

MEDICAL DEVICES

A SUNRISE SECTOR
IN INDIA



MEDICAL DEVICES

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COINMEN CONSULTANTS LLP

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FOREWORD

India is cruising on the path to become the world's fastest-growing economy. According to the World Bank's Global Economic Prospects, June 2019, India is estimated to have grown 7.2% in the fiscal year 2018-19.

This is further expected to accelerate to 7.5% in the financial year 2019 - 20.¹



However, unlike other developed economies, where manufacturing played a significant role in scripting a turnaround, India's growth story has been characterized by the dynamism of the services sector. The manufacturing industry, which once held promise, didn't bloom as expected.

The manufacturing sector's contribution to India's GDP has been stagnant at 16%,² thereby raising questions about India's development strategy. India is home to the highest percentage of young people in the world. Thus, the biggest mandate before the current government is to generate jobs for this young population.

As highlighted by the Planning Commission, —[t]he slow pace of growth in the manufacturing sector at this stage of India's development is not an acceptable outcome.... While the services sector has been growing fast, it alone cannot absorb the 250 million additional income-seekers that are expected to join the workforce in the next 15 years. Unless manufacturing becomes an engine of growth, providing at least 100 million additional decent jobs, it will be difficult for India's growth to be inclusive and sustainable over a long period.

Against this backdrop, the 'Make in India' campaign holds a lot of gravity. Under the Make in India initiative, the Government of India aims to increase the share of the manufacturing sector in the GDP to 25%, from the current 16%, and to create 100 million new jobs by 2022. These efforts are sure to help elevate India's manufacturing sector.

¹ <http://pubdocs.worldbank.org/en/719521555427519793/Global-Economic-Prospects-June-2019-Regional-Overview-SAR.pdf>

² <https://assets.kpmg/content/dam/kpmg/pdf/2014/11/BBG-Manufacturing.pdf>

INDUSTRY UPDATE

ELECTRONICS MANUFACTURING

The worldwide electronics industry was valued at approximately US \$1.86 trillion in 2015³. For the Financial Year (FY) 2015-16, the domestic Indian market for electronics hardware (electronic products and electronic components) stood at US \$64 billion.

Over the years, the production bases have shifted from the US and the European Union (EU) to Asia, whose share in global production has increased to over 60%. However, India represents a meagre 1.5% in the world's electronic hardware production.

The Indian Electronics industry has witnessed a sharp rise in demand, growing at the rate of 26% over the last four years (2014-2018)⁴. It is further projected to reach US \$400 billion by 2022⁵. Sadly, domestic manufacturing has not managed to keep pace with the burgeoning demand for electronics. The result being, approximately 58% of the local demand for electronic products and components are being fulfilled by imports.

³ https://www.skpgroup.com/data/resource/skp_electronics_industry_in_india_usenglish_revised_.pdf

⁴ <https://www.electronicsb2b.com/headlines/can-india-turn-into-an-electronics-manufacturing-giant/>

⁵ <https://www.electronicsb2b.com/headlines/can-india-turn-into-an-electronics-manufacturing-giant/>

Electronics is among the top three of India's imports and is soon expected to surpass crude oil, as well. With the intent to curb the growing electronic imports and simultaneously develop the domestic manufacturing capabilities, the government formulated the vision of '**Zero imports by 2020**'.

Opportunities for the Indian Electronics Manufacturing Sector

The government foresees 4 major sectors within the Indian Electronics manufacturing realm that hold the promise of tremendous growth. These are:



Medical Electronics sector



Strategic Electronics sector (Defense Electronics)



Automotive Electronics sector



Telecom sector (with the emergence of technologies like the Internet of Things (IOT), robotics and Artificial Intelligence (AI))

MEDICAL ELECTRONICS

Introduction

The importance of medical electronics manufacturing can be appreciated only by understanding the role which is played by medical devices in enriching our lives.

Medical devices are essential not just for screening, diagnosing and treating patients, but they also play a major role in monitoring a patients' essential health indicators on a regular basis which help them lead normal lives. They help improve the quality of care provided, and further the reach of healthcare access to a wider population. With the advancement in technology and the increasing sophistication of medical devices, the overall healthcare delivery system has improved around the globe.

Market Size - Global

The Global Medical Devices Market was valued at US \$425.5 billion in 2018 and is expected to grow at a CAGR of 5.4% to reach a market cap of US \$612.7 billion by the end of 2025⁶. United States of America, with about 45% market share is the dominant market for medical devices in the world followed by European market with a share of 30% and Japan with a share of 10% .⁷

A highly innovative and rapidly advancing industry, it encompasses areas such as diagnosis, treatment, and monitoring.

The major growth drivers globally are:

- ***Rising geriatric population seeking quality medical devices for chronic disease management***
- ***A rising prevalence of chronic conditions***
- ***Increase in surgical procedures and the related complexity of the same***
- ***Rising demand for innovative therapies to meet unmet medical conditions***
- ***Demand among healthcare professionals for medical equipment and devices on lease***
- ***Significant increase in the wearables market.***

Key players operational in the global medical devices industry include Medtronic, DePuy Synthes, Fresenius Medical Care, Philips Healthcare, GE Healthcare, Ethicon LLC, Siemens, Cardinal Health, Stryker, BD, Baxter International and others.

⁶ <https://www.fortunebusinessinsights.com/industry-reports/medical-devices-market-100085>

⁷ <http://pharmaceuticals.gov.in/sites/default/files/Draft%20National%20Medical%20Device%20Policy%20-%202015.pdf>

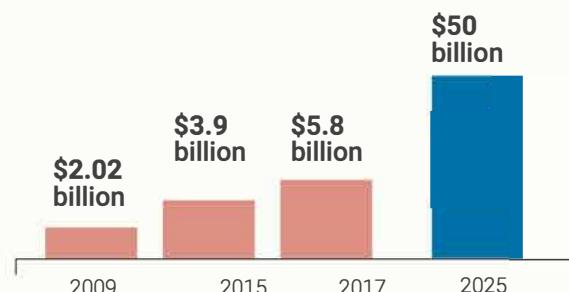
BACKGROUND

SETTING THE CONTEXT

The Healthcare market in India is expected to grow at an impressive CAGR of 16.28% and is projected to touch US \$372 billion by 2022.⁸ The growth in the healthcare market will be a strong impetus for the growth of the medical devices market that has been projected to grow to US \$11 billion by 2022.⁹

Valued at \$2.02 billion in 2009, the Indian medical devices industry steadily grew at a CAGR of 15.8% to \$3.9 billion in 2015¹⁰. In 2017, it was valued at US \$5.8 billion.¹¹ The current CAGR of 15-16% is much higher than the global industry growth rate of 4-6%.

Industry estimations reckon the Indian medical devices industry holds the potential to grow at 28% per annum to become a US \$50 billion industry by 2025¹².



Currently, India is the fourth largest medical devices market in Asia after Japan, China and South Korea and globally, it is among the top 20¹³.

India presents an excellent growth market for medical device companies, owed to its huge population and the under-penetration of medical devices (which is minuscule in comparison to other developed/developing countries). Further, the push provided by the Government through programs such as the National Rural Health Mission, which aims to provide technology at the grassroots level to advance the reach of healthcare among the masses, only adds to India's enormous potential.

