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Enabling growth and innovation in the Indian medical devices sector

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Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

Dated 22nd April, 2022

Foreword

The potential for growth in the Indian medical devices sector is large especially in the high-end complex device segments where the import-dependence is around 80 per cent. The government intends to boost infrastructure and ecosystem, enabling domestic manufacturing as part of *Atma Nirbhar Bharat Abhiyan*.

Several policy and program interventions and initiatives have been rolled out to promote domestic manufacturing of medical devices. Recognizing the need for higher levels of investments for the creation of testing and laboratory facilities, the Department has approved support for setting up of four Medical Devices Parks. This scheme will provide financial assistance of maximum USD 13.5 million (~ INR 100 Crore) to each of the four medical device parks. This scheme is intended to enable creation of world class *Common Infrastructure Facilities* for increased global competitiveness and for better availability and affordability of medical devices thereby creating a robust ecosystem for domestic manufacturing of devices. The government has approved financial assistance of USD 3.38 million (~INR 25 Crore) for establishment of *Common Facility Centre* for superconducting magnetic coils testing & research facility, which would facilitate the manufacturing of MRIs in the country.

With a view to enhance domestic manufacturing, the government has also introduced the Production Linked Incentive (PLI) Schemes for medical device sector in 2020 with an outlay of USD 464 million (INR 3,420 Crore) for the period 2020-21 to 2027-28; and provides financial incentive of 5 % on incremental sales of medical devices to selected domestic manufacturers, intended to boost domestic manufacturing and attract large investments in the medical device sector. 21 projects have already been approved with a total committed investment of USD 141 million (INR 1,059.33 Crore). Further, the Production Linked Incentive Scheme for Pharmaceuticals (PLI 2.0) introduced in 2021, lists domestic manufacturing of in-vitro diagnostic devices as one of the product categories and 5 in-vitro diagnostic devices) applications have been selected.

The current demand supply dynamics of the Indian medical devices sector provide a significant opportunity for investments for manufacturing in India. A Project Development Cell has been set up in the Department of Pharmaceuticals to help investors find potential partners in India for Joint Venture and to assist investors for clearances such as land allotment, company incorporation, etc. The government has also taken necessary steps to support industry players by undertaking initiatives to improve ease of doing business in India. A Standing Forum of the various Industry Associations related to medical devices has been established for providing inputs to the Department on various policy and regulatory matters.

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The Department, with stakeholder consultation, is drafting a National Policy for Medical Devices, which will provide the enabling environment with policy framework to the sunrise MedTech sector.

This thought leadership report, prepared by *APACMed, Invest India and KPMG* in India highlights some of the important areas that need to be focused on for realizing

the industry's growth-potential. It clearly highlights the growth opportunities in the industry, focus areas for growth and recommendations for realizing the vision of a self-reliant medical devices sector. The government is committed to ensure that India reaches its potential of attaining self-reliance in the medical device sector and all stakeholders viz. patient community, healthcare sector, industry players, scientists, academia are benefited from its growth journey.

Aparna

(S. Aparna)

Foreword

India is one of the fastest growing markets in the global medical devices industry, expected to grow at a CAGR of 15 per cent. The Indian medical devices sector was recognized as a focus sector by the Government of India as part of Make in India campaign in 2014. Since then, the industry has evolved in terms of deepening its prowess in the value chain across device-segments ranging from low-tech segment like consumables to the more sophisticated ones like diagnosis devices, high-end surgical equipment, etc. The Indian medical devices sector presents an unprecedented growth opportunity backed by inherent growth in demand arising from increasing healthcare needs along with government's commitment towards providing an enabling policy-environment for domestic manufacturing. The pandemic has forced global companies to explore alternative sourcing to de-risk their supply chains and India has the potential to be a preferred destination for global manufacturing.

Indian medical devices sector is heavily dependent on imports, especially in the sophisticated device segments like surgical equipment, patient aids and implants. Nearly 70-80 per cent of the sector's overall requirement is met through imports.

India has the potential to become USD50 billion market over the next few years. To achieve this, the government, industry, and academia need to collaborate to work towards a comprehensive vision for the industry. There is a lot that India can learn from other emerging economies to drive exponential growth in this sector which have been highlighted as part of this report.

India needs to proactively boost manufacturing within the country to support the growing healthcare needs in the country. The government can focus on addressing some of the challenges around long term predictability of policies, taxation, availability of robust supplier market, R&D and skill-development to attract manufacturing in India. The recently launched government schemes such as PLI (Production Linked Incentive), clusters of medical devices parks, improved regulatory approval processes like single window clearance, perpetual license, etc. are steps in the right-direction to support domestic manufacturing.

The industry needs a clear long-term actionable roadmap along with a favourable policy regime. It is important for the industry to have government support and rapid policy implementation to enable India to become a world leader in this sector.

This thought leadership report is a collaborative effort between APACMed, Invest India and KPMG in India. The report has been developed with the objective of outlining the growth-prospects, key challenges, and the potential way forward. We hope the recommendations discussed in this report are discussed at the right forum and are useful to policy makers in drafting a growth agenda for the sector.

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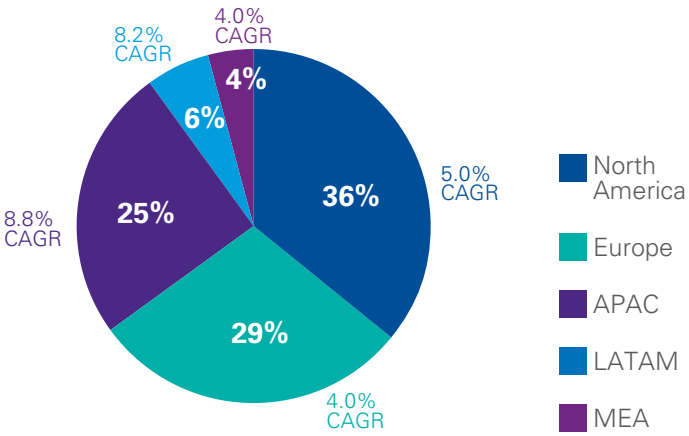
Medical devices industry in India today

Introduction

Market opportunity

The global Medical Devices industry was valued at USD 455.3 billion in 2021[1] and is expected to grow at a CAGR of 6 per cent. The APAC (Asia Pacific) region constitutes 25 per cent share in the global medical devices market and is projected to grow at 8.8 per cent CAGR.[2]

Figure 1: Global medical devices sector - Region-wise market share and growth rate



Note: CAGR is from FY 18 to FY 23

Table 1: Market growth potential in medical devices sector – India vs. other emerging markets[3]

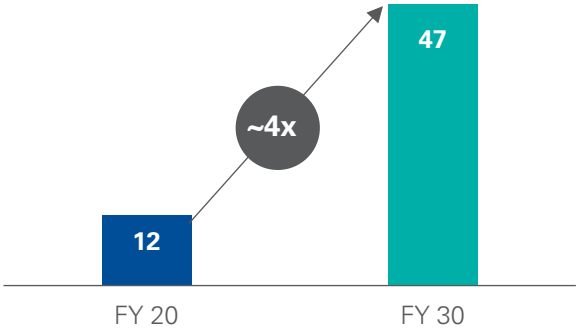
India is the fastest growing medical devices market amongst the emerging markets		
Country	Est. medical device market (USD billion)	Estimated CAGR
India	12.0	15.0%
Singapore	1.8	11.1%
Philippines	0.2	10.7%
China	32.0	9.3%
Brazil	10.3	8.8%
Thailand	1.2	8.5%
Vietnam	0.8	8.0%

The Indian medical devices industry was estimated to be USD 12 billion in 2020 and is expected to grow at a CAGR of 15 per cent which is 2.5x the global growth rate.[4] India is among the top 20 medical device markets and is the fourth largest medical device market in Asia after Japan, China, and South Korea.

