Health and Medical Equipment and Devices - How India Can Move from Import Dependency to Being a Global Manufacturing Hub

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Foreword

The Rajiv Gandhi Institute for Contemporary Studies (RGICS) is the knowledge affiliate of the Rajiv Gandhi Foundation. RGICS carries out research and analysis as well as policy advocacy on contemporary challenges facing India. RGICS currently undertakes research studies on the following five themes of general public utility including:

- Constitutional Values and Democratic Institutions
- Growth with Employment
- Governance and Development
- Environment, Natural Resources and Sustainability
- India's Place in the World

Due to the heightened interest in the health sector after the COVID pandemic, the RGICS, under the theme Growth and Development, along with the staff of the Rajiv Socio-technical Knowledge, Innovation and Learning Labs (SKILLabs) undertook a study of the Health and Medical Devices Sector. The study was led by Mr Manideep Ray, an experienced professional who has worked for three decades in the HMED sector in India and abroad, with some of the biggest corporate names. He was assisted by Mr Subho Chakraborty, Senior Research Associate, to undertake a detailed study of the sector.

Even through India has a huge domestic market for HMED, we import low tech HMED from cheap export hubs like China and import high-tech HMED from developed countries like USA. To break the status quo and emerge as a manufacturing powerhouse, India has to incentivize local production while discouraging imports, foster tie ups between research laboratories and HMED manufacturers, increase exports even if it means selling at a loss initially, encourage med-tech start-ups and medical tourism, empower the insurance industry and bring about stricter regulations and smoother coordination among the many segments comprising the healthcare industry.

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- Dr Jitendar Sharma, Sr Advisor, Niti Aayog and CEO, AMTZ
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- Mr. Rajesh Nair of Medirays
- Mr. Sanjiv Marjara of Allengers

We hope the paper is found useful by stakeholders in the sector and it encourages various state governments to establish HMED Parks and create manufacturing hubs.

Vijay Mahajan, Director,
Rajiv Gandhi Institute for Contemporary Studies (RGICS)

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Executive Summary

India's economy is one of the top five in the world, as well as being one of the fastest growing. Demographically speaking, India is the second most populous country, and poised to overtake China in the coming few years. We are also one of the youngest countries by mean age. With a population that large, ensuring quality health and nutrition for the citizens, is understandably a proportionally big challenge. India already has some of the highest incidences of certain diseases, and is about to "lead" in many more, as our lifestyle changes and population ages. In this paper we attempted to explore how India is prepared to tackle the problem of ensuring adequate health and nutrition for its citizens. In particular, we focused on the Health and Medical Equipment and Devices (HMED) segment of the overall health industry (which broadly speaking, also comprises of the pharmaceutical, hospital and insurance industries) and tried to present a snap shot of what the present scenario looks like, how we compare with other OECD countries and how we can mitigate our import dependency and become a self-sufficient HMED export hub, within a decade.

In our assessment we went through numerous reports, studies and white papers and also spoke to the AIMED (Association of Indian Medical Device Industry, the mouthpiece representing over 300 HMED manufacturing companies in India), companies like Allengers (the biggest manufacturer of X-Ray equipment in India) and Medirays (a Mumbai based HMED company specializing in MRI and CT Scanners). We studied the Tijuana Economic Development Corporation, one of the biggest Med Tech manufacturing hubs in the world, located in Mexico. We also studied the Andhra Pradesh Medtech Zone (AMTZ), India's pioneering effort in HMED. We tried to identify the current lacunae in India's HMED manufacturing scene and to suggest a plausible roadmap, using which a HMED manufacturing hub could be set up in one or more states in India, which would serve as a significant step in giving India a robust and self-sustainable HMED sector.

Key findings in our study include the high import dependency that India has, the outdated and ineffective laws and duty structure that India uses which discourage local

manufacturing and R&D, facts and figures about the nascent but promising HMED start-up scene in India, the promising Medical Tourism sector, some new rules and incentives that the Indian government has announced to spur the HMED industry, the improvements that India needs to bring about in allied industries like Insurance and hospitals, the need for a common certification and testing facility, some innovative rules and schemes used by other OECD countries to tackle similar problems in the past, and - based on the many interactions we have had with various segments of the HMED ecosystem - a comprehensive guideline about how best to go about changing the current import dependent paradigm.

At present, we import low tech HMED from cheap export hubs like China and import high-tech HMED from developed countries like USA. To break the status quo and emerge as a manufacturing powerhouse, India has to incentivize local production while discouraging imports, foster tie ups between research laboratories and HMED manufacturers, increase exports even if it means selling at a loss initially, encourage med-tech start-ups and medical tourism, empower the insurance industry and bring about stricter regulations and smoother coordination among the many segments comprising the healthcare industry.

India would have to expand as well as stabilize the domestic demand for HMED sector products. After this, a three phase strategy is proposed to develop India into a global manufacturing hub for the HMED Sector. In the first phase, we should focus on boosting capacity in routine and lower tech HMED items like Clinical and Digital thermometers, Syringes, Stethoscopes, Oxymeters, Oxygen Concentrators, Catheters and Electrocardiographs which were mainly imported from China, directly or through Singapore. These kinds of items can not only be easily manufactured in India but also must be manufactured here. If cost is an issue, we should put our best engineers to work to meet and beat the costs of imported items. This just requires a dedicated task force to do so.

In the second phase, in the Coming Five Years we need to get into manufacturing Medium Tech HMEDs like Electrophysiology probes and lead wires, diagnostic ultrasound scanners, wearables/disposable smart health monitors, implants/prosthetics, patient-aid equipment and instruments. Two related industries where India has reasonable manufacturing capability are (i) plastics and metal work and (ii) customized circuits. In the third phase, in about a decade, India can manufacture for domestic use as well as exports of high tech times such as X-ray generators for X-Ray based diagnostic systems, Computerised Tomography (CT) scanners, Magnetic Resonance Imaging (MRI) scanners, Hemodialysis systems, Cancer care devices, and Anaesthetic devices

A National Policy for Medical Devices was announced in 2017. A pioneer MedTech facility came up between 2017 and 2018 – the Andhra Pradesh Med Tech Zone (AMTZ)

at Vishakhapatnam. Based on this experience and to give an impetus to efforts toward building indigenous MedTech capability, the Government of India (GoI) announced a scheme viz. Assistance to Medical Device Industry for Common Facility Center. In response to that, MedTech parks have come up in Kerala, Telangana and Tamil Nadu and these are described in the report. The GoI set up a National Medical Devices Promotion Council to promote local manufacturing of high end medical devices for domestic as well as export markets, by attracting investments from Indian and foreign investors.

More recently, the GoI announced the Production Linked Incentives Scheme (PLI) Scheme for Medical Devices with a 5 percent incentive on incremental sales of devices manufactured in the country. This is to boost domestic manufacturing and attract large investment in higher technology medical devices segments such as cancer care devices, radiology and imaging devices, anesthetics devices, implants etc. Incentives of up to INR 3,420 Crore will be awarded in the scheme tenure. Thus there is every reason to be hopeful, that within a decade, just like India's pharmaceutical and automobile industry, our HMED industry also will become not only self-sufficient but also a flourishing global manufacturing powerhouse.

2. Introduction

2.1 Overview of Population Health in India[1]

Though the perception about the health status of the India population has changed dramatically due to the COVID-19 pandemic, we must step back from the immediate and take a longer-term and wider than COVID view.

Millions in India have benefitted from remarkable progress in public health in the past few decades. India has achieved many milestones such as controlling HIV proliferation, eradicating Polio virus, significantly bringing down population indicators such as infant mortality rate (IMR), maternal mortality rate (MMR), and hunger levels. Life expectancy at birth has increased to 68.3 years in 2015, up from 58 years in 1992-93 and IMR has decreased from 78.5 to 41 per 1000 live births from 1992-93 to 2014-15. The MMR has decreased to 130 per 100,000 live births from 437 in the same period. The World Health Organization (WHO) has declared India free from polio and maternal and neonatal tetanus in 2014 and 2015 respectively (Patel, et al. 2015) (Yasmeen 2019) (Indian Institute for Population Sciences 1993).

This progress, although encouraging, is far below comparable countries. On IMR, India, with a figure of 33 per 100 live births in 2017, still fares below the global average (29) and also its neighbors including Myanmar (30), Nepal (28), Bangladesh (27), Bhutan (26), Sri Lanka (8) and China (8). The incidents of infants who died in hospitals in the past year alone, whether in Uttar Pradesh, Rajasthan, Gujarat or elsewhere in India, are a grim reminder of the state of health system in India, especially in the public sector (The Wire 2020). A report points to inequality in health status between states, with Overall Performance Index (OPI) scores varying from 33.69 in Uttar Pradesh to 80 for Kerala in 2015-16 (NITI Aayog 2018).

Globally, the Indian health system is among the worst performers. According to Global Healthcare Access and Quality Index published in 2017, India was ranked at 154 among 195 countries studied for 1990-2015 period. The Healthcare Access and Quality Index is based on death rates for 32 diseases that can be avoided or effectively treated with

1 This section is taken from "A Critical Overview of the Health System in India" 2019, by Yuvraj Kalia, Fellow, Rajiv Gandhi Institute for Contemporary Studies (RGICS). Accessible at https://www.rgics.org/wp-content/uploads/A-Critical-Overview-of-the-Health-System-in-India.pdf

proper medical care, also tracked progress in each nation compared to the benchmark year of 1990 (GBD 2015 Healthcare Access and Quality Collaborators 2017).

In the last few decades, non-communicable diseases (NCDs) such as cardiovascular diseases, diabetes, chronic obstructive pulmonary disease, cancer, etc. and injuries have shown increased proportion in terms of disease burden and causes of mortality. While disease burden due to communicable disease, such as infectious and parasitic diseases, decreased marginally, that from NCDs has significantly increased (Yadav and Arokiasamy 2014). As early as 2004, deaths due to NCDs was twice that of communicable diseases. NCDs caused 50.1% of the deaths in the country that year. In the same year, Indians spent USD 9.1 billion or 3.3% of India's GDP to manage their NCDs (Taylor 2010). Latest studies point to characteristics peculiar to India. While NCDs typically affect population above the age of 55 years in developed countries, their onset can be seen in India a decade earlier (>45 years) and effects younger population too (Arokiasamy 2018).

The issue of escalating disease burden and mortality due to NCDs needs attention. The cardiovascular diseases, chronic obstructive pulmonary disease (COPD) and asthma, and diabetes have emerged as the top three NCDs in India. "In absolute terms, cardiovascular diseases, respiratory diseases, and diabetes kill around 4 million Indians annually (as in 2016), and most of these deaths are premature, occurring among Indians aged 30–70 years". This should be compared with 385,000 deaths cumulatively reported due to the COVID-19 pandemic, as of 20th Jun 2021. Just the mortality numbers tell us that the silent, slower NCD epidemic should have attracted ten times as much attention, resources and efforts to combat it, as COVID-19.

The fact is that, to date, India does not have a reliable data on prevalence on NCDs, as large proportion of those suffering go undiagnosed due to lack of awareness and access to adequate healthcare facilities (Arokiasamy 2018). In addition, there are significant variations in prevalence of and mortality due to NCDs among different income groups and across states. Share of mortality due to NCDs in highest among high income group at 77%, and high in middle income group at 50%. Lower income groups, with highest years of life lost per 1000 population (at 234) show 69% of mortality due to communicable diseases (Taylor 2010). The National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke launched in India in 2010, recognizing the need has a component on screening to diagnose NCDs (Yadav and Arokiasamy 2014).

The National Health Policy (NHP), 2017 was the first since 2002 when last national policy was adopted, India has undergone significant transition in terms of disease burden and health levels. Since then, the healthcare sector has shown tremendous

growth after 2002 policy was put in place, recording a double-digit growth every year. The increasing cost of healthcare and extraordinarily high out-of-pocket expenditure on health pushes millions into poverty every year.

The NHP 2017 clearly outlined the position of the government on three significant areas.

- First, the goal was to ensure universal access to comprehensive healthcare through "public health sector with focus on quality" in the long run.
- Second, greater role for private sector "to fill the gap" in provision of a detailed set of services in short term. These included "training, skill development, community training for mental health, disaster management, purchase of services to fill gaps and preferentially for Central Government Health Scheme members, and primary healthcare in urban areas. There will also be collaboration with the private sector for infectious disease control, immunization services, disease surveillance and health information and manufacture of medical devices. The policy also seeks to take steps to improve, upgrade and incentivize the quality of services being provided by the private sector in rural and remote areas and among underserved populations and provisioning of diagnostic laboratory support" (MoHFW 2017) (S. Rao 2017).
- Third, the acceptance of a differential financing model – per capita basis for primary care; performance-based reimbursements for operational costs of the facilities; and fiscal allocations based on "financial ability, developmental needs and high priority districts."
- And fourth, institutional reforms required and proposed institutions in a number of areas. The NHP proposes to establish "National Institute for Chronic Diseases, National Health Standards Organization, National Allied Professional Council, medical tribunals, National Digital Authority, a system for health technology assessment and at the Centre and in states a multi-stakeholder institutional mechanisms in the form of autonomous societies or government-owned trusts to purchase services from the providers – government, not-for-profit and for profit, in that order – and a Common Sector Innovation Council as a platform for a more effective collaboration with the departments engaged in medical research and discovery." (MoHFW 2017) (S. Rao 2017).

There are number of concerns with the NHP 2017. First, the ambitious goals of universal health coverage are not matched with commensurate funding. The policy largely reiterated the spending targets set by the High-Level Expert Group on Health in 2012 for 12th five-year plan, and as stated earlier, sets a target of 2.5% of GDP for

2025. This is grossly inadequate. For example, in primary care, where the NHP envisages public sector provision as per Indian Public Health Standards, estimates of MoHFW show investment requirement of INR 1.4 lakh cores. This does not seem feasible with the current or the envisaged rate of public spending on healthcare (MoHFW 2017) (MoHFW 2017).

Secondly, the NHP puts little effort to address the limited agency capability of the public sector and institutions which led some of the earlier targets from 1983 and 2002 policies not being met. The NHP aims to "strategically" utilize capacity in private sector to address the "gaps in public sector" in the "short term". There is no clarity on how public sector will be strengthened. In addition, the private sector already caters to 80% of the outpatient demand and more than 60% of the inpatient care. In such a scenario, gap filling by private sector is a misnomer and lack of clarity on the short term and incentivizing the dominant private sector raises a red flag about the capacity of public sector in the future.

Third, while the NHP strongly pushes for a larger role for private sector, it is rather weak on its commitment to regulations for the health system. Be it establishment of an autonomous drug regulator; strengthening of Clinical Establishments Act; inspection, monitoring and maintenance of public facilities; the NHP is silent on key areas of regulation (MoHFW 2017) (MoHFW 2017) (S. Rao 2017) (Mohan 2017).