⁸ <https://www.ibef.org/download/healthcare-jan-2019.pdf>

⁹ <https://www.ibef.org/download/healthcare-jan-2019.pdf>

¹⁰ <http://www.makeinindia.com/article/-/v/sector-survey-medical-devices>

¹¹ <https://www.financialexpress.com/industry/why-2017-is-a-landmark-year-for-the-medical-device-industry-in-india/550425/>

¹² https://static.investindia.gov.in/s3fs-public/2018-10/Japan%20-%20Medical%20Device%20v4_for%20web_0.pdf

¹³ https://static.investindia.gov.in/s3fs-public/2018-10/Japan%20-%20Medical%20Device%20v4_for%20web_0.pdf

The total healthcare expenditure in India was estimated

3.8%

of the GDP in 2016¹⁴

against a global average of 10%¹⁵. Of the total expenditure, about 30% is contributed by the public sector, putting the public health expenditure in India at 1.3% of the GDP¹⁶.

However, the National Health Policy 2017 proposes to increase this to

2.5%

of the GDP by 2025

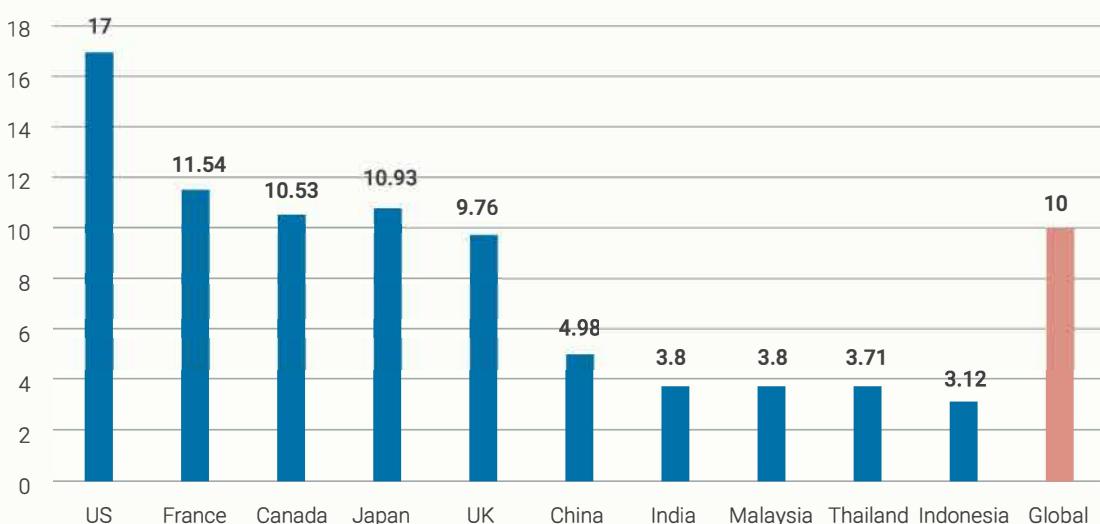
Further, the out-of-pocket expenditure is also high at

61%

in 2016¹⁷

with only 44%¹⁸ of the population being covered by health insurance (of any kind).

Total Healthcare Expenditure as a % of GDP, as compared to other countries*



*Source for other countries Health Expenditure figures:

https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS?name_desc=falsez

If one considers per capita spend on medical devices in India, it is the lowest among BRICS countries. This under-penetration of medical devices in India represents a promising growth opportunity.

The lucrative market potential can be judged from the growing number of multinational companies establishing their presence in India. Nearly all the top 40 global medical devices companies are present here. A majority of them have their production bases outside India and import for the Indian market.

¹⁴ https://mohfw.gov.in/sites/default/files/NHA_Estimates_Report_2015-16.pdf

¹⁵ https://www.who.int/gho/health_financing/en/

¹⁶ <https://www.prsindia.org/theprsblog/healthcare-financing-who-paying>

¹⁷ https://mohfw.gov.in/sites/default/files/NHA_Estimates_Report_2015-16.pdf

¹⁸ <https://www.livemint.com/Money/YopMGGZH7w65WTTxgPLOSK/56-Indians-still-dont-have-a-health-cover.html>

MEDICAL DEVICES

INDIAN MANUFACTURING CAPABILITIES

India is largely import-dependent for meeting its medical devices need. If all the products in the category “medical devices” is taken together, India imports around 80% of its medical device requirement with almost a fourth of it sourced from the US¹⁹. For the FY 2018-19, imports jumped 24% to US \$5399 million from US \$4362.5 million in FY 2017-18.

The high dependence on imports can be attributed to the following factors:

- An inverted duty structure which favors import of finished goods over raw materials/components for medical devices manufacturing
- Limited access to technology, IP Protection
- Absence of transparent and well-defined policies specific to medical devices
- Lack of component-manufacturing ecosystem
- An under-developed skill base to support domestic manufacturing
- Global capacities and technological superiority in MNC manufacturing

The Indian Medical Devices Import figures for the last 5 years ²⁰



¹⁹

https://www.business-standard.com/article/companies/import-of-medical-devices-from-us-on-the-rise-here-s-all-you-need-to-know-118061000756_1.html

²⁰

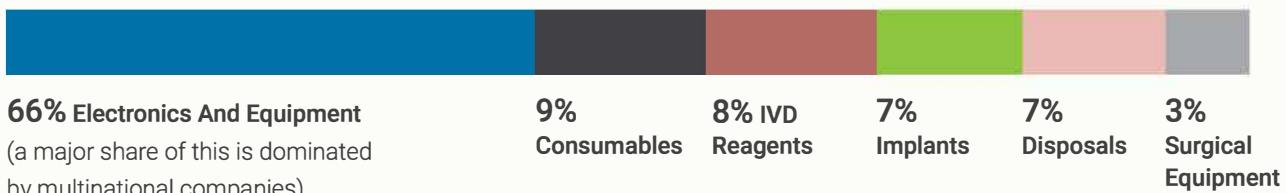
https://www.business-standard.com/article/companies/import-of-medical-devices-from-us-on-the-rise-here-s-all-you-need-to-know-118061000756_1.html

India's highly fragmented medical devices industry is dominated by multinationals such as GE, J&J, Philips, Wipro, Abbott, Siemens, Baxter and Fresenius, which control about 75-80% of the Indian market.

Domestic Manufacturers with over US\$ 70 million revenues a year are: Trivitron, Transasia Biomedicals, Hindustan Syringes & Medical Devices and PolyMedicure

Though India has an estimated 900-1000 domestic medical devices manufacturers, with only 15 companies having a turnover of above US \$25 million. More than 80% of domestic manufacturers are in the small-scale sector, with a turnover of less than US \$1.5 million.

Of the US \$5399 million imports in 2018-19,



The domestic firms are focused on manufacturing at the lower end of the spectrum which enjoys high volumes, while the large MNCs cater to the specialized and costly segment with extensive service networks. These firms are backed by multiple approvals and certification of accredited organizations. Further, the capacity to produce verified clinical trial records has enabled them to grow their market share at the expense of indigenous companies who lack both standardization and certification.