The medical devices sector in India has the potential to grow ~4x the current market size by FY30, backed by growing healthcare needs and government's commitment to facilitate growth.

The Indian medical device industry was given the status of an independent industry in 2014 and accorded the status of 'Sunrise' sector under the Make in India campaign in 2014.

Figure 2: Market size projection of Indian medical devices sector (in USD billion)[3]

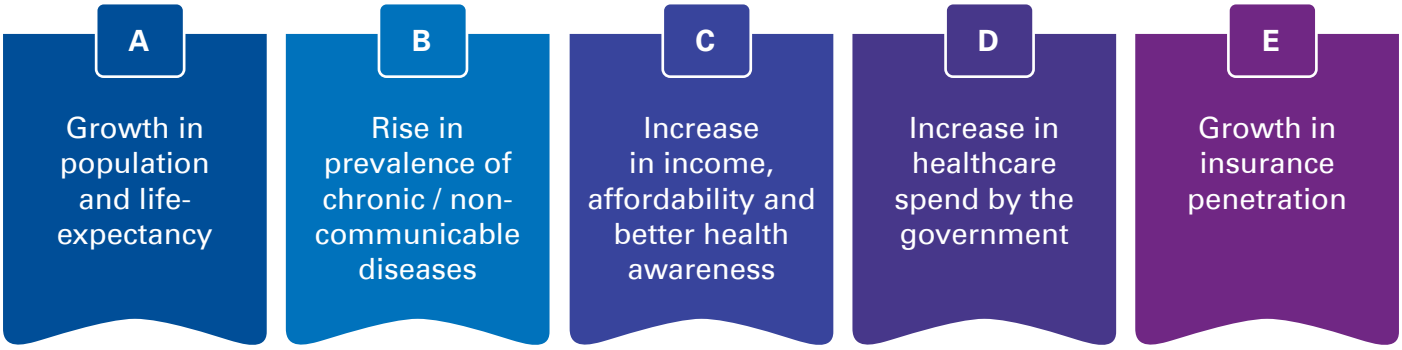


1. Fortune Business Insights, as accessed in February 2022
2. The Rise of Global Medical Technology, IQVIA, 2018
3. Medical Market, Pacific Bridge Medical, as accessed in May 2021
4. Medical Devices sector, Invest India, as accessed in February 2022

Key trends driving growth in medical devices sector in India

India is poised to become the 3rd largest economy by 2030.[5] Its GDP is expected to grow at 7.8 per cent in FY 23.[6] This growth in its GDP is expected to percolate to some of the priority sectors like healthcare and medical devices. The medical devices sector has seen some tailwinds owing to structural changes in the economy over the years.

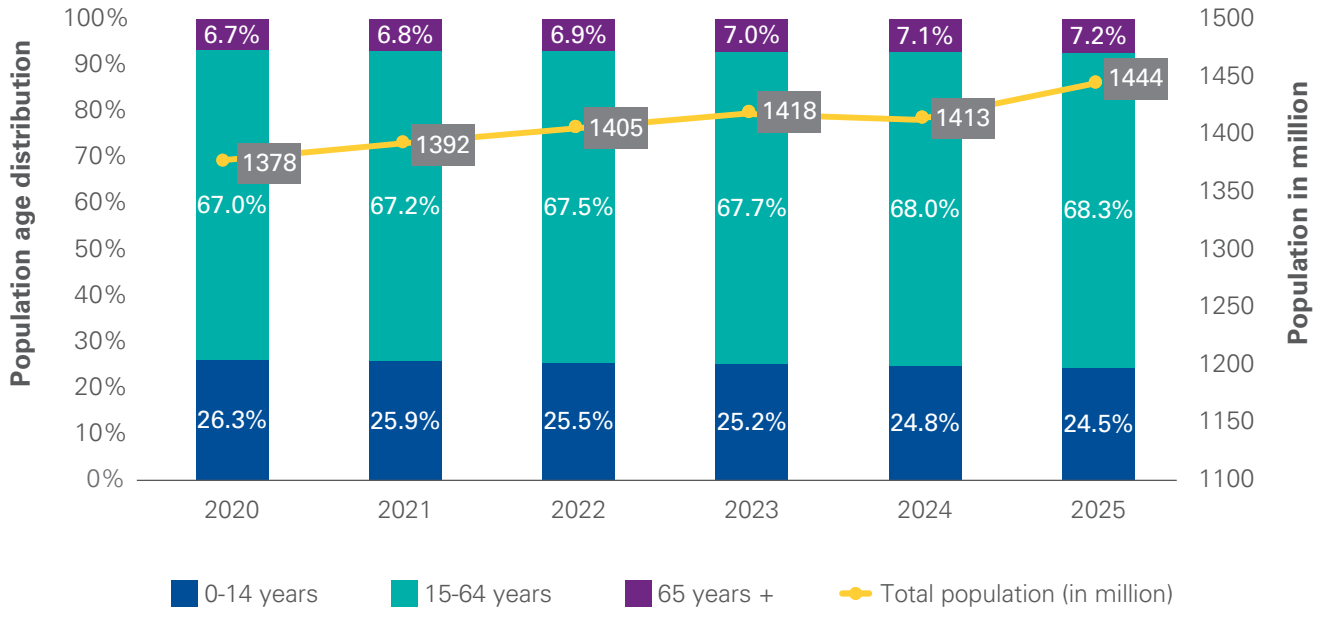
Key trends driving growth in this sector are:



A. Growth in population and life-expectancy driving healthcare needs

India's population is set to touch 1.4 billion by 2025. The average life expectancy is expected to increase to 70+ years in 2022 from 67 years in 2015.[7] The growth in >65 years population-segment implies increased healthcare requirements for geriatric care and treatment.