The United Nations captures vital parameters of Health, Nutrition, Population, etc. providing the overall 'Healthcare Scenario' for India as follows (we have also shown data from some other OECD countries for comparison)

HEALTH DATA FROM WORLD BANK 2019 (in bold) or 2017 (not bold)	Ireland	India	USA	China	Mexico	Singapore	Thaiand
Age dependency ratio (% of working-age population)	**54.73**	**49.24**	**53.27**	**41.39**	**50.6**	**32.84**	**41.3**
Current health expenditure (% of GDP)	7.15	3.53	17	5.15	5.51	4.41	3.83
Diabetes prevalence (% of population ages 20 to 79)	**3.2**	**10.4**	**10.8**	**9.2**	**13.5**	**5.5**	**7**
Domestic general government health expenditure (% of GDP)	5.2	0.95	8.54	2.91	2.84	2.12	2.93
Domestic private health expenditure per capita, PPP (current $)	1528.56	182.62	5078.86	362.97	519.77	2172.26	159.23
External health expenditure per capita, PPP (current international $)	0	2.04	0	0.0037	0	0	1.54
Fertility rate, total (births per woman)	**1.7**	**2.2**	**1.705**	**1.69**	**2.103**	**1.14**	**1.514**
Hospital beds (per 1,000 people)	2.97	0.53	2.87	4.31	0.99	2.49	..
Incidence of tuberculosis (per 100,000 people)	**5.8**	**193**	**3**	**58**	**23**	**41**	**150**
Number of infant deaths	**173**	**678728**	**21779**	**112595**	**26936**	**103**	**5493**
Physicians (per 1,000 people)	3.29	0.7779	2.612	1.9798	2.3827	..	0.8075
Population ages 65 and above (% of total population)	**14.22**	**6.37**	**16.2**	**11.47**	**7.41**	**12.39**	**12.4**
Rural population (% of total population)	**36.59**	**65.52**	**17.54**	**39.692**	**19.55**	**0**	**49.308**

The above table shows 2019 (and sometimes 2017) data from many OECD countries, across multiple health and nutrition parameters. Source: World Bank Data Archives, accessed in July 2021

Studying the quantum and trend of the parameters listed in the UN report, following can be inferred

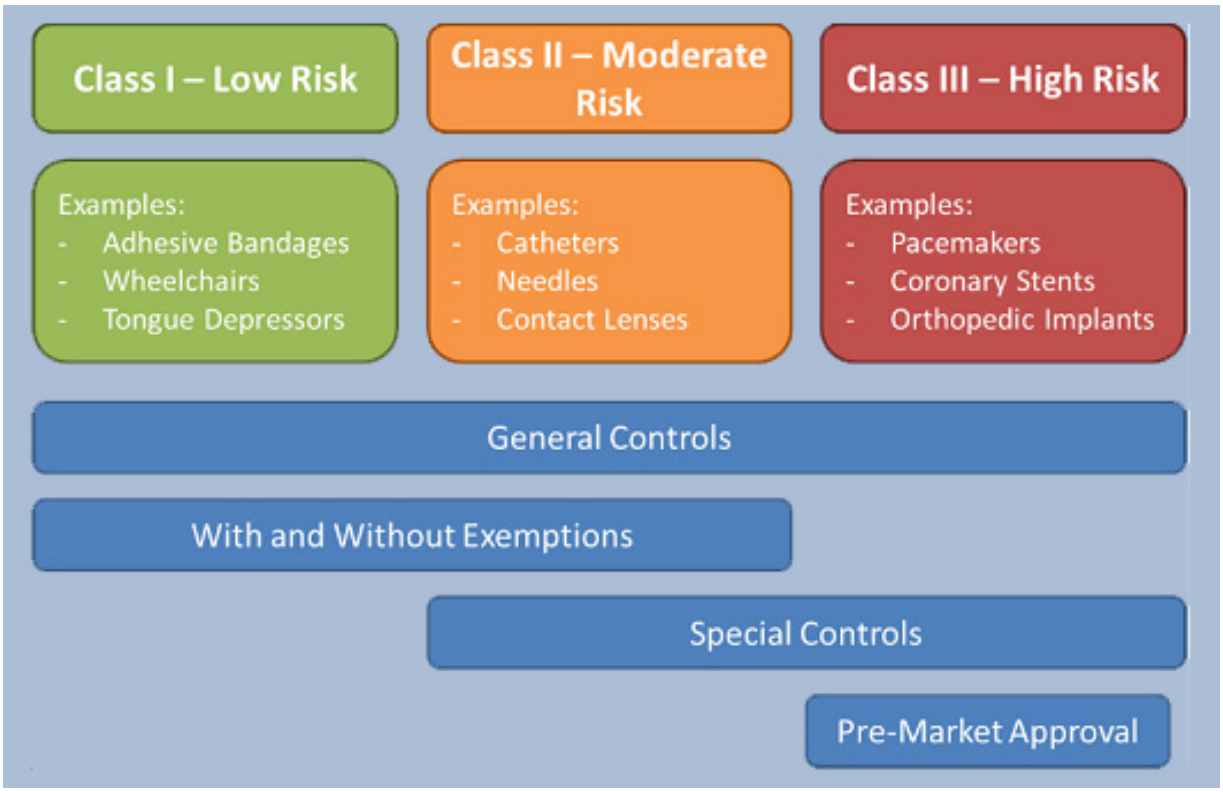
- 'External health expenditure per capita, PPP' being strikingly lower than 'domestic private health expenditure' clearly establishes 'health insurance availability'. The expenses rose nearly 40% in the covered decade, either insured headcount grew or availability of 'external i.e. hospital and day-care clinic procedures' grew substantially implying technological progress, hence Medical Devices market must have grown well in latter scenario.
- 'Domestic private health expenditure' of Rs 14K per person is thick spending, and shows potential of Pharma industry, as insurance business isn't covering so unlike developed countries. Whatever proportion of this is due to chronic health issues/NCDs (though major share is likely accredited to seasonal, occasional, and flu-based ailments) can be mitigated to domiciliary Healthcare Devices and Wearables.
- Diabetes prevalence is high on a raw-vision, un-compared to similar underdeveloped as well as developed countries, implying market potential for 'diabetes care' technologies including hemodialysis systems from Medical Devices sector.
- Though a proposed health expenditure of 5% of GDP is done by various experts and advisors to GOI, an expenditure of 3.54% of GDP in the sector, as captured in the report, may compete with other under developed countries. Only a meagre approx. 8% of that expenditure goes to 'capital health expenditure' as quoted in the report, hence health infra development doesn't attract enough budget. In a world class corporate hospital in India, 25-32% of the capital expenditure goes to medical devices. Hence services and consumables have an exorbitant share in Indian health spends, and this may not be an aspirational indicator for Medical Devices (non-consumables cum durables) sector.
- Number of 'hospital beds' per capita is poor compared to any international benchmark, which vindicates low 'capital health expenditure'/infrastructural development as mentioned in preceding clause.
- Parameters 'Age dependency ratio (% of working-age population)' and 'Population ages 65 and above, total' suggest that Indian population is aging fast, and conservative and routine health infra needs boost including relevant Medical Devices, provided the older population in a considerable ratio has affordability of healthcare services.

- Though mortality at birth which has come down in India in last decades, can be attributed to 'births attended by skilled health staff', overall staffing in health services remain alarmingly low, indicating accessibility to healthcare is still a challenging factor.
- Rural population (% of total population)', 'rural population', 'urban population growth (annual %)', 'urban population', 'urban population (% of total population)' suggest that rural population growth by birth have seen fall in recent years; migration to urban areas is consistently happening, as birth rates in urban areas are known to be far less compared to rural. The phenomenon will demand more health infra encapsulating Medical Devices in urban areas, a lot of which has to be govt. aided.

2.2 The Healthcare and Medical Equipment and Devices (HMED) Sector

The range of products, devices and equipment that the Healthcare and Medical Equipment and Devices (HMED) sector covers is quite wide as well as specialized. Its breadth stems from the fact that there are many lower end technology products, from hospital beds to digital thermometers, and at the other end are many high-tech products such as Computerized Tomography (CT) Scanners and Robotic Endoscopy Surgical devices.

FDA (US Food and Drug Administration) standards of classifying medical devices are as follows:



To give the reader an idea of the range, the reader may look at the product categories listed by Medtronic, the world's largest medical equipment and devices company, in Appendix 6.1

In contrast, if we study the detail of the National Industrial Classification code 3250 - Manufacture of medical and dental instruments and supplies, we find all of the above would be classified as "manufacture of medical and dental equipment, not elsewhere classified". Fortunately, the India industry is a little ahead of the NIC.

The future trends including wearable devices, device connectivity and Telemedicine, and robotic surgeries are some of the latest technologies expected to drive the size of the market in the next five years (Technova, 2020). Yet Indian R&D in these areas is very far behind the world. To understand what the difference is between conventional and robotic surgery, let use the following promotional from Stryker, one of the large US HMED manufacturers; and a take glance of disruptive robotic health aids, and telemedicine activities.

The Power of SmartRobotics™

Total knee replacements in the United States are expected to increase 673% by 2030, yet studies have shown that approximately 30% of patients are dissatisfied after conventional surgery. Similarly, 22% of conventional total hip patients have rated their satisfaction for their total hip procedure as 3 or less out of 5 (n=14,500).3, 4 This is where Mako SmartRobotics™ can help make a difference.

The information Mako's CT-based planning provides helps a surgeon know more about their patient and the procedure—meaning they know more with Mako. Specifically, the CT scan allows a surgeon to see a patient's individual anatomy, including osteophytes, cysts and bone defects. This knowledge of the patient's anatomy can give surgeons more confidence to perform difficult cases, enabling them to achieve functional implant positioning through executing their plan with precision and accuracy.

Mako's AccuStop™ haptic technology incorporates the information from a patient's personalized CT-based plan and enables surgeons to cut less, by cutting precisely what they've planned. This has demonstrated less soft tissue damage in Mako Total Knee surgeries and greater bone preservation in Mako Total Knee, Total Hip, and Partial Knee surgeries… "A recent study comparing Mako Total Knee Surgery using Stryker's implants with manual surgery and manual instruments concluded that patients performed better [and] had improved outcomes, like less pain, less opioid use, shorter length of stay in the hospital, and less physical therapy sessions. And, in a minimum 5-year outcomes propensity score matched study, Mako Total Hip showed more favourable outcomes and more accurate placement in the safe zone, while Mako Partial Knee demonstrated 98% survivorship at 10-year follow-up (Stryker, 2021).

Intuitive's (a company listed in US stock exchanges as 'Advanced Innovative Technology' company, grouped with likes of Google) robots are used for minimally invasive surgery. Designed to enhance surgeon capabilities - The da Vinci surgical system was one of the first robotic-assisted, minimally invasive surgical systems cleared by the FDA. To date, the family of da Vinci technologies has been used by surgeons in all 50 U.S. states and 67 countries around the world to perform more than 8.5 million procedures. Equipped with advanced vision technologies, energy systems, stapling and instruments, the continually upgraded da Vinci platform has been used for millions of surgeries since the late 1990s. The newer Ion™ is used for minimally invasive peripheral lung biopsies.

Milestone: For the third quarter of 2018, Intuitive reported a 20 percent uptick in surgical procedures employing its da Vinci Surgical Systems — the best growth in three years due largely to jumps in general and urologic surgery.

"The Indian RAS market is at an evolutional stage now. All that the sector needs for further growth is the ecosystem to open up a bit more. From including RAS in medical insurances, to more surgeons up-skilling themselves with the latest that global medical technology can offer, we still have a lot of ground to cover before RAS can become widely adopted. Currently, we have a higher penetration in metro cities where Tier I healthcare providers have a presence. In the recent past we have installed our systems in institutions such as AIIMS Jodhpur, AIIMS Rishikesh, and private centres in Tier 2 cities and while it shows the growing appetite in Tier 2 markets and beyond, there is a need for better healthcare infrastructure in these markets. Most importantly, surgeons in these markets should be willing to adapt and get trained in using the latest technology." as per Mr. Mandeep Singh Kumar, VP & GM, Intuitive India (Intuitive, 2021).

TransEnterix

TransEnterix

TransEnterix, now known as Asensus Surgical's Senhance Surgical System for laparoscopic procedures features fully reusable instruments and can integrate with existing technology. The company says time and cost investments are about the same as those for manual laparoscopies. Milestone: TransEnterix had demonstrated its Senhance Surgical System, the First Digital Laparoscopic Surgical Platform at the American College of Surgeons Clinical Congress Oct 21-25, 2018 in Boston.

ReWalk Robotics

ReWalk makes exoskeletons for personal and commercial rehab use.The light, battery-powered system, the ReWalk Personal 6.0, is a wearable exoskeleton with motors located at the hip and knee joints. Body shifting spurs motion that the company claims is like that of human legs. Milestone: A Portland, Oregon police officer who was paralyzed almost five years ago while on duty, recently wore ReWalk's exoskeletons to stand while raising his hand and swearing an oath as he was promoted to sergeant. (Builtin, 2021)

The global telemedicine market size was USD 41.63 billion in 2019. The global impact of COVID-19 has been unprecedented and staggering, with telemedicine witnessing a positive demand shock across all regions amid the pandemic. $186.5 billion is expected to be the market size of the telemedicine industry by 2026, according to Fortune Business Magazine.

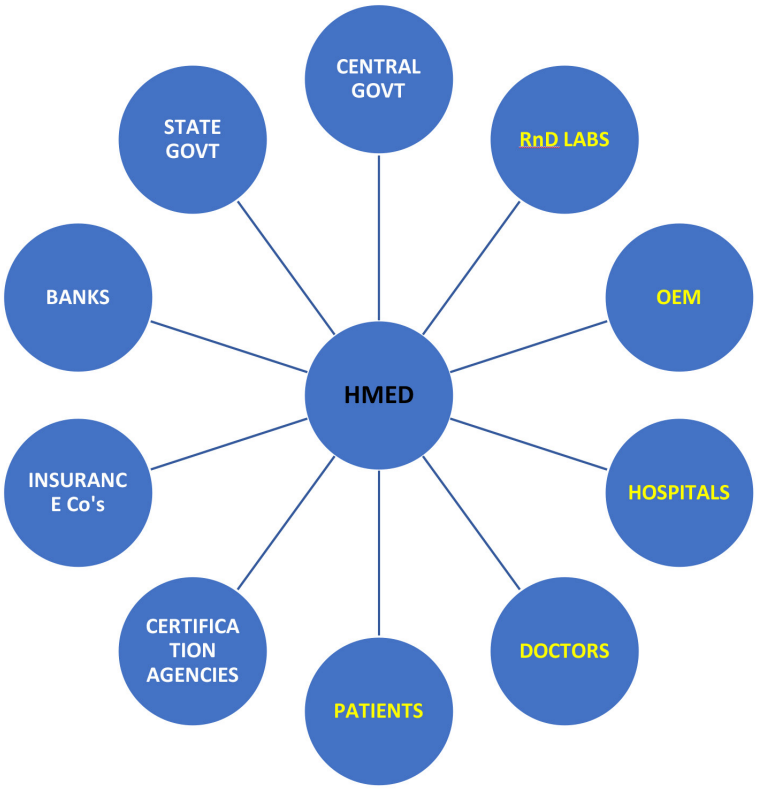
A Telemedicine Technology as a case study: GYANT's chat-based products use AI to collect and analyse patients' medical history and help him navigate today's increasingly complex healthcare offerings. Within minutes, the patient receives a disposition, self-care advice, or referral to the appropriate care setting.

For the healthcare provider, GYANT's AI populates the patient chart, bringing the efficiency of e-visits to a telehealth or in-person encounter and alleviating the charting workload. Post-encounter, GYANT automates

proactive outreach to the patient with diagnosis-specific follow-up protocols, promoting treatment plan adherence and improving outcomes. This proactive outreach software also serves perioperative settings to ensure patients properly prepare for surgeries and procedures. Uniqueness: GYANT brings a user experience that is unrivalled, resulting in a surprisingly delightful healthcare encounter for the patient. GYANT's average patient rating is 4.9 stars; 85% of patients indicate that they would use the service again; and re-engagement rates are at 70%. 94% of patients that begin an encounter with GYANT follow it through to completion.

Practo is an emergent and well-known Telemedicine platform in India for out-patient management – consultation & advisory, it was launched as online patient booking platform for clinics across India. According to data captured by Practo for a period of March-November 2020, Non-metros saw the highest growth of 7x in online consultations, as compared to the same period in the previous year. During the same period in 2019, the split between metro: non-metro for online consultations stood at 75:25. This time, it was 60:40, demonstrating that the number of online consultations from non-metro cities is on the rise. Tier 2+ cities like Manjeri, Arrah, Balasore, Etah, Orai, Khopoli, Jagtial, and Shivpuri used telemedicine for the first time in this time period. Cities like Meerut, Jammu, Srinagar, Nellore, Kochi, Gorakhpur, Kakinada, Tirupati, Bhagalpur, Gaya, and Shimoga recorded a 10x growth. Among metros, Chennai witnessed the highest growth of 4x as compared to the previous year. Bengaluru, Delhi-NCR, Mumbai, Pune, Hyderabad, and Kolkata grew by more than 300% as compared to last year. More and more elderly people are now getting used to technology. There was a 502% spike in online consultations from people above the age of 50 during this crisis, who contributed to 12% of overall consultations, as compared to just 5% the previous year. Previous year the men: women ratio stood at 75:25, while year 2020 during same period of Mar-Nov it's 68:32. Gynecologists and General Physicians were two of the most consulted specialists by women in 2020. (Plugandplaytechcenter, 2020) (Fortunebusinessinsights, 2021) (Practo, 2020)

The following diagram shows all the players in the HMED industry, with the ones in yellow labeling being the makers and end users and the ones in white being the facilitators of the HMED industry –



2.3 HMED Market Demand – Globally and in India

As per a study by Wolters Kluwer, a global health and information systems company based in the Netherlands, "the global medical devices market in 2020 was valued at $456.9 billion, which is an increase at a compounded annual growth rate (CAGR) of 4.4% since 2015. Despite an expected decline of -3.2% in 2020, it is expected to rebound in 2021 with a 6.1% CAGR and reach $603.5 billion in 2023 (Wolterskuler, 2021).

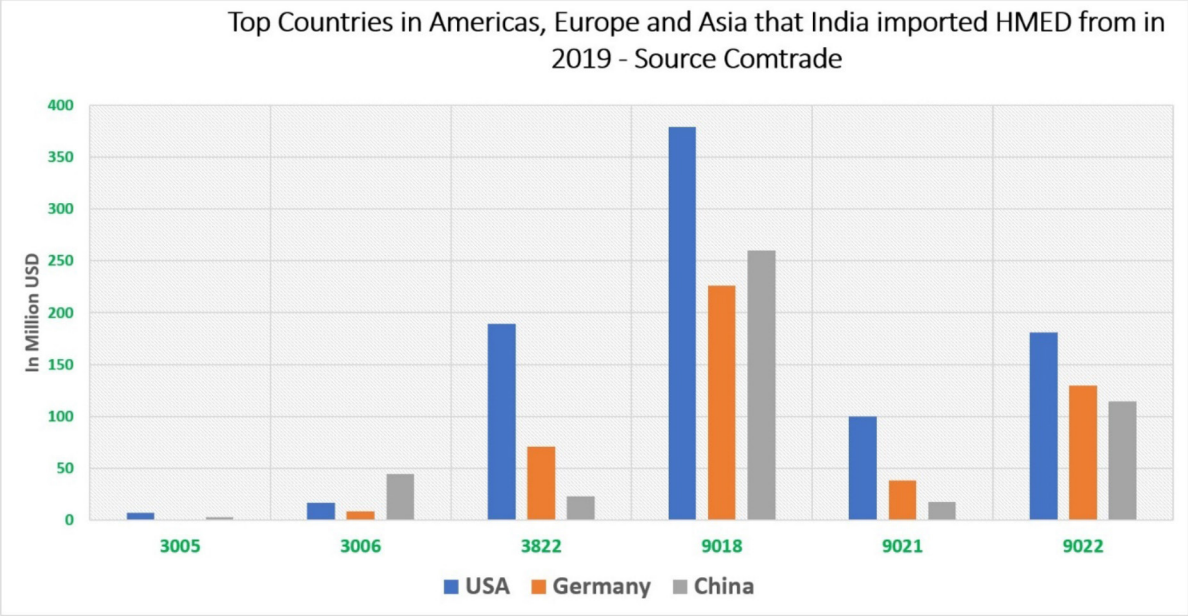
With rising incomes in the more populous middle and lower-middle income countries, including China, India, Indonesia, Pakistan, Brazil, Bangladesh, Nigeria and Mexico, the demand for HMED is only going to go up faster. Thus, we are looking at a potential trillion-dollar sector by 2030, globally.