Export of Indian Medical Devices

Export of Medical devices from India has seen consistent growth over the past 5 years. In 2018-19, it grew 29% to US \$1772 million²¹.

Segments in The Indian Medical Devices Industry²²

The major segments in the Indian Medical Devices Industry are:



INSTRUMENTS AND APPLIANCES

Largest segment of the medical devices industry in India, constituting 34% (US \$1.26 billion) of the total industry size in 2014.

- **Ophthalmic Instruments:** Instruments and appliances pertaining to ophthalmic use
- **Medical and Surgical Sterilizers:** All forms of medical and surgical sterilizers
- **Dental Products:** Capital equipment (dental drills, dental chairs and dental X-Ray) and instruments and supplies (dental cements, dental instruments and teeth and other fittings)
- **Therapeutic Appliances:** Mechano-therapy apparatus and therapeutic respiration apparatus
- **Other Instruments and Appliances:** Blood pressure monitors, endoscopy apparatus, dialysis apparatus, transfusion apparatus, anaesthetic apparatus and instruments, ultra-violet and infra-red ray apparatus



DIAGNOSTIC IMAGING

Represents the second largest segment of the medical devices industry in India constituting 31% (US \$1.2 billion) of the total industry size in 2014.

- **Electro-Diagnostic Apparatus:** Electro-cardiographs, ultrasound, MRI, scintigraphy apparatus and other electro-diagnostic apparatus
- **Radiation Apparatus:** CT scanners, X-Ray, and other A, B, C ray apparatus
- **Imaging parts and accessories:** Contrast media, medical X-Ray films (flat and rolled), X-Ray tubes and other imaging parts/accessories

²¹

https://www.business-standard.com/article/economy-policy/import-of-medical-devices-up-24-in-fy19-despite-cap-on-pricing-119062200829_1.html

²²

<https://www2.deloitte.com/content/dam/Deloitte/in/Documents/life-sciences-health-care/in-lshc-medical-devices-making-in-india-noex.pdf>



CONSUMABLES AND IMPLANTS

constituted 19% (US \$0.72 billion) of the total industry size in 2014.

- **Syringes, needles and catheters:** Syringes (with/without needles), tubular metal needles, needles for sutures, other needles, catheters, cannulae, etc.
- **Bandages and dressings:** Medical dressings (adhesive) and medical dressings (non-adhesive)
- **Suturing materials:** All forms of suturing materials
- **Others:** Stents, blood-grouping reagents, first aid boxes and kits, ostomy products and surgical gloves



PATIENT AIDS AND OTHERS

constitutes 16% (US \$0.59 billion) of the total industry size in 2014.

- **Prosthetics and orthopedics:** Fixation devices, artificial joints and other artificial body parts
- **Portable Aids:** Hearing aids, pacemakers and other portable aids
- **Others:** Wheelchairs and hospital furniture

Around 40-50% in the Consumables & Implants and Instruments & Appliances segments are imported. For the remaining sub-segments, the share of imports can go up to 80-90%.

Market Factors that will propel the Industry forward

Growing geriatric population: The ageing population in India which was 7.5% in 2001, increased to 8.6% in 2011 and is further predicted to be around 19% of the total population by the year 2020²³.

A rise in ageing population will command healthcare services, and thus require medical devices at healthcare facilities and homes.

Changing disease prevalence pattern (e.g. early onset of diabetes and heart diseases):

- India has earned the moniker of the diabetes capital of the world with the number of diabetes patients increasing rapidly. 49% of the diabetics reside in India, with an estimated 72 million cases in 2017. This alarming figure is expected to nearly double to 134 million by 2025²⁴.
- Coronary heart disease is a leading cause of death in India. 28% of Indians succumbed to heart ailments in 2016, almost doubling since 1990, when heart disease caused 15% of deaths²⁵.
- Research attributes more than 75% of India's disease burden by 2025 to non-communicable diseases, compared to 45% in 2010²⁶.

These statistics signal the requirement for affordable and quality medical devices for healthcare.

Rise in disposal incomes and affordability: Increasing urbanization in India is leading to rising socio-economic inclusion of rural and deprived into the mainstream economy. Urbanization in India was 34% in 2018²⁷ and is expected to reach 46% by 2025²⁸.

Increase in health insurance coverage: Moreover, with increasing awareness among the urbanizing population, health insurance coverage is expected to increase to 655 million by 2020.

Boom in medical tourism: India is one of the fastest-growing medical tourism destinations in Asia²⁹. Ranked as the 3rd most popular destination in 2015³⁰, it is currently growing at an impressive CAGR of 18% and is expected to be worth 9 billion by 2020³¹.

Heightened manufacturing innovation: In a bid to create customized products to meet the needs of all income segments, frugal engineering innovations are developing low-cost products that seem to be on par with existing products on quality.

Growing awareness among the middle class to focus on early detection and disease prevention.

²³ <https://india.unfpa.org/sites/default/files/pub-pdf/India%20Ageing%20Report%20-%202017%20%28Final%20Version%29.pdf>

²⁴

<https://www.firstpost.com/india/diabetes-is-indias-fastest-growing-disease-72-million-cases-recorded-in-2017-figure-expected-to-nearly-double-by-2025-4435203.html>

²⁵

https://www.business-standard.com/article/health/15-of-deaths-in-india-were-due-to-heart-diseases-in-1990-now-up-to-28-118091800130_1.html

²⁶ <https://www.ibtimes.co.in/india-see-rise-non-communicable-diseases-over-next-decade-report-671637>

²⁷ <https://data.worldbank.org/indicator/sp.urb.totl.in.zs>

²⁸ <https://www.teriin.org/resilient-cities/urbanisation.php>

²⁹

<https://www.indiatoday.in/travel/india/story/india-medical-tourism-asia-fastest-growing-yoga-ayurveda-advantage-healthcare-india-summit-medical-treatment-karnataka-ficci-report-us-russia-saudi-arabia-united-arab-emirates-lifest-1064130-2017-10-13>

³⁰ <https://edition.cnn.com/2019/02/13/health/india-medical-tourism-industry-intl/index.html>

³¹ <https://yourstory.com/mystory/india-as-a-hub-of-medical-tourism-nn2tmum2vu>

Non-Market Factors that will enable advancement of the industry

Development of healthcare infrastructure:

- A positive trend being noticed in the healthcare delivery is the setting up of corporate hospital chains, international companies and services providers, not just in metros but also tier 2 and tier 3 cities. This has led to a significant rise in the number of hospitals and hospital beds in India. India has been adding 100,000 hospital beds annually over the last decade³² with the current number now at 1 hospital bed for every 1050 patients³³. The National Health Policy mandates at least 2 beds per 1000 population³⁴.
- New formats are emerging which include chains of multi-speciality outpatient clinics, mother-and-child hospitals, short-stay surgery centres, IVF centres, etc. These are expected to drive the demand for medical devices.
- The diagnostic services market is predicted to continue growing at the rate of 27.5% for the next 3 years³⁵, with pathology expected to contribute approximately 58% of the total market, by revenue³⁶. These will further drive the demand for medical equipments.

Increasing focus of healthcare providers on quality and accreditation: Hospitals and laboratories have acknowledged the need to upgrade their existing medical technology to comply with accreditation requirements.