Figure-3: Projected population distribution in India for the period 2020-2025[8]

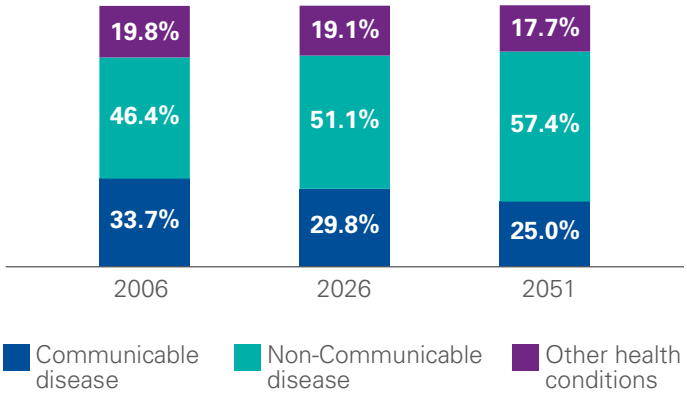


5. India to become 3rd largest economy by 2020: Report, The Times of India article, December 2020
6. RBI projects India GDP growth rate at 7.8% for FY23, Livemint news article, February 2022
7. India: Life expectancy, Statista, as accessed in February 2021
8. India age structure demographics, Index Mundi, November 2020

B. Rise in prevalence of chronic / non-communicable diseases

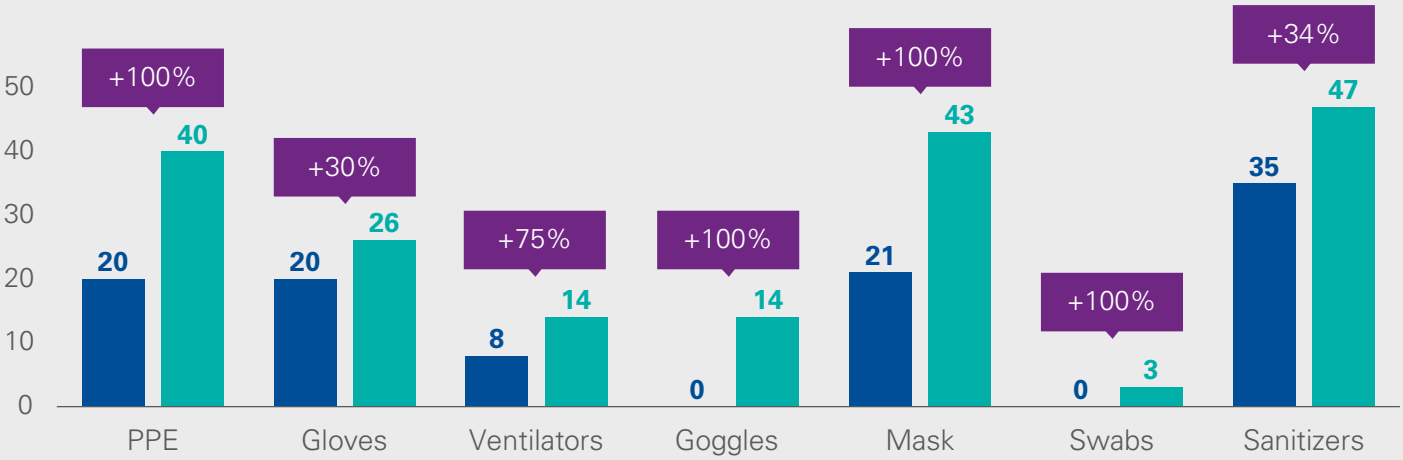
- Non-communicable diseases like diabetes, high blood pressure, cardiac conditions, cancer, etc. in India are on the rise. In 2006, about 46 per cent of the disease burden was due to chronic / non-communicable diseases. The share these diseases is expected to increase to about 57 per cent by 2051.[9]
- In case of chronic diseases, medical diagnostics and care are necessary at a very early stage and remain as continuous requirement throughout the patient's life.[10]
- The prevalence of non-communicable diseases is higher amongst the population-segment with >65 years age. With this segment growing, the prevalence of non-communicable diseases is expected to increase.

Figure 4: Projected share of chronic and non-communicable diseases in India (per cent)[9]



- With the onset of Covid-19, share of communicable and non-communicable diseases (as indicated in Figure-4) are likely to see some changes. For example, in FY 2020-21, the demand for elective surgeries saw a dip due to rise in treatment needs for Covid-19. However, the pandemic resulted in increased demand for devices such as pulse oximeters, blood monitoring systems, ventilators and consumables, which led to increase in supply-base in these device-segments during FY 20-21.

Figure-5: Growth in number of manufacturers due to Covid-19 pandemic during FY 20-21[11]