The domestic market for medical devices in India in 2017 was around $11B, which accounts for about 4% of the overall Indian healthcare market (World Health Organization and AMTZ, 2017)

Most of the Indian manufacturers of HMED make things at the lower end of the technology spectrum and are highly fragmented, with over 1000 mostly small firms manufacturing HMED without benefiting much from either of economies of scale or

scope (EEPC India, 2013). However, things are looking up – quite a few mergers and acquisitions have taken place among domestic Indian HMED manufacturers recently and some Indian companies have even bought international HMED companies, in an attempt to gain market access and tech prowess. (World Health Organization and AMTZ, 2017)

The medical devices industry growing at a CAGR of 15% holds the highest potential amongst all sectors of the healthcare industry (EconomicTimes, 2021). However, India has an import dependence of upwards of 80%. HMED is the 20th most exported product in the world and the global export market for medical devices and equipment is around $117B2 of which India exports about $2.1 bn worth, mostly in low tech and/or inexpensive MED (Investindia, 2020).



The above chart shows India's imports across the main types of HMED (in US Dollars) and their top sources. Source: Comtrade, Accessed July 2021. The specific type of HMED corresponding to the HS codes are –

3005 - Wadding, gauze, bandages (dressings, adhesive plasters, poultices), impregnated or coated with pharmaceutical substances or in forms or packings for retail sale, for medical, surgical or veterinary use; 3006 - Pharmaceutical goods; 3822 - Reagents; diagnostic or laboratory reagents on a backing and prepared diagnostic or laboratory reagents whether or not on a backing, other than those of heading no. 3002 or 3006; certified reference material.

9018 - Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic apparatus, other electro-medical apparatus and sight testing instruments

9021 - Orthopaedic appliances; including crutches, surgical belts and trusses; splints and other fracture appliances; artificial parts of the body; hearing aids and other which are worn, carried or implanted in the body to compensate for a defect or disability

9022 - X-ray, alpha, beta, gamma radiation apparatus; x-ray tubes, x-ray generators, high tension generators, control panels and desks, screens, examination or treatment tables, chairs and the like

2.4 HMED Demand Growth Drivers

The drivers of growth in HMED sector in India are as follows:

a) Increase in chronic diseases, especially non communicable diseases (NCDs) including diabetes, cardiovascular diseases, chronic obstructive pulmonary disease, and cancer. This category NCD is likely to constitute upwards of 75% of India's disease burden by 2025 (which used to be 45% in 2010). Other top NCD include cancer, cardiac diseases, stroke, pressure etc. One result of this is that medical stents are one of India's biggest HMED imports. Thus, we have to indigenize the manufacture of stents, if we are to avoid importing them (Deloitte, 2016).

b) Another factor driving growth in HMED is our ageing population – the percentage of people above 65 is steadily increasing, though on the whole India is has a lower median age than most developing countries (and almost all developed countries). This again entails more demand for healthcare and HMED (Deloitte, 2016).

c) A third factor aiding growth, is the rising income in India, resulting in bigger demand and affordability for healthcare. India's population segment with more than $5000 annual income is expected to touch 450m by 2025 and only poised to grow since. Hence the percentage of household income spent on healthcare is expected to reach 13% by 2025 (Deloitte, 2016)..

d) The number of people with health insurance is also currently lower than 50% of the population – implying that, thanks to rising incomes and benevolent new government schemes, the number of insured people is also expected to rise (Deloitte, 2016).

e) Of late the Indian government has implemented many policies to address the challenges of the health care sector – from allowing 100% FDI in the HMED sector, to Make in India initiative, coming up with a reliable standardization and certification framework etc. (Deloitte, 2016). In July 2015 the government announced a plan to open a medical college in every district (World Health Organization and AMTZ, 2017) – which too would necessitate a lot of HMED.

f) Another growth driver of HMED is increased affordability and penetration of mobile phones and internet, which increase awareness about the need for healthcare among the rural population, which now can also be served remotely, through telemedicine.

g) Hospital industry in India is expected to reach USD 132 bn by 2023 to USD 61.8 bn in 2017 practically growing at a CAGR of 16% (Technova, 2020). In 2016, the hospital infrastructure in India had a shortage of beds – India has an estimated 1.1 beds per 1,000 people which is far behind the WHO recommendation of 3.5 beds per 1000 people (World Health Organization and AMTZ, 2017). India needs 4 million beds for the recommended capacity. And this increase in beds will further drive the demand for medical devices.

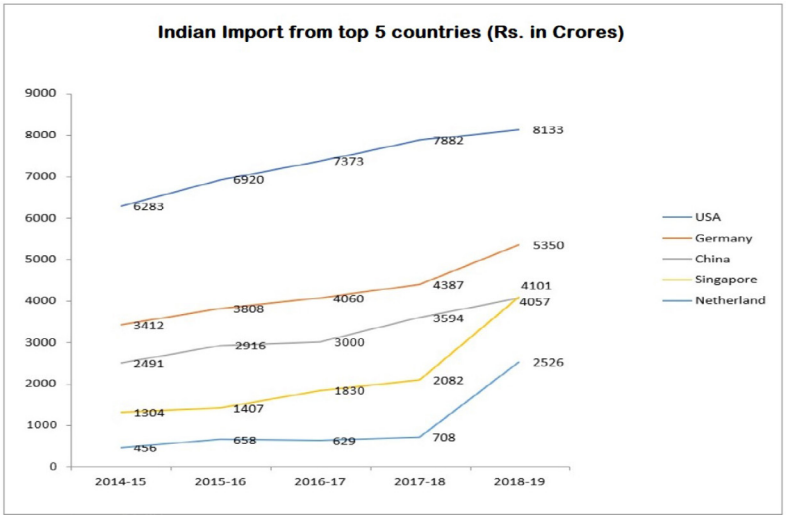
h) Healthcare costs in India are one among the lowest in the world even after adjusting to purchasing power parity (Advamed, 2018). This attracts people from other lower income countries for medical treatment to India. Indian Medical Tourism market is growing at 18% y-o-y and expected to reach USD 9 bn by 2020 (Technova, 2020).

3 Supply of HMED – From Import Dependence to Export Hub

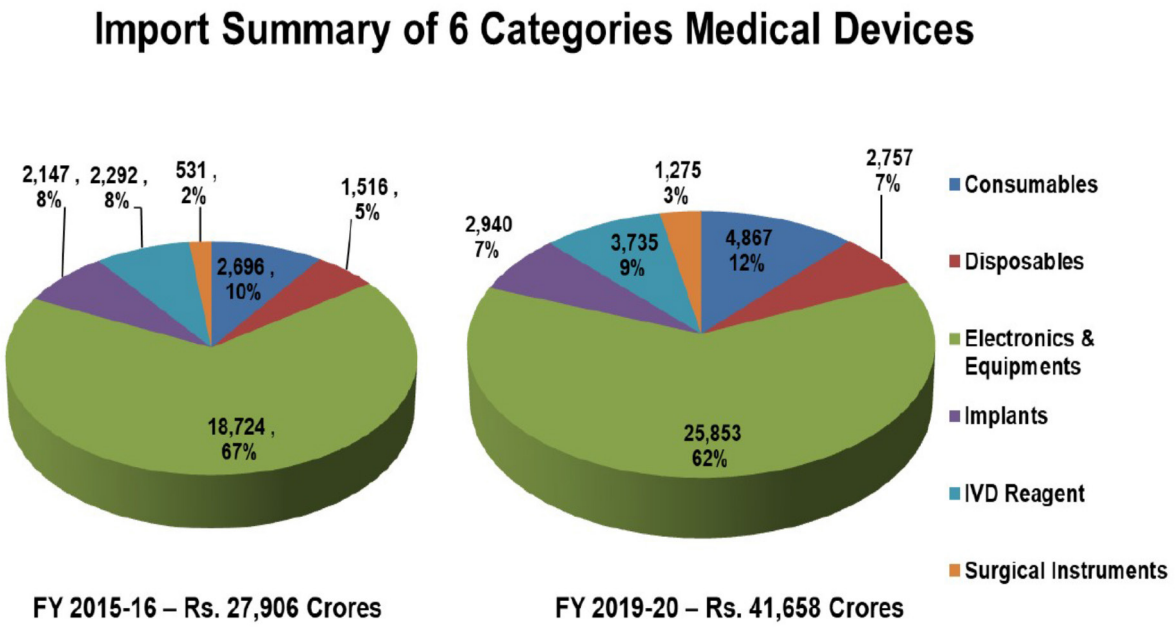
3.1 Dependence on imports, specifically from United States

India has an 80+ % import dependency on medical devices – costing around Rs 42,000 crore yearly. Most of the imports are from USA, Germany, Netherland, China and Singapore. The USA dominates the Indian HMED import scene, with Singapore and Netherlands showing the highest growth in recent years. While USA is the biggest source country across all types of HMED except "Disposables" (where Singapore dominates), the type of HMED where India's import from USA is highest, is the "Electronics Equipment" segment.

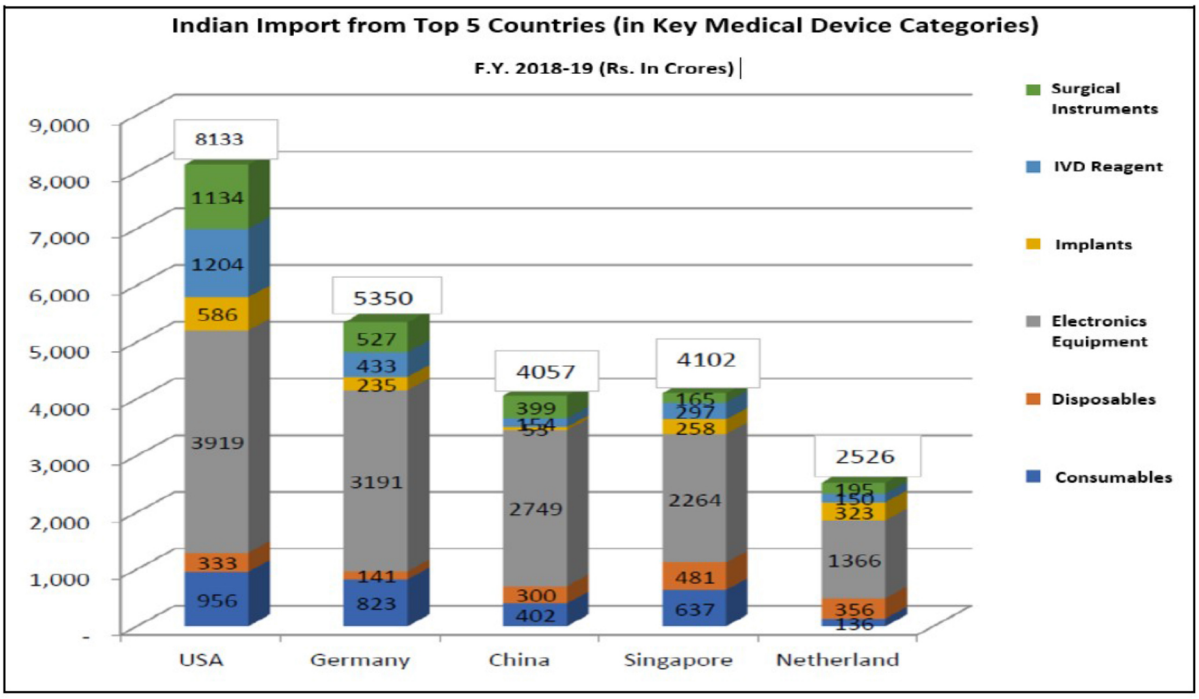
This segment is also the biggest segment of import for India from all the other top countries. Diagnostic imaging is the largest segment within this "Electronics Equipment" and also in the overall Indian medical device market, expected to touch USD 2.47 bn in 2020 (World Health Organization and AMTZ, 2017). Since this segment alone accounts for more than 50% of India's HMED import bill, it is clear that here is where the government, Indian manufacturers, research labs, academia etc. need to focus and collaborate most, so as to improve India's indigenous manufacturing prowess. This is also the most research and technology intensive of all the segments.



The Graph above shows top 5 source countries for India's HMED imports. Courtesy: AIMED



The Pie Charts above show the growth of imported HMED to India. Courtesy: AIMED



The chart above shows the breakup of HMED types from top 5 countries. Courtesy: AIMED

3.2 Some Undesirable Practices Due to Import Dependency

The high dependency on imports in the HMED sector led to several undesirable practices such as importing obsolete or out of date equipment from abroad, and overcharging for items such as stents and implants. These are discussed below.

3.2.1 Imported Out of Date HMEDs

In general, any under-developed country is a potential market for phasing out old technologies as they become cheaper and get obsolete in developed countries. Studies and opinions in this regard certify such concerns (TheHealthSite, 2015). According to Rajiv Nath, the head of AIMED – foreign MNC's take the "refurbished" HMED route to dump second hand or obsolete equipment on Indian market, while compromising some quality, and perhaps to some extent, the safety of patients. The Indian hospitals and clinics buy these to save costs (SmeFutures, 2019). So, this "using India as a dump yard" scheme works in two ways – either dumping of new HMED made from obsolete technologies which are no longer sellable in developed countries or the dumping of used/ refurbished HMED, which use current technology but are of questionable operational efficiency. According to Mr. Nath, this practice results in job losses to the Indian market and also low import duty, while increasing the overall health care burden due to sub-optimal treatment. Hence AIMED supports at least some restrictions, if not an overall ban on pre-owned and refurbished HMED (SmeFutures, 2019).

3.2.2 Overcharging for Stents and Implants

A Rajya Sabha committee in 2015 asked the National Pharmaceutical Pricing Authority (NPPA) to conduct a study on the cardiac stent prices. NPPA, in its report, found that most of the stents in the country are imported. In the absence of price regulation for stents, there is extreme overcharging when compared to their manufacturing cost. The Delhi High Court asked the government to take action responding to a public interest litigation (PIL) filed by advocate Birendra Sangwan in which he had accused hospitals of overcharging for cardiac stents. As per the data submitted by companies to the NPPA, the average cost of drug eluting stent for domestic companies is around Rs 8,000 but it is sold to patients for Rs 24,000 to Rs 1.5 lakh.

The NPPA then put a ceiling on prices of cardiac stent—a small mesh tube that's used to treat narrow or weak arteries. Cardiac stents are often used as part of a percutaneous coronary intervention (PCI), a procedure that restores blood flow through narrow or blocked arteries. In a notification published on 14th Feb 2017, the NPPA set the price of bare metal stent to Rs 7,260 and drug eluting stents (DES) including metallic DES and bio-resorb able vascular scaffold (BVS)/ biodegradable stents to Rs 29,600 (DownToEarth, 2017).

Similar accusations have been aired for knee joint and hip joint implants. Taking a stand of overcharging of knee implants, Ananth Kumar, Union Minister for Chemicals and Fertilisers, in August 2017 noted that the overcharging will be

strictly monitored and penalised. He said "The government has fixed the ceiling prices of orthopaedic implants used in knee surgeries. Based on the numbers, about 1 to 1.5 lakh orthopaedic knee procedures are done in India every year. There will be a saving of about Rs 1,500 crore for the people of India per annum. It is a step to prevent unethical profiteering and ensure affordable and quality healthcare for the last man," (https://www.thebridgechronicle.com)

3.3 Key Challenges facing the HMED Industry

This section is based on discussion with the AIMED, an umbrella Association of Indian Manufacturers of Medical Devices lists in its range - Consumables, Disposables, Equipment, Instruments, Electronics, Diagnostics and Implants. AIMED has a primary membership of over 300 manufacturers and has over 200 associate members. It claims to represent the interest of over 1200 Manufacturers of medical devices to address the manufacturer's problems.