About 636 hospitals in India are NABH accredited³⁷ with another 739 having submitted proposals for accreditation³⁸. Similarly, more than 1100 laboratories³⁹ in India are NABL accredited and the numbers are only expected to increase going forward.

Favourable regulations: Recognizing the need to revamp the regulatory framework pertaining to the medical devices industry, the Indian Government has implemented several policy measures to address the challenges being faced by them. Some of the major ones are:

- Allowing 100% FDI in medical devices under the automatic route
- 'Make in India' initiative for promoting indigenous manufacturing of medical devices
- Medical Devices Rules, 2017 drafted in conformity with the Global Harmonization Task Force framework.
- Draft Drugs & Cosmetics Amendments Bill (2015)

Outsourcing of manufacturing and R&D activities to India: Many MNCs are locating research centres in India which will serve both Indian and global markets.

³²<https://www.businesstoday.in/sectors/pharma/indian-healthcare-doctor-hospital-beds-needed-by-2034-pwc/story/215119.html>

³³<https://www.ibef.org/download/Healthcare-January-2017.pdf>

³⁴<https://mohfw.gov.in/sites/default/files/9147562941489753121.pdf>

³⁵<https://www.researchandmarkets.com/reports/3720508/indian-diagnostic-services-market-outlook-2020>

³⁶<https://www.expresshealthcare.in/lab-diagnostics/the-alchemy-of-growth-in-diagnostics/409423/>

³⁷<https://www.nabh.co/frmViewAccreditedHosp.aspx>

³⁸<https://www.nabh.co/frmViewApplicantHosp.aspx>

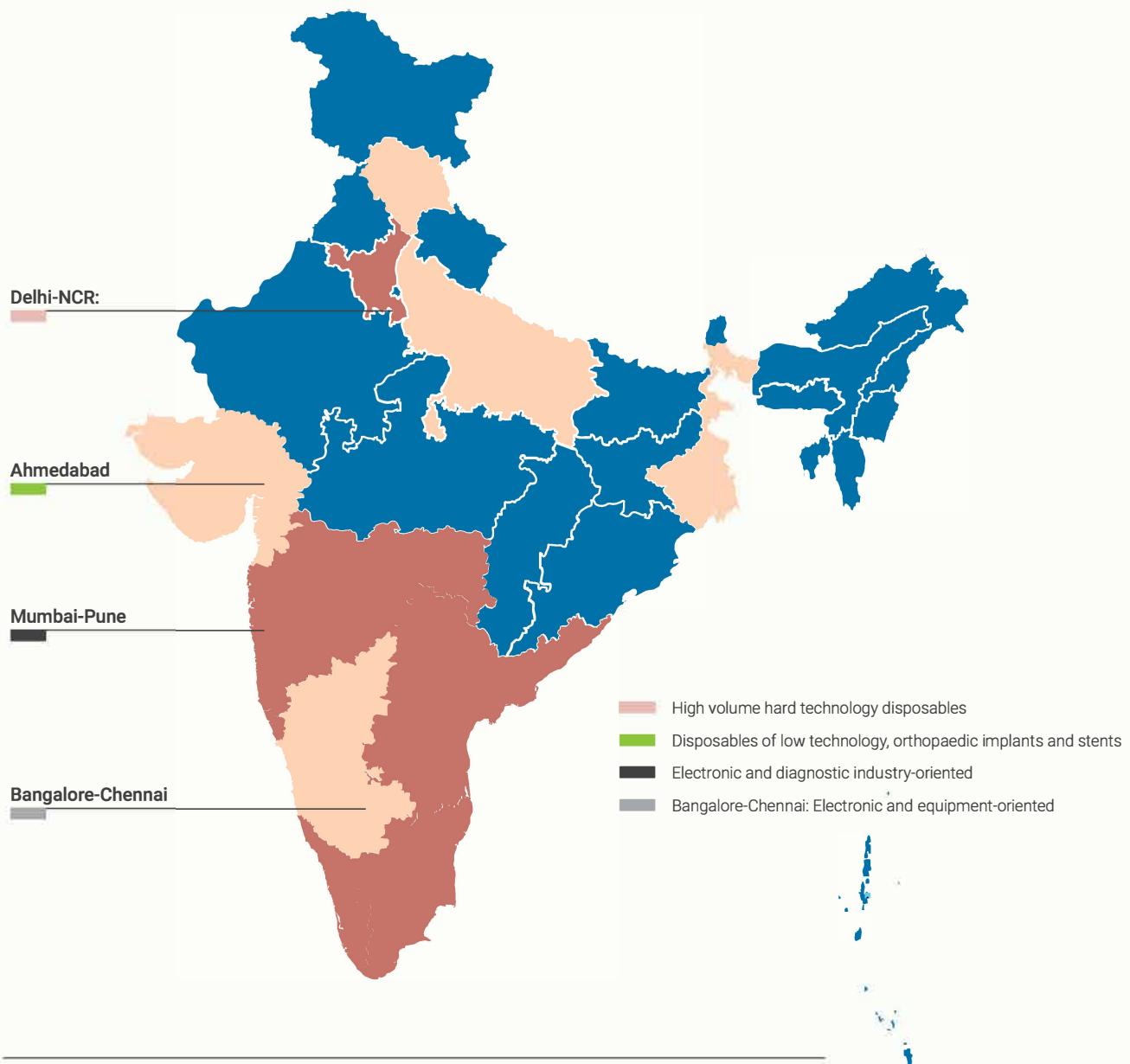
³⁹

<https://health.economictimes.indiatimes.com/news/industry/we-have-a-massive-plan-to-go-beyond-10000-20000-labs-in-next-5-years-a-nil-relia/69170528>

INDIAN MANUFACTURING LANDSCAPE

Maharashtra, Tamil Nadu and Andhra Pradesh are the leading states in India with a fairly developed ecosystem for indigenous medical devices manufacturing. Three major cities - Bangalore, Mumbai and Chennai have developed a manufacturing base and have further attracted R&D centres of major MNCs and domestic players.

The medical devices manufacturing landscape in India has developed in the form of clusters across the country. Currently, the following clusters exist for manufacturing of medical devices in India⁴⁰.



⁴⁰ <https://ehealth.eletsonline.com/2016/01/medical-devices-made-in-india/>

KARNATAKA

Banking on its strength of engineers, technocrats and high-skilled labour, Karnataka is a major medical devices manufacturing hub. It also boasts of many R&D centres of MNCs. The products manufactured in this belt are insulin pens, medical IT, Cardiac stents and implants, PCR machines.

Major Hubs: Bengaluru, Mangalore

Companies: GE Healthcare, Biocon, Medived, Skanray, Bigtec Labs, Prognosys Medical, etc.

TAMIL NADU

This is another state whose strength lies in its engineers, technocrats and high-skilled labour. Home to a number of well-known eye hospitals, this belt manufacturers Ophthalmology-related devices, diagnostics and critical life-support systems.

Major Hubs: HLL MediTech Park, Chennai

Companies: Roche, Trivitron Healthcare, Opto Circuits, Perfint Healthcare, Phoenix Health Systems, Schiller

MAHARASHTRA

Major Hubs: Mumbai, Pune, Nagpur, Aurangabad, Ambernath

Companies: Johnson & Johnson, Philips Healthcare, Siemens, Trivitron Co, Smith & Nephew.