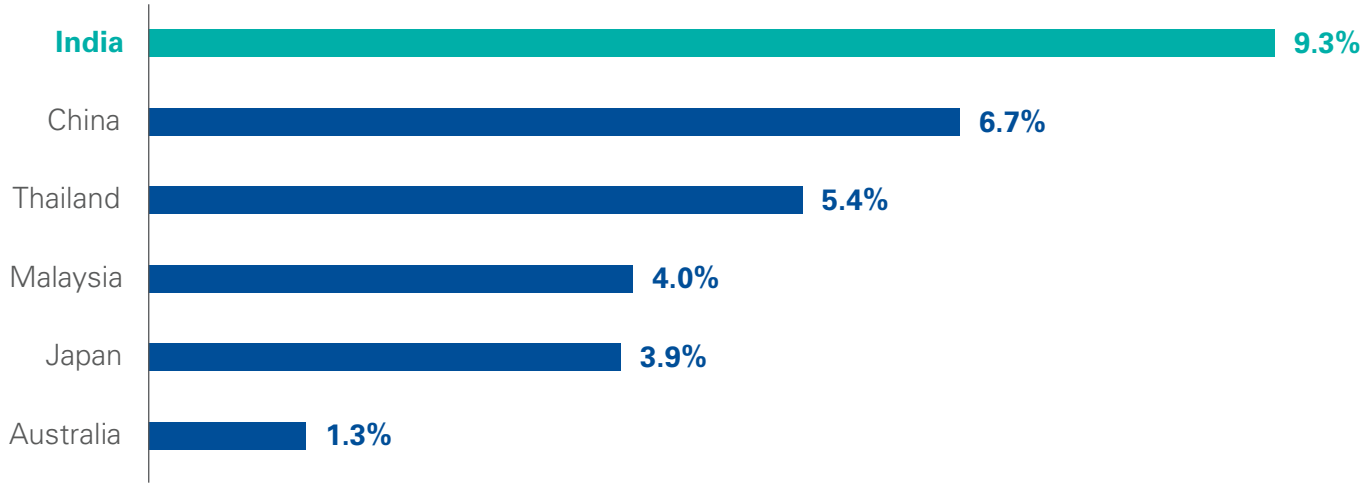


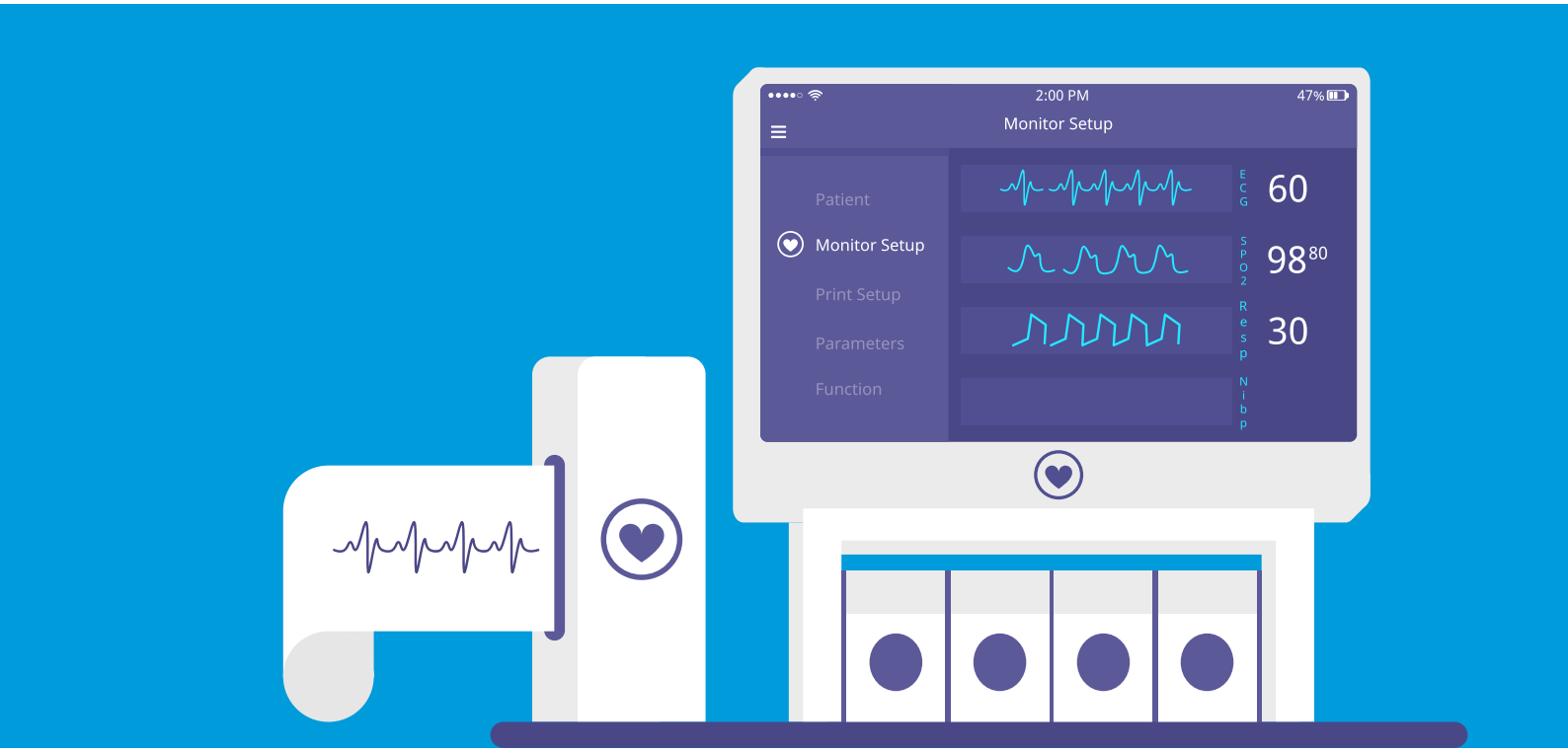
9. NCBI Resources, as accessed in May 2021
10. Rising Health Expenditure Due to Non-Communicable Diseases In India: An Outlook, PMC, Barik, D. and Arokiasamy, P., 2016
11. Medical Devices sector, Invest India, as accessed in February 2022

C. Increase in income, affordability and better health awareness

- The per capita income of the Indian population is expected to increase to USD 2,730 by 2025 from USD 1,875 in 2016.[12] The rising income levels have led to increased spends percolating to healthcare & medical devices sector. The growing prevalence of lifestyle related diseases has resulted in better health awareness among the Indian population. With better availability of medical technology and access to healthcare services, the number of consultations, diagnosis and medical procedures have increased resulting in increased per capita spend on healthcare. India is projected to have the highest growth rate in healthcare spend per capita as compared to other APAC countries.

Figure 6: Growth rate in healthcare spending per capita (FY14-23F)– India vs. other APAC markets[13]





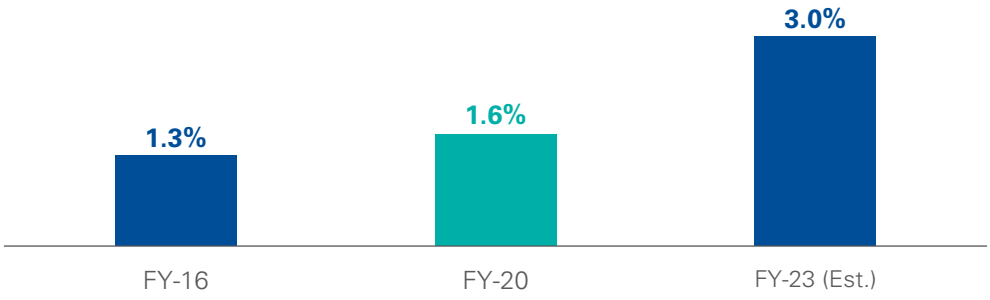
12. India GDP per capita, Trading Economics, as accessed in February 2021

13. Healthcare sector reports for all six countries, EIU, 2021

D. Increase in healthcare spend by the government

- Healthcare has assumed prominence as one of the focus sectors post the COVID 19 pandemic. The government's healthcare focus has been aimed at improving primary, secondary and tertiary healthcare systems, strengthening existing health institutions, creating new facilities to cater to detection and cure of new and emerging diseases.[14]
- As part of the budget announced for FY 22-23, the government has proposed a 614% growth in allocation for PM Ayushman Bharat Health Infrastructure. INR 86,200 Crore has been allocated to the Healthcare sector with a special focus on Mental Health. The government has also proposed launch of the National Tele Mental Health Programme with a network of 23 centers for quality counseling & care services to be launched.[15]
- The government's expenditure on healthcare has increased to 1.6 per cent of the GDP in FY20 from 1.3 per cent in FY16 and is estimated to be ~3 per cent of the country's GDP by 2023[16]
- Healthcare's share of GDP is expected to rise by 19.7 per cent by 2027[17]

Figure 7: Growth projection of expenditure on healthcare as a percentage of GDP in India[16]