The domestic HMED industry has not been able to grow with the demand, neither in volume nor in the level of technological sophistication needed for certain devices – leading to a dependence on imports of up to 80% in some HMED segments. Some of the main reasons for reaching such a situation and for finding it tough to change this paradigm are as follows –

a) The regulatory process for HMED falls under Drugs and Cosmetics Act and is a major hindrance. It causes delays, often up to two years (for implantable devices). Such time lag may be justified for the Pharma industry but in HMED it only acts as a hindrance (EEPC India, 2013). Things have improved after the notification of Medical Devices Rules, 2017.

b) The import duty structure (zero to 5% basic duty + nil special additional duty or SAD) incentivises Indian industry to import and trade as opposed to getting into manufacturing (EEPC India, 2013). As per AIMED, when there is nil or low import tariff structure and foreign Governments like China are giving subsidies of up to 17% to their HMED Industry for export, no Indian player wants to take burden of manufacturing and even experienced Manufacturers take easy route of importing and selling in India.

c) Possibly as a consequence of the above, the Indian HMED sector also invests very sparsely in R&D and relies on a mix of technology transfer and reverse engineering. To change this paradigm the government should incentivise expenditure on R&D, either in house (in the MED company) or by commissioning Indian research laboratories, with fiscal benefits like tax rebates and subsidies (EEPC India, 2013).

d) As per our interactions with AIMED, most Overseas MNCs are not keen to set up factories in India since they have no barriers to market access, but instead have been given free access, with negligible Custom Duties between 0 to 7.5%. Though, Health Cess of 5% was imposed in Budget 2020, it was withdrawn along with Basic Custom Duty on some Medical Devices, due to lobbying by the Indian subsidiaries of overseas MNCs.

e) Indian manufacturers are facing further loss of competitiveness post GST, since now the cost of imports is down by 11% as importers can avail GST input credit which they earlier could not. Direct importing not only takes away local employment generation opportunities but also drains valuable foreign exchange and slows down the Economy.

f) India used to lack indigenous certification agencies to enforce quality control. The HMED approval process also takes a lot of time, delaying the product life cycle. Lack of IP protection laws also deters global players to invest in R and D in their India operations (Deloitte, 2016). The certification scenario has improved significantly since the opening of AMTZ.

g) Setting up manufacturing facilities in India often come with logistical issues. India, as of now does not have an effective transportation and component supply chain infrastructure in place. Most of the components for domestic manufacture, are also imported – so in order to facilitate HMED manufacturing in India, we have also to first upgrade the HMED components manufacturing and supply ecosystem (Deloitte, 2016).

h) India ranks low in the ease of doing business for reasons ranging from unnecessarily complicated regulations to unfavorable labor laws and lack of skilled workforce needed for carrying out installation, repair and service work (Deloitte, 2016).

i) Another challenge facing India's HMED industry is the cost of financing which could amount to as much as 15% of the costs. What is needed is a comprehensive debt financing scheme with easier repayment options (Deloitte, 2016).

3.4 Suggestions from HMED Industry Players

AIMED sought a Phased Manufacturing Plan and predictable WTO permissible tariff structure linked with manufacturing capacity and international competitiveness capabilities to not only stem the rising tide of imports but reverse it, for only 59 items of listed 150 HS Code Tariff Line under applicable for Medical Devices by the following.

I - Levy a minimal Basic Duty of 5% for 8 items in HS Codes 30.06, 38.22 and 90.27 (where there is no indigenous manufacturing or insufficient capacity,

items having export turnover less than Rs. 5 Crore) as per list enclosed. But there needs to be a predictable Policy of increasing this to 7.5% in 2 years and 10% in 3 years or on establishment of a Manufacturing Unit whichever is earlier as an assured minimal protection.

2 - Increase Basic Duty to minimum 7.5% for 2 items in HS Codes 90.27 (no change in Custom Duty for 16 items, where the Duty is already 7.5% or more), where manufacturing is established for items having export turnover between Rs. 5 Crore to Rs. 10 Crore as per list enclosed. Though export turnover in HS Code 90.22 (X-Ray Tubes) exceeds Rs. 100 Crore, being a Component for Finished Medical Devices, the Duty may be maintained at 7.5% as currently being the case.

3 - Revert Basic Duty to minimum 10% for 5 items in HS Codes 38.22 and 90.27 (no change in Custom Duty for 37 items, where the Duty is already 10% or more), having export turnover between Rs. 10 Crore to Rs. 100 Crore as per list enclosed.

4 - Revert Basic Duty to minimum 15% for 43 items in HS Codes 30.02, 30.05, 30.06, 34.01, 38.22, 40.14, 40.15, 90.18, 90.21, 90.22 and 90.27 (no change in Custom Duty for 2 items, where the Duty is already 15% or more), having export turnover of more than Rs. 100 Crore, i.e., proven international competitiveness and undisputed production capabilities so no distress to consumers in availability as per list enclosed.

5 - Items having 0% Basic Duty as per ITA-1 List / where Trade Agreements renegotiation is not possible, please disallow GST Input Credit of 12% to importers of these items.

6 - Encourage a Phased Manufacturing Plan of Components by increasing duty to 5% Basic Duty on import of Part or Accessories for Medical Devices, up from 2.5% done in January 19th 2016 by Notification No. 4/2016 and then increase to 7.5% in 2nd year under heading HS Code 90.18, 90.19, 90.20, 90.21, 90.22.

7 - Consider 2.5% Basic Duty on import of Medical Grade Raw Materials for Medical Devices under heading also for HS Code 90.27, 30.06 and 38.22 on actual user condition, as had been done earlier for 90.18, etc., to include items in the Notification 50/2017 Dt: 30.06.2017

8 - Ensure compliance of the recently updated Rules and labelling requirement of mandating printing of MRP on each Unit Pack of the Consumer good (including Medical Devices) at the time of import, by deputing a Port Officer for checking each shipment of Consumer goods (including Medical Devices).

Based on interviews with several industry players as well as review of published documents, we found the following suggestions for the growth of the HMED sector in India:

1. India must focus on preventive healthcare – there is data to show from developed countries like UK and USA, that investing on preventive healthcare can prevent the number of instances of major diseases and reduce the overall healthcare bill (Bain, 2015).
2. Have a bigger and more effective network of testing and certifying agencies for MED which will be acceptable internationally – thus both increasing the quality of domestically produced MED and also making them acceptable in export markets.
3. Local manufacture increases the scope of technician level jobs for service and upkeep of MED – to tap into this opportunity the government should set up ITI style skills training institutes, focussing expressly on Med Tech.
4. Duty structure, as it stood, heavily favours imports and does not incentivise local manufacture or R&D. This paradigm should be changed to curb import and incentive the latter (Department of Pharmaceuticals, 2015). This was corrected in 2017.
5. Medical devices and equipment account for over 40% of the set-up cost of a hospital/clinic (Deloitte, 2016), thus making it prohibitive to open new facilities. The government should consider having a PPP scheme, where the government initially subsidizes some of the MED costs, but later earns from the hospital's revenues.
6. Since health-tech is mostly made of wearables and gym equipment (like treadmill, exercise bikes and gym equipment), the government should make both sectors attractive. The former is best done through health-tech startups and thus they should make equity-funding options easily available for health-tech focused startups.
7. There should be more health-tech exhibitions and trade fairs – both for international companies to showcase their products in India and vice versa.
8. Each state/region should have a HMED component manufacturing hub also – which makes international quality power supply, sensors, transducers, lighting systems etc. There should be a comprehensive certification centre within the med tech park.
9. In the light of current Indian HMED sector being comprised of highly fragmented small players, we also recommend the encouragement of mergers between many of them.

4 HMED - A Sunrise Sector for this Decade

The good news is that due to the efforts made in the 2011-2020 period, the HMED sector is all set to grow in India, not only to meet the domestic demand but also for exports.

4.1 National Medical Device Policy, 2017

Taking into account the size of the global as well as the Indian HMED market and consequently the size of this massive opportunity, in the coming years, India can be one of the top five manufacturing hubs of medical devices.

This will create lots of jobs, at every level of technological prowess – from research scientists to technicians, plus lots of manufacturing jobs. It can boost the Electronic System Design and Manufacturing (ESDM) industry and its downward supply chain; as well as the plastic, metal, electrical, and more industries whose cabinets, mechanical or electrical-conductor parts are essential to HMEDs; it can also support fabric/polymer and paper industries.

The Government of India has been steadily takings steps to realise this possibility. The first step towards this was the setting up of a Working Group on a National Medical Device Policy in 2015, which produced its draft report by the end of that year. This was then subjected to extensive discussions and consultations and eventually finalised as the National Medical Device Policy- 2017. It has the objective of contributing to the Make in India drive in the medical device sector by implementing the following -

(a) Providing measures for adequate facilitation for export promotion and appropriate correction to reduce import dependence

(b) Taking specific and time bound steps for building Indian medical device sector into a critical mass;

(c) Taking progressive steps for establishment of medical technology manufacturing zones and their linkages to industrial corridors; and

(d) Providing a comprehensive direction to all departments within the Government and all stakeholders of the industry for harmonized growth of the sector;

Some of the highlights of the policy were:

- To reduce dependence on Imports, the policy recommended a planned predictable tariff policy to enable business viability and to make investment in this sector attractive and provide nominal protection in a phased manner. It recommended a Basic Import Tariff at the peak rate of duty viz. 10% and duty on components to be 7.5% as an enabler for Make in India. It also recommended revisiting zero Basic Duty to zero in many medical electronic analysers, coupled with erecting Technical Barriers to Trade.
- The Government introduced 100% auto approval route for FDI in medical devices for both green field and brown field.
- The policy recommended facilitating setting up of Medical Technology Industrial Parks by State Government/Central Government/Industry Clusters
- The policy recommended facilitating setting up of medical devices testing laboratories under PPP mode as revenue generating self-sustaining business models while providing for low cost/subsidized testing facility for the industry
- To promote stakeholder engagement, the policy envisaged setting up of an autonomous facilitation body "National Medical Device Promotion Council (NMDPC)" to be created under the Department of Pharmaceuticals;

The Policy was followed by the announcement of the new, 250 page, detailed Medical Devices Rules (2017). These were notified under the Drugs under the Drugs and Cosmetics Act 1940 and Rules made thereunder in 1945. The purpose of this was to greatly update the rules to being those in line with new technological and business developments, and to remove bottlenecks to make in India and facilitate ease of doing business (Technova, 2020).

4.2 AMTZ – Pioneering Effort to Build the HMED Sector in India

The Andhra Pradesh MedTech Zone Limited (popularly known as AMTZ) is an enterprise, incorporated in April 2016, under the Government of Andhra Pradesh, a 270 Acre zone, dedicated for Medical Device Manufacturing. It is a first of its kind Med Tech Development Park in India. Their objective is to be a "One stop Shop" of all support systems of Med Tech and thereby simplify operations and reduce the cost of production. Their final aim is to reduce import dependency, make healthcare affordable to Indians and put India in the global map of HMED export. It was inaugurated on the 18th Dec 2018 by Shri. Chandrababu Naidu.

Aside from India's high dependence on imports, another motivation for setting up the AMTZ was that HMED manufacturing often requires certain facilities and equipment which are prohibitive for individual companies to set up – so AMTZ gives them a shared alternative. Another advantage is that the AMTZ is in an area near industrial corridors and is well connected by rail, road, air and sea. The AMTZ has been acting as a national resource centre for building the HMED sector and has helped several other states, including Kerala, Tamil Nadu and Telangana to set up med tech parks. The CEO of AMTZ Dr Jitendar Sharma is also a Senior Advisor to the Niti Aayog and was involved in formulating the National Policy on Medical Devices, 2017.

Part of the same AMTZ facility is the Kalam Institute of Health Technology. KIHT has access to both HMED academia and industry and aims to facilitate focused research on critical aspects pertaining to medical devices by supporting institutions involved with R&D, industry, policy makers and knowledge repositories. Among other things, KIHT does the following –

- Undertakes HTA (Health Technology Assessment) to appraise the innovative medical devices in terms of their clinical and cost effectiveness.
- Undertakes systematic review and meta-analysis of medical devices and health policies
- Supports repository of medical device-specific best practices, technology upgrades, skill building programs and knowledge sharing platforms.
- Undertakes research and analysis about concerns, rapid action requirement and long term strategy in Med Tech industry

They also do the following –

- Act as knowledge repository for export and import data on medical devices
- Act as advisory board on all matters relating to medical device sector
- Act as an advisory board on policy matters pertaining to medical devices
- Act as bridge between Start-ups and Corporates, and analysing Investments and advising accordingly

Source: (Kalam Institute of Health Technology, 2021)

In November 2018, KIHT has signed a MOU with the Government e-Market Place (GeM) for making KIHT the Technical Secretariat for public procurement of medical devices. This would benefit the government run healthcare system in India, because the HMED procurement has historically posed a challenge to Government agencies, who

were thus far dependent on inputs from users and industry when it came to framing procurement policies for hospitals. This is also good news for Indian companies which manufacture quality HMED, since the vested lobby of some MNC companies and their Indian partners are unlikely to work henceforth. (BioVoiceNews, 2018)

Some of the recent activities at the AMTZ include -

AMTZ has tied up with TUV Rheinland for the opening of its Biomaterial and EMC (Electromagnetic Compatibility) Testing Laboratories. The EMC Testing Laboratory has also been accredited by the American Association for Laboratory Accreditation (A2LA). At the Medical Device Centre of Excellence, TUV Rheinland offers customers an extensive list of services which includes Regulatory Compliance, Product Performance, Engineering Analysis and Reliability Services for various active and non-active medical devices such as Medical Ventilators, Face mask, X-ray Systems, Infant Care Devices, Health Monitoring Devices and Medical Implants (Bio Spectrum India, 2021).

The UK government and Andhra Pradesh MedTech Zone (AMTZ) have joined forces to plug the gap between the demand and supply of ventilators and essential medical equipment to fight the COVID-19 pandemic. Selected start-ups will be hosted at AMTZ's MediValley incubation centre, receiving financial, technical and infrastructure support necessary to make their equipment market-ready. The programme is part of a Memorandum of Understanding (MoU) signed recently between the UK government and AMTZ. The MoU aims to boost med-tech collaboration between the two countries by creating direct research and development linkages between UK companies and AMTZ's manufacturing and testing facilities, and to the wider Indian healthcare market (UKGovernment, 2021).

Sensing the impact of 3D printing on the healthcare sector and the future implications of the technology, the Andhra Pradesh MedTech Zone (AMTZ), inaugurated its 3D Bioprinting facility to develop artificial organs through 3D Bioprinting under the Bio Harmonised Aids for Rehabilitation and Treatment (BHARAT) programme to boost diagnostics and therapy. 3D printing is an innovative technology that encompasses all medical disciplines and offers new opportunities in diagnostics and therapy. From diagnostic visualization to surgical planning, patient-specific models will provide an added value for patients and physicians as part of the initiative (Manufactur3dMag, 2021).

4.3 Other Efforts to Promote HMED Manufacturing

In an effort toward indigenous MedTech infra building, Govt. of India announced sub-scheme (Department of Pharmaceuticals, 2019) viz. Assistance to Medical Device Industry for Common Facility Center under the umbrella scheme for Development of Pharmaceuticals Industry.

Under this sub-scheme, financial assistance to the tune of Rs.25 Crore or 70% of the project cost, whichever is less may be provided for creation of common facilities under any Medical Device Park promoted by State Governments/State Corporations.

Department of Pharmaceuticals has received three proposals under this sub-scheme from (i) Telangana Medical Device Park, Telangana (ii) Kerala State Industrial Development Corporation (KSIDC), Kerala & (iii) HLL, Medipark Ltd (HML), Tamil Nadu. Department of Pharmaceuticals has given 'in-principle" approval to all the said proposals. State Level Initiatives

The various medical device manufacturing clusters existing in India in 2017 are shown in the map below – most of them are in peninsular India, with the central and the eastern part of India having no representation.