ANDHRA PRADESH & TELANGANA

Major Hubs: Hyderabad, AMTZ MedTech Park in Visakhapatnam, Sri City SEZ, Namnapally, Upcoming MedTech park in Sultanpur

Companies: St. Jude Medical, Relisys Medical Devices, B Braun, Medtronic

HARYANA

The state is known for manufacturing low-end consumables and dental equipment. Its strength lies in availability of low-cost unskilled labour.

Major Hubs: Gurgaon, Manesar, Chandigarh, Bahadurgarh, Ballabgarh, Bawal – Faridabad

Companies: Boston Scientific Corp., Becton Dickinson India, Hindustan Syringes, Poly Medicure, etc.

DELHI

The biggest strength is its proximity to the Central Government. This area is known for its innovation in medtech.

GUJARAT

It's prominently known for its diamond industry. The laser-cutting technology used in diamond cutting was remodelled to assist in the manufacturing of stents.

Major Hubs: Surat, Bhilad, Ahmedabad, Vapi

Industrial Corridors

Companies: 3M Co. Bayer AG, Meril Life Sciences, Invent Bio-Med

PUDUCHERRY

KERALA

Palakkad

Thiruvananthapuram

Trivandrum

WEST BENGAL

Kolkata

UTTAR PRADESH

Kashipur

Noida: A medical devices testing lab was to be set up here. It would primarily test electrical and electronic medical devices in the country.

HIMACHAL PRADESH

Baddi

GOA

POLICIES

The medical devices industry in India was regulated by the Drug & Cosmetics Act, 1940 – which was essentially framed for and followed by the pharmaceutical industry.

Up until 2016, only 15 medical devices were notified as '**medical devices**' and had specific regulations governing them. The rest of the medical devices came under the category of 'drugs' and thus were regulated akin to the pharmaceutical industry.

Classifying 'medical devices' as drugs enabled the National Pharmaceutical Pricing Authority to fix a ceiling price on those medical devices that were deemed necessary to have a cap on their price. This was in accordance with the Drug Price Control Orders.

In a bid to attract Foreign Direct Investment (FDI) to the medical devices industry, the two sectors – pharmaceuticals and medical devices, were finally recognized as separate industries.

Separate regulations for the medical devices industry were devised for the following reasons:

- A robust legal framework to guide the fragmented medical devices industry in complying with international standards will boost India's position in the global market and portray it as a favored investment destination.
- A regulatory framework will help develop a more conducive environment for local/global manufacturers to set up factories in India.
- Regulations will lend authenticity to the indigenously manufactured products by ensuring they meet the required standards, thereby improving their acceptance among Indian and global customers.

Medical Devices Rules 2017

The Medical Devices Rules are a subordinate legislation under the Drugs and Cosmetics Act, 1940 and became enforceable from January 2018. They are in conformity with the Global Harmonization Task Force (GHTF) framework - a voluntary group setup with the aim of standardizing the regulations for medical devices across the globe.

The most important change under these rules is recognizing medical devices as a separate category from the existing pharmaceuticals and drugs industry (under which it had been subsumed till then), thus bringing the over 10,000 types of medical devices in India, under focused regulations.

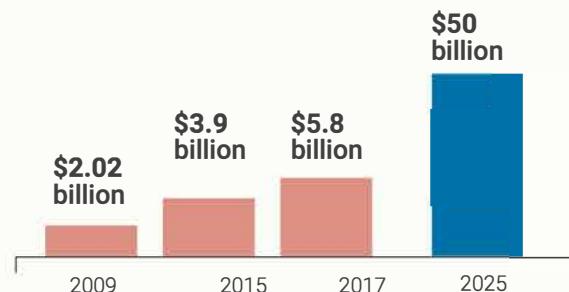
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⁸ <https://www.ibef.org/download/healthcare-jan-2019.pdf>

⁹ <https://www.ibef.org/download/healthcare-jan-2019.pdf>

¹⁰ <http://www.makeinindia.com/article/-/v/sector-survey-medical-devices>

¹¹ <https://www.financialexpress.com/industry/why-2017-is-a-landmark-year-for-the-medical-device-industry-in-india/550425/>

¹² https://static.investindia.gov.in/s3fs-public/2018-10/Japan%20-%20Medical%20Device%20v4_for%20web_0.pdf

¹³ https://static.investindia.gov.in/s3fs-public/2018-10/Japan%20-%20Medical%20Device%20v4_for%20web_0.pdf

With these new rules, the government aims to:

- Develop a robust standardization framework in India which is on par with international standards
- Facilitate ease of doing business
- Ensure a transparent and predictable regulatory framework, which will boost the confidence of investors
- Remove regulatory bottlenecks for setting up manufacturing units in India
- Leverage the comparative cost advantage of manufacturing in India which can further improve the accessibility and affordability of medical devices across the globe
- Provide a conducive environment for fostering India specific innovation
- Improve the quality and range of medical products and services
- Provide assurance of the best quality, safety and performance of medical devices
- Improve the competitiveness of local firms by providing incentives to become more efficient and innovative
- Create a robust ecosystem for all stakeholders including innovators, manufacturers, providers, consumers, buyers, and regulators

Under the new Medical Devices Rules 2017, medical devices will be classified, as per GHTF practice, on the basis of their associated risks into:

- Class A (low risk)
- Class B (low moderate risk)
- Class C (moderate high risk) and
- Class D (high risk)

Manufacturers of each of these categories need to be cognizant of the risk-proportionate regulatory requirements as specified in the Rules and comply with them.

To raise the professional standards of regulatory assessments applied to medical devices, a system of 'Third Party Conformity Assessment and Certification' has been envisaged. This will be implemented by setting up Government Notified Bodies – to audit the manufacture, sale, or distribution of medical devices for establishing conformity to the new rules. The participation of third-party bodies is a key feature of regulatory mechanism in the US and Europe.

The organization responsible for accrediting these Notified Bodies will be the National Accreditation Board for Certification Bodies (NABCB). The NABCB will assess the competence of the said Notified Bodies in terms of required human resources and other requirements.

Once accredited, the Notified Bodies will verify and assess the Quality Management System of Medical Device Manufacturers of Class A and Class B category. If required, they may be asked to assist with the assessment of manufacturers of Class C and Class D medical devices, as well.

Unique identification requirements: Medical devices and IVDs will require unique identification starting January 1, 2022.

Licensing

CLASS A MANUFACTURER

To encourage a culture of self-compliance, the manufacturing license for Class A medical devices shall be granted without a prior audit of the manufacturing site. The expectation is for the manufacturer to conduct a self-certification of his manufacturing plant within 120 days of granting of the license.

Based on the self-certification conducted and submitted, the license will be issued. This process of license issuance based on self-certification and a few necessary checks to ensure compliance is a welcome departure from the inspection-based regime, prevalent before.

The self-certified manufacturing site will be later audited by the relevant Notified Body to verify its conformance with the rules of the Quality Management System.

CLASS B MANUFACTURER

For Class B devices, the audit of the manufacturing site needs to be conducted within a timeframe of 90 days from the date of application. The license will be granted on the audit being successful and the manufacturing setup being in conformity with the relevant regulations applicable to the category.