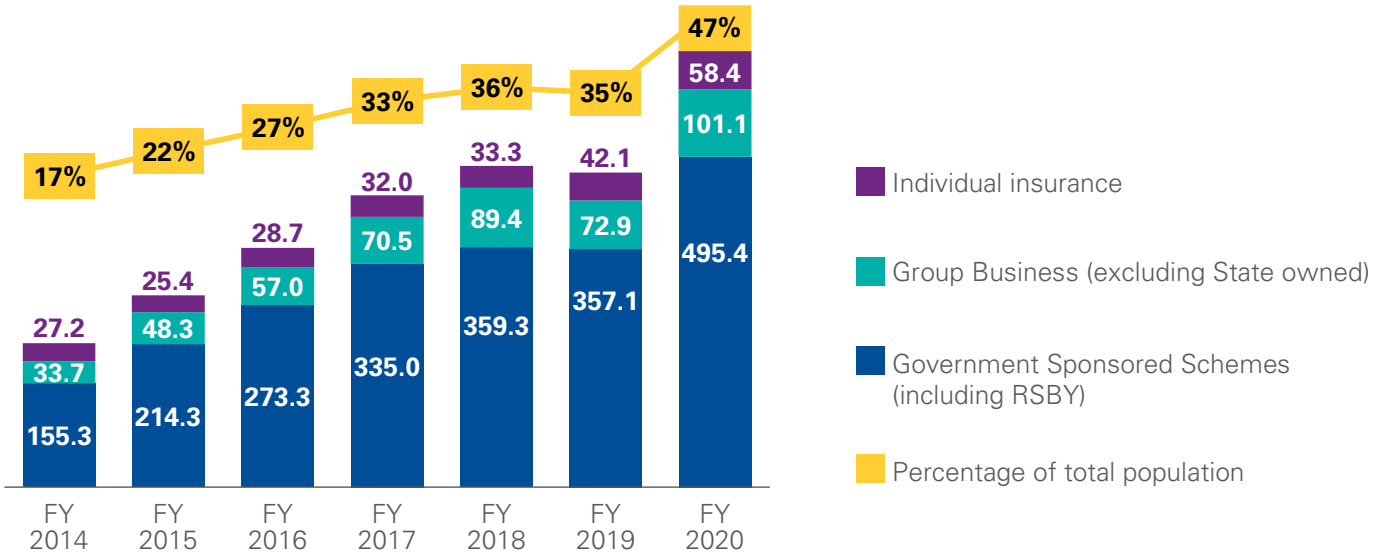


14. Union Budget 2021 | Budget proposes 137% hike in health, well-being spend, The Hindu, February 2021
15. MyGov website as accessed in February 2022
16. India emerging as a global wellness and Ayurveda hub, IBEF Blog, February 2021
17. Medical Devices sector, Invest India, as accessed in February 2022

E. Increase in health insurance penetration

- In India, the population covered under various health insurance schemes has increased from 17 per cent in 2014 to 47 per cent in 2020[18]
- Government sponsored schemes like Ayushman Bharat (universal healthcare scheme), Rashtriya Swasthya Bima Yojna (RSBY), etc. have been instrumental in increasing health insurance penetration especially in the low-income segments and rural population
- India has witnessed a 24 per cent reduction in citizens' out of pocket expenditure (OOPE) on healthcare during 2014-18 compared to 7.5% during 2004-14 under the National Health Mission.[19] However, the share of OOPE in India (as a percentage of total healthcare spends) is about 55 per cent, which is the highest amongst the BRICS nations.
  By increasing the population covered under health insurance, healthcare services can be made more affordable to the larger population, thereby increasing the demand for medical devices.

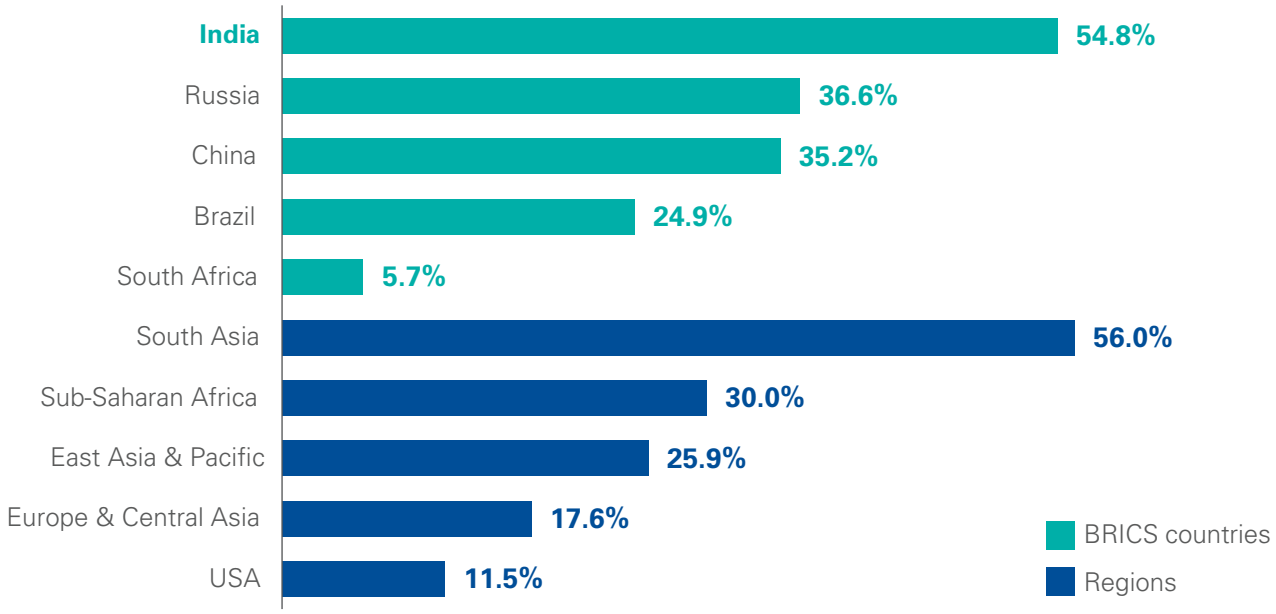
Figure 8: Number of people with health insurance in India (in millions) - Year-wise percentage population covered under health insurance[18]



18. India: people with health insurance 2020, Statista, March 2021

19. MyGov website as accessed in February 2022

Figure 9: Out of Pocket Expenditure as a per cent of health expenditure – India vs. other regions and BRICS countries[20]



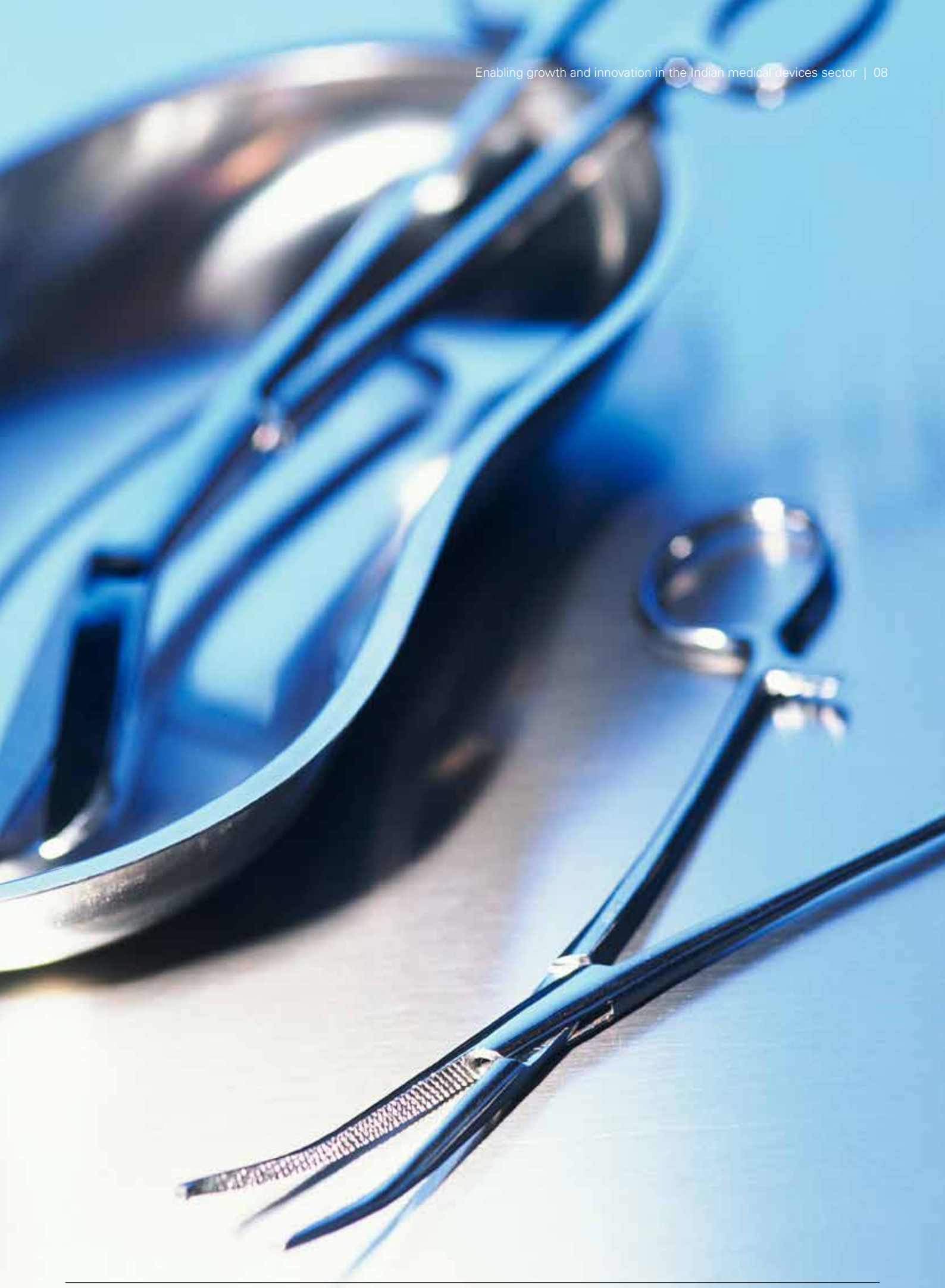
High optimism amongst industry leaders on the growth prospects of Indian medical devices sector[21]