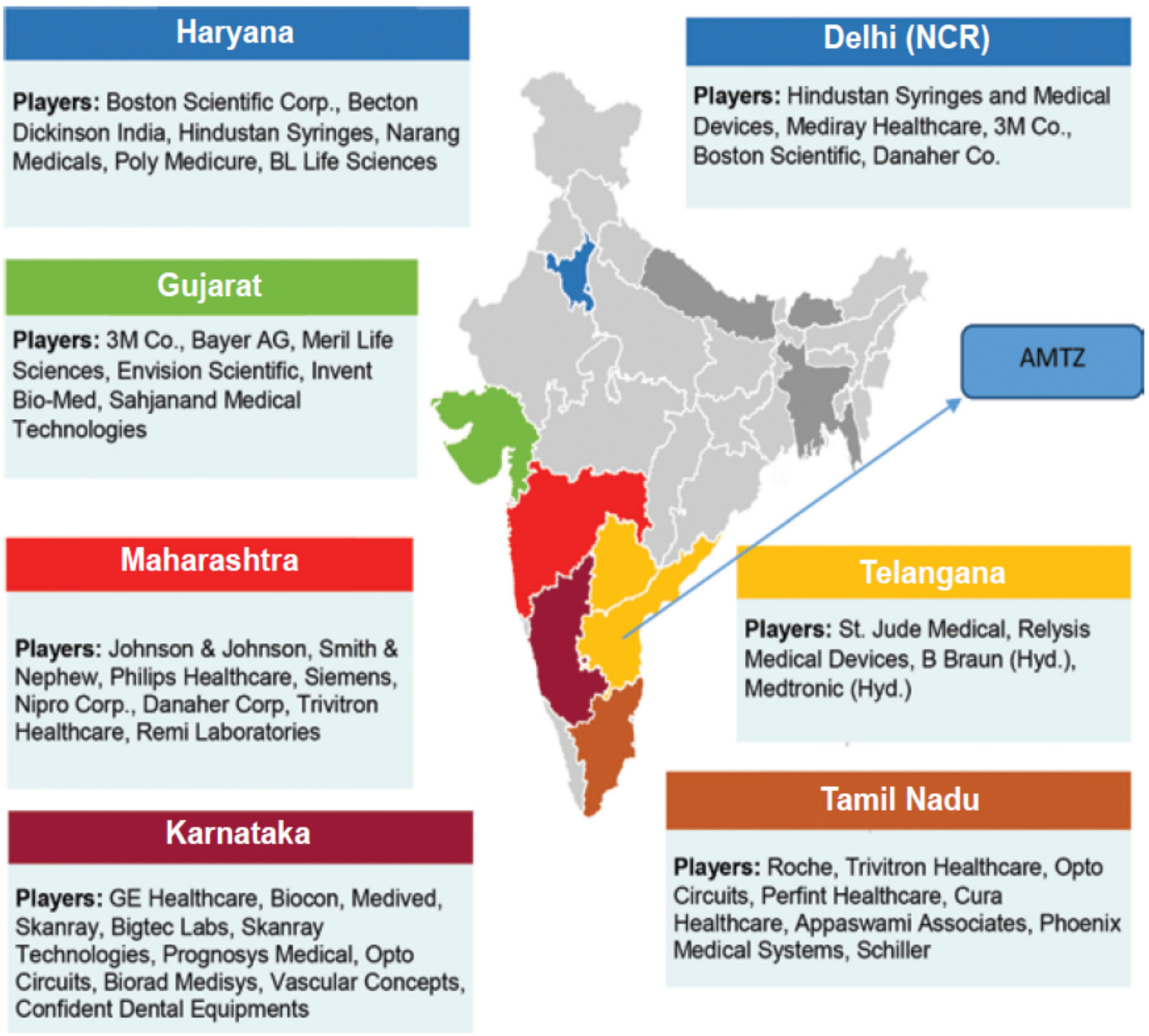


Figure 6: Medical Device Clusters in India

Map showing the locations and companies of various HMED manufacturing facilities in India. Source: (World Health Organization and AMTZ, 2017)

The next generation HMED tech parks came up with the mentorship of the Andhra Pradesh Med Tech Zone (AMTZ) in the three southern states of Kerala, Tamil Nadu and Telangana and one was announced in Punjab in 2021

MedSpark, Kerala

As per a news item in the Economic Times 22 Sep 2020:"Kerala will soon house one of the first medical device parks in the country, focusing on the high-risk medical device sector to provide a full range of services for the medical devices industry like Research and Development (R and D) support, testing, and evaluation. According to an official release of the Union Ministry of Science and Technology,

MedSpark, the medical devices park envisaged as a joint initiative of Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), an autonomous institute of the Department of Science and Technology (DST), Government of India (GOI), and the Kerala State Industrial Development Corporation Ltd (KSIDC), the industrial and investment promotion agency of the Government of Kerala is going to be established in the Life Science Park, Thonnakkal, Thiruvananthapuram.

"This medical device park will stand out with its emphasis on the high-risk medical device sector involving medical implants and extracorporeal devices, in which SCTIMST scores with its knowledge. The services available in the park can be utilized by the medical device industries located within the MedSpark as well from other parts of India. This will benefit small and medium-sized medical devices industries, which dominate the medical devices sector," the release said.

MedSpark can leverage the existing advantage of the Kerala State in the high-risk medical device manufacture and develop it into the most sought after destination for setting up medical device industry in India, it said. According to the release, Kerala has a number of medical device companies with an annual turnover in excess of Rs 750 crores, most of them operating with technologies transferred from SCTIMST. It is expected that the project would provide direct employment to 1200 people. Besides, employment generation up to 4000-5000 jobs through the supporting industries like OEM suppliers, service providers, and marketing/post-marketing support activities, the release said.

KT Rama Rao, Minister for Industries, Commerce and IT, Govt. of Telangana has handed over allotment letters to 5 MedTech companies who are setting up their units at Medical Devices Park in Hyderabad. The companies include Jagore Life Sciences Pvt Ltd, Majik Medical Solutions Pvt Ltd, Arni Medica Pvt Ltd, Trident Technologies and Pulse Pharmaceuticals. The foundation stone for this park was laid down in 2017 at Sangareddy district. "Within a span of 2 years, over 20 companies are expected to set up their manufacturing units and R&D centres in the Medical Devices Park", said Rama Rao (BioSpectrumIndia, 2021)

4.4 Localising High Tech HMED Production

In April 2020, Indian Government approached 1000 companies in USA including medical device major Abbott to offer incentives for manufacturers seeking to move out of China (Technova, 2020). This was an attempt to go up the value chain in HMED manufacturing.

The Government of India then announced the Production Lined Incentives Scheme (PLI) Scheme for Medical Devices. The salient feature of the scheme is that the government will provide 5 per cent incentive on incremental sales of devices manufactured in the country, to boost domestic manufacturing and attract large investment in higher technology medical devices segments such as cancer care devices, radiology and imaging devices, anesthetics devices, implants etc. Incentives of up to INR 3,420 Crore will be awarded in the scheme tenure.

Medical Device Segment	Indicative Eligible Products
Cancer care / Radiotherapy	Brachytherapy Systems, Rotational Cobalt Machine, Radiotherapy Simulation Systems, Linear Accelerator (LINAC), Workstations- Radiotherapy Planning, Proton therapy system and other products* in this target segment.
Radiology, Imaging and Nuclear Imaging Devices	CT Scan, MRI, Ultrasonography, X-ray equipment, mammography, C-arm, Cath-Lab, Positron Emission Tomography (PET) Systems, Single-photon emission tomography (SPECT), Cyclotrons and other products* in this target segment.

Anaesthetics, Cardio-Respiratory and Renal Care	Needles-Anaesthesia, Syringes-Anaesthesia, Anaesthesia workstation, Anaesthesia Unit Gas Scavengers, Anaesthesia Kits, Masks —Anaesthesia, Anaesthesia Unit Vaporizers, Anaesthesia Unit Ventilators, Automated external defibrillators (AEDs), Dialyzer, Dialysis Machine, Peritoneal dialysis kits, Biopsy Kits- Renal, Dialyser reprocessing I Lithotripters-Extracorporeal —Renal and other products* in this target segment.
All Implants	Cochlear Implants, Hip Implants, Knee Implants, Spinal and neuro-surgical implants, Uro-gynecologic Surgical Mesh Implants, Hernia Surgical Mesh Implants, Cerebral Spinal Fluid (CSF) Shunt Systems, Implanted Pacemakers, insulin pump, implanted neuro-stimulated device like Deep Brain Stimulator, Intraocular lenses, heart valves, stents and other products* in this target segment.

Some encouraging events have taken place recently, which are likely to stand Indian HMED manufacturing sector in good stead and/or result in the opening of more HMED manufacturing hubs. We list a few below, based on a report of the (Indian Brand Equity Foundation, 2021).

- In January 2020, GoI set up a National Medical Devices Promotion Council to promote local manufacturing of high-end medical devices and attract investments in the sector
- To boost domestic manufacturing of HMED and attract investments, the Department of Pharmaceuticals launched a PLI scheme for domestic manufacturing of HMED, with a total outlay of funds worth Rs.3,420 crore (US$ 468.78 million) for the period FY21-FY28
- In February 2021, Punjab announced that a park for medical devices is being proposed in Rajpura, Punjab, across an area of 210 acres, with an estimated project cost of ~ Rs. 180 crore (US$ 24.67 million)
- In January 2021, Tamil Nadu government proposed to build a medical devices park (spanning 350 acres) near Oragadam in Kancheepuram district. The estimated cost for developing this project is Rs 430 crore (US$ 58.92 million)
- New Delhi-based SS Innovations, promoted by robotic cardiothoracic surgeon Dr. Sudhir P Srivastava, announced it will commercially launch India's first and

cheapest robot surgical system soon. The company plans to manufacture 100 units in 2021 of its new 'Mantra' multi-arm surgical robotics system, which was indigenously developed over the last three years, and sell >1,000 units in the next five years

- In February 2021, Siemens Healthineers introduced Corindus, a robotic system, to drive cardiovascular interventions with robotic assistance in India
- In March 2021, Transasia Bio-Medical Ltd., a Mumbai-based in-vitro diagnostic company, announced plans to invest Rs. 150 crore ($21 million) to set up a manufacturing unit at the Medical Devices Park in Sultanpur, Telangana. The company plans to manufacture state-of-the-art high-technology analyzers in the unit to address biochemistry, immunology, hematology, molecular testing in addition to COVID-19, HIV, dengue, and TB testing for domestic and export markets
- In April 2021, Medtronic inaugurated a Medtronic Engineering and Innovation Centre (MEIC) in Hyderabad to leverage India's large pool of diverse and qualified talent to accelerate its innovative work in the medical technology space in the country. In June 2021, Medtronic India Private Limited announced the launch of Micra AV - a miniaturised, fully self-contained pacemaker that delivers advanced pacing technology to atrioventricular (AV) block patients via a minimally invasive approach.
- On March 25, 2021, the Department of Pharmaceuticals (DoP) released a revised notice on the Public Procurement Order (PPO), incorporating 19 medical devices in the revised guidelines of the PPO, which is expected to improve domestic medical devices manufacturing (and strengthen 'Make in India') and reduce import bills by ~Rs. 4,000 crore (US$ 538.62 million)

4.5 Product Development and R & D Starting to Happen

India has taken some steps for fostering MED start-ups. A research collaboration was set up between Stanford University and Department of Bio Technology which led to the development of a prosthetic Jaipur Knee which costs less than 1% of the titanium alternative. In 2018, Government of India and the World Bank also signed an agreement to help India in developing innovations in iopharmaceutical and medical devices. The 'Innovate in India for Inclusiveness Project (I3)'was awarded to BIRAC, which stand for Biotechnology Industry Research Assistance Programme (Research and Information Systems, 2020).

Some startups incubated by BIRAC so far are shown in the box below (BIRAC, 2019).

Several BIRAC supported startups and SMEs have received recognition from other national and international agencies for their products and technology development.

- **Windmill Health Technologies Pvt. Ltd.,** New Delhi won the BIRAC National Award for Indigenous Product Commercialization on the occasion of Technology Day event on May 11th 2017 at New Delhi.
- **Pandorum Technologies Pvt. Ltd,** Bengaluru received the too innovator award at the ET start-up award 2017.
- **Bugworks Research India Pvt. Ltd**, Bengaluru featured in the list of top 30 start-ups for 2017 in Indsight India and won a global grant from CARB-X
- **Module innovations and Embryyo Technologies** won the discovery award round 2 of Longitude Prize funded by Merck
- **String Bio Pvt. Ltd,** Bengaluru bagged a US$ 100,000 grant at the inaugural Future Food Asia Award
- **Achira Labs Pvt. Ltd,** Bengaluru raised investments from Catarman Ventures.
- **Amrita Vishwa Vidyapeetham** and **Wipro** jointly won the Aegis Graham Bell award 2017 for "Innovation in mHealth" category for first of its kind and cost effective Diabetes management solution.

SAMEER (Society for Applied Microwave Electronics Engineering and Research) was set up as an autonomous R & D laboratory at Mumbai under the then Department of Electronics (now MEITy), Government of India with a broad mandate to undertake R & D work in the areas of Microwave Engineering and Electromagnetic Engineering Technology. It has branches in Mumbai, Chennai and Kolkata. SAMEER is pursuing research and development in the field of Opto electronics, Medical Electronics, Radar based instrumentation, Atmospheric remote sensing & Meteorology, RF & Microwave systems and components, Navigational electronics etc. Most of the work regarding the development of high-tech Medical devices is carried out in Sameer Mumbai. Many of its R&D outputs and spin-offs have found applications and acceptance in industry (SAMEER, 2021).

SAMEER also developed Linear Accelerator at a nominal cost (SAMEER, 2021), a hi-tech machine used in Oncology for radiating carcinoma, whose global market is dominated

by American Varian Medical Systems, Inc. (merged with Siemens Healthineers in April 2021) and Swedish Elekta.

For an insight, we interacted in late March 2021 with Dr. Rajesh Harsh of SAMEER, the lead scientist who is driving design through research for complete development of Magnetic Resonance Imaging system, a diagnostic radiology and neuro-radiology device, popularly known by its acronym MRI. A modality, whose world market is again dominated by large MedTech majors like Siemens Healthineers, General Electric Healthcare, Philips Healthcare, Canon (erstwhile Toshiba) Medical Systems Corp., is being developed by SAMEER affordably at much less than half the average commercial price of the machine.

The salient data provided by Dr. Rajesh Harsh are as follows:

1. SAMEER adopted a 'different approach' of MRI product development, clear objective being building all sub-systems locally with effective cost. Unlike big MedTech corporates like GE, Siemens, etc. whom Dr. Harsh calls 'system integrators', using OEM sub-systems from existing global market. The project was started in 2015, as a joint program with C-DAC (Centre for Development of Advanced Computing, MEITy). Academia and 'domain knowledge experts' like Magnetic Imaging Research Centre of Dayanand Sagar Institute, Bengaluru, headed by Dr. Sairam were involved by SAMEER for 'concept launch' and initial 3 years of design and development.

2. Following 'end to end development in India' mission for the MRI, the computing systems and software were developed by C-DAC, and all the main scanner sub-systems including RF(Radio-Frequency), Gradient signal units, and imaging coils (basically arrayed antennas), were developed by SAMEER. For the initial lot of the product, gradient power amplifiers, also called 'Axis amplifiers' – a complex power electronic module, and gradient coils subsystems – a hi-tech 3 dimensional field generating compact and externally cooled electric winding, were sourced from global OEMs, as they were extremely 'generic' across the product industry. The local development for these two subsystems shall begin after the first batch of product is rolled out. 11 technology verticals have been assorted by SAMEER which congregate to produce complete MRI scanner.

3. Main magnet, consisting of cryogen-cooled superconductor, was procured for the initial product design and development, and total bill of material listing all electronics and other associate sub-systems was about

INR 1.9 Cr. Typically a comparative global product from GE or Siemens cost more than INR 5 Cr (market insight). SAMEER has endowed local 'main superconductive magnet' development to BARC, who is working on a 'helium/cryogen efficient' magnet development to run with just 7 litres of liquid Helium, which is both naturally scarce and very expensive. At the same time, another product development project for 'traditional 1.5 Tesla superconducting magnet' has been endowed to IUAC (Inter-University Accelerator Centre). By the end of 2021, the first field-deployable MRI from SAMEER shall be ready. The MRI in SAMEERs laboratory is already 'generating clinical images'. 'Animal trials' are on. The indigenous main magnets shall be integrated in the scanner system tentatively by Feb. 2022. SAMEER and Dr. Harsh targets that industrial level production, and MRI systems for purchase by clinical entities are available by 75th Indian Independence day on 15th Aug. 2022.

4. Current installed base in India is around 3500 MRIs. 400 plus systems were imported in year 2019. To reach basic recommended availability to Indian population, there is a deficit of at least 5000 systems. 5 to 6 major production companies, supplied by approximately another 50 companies in the downward (components and parts manufacturers) supply chain are required in the industry to meet the demand of making every Indian getting a quality and affordable MRI examination done. After the release of 'Proof of Concept' by SAMEER, leading Indian radiology and cardiology manufacturer Allengers, and experienced/veteran market players like Sanrad and Medirays have involved themselves in 'Expression of Interest' to initiate industrial production of SAMEER's patented MRI system. Dr. Harsh says government is needed to give 'Guarantee of Purchase', this will be enabler to fix prices before hand by MEITy.

A capital intensive product like this MRI, can't be sold to private sector customers at roll out. One government buys at least 10 units, it gives required confidence to the eco-system and vibes out assurance of incentive to industrial producers who undertake to manufacture the final design of SAMEER's MRI system.

5. Dr. Harsh and SAMEER have strived to formulate the consortium or 'development eco-system' behind this design and development mission. He stresses that all stakeholders must be on 'same platform' to achieve 'production and product-success'. He cited example of the very accomplished and reputed 'space research in India' and attributed them with same coherence he spoke about.

In the directive, SAMEER proposed a Centre of Excellence (CoE) to be built with SAMEER and C-DAC scientists, and entire participating industry is to be connected to CoE. A 10 years of uninterrupted cooperation is required between industrial manufacturers and CoE for 'quality development and transfer' of 'world class technology' for production. According to Dr. Harsh, a lag of 5% in terms of 'specifications and requirements' remains inside such 'project development', due to inevitable force-majeure.

To build an inclusive eco-system, SAMEER has set up 'Technology Advisory Committee' comprising of six leading radiologists (who are ultimate technology evaluators and end-user to assess the diagnostic quality of such products) from India, also annexing the IRIA (Indian Radiology and Imaging Association) with their President Dr. D.P. Patkar himself being a premier of this committee. A 'National Screening Committee' also evaluates the product quality.

6. The product-lifecycle and machine up-time performance requirements for an efficient patient screening during field deployment of the MRI product has been taken stock of, during the development cycle itself, ensuring technical-service friendliness, and quick cum cost-effective reverse engineering provisions.

There are more important local players like Allengers, who make international quality (ISO certified) X Ray machines and are now diversifying into CT scanners as well. Allengers is also the industry partner of SAMEER Mumbai, for the MRI device that the latter is developing.

In an interview, Mr. Sanjeev Marjara, R&D Head at Allengers, shared the following

1. The biggest challenge for other Indian companies that want to be a hi-tech MedTech manufacturer is investment – hence some government funding and incentives are in order necessary. Allengers had faced dearth of investment in nascent times.

2. For Indian companies that are already manufacturing MED, the main requirement is support from the govt. (e.g. increasing import duty of foreign MED, removing FDA and CE approval requirement for sale in India).