On approval by the Notified Body, the manufacturer of Class A and Class B medical devices will be licensed by the concerned State Licensing Authority. The Quality Management System for all the manufacturing sites needs to be aligned with ISO 13485.

CLASS C & CLASS D MANUFACTURERS

are required to apply to the **Central Licensing Authority**. When necessary, assistance of experts and notified bodies will be taken.

IMPORT OF MEDICAL DEVICES

The import of all medical devices will continue to be regulated by the Central Drug Standard Control Organization (CDSCO). For the testing of medical devices, a network of NABL-accredited laboratories is planned to be set up by the Govt. and other entities.

CLINICAL TRIALS

The clinical trial requirements have been relaxed, as well. Earlier, medical devices were required to adhere to the highly stringent 4-phase process applicable to the pharmaceutical industry. With the Medical Devices Rules 2017 coming into force, separate provisions that are on par with international practices will apply.

- Clinical trial process for medical devices will consist of 2 phases
- The test licenses for clinical trials will remain valid for a term of 3 years (earlier these were valid for only 1 year).

However, the clinical trial process will continue to be managed by the CDSCO, which derives its power from the Drugs and Cosmetics Act, 1940.

The conduct of clinical investigation, though followed according to international practices, needs to ensure:

- Patient safety and welfare Discovery of new medical devices

Subjects of clinical investigation will be provided with Medical management and compensation in compliance with the Government's predefined and objective criteria.

NEW FEATURES

- For the first time, there will be no requirement of periodic renewal of licenses.
- The manufacturing and import licenses will remain in force till they are either suspended/ cancelled /surrendered.
- The entire licensing procedure - right from the submission of application till the granting of license shall be conducted through an online electronic platform with defined timelines for the same.

Legal Metrology (Packages Commodities) Rules 2011

The LM Rules mandate that all pre-packaged commodities ("pre-packaged goods") should carry declarations and particulars, which may be prescribed by the Government from time to time. Regulated medical devices were exempt from complying with these rules.

However, it was noticed that medical devices were being sold according to the paying capacity of the consumer, leading to numerous complaints from consumers. Even after capping of MRP, many companies were not displaying the same.

To encourage a transparent system, the label of regulated medical devices will have to carry the following additional declarations and particulars:

- i. Maximum retail price ("MRP");
- ii. Common or generic name of the commodity;
- iii. Month and year in which the commodity is manufactured or packed or imported;
- iv. Name, address, telephone number, e-mail address of the person who can be or the office which can be contacted, in case of consumer complaints;
- v. Actual corporate name and complete address of domestic manufacturer or importer or packer;
- vi. Other particulars and declarations as mandated by the Rules

These rules became applicable to all regulated medical devices from 1st January 2018⁴¹.

National Health Policy 2017

The National Health Policy 2017, when released in 2017, proposed to increase public health spending to 2.5% of GDP from 1.4% of GDP (in 2014) as well as increase the life expectancy to 70 years by 2025. This policy is also geared towards easing the manufacturing of drugs and medical devices, by improving public sector capacity for manufacturing essential drugs and vaccines.

⁴¹

<https://health.economictimes.indiatimes.com/news/medical-devices/2017-in-review-milestones-in-the-medical-device-revolution-in-india/62250639>



'Make in India' Campaign

The Make in India campaign launched in Sept 2014 aims to develop India into a global manufacturing hub by attracting foreign capital and technology into the country. Medical devices manufacturing is one of the 25 focused sectors identified for this campaign.

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The Make in India campaign has managed to improve the domestic manufacturing numbers for the Indian mobile manufacturing sector and the same has been envisaged for other significant electronics sectors – medical devices being one of them.

The past few years has seen constant sparring between India and the US over price curbs imposed on medical devices. Price curbs are also being blamed for the steep fall in FDI inflow into the sector. To reduce the reliance on imports and lower costs, NITI Aayog, the Indian Government's think tank, is currently developing a roadmap to promote the development of medical devices under the Make in India initiative⁴².

The incentive package being drafted could provide a capital subsidy of up to 25% to medical device manufacturers⁴³, in line with the plan already in place for the electronics industry. They may also consider part-funding of capital expenditure incurred on research and production, which will benefit manufacturers and startups alike.

⁴²

<https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/make-in-india-plan-in-works-to-attract-medical-device-companies/articleshow/70709202.cms>

⁴³

<https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/make-in-india-plan-in-works-to-attract-medical-device-companies/articleshow/70709202.cms>

FDI Inflow

India has permitted 100% foreign direct investment (FDI) through the automatic route in the medical devices sector, for brownfield as well greenfield setups. This change in FDI came through in 2015, following which there was a sizeable inflow of FDI. The next year, 2016, witnessed a peak FDI inflow of \$439 million⁴⁴.

However, post that, FDI has declined rapidly. The reason for this decline has been attributed to the implementation of price-control (on medical devices). This is a clear signal from the Government that the intent is to boost domestic manufacturing of medical devices by inviting foreign partners to build factories rather than build warehouses to pursue trading (which is their current strategy).

Recent Developments For Implantable Medical Devices⁴⁵

In February 2019, the Government brought implantable medical devices under the purview of the Drugs and Cosmetics Act, 1940 with the intent to regulate their sale, manufacture and import. This is to ensure that only safe and tested medical devices are bought by patients, and to prevent fiascos like the one involving Johnson and Johnson hip implants.

⁴⁴ FDI in medical device dwindle, industry blames government policy – April 2019
(<https://www.businessstoday.in/top-story/fdi-in-medical-device-dwindles-industry-blames-government-policy/story/339767.html>)

⁴⁵

<https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/make-in-india-plan-in-works-to-attract-medical-device-companies/articleshow/70709202.cms>

RESEARCH AND DEVELOPMENT IN THE MEDICAL DEVICES SECTOR

The Government recognizes the role played by medical devices in preventive care and disease management, which has the potential to improve the quality of life for patients and families alike. For the medical devices industry to thrive and keep pace with the demands of the healthcare ecosystem, it must invest in Research & Development (R&D) on an ongoing basis.

The R&D landscape in India can be divided along the following lines:

- R&D facilities of global medical devices players
- Medical device players customizing products for the Indian market
- Startups in the medical technology space
- Government's assistance to R&D

R&D facilities of global medical devices players

BOSTON SCIENTIFIC

Spread over an area of 100,000 square feet in Gurgaon, Boston Scientific has established an R&D, training and commercial center to develop products suitable for the Indian and Asian markets and to train physicians to use them effectively. The R&D center will focus on creating market-appropriate products for unmet clinical needs in emerging markets and will also serve as a global product engineering center.

Further, the global MedTech leader introduced the 'Boston Scientific Navigation Express' - a mobile van showcasing groundbreaking medical innovations, in July 2016. This unique initiative conducted a tour of 130 hospitals in 52 cities to demonstrate the latest technologies to nearly 2690 medical professionals⁴⁶. These strategic investments by Boston Scientific underlines their commitment to India.

MEDTRONIC

Medtronic has set up a captive engineering research and development centre in Hyderabad providing support to global business units for improving procedural outcomes and developing future products. This 90,000 sq. ft. lab has 230 highly qualified engineers and is equipped with state-of-the-art technology.

