitbit smartwatches can monitor SpO2 (blood oxygen), pulse/heart rate, skin temperature, ECG, and stress. More such technologies are cropping up to facilitate remote patient care and monitoring, increasing the patient's engagement with their healthcare and treatment. Medical practitioners can use smartphone cameras and their microphones of their patients to detect melanoma, analyze patient injuries, assess coughs, monitor skin infections or eye problems. In addition, wireless sensors can assist in administering and monitoring medication and assessing rehabilitation.

Office: 1/53C opposite to KIMS Main Gate, Jayanagar Extensions, Vidyanagar, Hubli-580021. Toll Free: 1800 889 0255 Email: contactus@sukhanidhi.in

The advances in medical devices and wearable tech also facilitate remote patient monitoring. Patient homes can be equipped with the right technologies to remotely monitor their vitals, symptoms, and healing over low-latency, high-bandwidth 5G networks. Such networks enable anything from live-streaming patients and their conditions to monitoring their vitals using the medical devices in real-time. As a result, hospitals can reduce their overall costs and accommodate larger patients by quickly discharging patients in recovery and monitoring their vitals remotely. Besides, 5G networks streamline real-time data transfers, which is crucial for a fast and accurate diagnosis. A 5G device is two to five times faster than one based on Wi-Fi or 4G.

Production Linked Incentive (PLI) scheme for promoting domestic manufacturing of medical devices

The domestic medical devices industry faces challenges related to considerable cost of manufacturing disability, among other things, on account of lack of adequate infrastructure, domestic supply chain and logistics, high cost of finance, inadequate availability of quality power, limited design capabilities and low investments on R&D and skill development. With a view to address these challenges in manufacturing of medical devices in India vis-a-vis other major manufacturing economies, a scheme called 'Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices' was approved by the Government of India on March 20, 2020.
The Scheme is applicable only to the Greenfield projects and intends to boost domestic manufacturing and attract large investments in the Medical Devices Sector. The tenure of the scheme is from 2020-21 to 2027-28 with total financial outlay of Rs 3,420 crore. Under the Scheme, financial incentive will be given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the Target segments of the scheme, for a period of five years. The products under the scheme have been categorized under following four categories:

- Cancer care / Radiotherapy medical devices
- Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging devices
- Anesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care medical devices
- All Implants including implantable electronic devices

Policy and Regulatory environment

To ensure quality healthcare, the Indian government increased the list of medical devices covered under the Drugs and Cosmetics Act of 1940, bringing several categories of implantable devices under the provision of the Medical Device Rules (MDR) 2017. Medical devices in India are classified according to the risk to patient health. The current risk classifications are Class A: devices with the lowest risk (e.g., surgical dressings and alcohol swabs); Class B: devices with low to moderate risk (e.g., needle kits and cervical drains); Class C: devices with moderate to high risk (e.g., bone cement, bifurcation stents and catheters); and Class D: devices with high risk (e.g., coronary stents and cardiac catheterization kits).

In January 2022, the Indian government issued a notification requiring all medical device companies to register their devices with the Central Drugs Standard Control Organization in compliance with a mandatory ISO 13485 certification. This requirement is designed to ensure the safe production and control of medical devices and in-vitro diagnostic products. Previously, medical devices were subject to a voluntary registration scheme. Starting in October 2021, Class A and B medical devices were subject to mandatory registration, and from September 2022, Class C and D medical devices will be subject to mandatory registration. When the mandatory registration period expires in September 2023, the medical device classes will transition to a licensing regime.

In February 2022, the Department of Pharmaceuticals amended the list of medical devices exempted from India's Procurement Order 2017 to ensure patient access to critical medical technologies not currently produced in India.

Government initiatives/ recent developments

- In July 2022, the government tabled a draft for the new Drugs, Medical Devices and Cosmetics Bill 2022, to assure and offer thorough legal protections to ensure that the medical items sold in India are reliable, efficient, and up to required standards.
- The government of India has decided to set up a separate Export Promotion Council (EPC) for Medical Devices, to boost exports of medical devices.
- Health Regulator geared up for smooth transition to licensing of Class A and B Medical Devices with effective from October 01, 2022.
- Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram has focusing on the development of medical device technologies which are at par with any product available internationally, with respect to their quality and functional efficacy, at the same time ensuring that these products are made available to the Indian patients at an affordable cost.
- Chitra Triunal Institute of Medical Science and Technology is in the process of setting up a medical device park, MedSpark, as a joint initiative with the Kerala State Industrial Development Corporation, Government of Kerala.
- The government of India implements the scheme 'Promotion of Medical Devices Parks', with a total financial outlay of Rs 400 crore and the maximum assistance under the scheme for one Medical Device Park would be limited to Rs 100 crore. The tenure of the scheme is from FY 2020-2021 to FY 2024-2025 and the selected Medical Device Park project will be implemented by a State Implementing Agency (SIA).

Outlook

Indian medical devices industry has the power to emerge as the global leader in manufacturing and innovation in next 25 years. The growing demand for quality healthcare and the absence of matching delivery mechanisms pose both a challenge and an opportunity in the Indian market. Factors such as the rising prevalence of chronic and related increases in disability-adjusted life years, technological advancements in medical devices, and a consistent increase in the aging population is likely to boost market growth.

Moreover, the rising focus on developing technologically advanced medical devices is contributing to the market growth. Besides, government of India has decided to set up a separate Export Promotion Council (EPC) for Medical Devices, to boost exports of medical devices and Health Regulator geared up for smooth transition to licensing of Class A and B Medical Devices with effective from October 01, 2022 to support the industry. The growth of the medical devices industry in India will be sustained, as government of India has approved Production Linked Incentive Scheme for promoting domestic manufacturing of medical devices from 2020-21 to 2027-28.