3. Allengers would be willing to endow money to research labs in India for them to do R&D and develop world class MED products – whose rights

would belong to Allengers. In fact, design and development partner for targeted futuristic MRI product for Allengers is SAMEER and Allengers is in close collaboration with MEITy (governing GOI Ministry for SAMEER) for this ambitious manufacturing project.

4. Allengers has already developed products on own and in this route – like Cath Lab, and "the first Designed till Manufactured in India CT Scanner" and launched the latter in 2020.

5. Allengers welcomes Govt. schemes that incentivizes such industry - R&D cooperation and recommends synergy within the MedTech eco-system.

6. Allengers has already locally developed, and manufacturing flat panel X-Ray detectors; and the same is being used in Allengers Angiography/ Image guided therapy systems.

7. Allengers is making their own High frequency/RF HV generators.

8. Allengers is in tie up with a foreign company (for manufacturing X-Ray tubes) for whom they are the local partners – we request to know if you support more such tie ups between foreign companies and Indian MED companies – after all Chinese manufacturers also gained a lot of knowhow thanks to their govt. mandating that all foreign companies have Chinese local partners.

In an interview with RGICS, Mr. Rajesh Nair, Vice President, Medirays Corp. CT and MRI business, told about their quest of about two decades in reverse and re-engineering of CT-MRI systems, making Medirays a lead player in Indian market in this segment. He asserted that to become 'engineering expert in this domain takes lifetime', but a basic level of product lifecycle management skill can be built in about 3 years with professionally planned On Job Trainings and structured field deployment of engineering manpower.

Medirays having assisted SAMEER's MRI development team (ref Section 4.3.1) constantly in fixing failures for the former's systems under development, as and when required. Echoing Allengers tone, he underscored the gravitas of funding and economics in capital intensive MedTech like CT-MRI, and reiterated the need to have a vibrant downward supply chain to cater to final structure of such HMEDs as quoted by Dr. Harsh. He said that Medirays, with decades of expertise in re-engineering, has been able to 'forward engineer' or build CT scanner subsystems, though producing entire

system faces challenges with economical supply chain and engineering-infrastructure resources from the indigenous eco-system.

Indian Parent companies with export market e.g. Transasia Bio-Medical, Skanray, Opto circuits do their own R and D and manufacturing in India at scale. These companies also have manufacturing activities abroad, most of them have acquired companies overseas (TransAsia, 2021) (SkanRay, 2021) (OptoIndia, 2021).

GE did major R and D investment in Bengaluru and caters to GE Healthcare innovations9. GE in a joint-venture with Bharat Electronics Ltd., called GE-BE Pvt. Ltd., had been making state of art X-ray generators for CT (Computed Tomography) scanners and other X-Ray based diagnostic systems for their global market/installed base, and CT X-Ray tubes which caters globally. GE Healthcare had been manufacturing subsystems for their global base of MRI (Magnetic Resonance Imaging) scanners in Bengaluru facilities, on and off. In 2021, GE rolled out a make in India ultrasound scanner VersanaTM, after a void in local ultrasound production.

With most MNCs' strong presence in India, like GE, Philips Health Systems has moved a Health Innovation Campus to Pune around 2012 (Phillips, 2021). The facility, Philips Electronics India Ltd. DMC (Design Manufacturing Centre) Pune develops hi-tech products for Philips Healthcare's global market. Advanced Angiography/Image Guided Therapy systems designed here have made it to world market. Siemens India Ltd.'s Medical Technology division, now globally known as Siemens-Healthineers, produced the first indigenous diagnostic X-Ray machine in India.

Medtronic has established a development centre in Whitefield, Bangalore. The Renal Care Solutions (RCS) business unit of Medtronic established Medtronic India Development Centre (MIDC) in Bangalore in 2013, to develop key aspects of the RCS product portfolio. One of the key projects is a portable hemodialysis system. It is specifically suited to address the barriers that prevent wider availability of therapy for patients with end-stage renal disease in emerging economies. This system will include features such as portability, reduced water consumption, and a state-of-the art graphical user interface. The new portable hemodialysis system offers a unique product offering that not only provides strong patient benefits but also helps significantly improve access to the hemodialysis solution to patients in key emerging markets like India.

MIDC currently houses 80 team members with interdisciplinary skills, including Software and Embedded Systems Development, Mechanical/Electronics/Chemical/ Systems Engineering, Human Factors Engineering, Supplier Management, Quality/ Reliability, Manufacturing Design Transfer and Configuration Management. The MIDC has multiple pending global design patents (Medtronic, 2021). Consolidating on the

above feat Medtronic was in the news, as quoted by Business Today Magazine since 2020, to be rolling out a plan to expand its Hyderabad research and development (R&D) center into its second largest research hub in five years. The company has committed an investment of Rs 1,200 crore for the purpose. "Medtronic Engineering & Innovation Centre (MEIC) will be the largest global R&D center outside of the US for Medtronic" as Medtronic MD Indian subcontinent, Madan Krishnan.

Medtronic Engineering & Innovation Centre (MEIC)

Medtronic Engineering & Innovation Centre (MEIC) investment planned for a span of five years will see its employee strength go up from the existing 350 to about 1,000. The MEIC will provide software and engineering services across four key verticals - cardiac, neuro, renal and minimally invasive surgery - of the company. Krishnan said the state government of Telangana and Medtronic have been in discussion for the last two years regarding the modalities of investment. "The investment is a vote (of trust) for India and Telangana. The state government has been consistent and persistent in their approach over several years," he said.

Taking the plans to reality, the 150,000 square feet facility was inaugurated in April 2021 by Mr. KT Rama Rao, Minister for Municipal Administration & Urban Development, Industries & Commerce, and Information Technology and his team of officials from the Government of Telangana. Joining the event virtually were S Aparna, secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, Joel Reifman, US consul general, Hyderabad, and Geoff Martha, Medtronic Chairman and CEO.

With this expansion, MEIC aims to leverage the sizable pool of diverse and skilled talent in India to continue its pioneering work in the medical technology space and add further to Medtronic's 150 plus patents and 400 plus IP disclosures globally that MEIC has been a part of. Globally, Medtronic has spent approximately $2.3 billion annually in research and development in recent years, and MEIC recently received an investment of Rs. 1,200 crore ($160 million) for expansion in Hyderabad over five years aiming to foster global innovation and create several job opportunities.

Here is a sample of some of the India centric products made by HMED companies and recent Indian HMED Startups

1. Phoenix Medical Systems is a manufacturer of infant and maternal care

products and assistive devices. The Phoenix range of maternal and infant care products includes warming systems, jaundice management units, respiratory care equipment and obstetric and gynecological tables. Phoenix also makes SmartCare, an electronic travel aid, refreshable Braille readers and standing wheelchairs (Phoenixmedicalsystems, 2021)

2. Cardiac Design Labs have come up with the following - MIRCaM Platform with the following features and capabilities: Master database, Remote connectivity, Offline test access for review and reporting, Real-time access for monitoring; Full disclosure analysis and interpretation algorithms software and Analytics, which enables
    - Tele-ECG reporting
    - Holter - Full disclosure analysis and reporting
    - Event reporting (Remote)
    - Remote monitoring for wards, home and ambulances.

    (Cardiacdesignlabs, 2021)

3. Embryyo team invented and demonstrated proof-of-concept of a novel inserter tool for an implantable device for women's health. Team Embryyo won the 'success story award' for their novel self-expandable non-vascular stent, at the Industry-Academia Interaction Meet at IISF '18. (Embryyo, 2021).

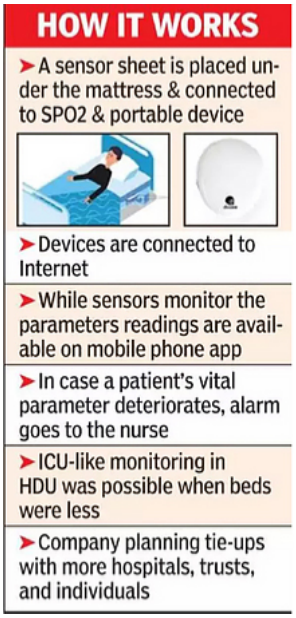
4. The following are some of the HMED made by perfinhealthcare.

    MAXIO ® is an image-guided, physician controlled stereotactic accessory to a Computed Tomography (CT) system. ROBIO ® EX is a CT & PET-CT guided robotic positioning system that assists with fast and accurate tumor. NAVIOS is a computer based, workflow assistance solution, for CT guided percutaneous ablation procedures (Perfinhealthcare, 2021)

5. HRS Navigation: Have designed a navigation system - easyNav™ that offers an end to end solution for innovative image guided surgeries. easyNav™ navigation system is based on optical pattern recognition technology which uses stereoscopic vision camera to detect and track specially-marked objects. Unlike competitive systems which use mounting and unmounting of single-use components such as glions and batteries for each surgery, easyNav™ uses permanent auto-clavable tools which makes it totally consumable-less navigation system. easyNav™ is the only optical navigation system which can be used in infant cranial surgeries with its unique PediaTrack patient Tracker. easyNav™ has single cart design and can be easily positioned even where space is at a premium (Happy Reliable Surgeries, 2021)

Promising start-up companies in the HMED sector

One of these is Dozee, based in Bangalore. Dozee is a pioneer in contactless, continuous remote patient monitoring (RPM) in hospitals and at home, delivering unparalleled patient safety and maximizing utilization of ICU beds. This company had by the middle of 2021 already installed its systems in over 200 hospitals, monitoring over 5000 beds. (Dozee, 2020)



Another start up, based in Hyderabad is Makers' Hive, which has developed "Kal-Arm", India's first fully functional Bionic Hand, with 18 pre-defined grips and bespoke aesthetics. It is 3D-printed, EMG sensors embedded, lightweight and affordable bionic hand, for persons with upper-limb below-elbow amputations that can give India an edge to become globally competitive in the Prosthesis Industry. (Makers Hive, 2020)

4.5.1 Related and Supporting Services for HMED Sector Are Coming Up

Medical equipment repairer careers are expected to grow in the coming years to meet the needs of the rapidly expanding healthcare sector. Reasons for this job growth include increased demand for healthcare services and advancing technologies and tools that require more complex skills to fix. This includes technologies such as MRI, ultrasound and X-ray machines, as well as older, simpler items, such as electric beds or wheelchairs.

Medical equipment repairer jobs require skills ranging from calibrating components to soldering connections. Troubleshooting micro-processing and microcomputer skills, fixing software bugs, and connecting systems to remote servers are also necessary in case of all high tech therapy, imaging, monitoring, etc. systems which collect large volumes of patient data and work in tandem with 'treatment planning systems'.

The National Institute of Electronics and Information Technology (NIELIT) of the GoI offer a Post Diploma in Repair and Maintenace of Hospital Equipment.

The National Commission for Allied and Healthcare Professions Bill was passed in March 2021. This bill separately defines an allied health professional and a healthcare professional. An allied health professional has been defined as – "an associate, technician, or technologist trained to support the diagnosis and treatment of any illness, disease, injury, or impairment. Such a professional should have obtained a diploma or degree under this Bill." The following specializations related to HMED have been identified under the Allied and Healthcare Professions

Medical Radiology, Imaging, and Therapeutic Technology Professional	(i) Medical Physicist (ii) Nuclear Medicine Technologist (iii) Radiology and Imaging Technologist Diagnostic Medical Radiographer, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), Mammographer, Diagnostic Medical Sonographers] (iv) Radiotherapy Technologist (v) Dosimetrist
Biomedical and Medical Equipment Technology Professional	(i) Biomedical Engineer (ii) Medical Equipment Technologist
Cardio-vascular, Neuroscience and Pulmonary Technology Professional	(i) Cardiovascular Technologists, (ii) Perfusionist, (iii) Respiratory Technologist (iv) Electrocardiogram Technologist or Echocardiogram Technologist (v) Electroencephalogram or Electroneurodiagnostic or Electromyography Technologists or Neuro Laboratory Technologists or Sleep Laboratory Technologists
Renal Technology Professional	Dialysis Therapy Technologists or Urology Technologists

5 Recommended Strategy

Based on our study, we propose a three phase strategy for the growth of the HMED sector in India.

Phase I - Boosting Capacity in Routine and Lower Tech HMED

Phase II- Manufacturing Medium Tech HMEDs in the Coming Five Years

Phase III Tapping the Potential Global Export Market

But before India becomes a global exporter of HMEDs, India has to ensure that the domestic demand base is expanded and stabilized.

5.1 Expanding and Stabilizing Domestic Demand for HMEDs

India needs an overall enhancement in health sector expenditure. India has to increase the current share of India's GDP allocated to healthcare (1.6% of GDP) to around 3.5% of our GDP in the near future (Deloitte, 2016).

The insurance sector has to be revived and the premium for health insurance has to be brought down, so that almost all Indians can afford medical insurance. A robust medical insurance sector, ensures that almost all people who need medical treatment can afford them, effectively increasing the "customer base" or demand of healthcare (Deloitte, 2016).

Thanks to the cost of surgery being around a tenth of the corresponding bill in developed countries, India is fast emerging as a destination for medical tourism, with Kidney and Liver transplantation being the most sought-after procedures. Each procedure involves the use of HMED and hence India's medical tourism boom presents a big opportunity for Indian HMED manufacturers. India should also set up exclusive hospitals for medical tourism, which should, as far as possible use Indian made HMED (Economic Representation of Flanders, 2018)

As of now, the government remains the biggest buyer of any HMED – so they should mandate that government owned hospitals and clinics, should, as far as possible, buy

from Indian OEM's or at least Made-in-India HMED by foreign companies – this was one of the points categorically mentioned by SAMEER Mumbai. Similar measures have been taken by other BRICs countries like Brazil (Innovation Law and Good Law), to promote local OEMs of medical and health equipment (Deloitte, 2016).

Many State Level and World Bank assisted Public Health Tenders have a Price benefit of 10% to 15% for Indian Origin goods to help establish the Domestic Industry of Medical Devices. In the absence of enforcement of labelling of Country of Origin, Manufacturer traders have the same benefit as would be available to an Indian Manufacturer who has spent a considerable amount of money to establish a factory and infrastructure to manufacture these Devices. Thus price contracts and long-term trade-MOUs between HMED manufacturers, and Healthcare Services Providers, both Government and private, will encourage and vitalize consistent domestic HMED manufacturing.

5.2 Boosting Capacity in Routine and Lower Tech HMED

One of the interesting factoids of HMED import data for i2019-20 shows that there was a lot of import of such low-tech items like

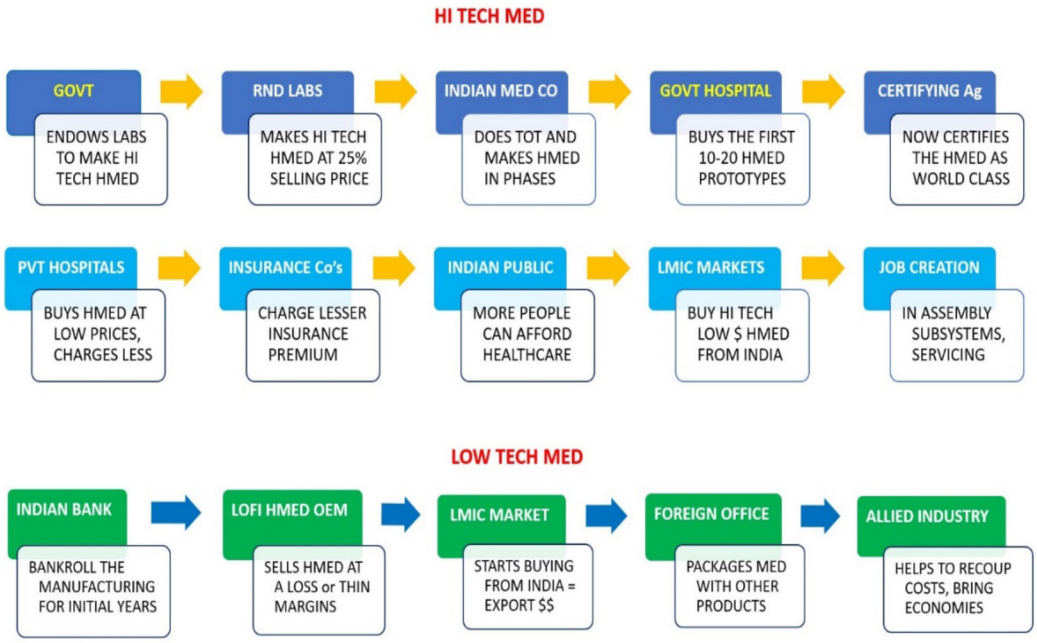
- Stethoscopes (HS code 9018 90 12 to the extent of $ 87.7 million
- Syringes (HS code 9018 39 10) to the extent of $ 78.8 million
- Catheters urinary (HS code 9018 31 00) to the extent of $ 83.2 million
- Clinical Thermometers (HS code 9025 11 10) to the extent of $ 8.9 million
- Digital thermometers (HS code 9025 19 10) to the extent of $ 7.8 million and
- Electrocardiographs (HS code 9018 11 00) to the extent of $19 million in 2019-20 (EXIManalytics, 2021).

Unlike the medium to higher technology HMED items, these above five were mainly imported from China, directly or through Singapore, although the US and EU were the second and third important sources. The main consideration was the lower cost of imports from China.

These kinds of items can, not just be easily manufactured in India, but also must be manufactured here. If cost is an issue, we should put our best engineers to work to meet and beat the costs of imported items. This just requires a dedicated task force to do so.