COVIDIEN

Covidien has set up a 40,000 sq. ft. R&D centre in Hyderabad, India with an aim to tailor products to local market needs, increase speed-to-market, and develop breakthrough platforms.

STRYKER

Stryker has set up a global R&D centre in Gurgaon for developing next generation technologies and high-end medical devices. The center also operates as a global talent hub, where Indian surgeons and engineers are trained on latest technologies.

⁴⁶ <https://www.biophicenews.com/boston-scientifics-navigation-express-completes-its-6-month-long-tour/>

Medical device players customizing products for the Indian market

GE HEALTHCARE

Compact CT scanners which consume less power

GE Healthcare developed a CT scan system that uses 40% less power, produces less radiation and is 40% cheaper than imported equivalents. It has a substantially smaller size (can fit in smaller clinics and hospitals) and a higher throughput (scan time is 28% faster).

Also, General Electric's low-cost electrocardiogram (ECG) – developed keeping in mind the pricing pressure of developing economies, was extremely effective and went on to disrupt developed markets.

SKANRAY TECHNOLOGIES

Affordable X-ray imaging systems

Skanray created a high frequency digital X-ray machine that can cater to the needs of both large hospitals as well as small clinics. The cost of the device is a fraction of that of the imported machines. This wireless device is extremely light-weight and can be easily manoeuvred in congested hospital settings.

PHILIPS HEALTHCARE

Accessible and affordable cardiac care in tier II & tier III cities

Philips Intuis, an advanced entry-level catheterization lab, is helping provide affordable cardiac care in smaller cities and towns in India. It has a live image guidance technology which can help vascular specialists to decide, guide and confirm the right therapy for their patients in real time.

CURA HEALTHCARE:

Affordable digital radiology systems for all resource settings

Cura manufactures direct digital radiology systems that can be floor-mounted, ceiling-suspended, or retrofitted and are suitable for both small hospitals and large healthcare institutions. Moreover, it is powered by just 15 amp and can take up to 50 images without power.

POLY MEDICURE

Innovative 'single use' medical devices

Poly Medicure produces over 125 different types of medical devices at 5 manufacturing plants in India. It is the largest exporter of single use medical devices in India. In addition to manufacturing, it also invests heavily in designing in India and holds more than 140 patents in various countries and has around 350 pending patent applications.

MERIL LIFE

Affordable cardiovascular devices

Meril has developed new concepts in engineering employing novel designs, drug delivery technologies (for stents & balloons) and affordable catheter-based systems that effectively bridge the gap between countries with ailing populations and struggling healthcare needs.

TRANSASIA BIOMEDICALS

In-Vitro Diagnostic (IVD) for India

Transasia Biomedicals Ltd is India's biggest IVD company. Since 1991, it had adopted the 'Make In India' concept with indigenous manufacturing of sophisticated, state-of-the-art blood analyzers and reagents.

SAHAJANAND MEDICAL TECHNOLOGIES (SMT)

Affordable coronary stents

SMT, India's biggest stent manufacturer, has been successful in manufacturing affordable stents of world class quality. It has successfully introduced biodegradable polymer to the coronary stent industry, a highly sought-after technology in India as well as globally.

Startups in the medical technology space

SATTVA

Fetal Heartrate Monitor

Fetal Lite is a portable, lightweight device that can take an electrocardiogram of a foetus during labour. It can work in low-resource settings and can be operated by a layperson as it gives easy to understand alarms in case of foetal distress.

COEO LABS

Ventilators

Ceo Labs has designed a device to tackle ventilator-associated pneumonia in premature babies and patients on ventilators, a major cause of death in roughly 40 per cent of patients on breathing support in India. Currently in the prototype stage, this device is set to be launched at a price point 30% cheaper than competing devices.

WRIG NANOSYSTEMS

Hemometer

Developed a mobile phone-sized device called TrueHb Hemometer to measure haemoglobin in a few minutes.

FORUS HEALTH

Neonatal retinal scanner

3nethra Neo by Forus screens prematurely born babies who could potentially have a condition wherein abnormal blood vessels grow in the retina. This condition can result in permanent blindness of the child, if not detected and treated early.

REMIDIO

Retinal Imaging system

Fundus connects to a mobile phone camera to take pictures of the central part of the retina to diagnose diabetic neuropathy. This device is battery operated and can be installed even in remote centres. The images can be transferred in real time to a physician's phone for consultation.

CARDIOTRACK

Cardiotrack sensors – Remote health diagnostic

A portable and digitized diagnostic solution which enables instantaneous cardiac monitoring and flow of information through Android-based smart devices between a physician and a cardiologist. This technology which costs less than half of an ECG machines solves the problem of accessibility as well as affordability.

AXIO

Haemostatic emergency dressing

Traumatic bleeding is one of the biggest causes of death, which can occur in situations such as road accidents in India. Axio's haemostat works on adhesion rather than absorption technology and can be applied easily on external wounds to stop profuse bleeding. This product is robust, affordable and can be easily administered by a layman.

TRICOG HEALTH SERVICES

Cloud based ECG machine for faster diagnosis

Tricog Health services has designed a cloud-based ECG machine which enables the doctor to take a patient's ECG, send the information to a centrally located hub where the results can be interpreted by a qualified expert. The reports are then transmitted back through mobile phone. This increases the speed of the diagnosis and increases access.

Government's assistance to R&D

Medical technology can assist the Government in achieving its National Health Policy 2017 goal of promoting enhanced patient care in remote areas through remote diagnosis, telemedicine, Internet of Medical Things (IOMT) and m-health.

A large prevalence of non-communicable diseases in the rural population, which are non-life threatening immediately, can be attributed to⁴⁷:

- Lack of infrastructure options for screening and preventive services
- Lack of awareness on disease management options

To bring down the costs of technology and make it more accessible to the masses, the Government, through the Medical Electronics and Health Informatics Programme, encourages businesses, R&D institutions and academia to develop new systems or devices⁴⁸.

The Ministry of Electronics & Information Technology has sponsored many R&D projects in the area of Medical Electronics & Health Informatics. A few of these technologies have already been transferred to potential manufacturers for commercial production.

These include:

- 6MeV Linear Accelerator (LINAC)
- Closed Loop Anaesthesia Delivery System (CLADS)
- Microwave Disinfection System for Hospital Waste.

⁴⁷ <https://www.infosys.com/consulting/insights/Documents/indian-medical-device-industry.pdf>

⁴⁸ <https://meity.gov.in/content/rd-medical-electronics-health-informatics-division>

Living Lab in Bangalore⁴⁹, in collaboration with the Govt. of Karnataka

The Netherlands has partnered with the Government of Karnataka to co-develop technology solutions in healthcare, IT and cyber-security. The Karnataka government has signed a Letter of Intent (LOI) to setup a Living Lab here.

Living Lab, whose objective is to 'improve access to affordable healthcare via means of eHealth & medical devices' is a growing ecosystem that connects government, industry and academia to co-create innovative solutions for shared societal challenges. The Living Lab initiative is already underway in other emerging economies such as China, Brazil, Indonesia with Bengaluru being the latest one to join this network.