KPMG in India's survey reveals industry leaders' views on their perception of the Indian medical devices sector and key drivers of its growth.

- Nearly **75%** believe that there is immense growth-potential driven by the rising demand of devices across segments which makes it an attractive market
- **63%** said that the large talent pool for R&D and skilled labour for manufacturing will enable growth

20 Out of pocket expenditure (% of current health expenditure), World Bank Data, 2019

21. KPMG in India analysis



Industry structure in India

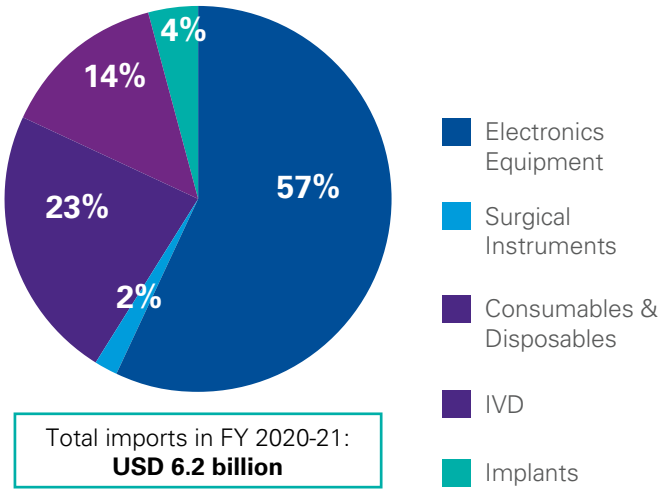
Key segments of medical devices sector in India

The Indian medical devices sector is broadly classified into 5 segments – Electronics equipment, Surgical instruments, Implants, IVD (In-vitro Diagnostic) devices / reagents and Consumables & Disposables.

The device market is highly import-dependent. Imports constitute ~70-80 per cent of the market.[22] Import-dependence is higher in high-end sophisticated device-segments. Domestic manufacturing is largely focused on low cost- high volume segment (like Consumables and Disposables).

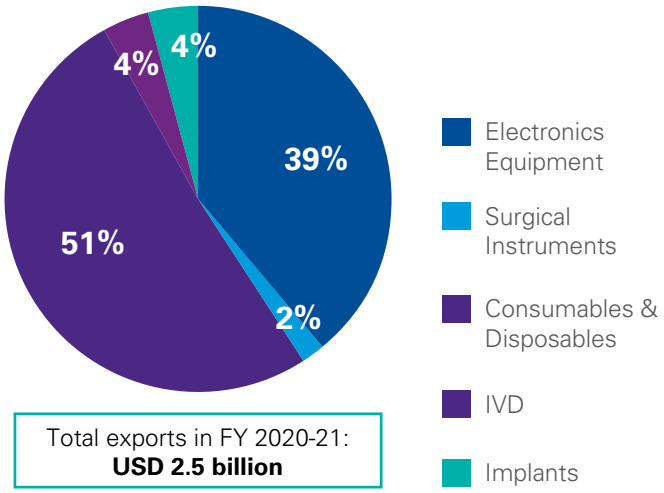
Figure 10: Share of device segments in total imports and exports in the Indian medical device sectors[23]

Share of device segments in total imports during FY 2020-21



Total imports in FY 2020-21: **USD 6.2 billion**

Share of device segments in total exports during FY 2020-21



Total exports in FY 2020-21: **USD 2.5 billion**

Electronics Equipment & Surgical Instruments: These segments together account for the highest imports in the medical devices sector. These include high-end technology devices such as MRI machines, CT scanners, ultrasound machines, X-ray machines, cancer diagnostics, dental drills, minimally invasive surgical devices, Polymerase Chain Reaction (PCR) technologies, etc. Manufacturing of these devices involves complex electro-mechanical assemblies requiring manufacturing technologies like PCBs, controllers, sensors, embedded software, electro-physics, electromagnetics, laser-cutting, etc. Large MNCs like GE Healthcare, Philips Healthcare, Schiller Healthcare, Danaher Corporation, Roche Diagnostics, etc. have a major presence in these segments.

Consumables and Disposables: Products in this segment include bandages and dressings, suturing material, syringes, disposable catheter cables, gloves, blood bags, etc. These devices can be manufactured using simpler processes like moulding, extrusion, polishing / coating, simple mechanical assemblies, sterilization, etc. The market in this segment is highly competitive due to low entry barriers. This segment is a top exporting segment accounting for 51 per cent of the total exports of medical devices from India in FY 2021.

Implants: Products in this segment include knee and hip implants, artificial joints, dental fixtures. This segment largely comprises of high-risk devices.

IVD: Products in this segment include IVD reagents / chemicals, calibrator, control material kit, etc.