Based on our one-to-one interactions with R&D Labs, Manufacturers etc., we recommend the above two strategies for (a) indigenizing High Tech HMED manufacture and for (b) increasing out export footprint in the low-tech segment. In a nutshell, India has to play a double game – catch up with technologically advanced counties like USA, Germany etc. in the high tech HMED sector and match the low price-points of countries like China in the lower end HMED segment (e.g.: disposables), by initially

selling at a loss to grab export markets, and then letting the economies of scale and scope kick in and make the process sustainable over the long term.



In a 2017 paper called "Medical Device Manufacturing in India – A Sunrise" – published by WHO and AMTZ, the team headed by Dr Jitendar Sharma, CE), AMTZ, evaluated all the types of HMED under a host of parameters like import dependency, existing manufacturing capability and came up with the following table to indicate which types of HMED have the highest potential of attracting domestic and/or foreign investment. We are reproducing the table as it is below –

Key Segment	Sub-segment	% of Import dependency[14]	Share of the overall Medical Device market	Overall attractiveness for Indian Manufacturers to invest in this segment
Consumables	Cardiac Catheter, Other needle, Syringe, Lab reagent, Suture, Strips & cartridge, Dialysers and Filters, cannula	35%	16%	High
Dental Product	Dental Implant, Artificial teeth, Dental instruments	60%	3%	Medium
Diagnostic Imaging	X-Ray tubes, USG Probe, Radiation beam delivery system, Radiation generator unit, CT Scan, MRI, PET Scan, ALPHA, BTA/GMA Radiation for other use in radiography equipment	52%	30%	Very High

Key Segment	Sub-segment	% of Import dependency[14]	Share of the overall Medical Device market	Overall attractiveness for Indian Manufacturers to invest in this segment
IV Diagnostics	Lab reagent & accessories	67%	10%	High
Orthopaedic & Prosthetics	Artificial joints & joint implants	62%	8%	High
Others	Artificial dialysis apparatus & haemodialyser, defibrillator, Lithotripsy equipment, ECHO, EEG, ECG, anesthesia equipments, Laparoscope, endoscope	83%	24%	Very High
Patient Aids	Pacemaker, Hearing aid, Cochlear implant, Stents	50%	9%	Medium

Table indicates which types of HMED are the most attractive for investment.
Source: (World Health Organization and AMTZ, 2017)

5.3 Manufacturing Medium Tech HMEDs in the Coming Five Years

Like in many other industries like electronics e.g. smartphones, here too China and Korea made components/finished products are imported and assembled, and also rebranded by Indian medical device companies. Bengaluru headquartered BPL Medical Technologies import Chinese "Edan" and Korean "E-Cube" diagnostic ultrasound scanners, ECGs, other complete devices, and sell under their trademark (Source: Import Data of BPL and industry insiders).

Similarly, Medion Holdings Pvt. Ltd. which is the principal shareholder of 'Konica-Minolta – India', import Chinese 'Sonoscope' ultrasound scanners, rebrand and sell them under 'Konica-Minolta' trademark. Interestingly Konica-Minolta, a Japanese MNC in medical imaging, doesn't sell such products in other countries besides India (Source: Import Data of KM and industry insiders).

The government needs to give incentives to manufacture these items in India rather than just assemble them. The PLI scheme is a good step in this direction.

In addition to the above there are many new emerging areas, where India has started building manufacturing experience as well infrastructure. These medium tech areas can be used to go up the value chain in the HMED sector in the next three to five years.

a) Considering that India is emerging as a strong wearables/disposables market selling approximately 2 million units in 2017 and expected to reach 129 million units by 2030 and India being a sizeable exporter of such devices/equipment, Government and industry may work in tandem to achieve complete self-sufficiency in this segment, and boost such exports, by at least few folds in the short term (Technova, 2020)

b) 'Smart health monitors' used as wearable devices and domestic gadgets are essential health-check/preventive-health infrastructure, pertinent to providing for our surging urban population; and fall in commodity category of 'smart gadgets' as well. Smart-phone and other smart-gadget manufacturers have immense scope of boosting production of such low-cost indigenous technology; fringing and also hedging the core HMED manufacturing.

c) Implants/prosthetics, patient-aid equipment and instruments, consumables and implants segments have attracted the most FDI (World Health Organization and AMTZ, 2017).

Two related industries where India has reasonable manufacturing capability are (i) plastics and metal work and (ii) Customised circuits. Plastics essentially form the body/cabinet of insulated HMEDs. Metals are also essential for encasing various MEDs including surgical tools and most dental chairs. Electrophysiology probes and lead wires, cabling more complex and extremely long gadgets as found in high-end MEDs like MRIs, constitute an electrical component (metal based) industry as well.

A boost in HMED manufacturing is definitely beneficial for such component industries like metal and plastics. Customised circuits like Data Acquisition Systems using analog amplifiers and ADC etc., Graphic Processors, DC Power Supplies, FPGAs/embedded technologies, PLCs, even Wi-Fi transceivers find regular use in HMEDs. They in turn boost local semiconductor/ VLSI components / PCBs /instrumentation/wireless-communication products industry, which is coming up in India due upsurge of the mobile telecommunications sector.

To promote local manufacturing of high end HMED and attract investment, the government has set up a National Medical Devices Promotion Council. The rationale behind such a body, along the lines of the Pharmaceutical Export Promotion Council of India, is to have a platform that can address issues from all the stake holders of the HMED industry and eventually transform Indian into a global manufacturing hub of moderately priced, high tech HMED (The Health Master, 2020).

5.4 Tapping the Potential Global Export Market

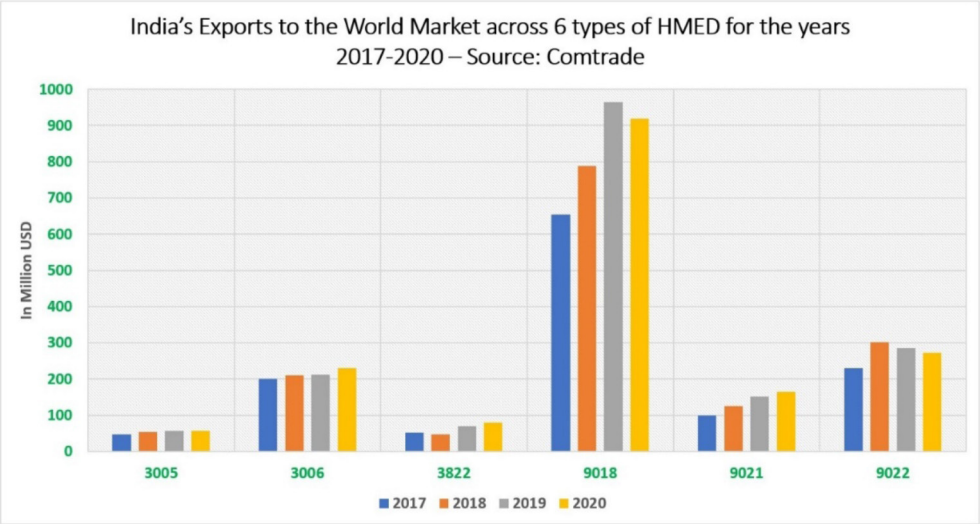
One policy, which is amending the situation and simultaneously helping India meet our surging demand without having to import HMED, is that the Indian Government

now allows 100% FDI in HMED for greenfield and brownfield investments. The FDI has first to be approved by FIPB. This is increasing the Make in India component of the MED. However, for meeting the increasing demand for MED, the Government has to completely separate HMED from the Pharmaceuticals making it easier for MNC's to set up manufacturing in India, which will generate local employment and also give Indian citizens access to knowhow and cutting edge technology (EEPC India, 2013).

For HMED manufacturing in India to substantially mitigate imports – which stand at over 80% of and also succeed at exports, the following steps are also needed

a) The efficient manufacturing of all HMED components locally in India. All linkages with allied industry have to be logistically viable (Deloitte, 2016).

b) A flourishing HMED tech sector would also need a vast pool of skilled and qualified labour – both engineers and scientists to help develop and fabricate the HMED and doctors and nurses to operate the HMED (Deloitte, 2016). To go with them, there would also need to be many qualified and trained technicians for servicing and upkeep of the HMED.



The above graph shows India's exports to the world market across all types of HMED for the years 2017-2020. As we can see category 9018 earns the highest export dollars, while a lot of work needs to be done for the other types of HMED to boost up our export footprint. The exact types of HMED that each code represents has been given before.

Dr Jitendar Sharma, CEO, AMTZ, who is also a senior advisor of the NITI Aayog drew up a list of 10 devices which have the most potential for export. The plan it to eliminate bottlenecks in the HMED manufacturing industry and hasten the process of exporting with incentives like subsidies and preference so that exports of HMED

from India receives a fillip. Devices under the NITI Aayog scanner for providing priority subsidy or funding are - cardiac stents, orthopaedic implants, surgical blades, catheters, X-Ray machines, syringes and needles, blood bags, CT Scanners and MRI Machines (The Health Master, 2020).

India also has to make rules and incentives to encourage endowments to Research labs, so as to develop Medical Technology indigenously, instead of importing the Med-Tech device or the technology with which to manufacture it.

5.5 Conclusion

One thing we can assert is that the Med-tech sector does not work in isolation – to improve it, we have to bring about improvements across the board – in rules and regulations, certifying agencies, financing, insurance sector, healthcare (hospital) sector, medical colleges et al. Hence the dynamics of healthcare segment is a copy book case of the chain being only as strong as the weakest link – even if we leave any one segment unattended, it will bring the whole HMED sector down. On the other hand, to improve the paradigm, we have to improve all the linkages proportionally. On the whole, the situation is rather dismal – currently, most of our HMED is imported, only a few Indians have insurance, there are lot lesser hospitals (beds) than needed, there are few Indian OEM's (most are foreign) and also fewer trained personnel (doctors and nurses) than required, which is itself because of fewer medical colleges!

So, the overall healthcare industry seems to be playing a "low volume, high margin" game. The thrust of our recommendations was to shift things towards a "high volume, low margin" paradigm (making insurance and healthcare available to as many Indians as possible) and attaining production sufficiency (i.e. indigenizing HMED manufacture). That is on the quantitative side – on the qualitative side, we suggested changes which will hugely increase industry-laboratory cooperation, reduce imports, raise HMED production and exports, improve regulation, financing and certification and/or standardization and raise general awareness about health.

To really turn things around and firstly become self-sufficient in HMED equipment manufacture and then become a hub of HMED export, India has to improve on two fronts simultaneously. We need to catch up with the developed countries in technology and also match the low-price points (for low tech HMED) of manufacturing hubs like China. Based on our primary research, we have elaborated a flowchart for achieving the same in section 4.2.

As for the changes required in the overall scheme of things under the aegis of which India's HMED manufacturing industry operates, they have been elaborated in our state and national level recommendations. Even if most, if not all, of these changes

in the factor conditions can be brought about within a short span of time, there is every reason to be hopeful, that within a decade, just like India's pharmaceutical and automobile industry, our HMED industry also will become not only self-sufficient but also a flourishing global manufacturing powerhouse.

6 Appendices

6.1 Product Categories of Medtronics

ADVANCED SURGICAL TECHNOLOGY	▪ Ablation Systems(opens new window) ▪ Electrosurgical Hardware(opens new window) ▪ Electrosurgical Instruments(opens new window) ▪ Smoke Evacuation Systems(opens new window) ▪ Ultrasonic Dissection(opens new window) ▪ Vessel Sealing(opens new window)
CARDIAC RHYTHM	▪ Ablation Products for Arrhythmias ▪ Ablation Products for Atrial Fibrillation ▪ Absorbable Antibacterial Envelopes ▪ Cardiac Mapping Products ▪ Cardiac Monitors ▪ Cardiac Resynchronization Therapy (CRT) Systems ▪ Electrosurgical Products ▪ Implantable Cardiac Defibrillator (ICD) Systems ▪ Pacing Systems ▪ Managing Your Patients ▪ Ventricular Assist Devices (VAD)

CARDIOVASCULAR	**6.1.1.1 CARDIAC PRODUCTS** ▪ Ablation Products — Surgical ▪ Aortic Stent Graft Products ▪ Blood Management and Diagnostics ▪ Cannulae ▪ Cardiopulmonary Products ▪ Electrosurgical Products ▪ Extracorporeal Life Support (ECLS) ▪ Heart Valve Replacement ▪ Surgical ▪ Transcatheter Aortic ▪ Transcatheter Pulmonary ▪ Pediatric Perfusion Products ▪ Revascularization Products (Surgical) ▪ Transradial Experience
	6.1.1.2 VASCULAR PRODUCTS ▪ Chronic Total Occlusion Devices ▪ Coronary ▪ Balloons ▪ Catheters ▪ Guidewires and Accessories ▪ Stents ▪ Deep Venous ▪ Directional Atherectomy Systems ▪ Drug-Coated Balloons ▪ Embolic Protection Devices ▪ Guidewires ▪ Infusion Therapy Products ▪ Peripheral and Biliary Stents ▪ Peripheral Embolization Products ▪ PTA Balloons ▪ Snares ▪ Superficial Vein Products ▪ Support Catheters

DIABETES	▪ Continuous Glucose Monitoring Systems ▪ Data Management Software ▪ Infusion Sets ▪ Insulin Pump Systems
DIGESTIVE and GASTROINTESTINAL	▪ Capsule Endoscopy Products (opens new window) ▪ Endoscopic Ultrasound Products (opens new window) ▪ Gastric Electrical Stimulation Systems ▪ Gastrointestinal Artificial Intelligence (opens new window) ▪ Gastrointestinal RF Ablation Products(opens new window) ▪ Gastrointestinal Thermosphere™ Ablation Products (opens new window) ▪ Hemorrhoid Energy Therapy System(opens new window) ▪ Motility Testing Products(opens new window) ▪ Reflux Testing Products(opens new window) ▪ Sacral Neuromodulation Systems ▪ Therapeutic Endoscopy(opens new window)
EAR, NOSE and THROAT	▪ ENT Catalog(opens new window) ▪ Ablation Systems(opens new window) ▪ Balloon Sinus Dilation ▪ Biomaterials, Nasal Packing and Ear Packing ▪ Bone Conduction Hearing Systems ▪ Electrosurgical Hardware(opens new window) ▪ Electrosurgical Instruments(opens new window) ▪ Image-Guided Surgery ▪ Inferior Turbinate Surgical ▪ Intraoperative Neuromonitoring Products ▪ Powered Surgical Equipment ▪ Sinus Irrigation Systems ▪ Sleep-Disordered Breathing ▪ Smoke Evacuation Systems(opens new window) ▪ Thyroid and Parathyroid Surgery ▪ Tonsil and Adenoid Removal ▪ Ultrasonic Dissection(opens new window) ▪ Vessel Sealing(opens new window)

GENERAL SURGERY	▪ Ablation Systems(opens new window) ▪ Electrosurgical Hardware(opens new window) ▪ Electrosurgical Instruments(opens new window) ▪ Electrosurgical Products ▪ Gastric Neurostimulation System ▪ Hemostasis(opens new window) ▪ Hand Instruments and Ligation Devices(opens new window) ▪ Hernia Repair(opens new window) ▪ Hysteroscopy Systems(opens new window) ▪ Lighted Retractors ▪ Nerve Monitoring Products ▪ OR Safety(opens new window) ▪ Sacral Neuromodulation Systems ▪ Smoke Evacuation Systems(opens new window) ▪ Surgical Stapling(opens new window) ▪ Trocars and Access Instruments(opens new window) ▪ Ultrasonic Dissection(opens new window) ▪ Vessel Sealing(opens new window) ▪ Wound Closure(opens new window)
GYNECOLOGICAL	▪ Hysteroscopy Systems(opens new window)
NEUROLOGICAL	▪ Access and Delivery Products ▪ Acute Ischemic Stroke Products ▪ Brain Arteriovenous Malformations Embolization Products ▪ Cranial Repair Products ▪ Cranial Robotics ▪ Critical Care Products ▪ Deep Brain Stimulation Systems ▪ Drug Infusion Systems for Chronic Pain ▪ Drug Infusion Systems for Severe Spasticity ▪ Hemorrhagic Stroke and Brain Aneurysm Products ▪ Infection Control Products ▪ Intrathecal Baclofen Therapy Systems ▪ Laser Ablation Technology ▪ Powered Surgical Instruments

NEUROLOGICAL	▪ Radiofrequency Ablation Products for Nerve Tissue ▪ Sacral Neuromodulation Systems ▪ Shunts ▪ Spinal Cord Neurostimulation Systems ▪ Spine Robotics ▪ Surgical Imaging Systems ▪ Surgical Navigation Systems
ORAL MAXILLOFACIAL and DENTAL	▪ Bone Grafting
PATIENT MONITORING	▪ Brain Monitoring(opens new window) ▪ Capnography Monitoring(opens new window) ▪ Cerebral/Somatic Oximetry(opens new window) ▪ Health Informatics and Monitoring(opens new window) ▪ OEM Monitoring Solutions(opens new window) ▪ Pulse Oximetry(opens new window) ▪ Temperature Management(opens new window)
RENAL CARE	▪ Dialysis Access and Maintenance Solutions(opens new window)
RESPIRATORY	▪ Interventional Lung Solutions(opens new window) ▪ Intubation(opens new window) ▪ Mechanical Ventilation(opens new window) ▪ Tracheostomy(opens new window) ▪ Ventilator Filters(opens new window)
SPINAL and ORTHOPAEDIC	▪ Balloon Kyphoplasty ▪ Bone Grafting ▪ Cervical Arthroplasty ▪ Corpectomy Devices ▪ Drug Infusion Systems for Chronic Pain ▪ Drug Infusion Systems for Severe Spasticity ▪ Electrosurgical Products ▪ High-Speed Surgical Drills and Tools ▪ Intraoperative Neuromonitoring Systems ▪ Nucleus Removal Tools