Establishing Medical Devices Parks / Medical Technology Institute

A. KALAM INSTITUTE OF HEALTH TECHNOLOGY (KIHT)⁵⁰

It carries the distinction of being India's first institute dedicated to medical technology. Located in Andhra Pradesh MedTech Zone (AMTZ), Visakhapatnam, it has been developed under the aegis of the Department of Biotechnology (DBT), which has provided 100% financial support.

The intent of KIHT is to identify critical gaps in medical technology and suggest the same to the government for funding. This will help bridge the gap between academic research and industrial market access.

B. ANDHRA PRADESH MEDICAL TECHNOLOGY ZONE IN VISAKHAPATNAM (AMTZ)

Spread over 270 acres (in two phases), the first phase of the AMTZ in Visakhapatnam was inaugurated in Dec 2018 by the Andhra Pradesh Chief Minister. All facilities essential for manufacturing, testing and certification of medical devices – right from a thermometer to CT scans have been constructed within the park⁵¹. It boasts of the largest 3D printing centre, bio-material testing, X-ray tube testing, prototyping, rapid tooling, CT Scan tube, largest gamma sterilisation plant for medical devices, R&D specialists and skill specialists⁵².

It has further been equipped with 2 world-class incubation facilities for innovators and startups in the medical devices manufacturing field. With great emphasis placed on quality control, 18 high-end industrial labs are being set up within the park.

80 units, including 17 startups are already functioning from the park premises. It is expected that 240 companies will be based out of the MedTech zone on completion of the 2nd phase, generating almost 25,000 jobs.

⁴⁹

<https://www.thehindubusinessline.com/news/netherlands-karnataka-to-co-develop-tech-solutions-in-healthcare-and-it/article25625203.ece>

⁵⁰ <http://pharmabiz.com/NewsDetails.aspx?aid=103359&sid=1>

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<http://www.newindianexpress.com/states/andhra-pradesh/2018/dec/14/cm-launches-medtech-zone-phase-1-80-firms-to-start-units-from-new-yr-1911382.html>

C. SULTANPUR, MEDAK DISTRICT, TELANGANA

The Sultanpur Medical Devices Park has been inaugurated with land allocations handed out to 14 industries. Spread over an area of 250 acres, it will have facilities for manufacturing, laboratory testing, prototyping and innovation.

The Govt. plans to sign MOUs with China Medical City located in Taizhou and another Medical Devices Park located in Gwangju in South Korea to exchange knowledge with them⁵³.

The park will also leverage the pharma and life-sciences strength of Hyderabad – which is a well-known medical tourism destination across Africa, Middle East and other countries.

D. MEDICAL DEVICES PARK IN NAGPUR⁵⁴

Currently in the planning phase, a medical devices park on a cluster-based approach at MIHAN, Nagpur is being deliberated between the Maharashtra Airport Development Company Ltd. (MADC) and medical device associations.

This multi-product Special Economic Zone is being developed for both API, formulations and medical devices. These units will have the benefits of:

- Duty free import or domestic procurement of goods for development, operation and maintenance of SEZ units
- 100% income tax exemption on export income for SEZ units for the first 5 years
- 50% for the next 5 years thereafter and 50% of the ploughed back export profit for the next 5 years
- External Commercial Borrowing (ECB) by SEZ units up to US\$ 500 million in a year without any maturity restriction through recognized banking channels
- Exemption from central sales tax
- Exemption from service tax
- Single-window clearance for central and state level approvals
- Exemption from state sales tax and other levies as extended by the state government and 100% FDI allowed

⁵³

https://www.business-standard.com/article/news-ians/14-companies-to-set-up-units-at-telangana-medical-devices-park-117061700736_1.html

⁵⁴ <http://www.pharmabiz.com/ArticleDetails.aspx?aid=112795&sid=1>

E. MEDICAL DEVICES PARK IN GUJARAT

This is currently in the planning stage. With the National Institute of Pharmaceutical Education and Research (NIPER) at Gandhinagar and plans afoot to expand the existing Central Institute of Plastic Engineering and Technology (CIPET) campus at Sanand⁵⁵, developing a medical devices park in Gujarat will boost the research and development ecosystem for this industry.

Further, Gujarat boasts of the largest number of licensed medical devices companies (numbering 170) against 240 in the entire country⁵⁶. Building a medical devices park in the state will only encourage the existing scenario.



ANDHRA PRADESH

Manufacturing of medium to high-end electronics and equipment related to medical devices.



MAHARASHTRA

Manufacturing consumables, orthopaedic implants and surgical instruments.



GUJARAT

Manufacturing of disposables and consumables.

⁵⁵

<https://www.thehindubusinessline.com/news/national/gujarat-to-have-indias-first-medical-devices-park/article7996430.ece>

⁵⁶<http://pharmabiz.com/ArticleDetails.aspx?aid=105498&sid=1>

CHALLENGES FOR MEDICAL DEVICES INDUSTRY IN INDIA

REGULATORY ENVIRONMENT

The Indian medical devices industry needs clear, unambiguous regulations to propel it forward. Even with the Medical Devices Rules 2017 coming into force, there are major areas (such as pricing of medical devices) which are still regulated according to the norms of the Drugs and Cosmetics Act 1940. Absence of an independent regulatory authority is a major deterrent for the advancement of the industry.

Further, increasing complexity of global regulatory requirements is seen as a top challenge for medtech companies. They are required to seek regulatory approvals for products and services in multiple jurisdictions, adding to the existing regulatory burden.

NON-EXISTENT COMPONENT SUPPLY CHAIN

A large portion of the ancillary components necessary for indigenous manufacturing of medical devices is imported. An effective component manufacturing ecosystem is a prerequisite for the evolution of the sector.

INADEQUATE TALENT BASE

Availability of skilled manpower and clinical staff essential for installing, operating, servicing and repairing medical devices can hamper the deployment and progress of this sector.

EXPENSIVE

Steep cost of medical devices hinders them from being deployed where necessary, impacting affordability of healthcare services

LOW FOCUS ON CONTEXTUAL INNOVATION

The products developed for the global markets are routinely deployed in Indian hospitals. This could lead to low suitability of these products.

HIGH COST OF RESEARCH & DEVELOPMENT

The medical devices industry has always held a special stake in innovation. With the intent to enhance the performance of their existing solutions and offer better life-saving technologies, continual investment in research and development is a pre-requisite. The R&D spends, for each company, are in the range of 5-15 percent of revenue. In a rapidly evolving and globalized marketplace, where the payment models are under pressure, justifying the R&D spend and continuing to innovate is a challenge.

Medical device players customizing products for the Indian market

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CONCLUSION

Notifying 'Medical Devices' as a priority sector and instituting various reforms to support it was a much-needed impetus to the fledgling Indian medical devices industry. Policies have always played a strong role in building an industry. A conducive environment and willing players (domestic manufacturers/MNCs/promising startups) could reinvent the entire healthcare delivery mechanism by addressing specific healthcare needs in an efficient and affordable manner.

The major challenges for this industry are building infrastructure and gaining access to raw materials. Setting up the medical devices parks supported by the right policies will encourage local manufacturing, thus reducing the country's dependence on imports. Innovation is critical for the success of this industry and it would bode well if the Government takes every opportunity to augment the R&D efforts made.

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