22. EMIS data, 2020

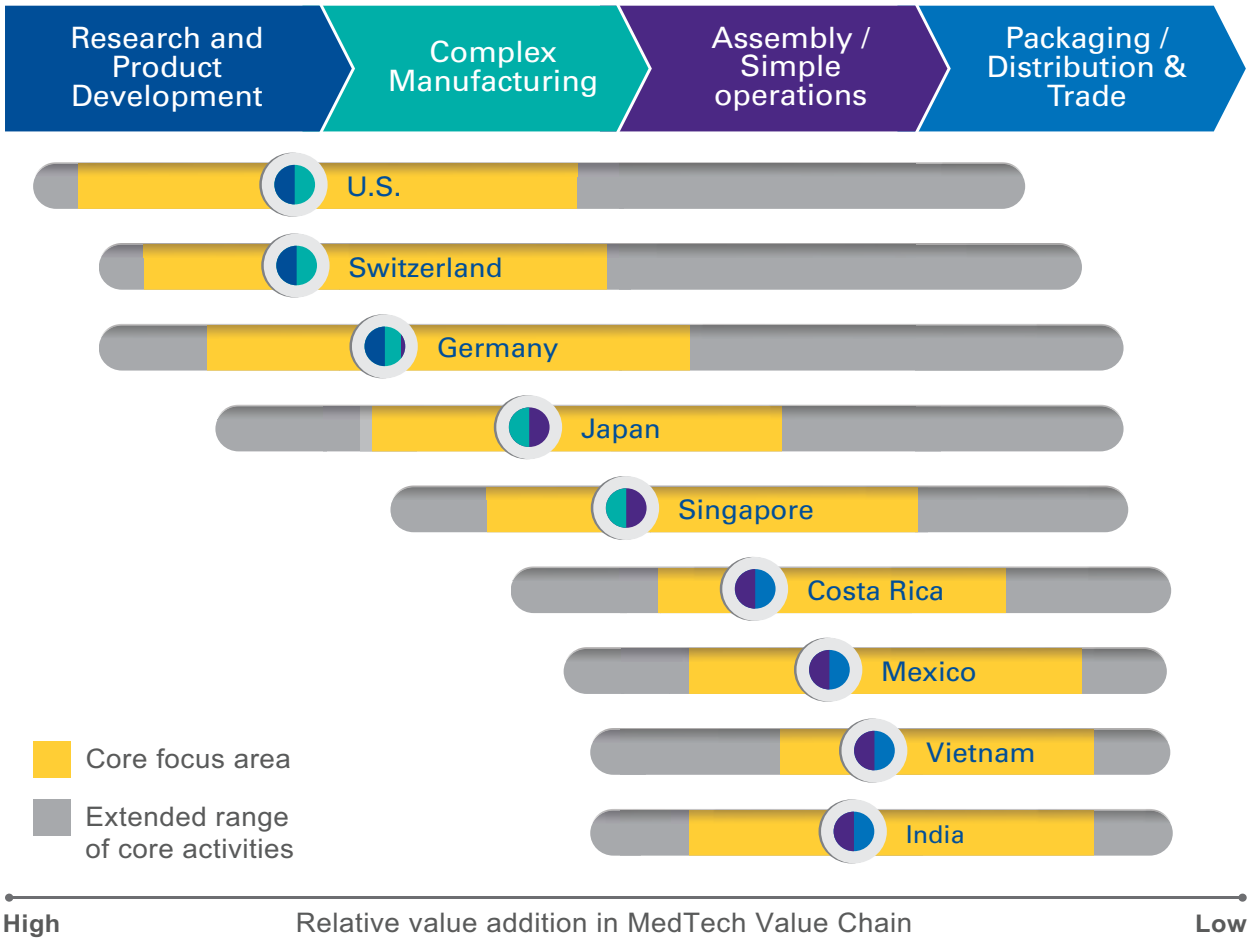
23. IMPEX data for Medical Devices in FY 2020-21, Invest India, 2021

India's presence in the medical devices value chain

Majority of R&D and manufacturing activities for global medical devices is done in the U.S. and the EU regions. They have an evolved medical devices sector with access to the latest technology, established infrastructure and trained workforce. Medical device companies in India are primarily engaged in sales and distribution, with limited presence in R&D and manufacturing.

Over the years, measures taken by the government, such as PLI schemes, medical device parks, single window clearance, perpetual licenses, etc. have attracted investments in R&D and manufacturing of high-end devices and components. Global players such as GE Healthcare, Philips, and Medtronic have set up their R&D and innovation centres in India and have started manufacturing of a few components locally. Many start-ups and SMEs such as InnAccel, EzeRx, Tricog Health, Pandorum Technologies among others, are working towards leveraging new-age technology for designing, developing and testing medical devices that solve priority healthcare problems.

Figure 11: Medical device sector value chain- India's position vis-à-vis other nations[24]

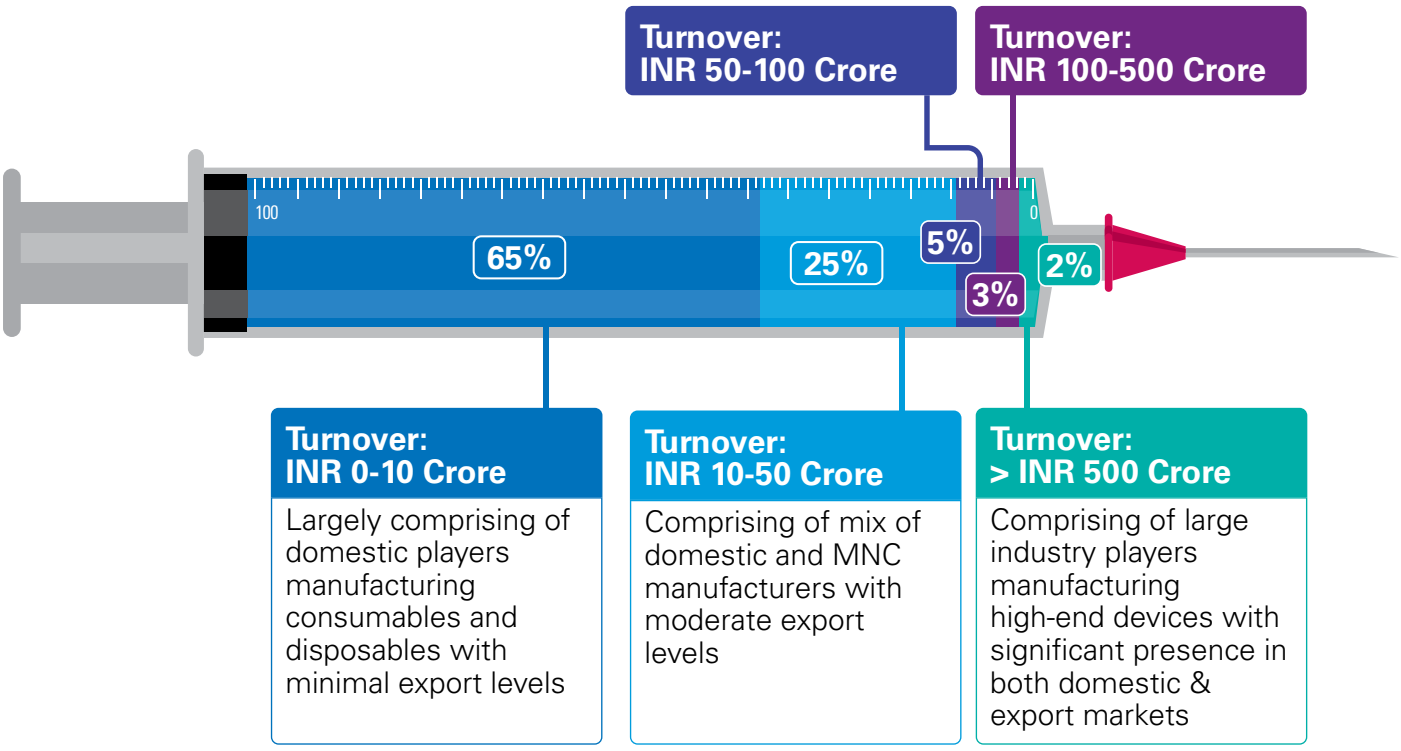


24. KPMG in India analysis

Footprint of medical devices companies in India

The Indian Medical Devices sector has a highly fragmented base of over 800 manufacturers with an average investment of USD 2.3–2.7 million and an average turnover of USD 6.2-6.9 million.[25] About 65 per cent of the total device manufacturers in India are domestic players. However, the major share of the market is catered by imports from MNCs, particularly in the sophisticated device segments, such as electronic equipment, surgical equipment and patient aid.