SPINAL and ORTHOPAEDIC	▪ Posterior Occipitocervical Upper-Thoracic Reconstructive Systems ▪ Radiofrequency Ablation System for Bone Tumors ▪ Spinal Cord Neurostimulation Systems ▪ Spine Robotics ▪ Surgical Imaging Systems(opens new window) ▪ Surgical Navigation Systems ▪ Tumor Management ▪ Vertebroplasty
SURGICAL NAVIGATION and IMAGING	▪ Visualization Solutions(opens new window)
UROLOGICAL	▪ Ablation Systems(opens new window) ▪ Electrosurgical Hardware(opens new window) ▪ Electrosurgical Instruments(opens new window) ▪ Percutaneous Tibial Neuromodulation Systems ▪ Percutaneous Tibial Neuromodulation System for Assisted Living Facilities ▪ Sacral Neuromodulation Systems ▪ Smoke Evacuation Systems(opens new window) ▪ Ultrasonic Dissection(opens new window) ▪ Vessel Sealing(opens new window)

6.2 Top 100 Medical Device Companies in the World[3]

COMPANY NAME	STOCK	TOTAL REVENUE	MARKET CAP	R and D SPEND	EMPLOYEE SIZE
Johnson and Johnson	JNJ	$82.06B	$368.91B	$11.4B	132,200
Novartis AG	NVS	$49.49B	$199.09B	$8.1B	103,941
Abbott Laboratories	ABT	$30.6B	$143.91B	$2.3B	103,000
Medtronic PLC	MDT	$30.56B	$137.53B	$2.33B	101,000
Baxter International	BAX	$11.1B	$129B	$655M	50,000
Danaher Corporation	DHR	$19.89B	$104.92B	$1.23B	71,000

3 https://www.greenlight.guru/blog/top-100-medical-device-companies

General Electric	GE	$95.21B	$97.98B	$4.16B	205,000
3M Company	MMM	$32.8B	$87.99B	$1.8B	93,516
Siemens Healthineers	SHL	€14.5B	$87.87B	€1.32B	52,000
Stryker Corporation	SYK	$13.6B	$73.87B	$856M	36,000
Becton, Dickinson and Company	BDX	$17.3B	$66.52B	$1.06B	70,093
Intuitive Surgical Inc.	ISRG	$3.08B	$64.84B	$418M	5,527
Allergan PLC	AGN	$15.78B	$63.77B	$2.22B	16,900
Hoya Corp	7741	¥565.81B JPY	¥3.49T JPY	¥28B JPY	34000
Boston Scientific Corp	BSX	$9.82B	$55.43B	$1.13B	32,000
Edwards LifeSciences Corp	EW	$3.8B	$44.53B	$646M	13,000
Koninklijke Philips N.V.	PHG	€19.5B	€38.63B	€1.76B	80,495
Draegerwerk AG and Co KGaA	ETR: DRW3	€2.59B	€30.16B	€780.75	1,417
Coloplast A/S	CLPBF	$17.93B DKK	$29.29B USD	$692M DKK	11,821
Zimmer Biomet Holdings	ZBH	$7.93B	$28.74B	$388M	19,000
Fresenius Medical Care AG and Co. KGaA	FMS	€16.54B	€25.67B	€134M	112,658
Olympus Corporation	7733	¥793.9 B	$25.18B	¥84,570M	35,124
Terumo Corporation	4543	¥587.8B	$25.09B	¥41.34M	23,319
ResMed Inc.	RMD	$2.6B	$24.4B	$180.6M	7,240
Smith and Nephew PLC	SNN	$4.9B	$20.21B	$246M	16,000
Align Technology	ALGN	$1.9B	$18.13B	$128.9M	11,660

The Cooper Companies Inc.	COO	$2.53B	$16.49B	$75M	12,000
Teleflex Inc.	TFX	$2.44B	$16.39B	$106.2	15,200
Cardinal Health Inc.	CAH	$145.5B	$15.76B	N/A	49,500
Straumann Holding AG	STMN.SW	CHF 1.59B	$15.09B	N/A	7,590
Steris PLC	STE	$2.78B	$13.86B	$63.03M	12,000
Hologic Inc.	HOLX	$3.21B	$12.85B	$218.7M	6,252
Waters Corporation	WAT	$2.41B	$12.6B	$143M	7,200
West Pharmaceutical Services	WST	$1.72B	$11.55B	$40.3M	7,700
Varian Medical Systems Inc.	VAR	$2.61B	$11.47B	$246M	10,062
Dentsply Sirona Inc.	XRAY	$3.98B	$11.04B	$160.5M	16,400
Masimo Corporation	MASI	$858M	$9.5B	$76.9M	1,500
Sartorius Stedim Biotech S.A.	SUVPF	€1.93B	€6.87B	€95.6M	9,016
Fisher and Paykel Healthcare Co. Ltd.	FPH	$1.07B NZD	$15.28B NZD	$428.2M NZD	4,500
Cochlear Limited	COH	$1.24B AUD	$12B AUD	$184.4M AUD	4,000
ABIOMED Inc.	ABMD	$769M	$6.99B	$94M	1,350
Asahi Intecc Co., Ltd.	7747	¥50.12B	¥734.13B	¥12.3B	7810
Hill-Rom Holdings Inc.	HRC	$2.91B	$6.74B	$139.5M	10,000
Amplifon SpA	AMPPF	€1.37B	€5.465B	None	16,000
Haemonetics Corporation	HAE	$967M	$5.56B	$35.7M	3,216
Shandong Weigao Group Medical Polymer	1066	¥8.8M	$5.02B	¥311.6M	9,562

Insulet Corporation	PODD	$738M	$4.92B	$129.7M	1350
Globus Medical Inc.	GMED	$785.4M	$4.7B	$60M	1,800
Getinge AB	GNGBF	SEK 24.2B	$4.68B	SEK 1.25B	10,515
Tandem Diabetes Care Inc.	TNDM	$183.9M	$4.64B	$8.7M	643
Integra LifeSciences Holdings Corporation	IART	$1.47B	$4.44B	$77.9M	4,500
Inogen Inc.	INGN	$361.9M	$4.311B	$3.62M	1020
Nevro Corp	NVRO	$387.2M	$4.25B	$48.45M	804
ICU Medical Inc.	ICUI	$1.4B	$4.15B	$52.8M	8,100
Wright Medical Group N.V.	WMGI	$836M	$3.91B	$59.1M	2,894
MicroPort Scientific Corporation	0853	$669.49M	$3.828B	$104.8M	5,000
NuVasive	NUVA	$1.1B	$3.42B	$61M	2,600
CONMED Corporation	CNMD	$859.63M	$2.78B	$42.1M	3,100
Gerresheimer AG	GXI	€1.39B	€2.13B	€ 0.00	9,872
Merit Medical Systems	MMSI	$882.7M	$2.04B	$59.53M	5,783
Prestige Brands Holdings	PBH	$975.77M	$1.93B	None	530
Ypsomed Holding AG	YPSN	CHF453.8M	CHF1.78B	CHF 41.9M	1,604
Glaukos Corporation	GKOS	$236.98M	$1.61B	$68.3M	600
Atricure Inc.	ATRC	$201.6M	$1.57B	$34.7M	620
STAAR Surgical Company	STAA	$150.2M	$1.42B	$25.2M	475
Cardiovascular Systems Inc.	CSII	$217M	$1.39B	$26.8M	652
Arjo AB	ARJOB	8.21B SEK	13.89B SEK	201M SEK	6123

Atrion Corporation	ATRI	$152.4M	$1.22B	$5.5M	570
Paul Hartmann AG	PLHNF	€2.12B	€1.1B	€478.86M	11,027
Luminex Corp	LMNX	$315.8M	$1.19B	$47.2M	1141
Mesa Laboratories Inc.	MLAB	$103.13M	$1.1B	$3.5M	366
CryoLife Inc.	CRY	$262.8M	$0.99B	$23.6M	1,100
Natus Medical Inc.	BABY	$495.1M	$940M	$58.73M	1,484
Biotage AB	BIOT	$1.1B SEK	$7.739B SEK	$78.6M SEK	464
Intersect ENT Inc.	XENT	$108.47M	$730M	$19.26M	393
Orthofix International N.V.	OFIX	$453M	$700M	$33.21M	954
Advanced Medical Solutions Group	AMS	£102.6M	545.82B	£3.07M	600
Consort Medical	CSRT	£305.1M	£502.1M	£7.9M	2,000
LeMaitre Vascular Inc.	LMAT	$105.56M	$580M	$8.1M	483
AxoGen Inc.	AXGN	$106.71M	$470M	$17.5M	297
AngioDynamics Inc.	ANGO	$344.28M	$440M	$25.45M	1,145
Owens and Minor Inc.	OMI	$9.83B	$380M	N/A	17,900
OraSure Technologies Inc.	OSUR	$181.74M	$380M	$16.3M	347
Cutera Inc.	CUTR	$162.7M	$330M	$14.3M	402
Utah Medical Products Inc.	UTMD	$41.9M	$320M	$454K	173
RTI Surgical Inc.	RTIX	$290.9M	$280M	$14.4M	891
ViewRay Inc.	VRAY	$81M	$280M	$4.01M	221
BioLife Solutions Inc.	BLFS	$19.7M	$280M	$315K	54
Invacare Corporation	IVC	$972.34M	$270M	$17.3M	4,200
SeaSpine Holdings Corporation	SPNE	$143M	$270M	$3.2M	386

IRadimed Corporation	IRMD	$30.4M	$270M	$1.5M	95
Tristel PLC	TSTL	£26.17M	£193.6M	None	111
GenMark Diagnostics Inc.	GNMK	$70.75M	$200M	$27.93M	477
Nemaura Medical Inc.	NMRD	None	$159.2M	$2.29B	10
FONAR Corporation	FONR	$81.5M	$130M	$1.7M	525
Harvard BioScience Inc.	HBIO	$120.77M	$110M	$11M	547
China Grand Pharmaceutical and Healthcare Holdings	Private	$5.95B HKD	$310.8M HKD	$137.4M HKD	8,006
TransEnterix Inc.	TRXC	$24.1M	$29.43M	$21.8M	189
Endologix Inc.	ELGX	$156.4M	$20M	$20.7M	528
B. Braun Melsungen AG	Private	€6.9 B	Privately Held	€318M	62,855

6.3 Top 11 Medical Device Companies in the USA[4]

Company	Revenue	Market Capitalization
Medtronic plc	$30.4 billion	$122 billion
Johnson & Johnson	$27.3 billion	$346 billion
Cardinal Health, Inc.	$15.6 billion	$13.3 billion
Abbott Laboratories	$16.8 billion	$127 billion
Siemens AG	$16 billion	$94.6 billion
Stryker Corporation	$13.3 billion	$58.6 billion
General Electric Company	$19.7 billion	$65.8 billion
Baxter International Inc.	$11 billion	$35 billion
3M Company	$6 billion	$111 billion
Boston Scientific Corporation	$9.8 billion	$48.9 billion
Becton, Dickinson and Company	$16 billion	$60.7 billion

4 https://www.universitylabpartners.org/blog/leading-medical-device-companies-2020

6.4 The Baja California Medical Device Manufacturing Cluster

Mexico as a Global Leader in HMED Manufacturing (Source: Feedback from TEDC)

Cali (California, UAS)-Baja (State Of Baja California, Mexico) Bi-National Mega Region

Acceding to GATT (WTO 'General Agreement on Tariffs and Trade') in 1986 opened up FDI and manufacturing projects in Mexico, mainly contributed by USA, along with other overseas entities. The NAFTA act in 1994, further emboldened by USMCA, have catalyzed huge growth of industrial exports from Baja California.

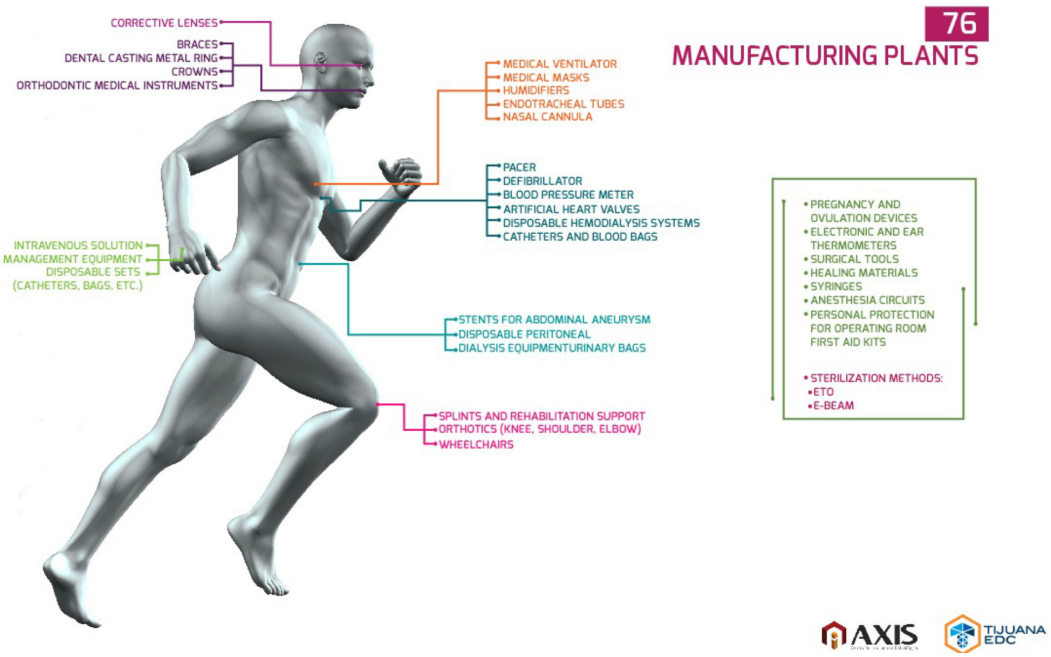
In 1988, Tijuana (largest industrial city of Baja California presently, of approx. 1.8-2 million with median age of as young as 27 years, the industrial zone sees 1700 fresh engineering graduates per year.) inaugurated Tijuana EDC (Economic Development Corporation), a non-profit organization to foster industrial and manufacturing activities and collaborate between companies and state/state-agencies, and is currently single biggest manufacturing cluster in the World as well as in North America, engaging 71 companies with 76 manufacturing plants in OEM (Original Equipment Manufacturing) plus CM (Contract Manufacturing) as of 2018. 42% of the manufacturing companies undertake contract manufacturing mainly creating products for hospitalization and surgery, and also plastic products. Tijuana EDC has fostered alliance of companies with at least three local universities, organizes Med-Summit event for the college forum for medical engineering; developed study programs, technological services, application projects and Dual Education Model, all aimed at training of professionals in the industry, updating and continuing education, and implementation of solutions for the companies by academia and students. The Baja California Medical Device industry is strongly promoted in national and international contexts including MEDICA Trade Fair in Germany and MD&M East and West in USA.

The EDC has approx. 63K strong workforce in Medical Device Manufacturing employed by 71 companies in 2017/18, out of total 170K workforce in the sector in entire Mexico, with National Gross Domestic Medical Device Production of almost 0.14 Billion USD in 2017. In Baja California, around 80% of medical device manufacturing operations belong to American companies including Medtronic, Thermo-Fisher Scientific, Becton Dickinson, Welch Allyn, Teleflex, etc.; 8% of them have Mexican origin, and rest have parents from Germany, Japan, France, Canada, UK, Iceland and New Zealand, one of the best known is Kiwi Fisher&Paykel. The

manufacturing industry is aided by robust infrastructure in Cali-Baja bi-national region comprising of Baja California, San Diego and Imperial Valley regions of California operating 2 border crossings, 3 international airports including cross-border terminal binational international airport of Tijuana, 2 specialized marine ports, and rail links across the two countries. In last 5 years Tijuana Medical Device Industry has grown at 10.6% YoY.

From simple packaging solutions at the beginning in 90s which were contributed by development in ESDM/electronics/TV industries in 80s, the Medical Device Manufacturing Industry through gradual transversal development of supply chain and skill development, now involves process automation, high precision machining/ metal works, injection & extrusion molding, system assemblies, and has imbibed process development. They have also developed locally sufficient calibration, sterilization and metal treatment services, and increased 'clean rooms' in large counts for quality and regulated manufacturing. More than 90% of the process operations in Baja California conform to FDA, CE and local quality standards. Diversifying into R&D, the cluster aims at futuristic digital manufacturing embracing nanotechnology, integrate artificial intelligence and improve process automations, as well as increase 3D printing to manufacture permissible devices. Green or sustainable manufacturing is also in fore of agenda. The initial breakthrough is established by Thermo-Fisher opening a Software Development Excellence Centre to carry out design processes that involve fusion of software and hardware for medical products being developed.

The Baja manufacturing cluster now boasts of a diversified portfolio of Medical Device products as shown below



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