Figure 12: Distribution of number of manufacturers in Indian medical devices sector[26]



25. Medical Devices Analysis, Engineering Export Promotion Council of India, 2021

26. Recommendations of the Task Force on the Medical devices sector in India, Government of India, 2015

Figure 13: Major manufacturing clusters of medical devices in India[27]

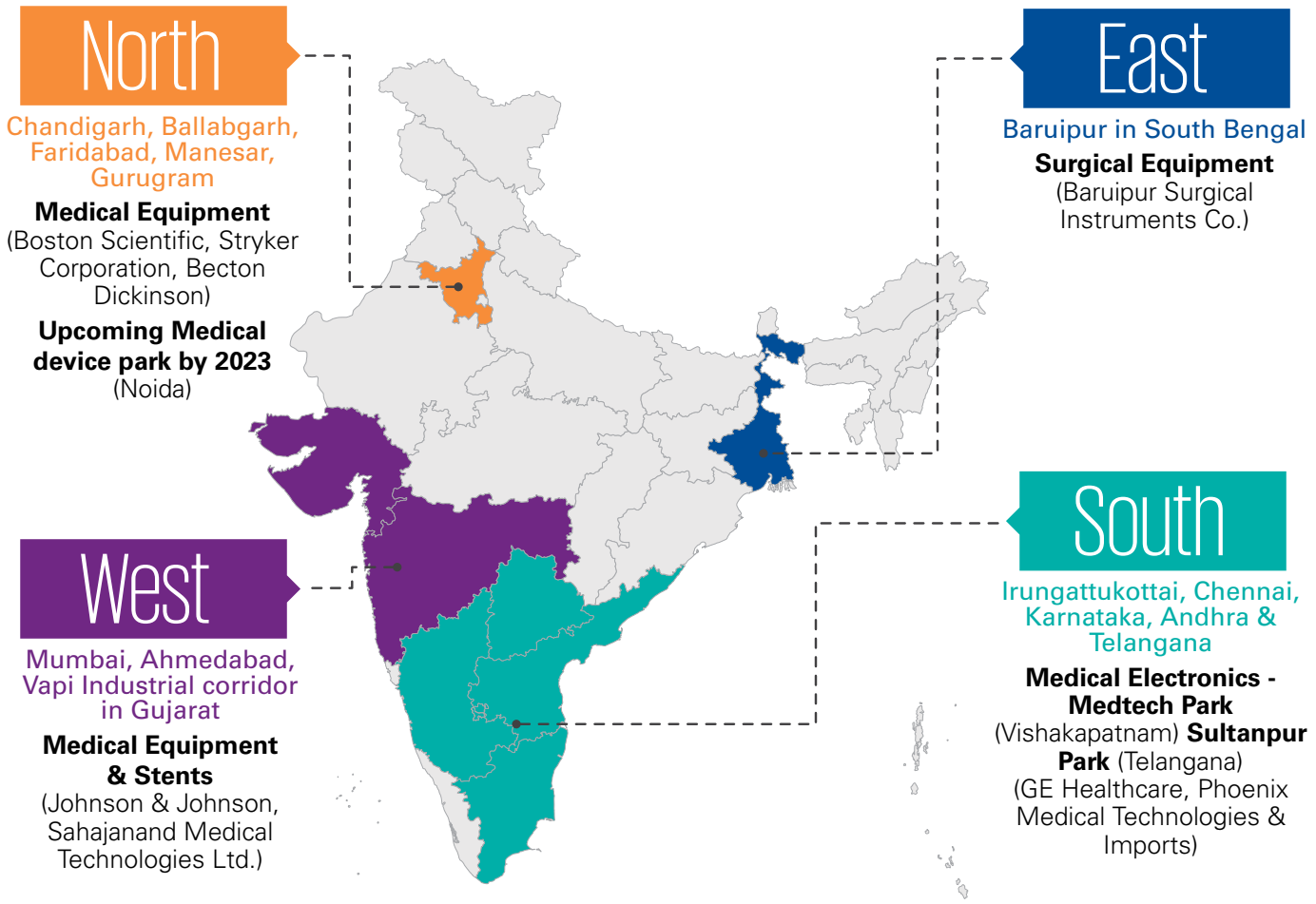


Table 2: Major medical device manufacturing clusters in India

Region	City	Product Segments and select organisations
North	Chandigarh, Ballabgarh, Faridabad, Manesar, Gurugram & Baddi	Medical Equipment (Boston Scientific, Stryker Corporation, Johnson & Johnson, Becton Dickinson)
East	Baruipur in South Bengal	Surgical Equipment (Baruipur Surgical Instruments Co.)
West	Mumbai, Ahmedabad, Vapi Industrial corridor in Gujarat	Medical Equipment (Johnson & Johnson) & Stents (Sahajanand Medical Technologies Ltd.)
South	Irungattukottai, Chennai, Karnataka, Andhra & Telangana	International Medical Electronics Manufacturers, Medteck Parks (Phoenix Medical Technologies & Imports)
Others	Bengaluru, Hyderabad, Pune, Bhiwadi (Rajasthan) and Chengalpattu (Tamil Nadu)	Medical Electronics (GE, B. Braun, Medtronic)

27. Medical Devices sector, Invest India, as accessed in February 2022

MNCs and domestic players have played critical roles towards the growth of medical devices sector in India

Medtronic[28]

Medtronic has been operating in India for more than 40 years and has transformed healthcare in India through its innovative products and services. It has introduced world-class technologies and customised solutions through its centers in India.

The company's businesses primarily fall into four groups namely the Cardiac and Vascular Group (CVG), the Restorative Therapies Group (RTG), the Diabetes Group and the Minimally Invasive Therapies Group (MITG).

The company promotes R&D in India through its two R&D centres:

i. Medtronic India Development Centre (MIDC), the R&D facility at Bangalore, develops the key aspects of Medtronic's renal care solutions business

ii. Medtronic Engineering and Innovation Center (MEIC) at Hyderabad provides high quality, cost effective engineering services to Medtronic's Minimally Invasive Therapies Group (MITG) businesses' global and regional business units

It has two Therapy and Procedure Training Centers in Mumbai and Dhaka and a Center of Innovation in Mumbai.

Medtronic has launched its first Surgical Robotic Experience Center (SREC) in South Asia located in Gurugram, Haryana focused on training & education of surgeons in robotic-assisted surgery.

The company has plans to bring manufacturing to India.

The company has made a mark on the MedTech industry in India by innovating products specialized for the unique needs and characteristics of the market.

Johnson & Johnson[29]

Johnson & Johnson India has made significant contributions for more than 60 years in the field of surgery.

The company has products dedicated to addressing unmet needs in India in orthopaedics, cancer surgery, cardiovascular disease, coronary artery disease, diabetes care, etc.

It has tailor-made offerings such as knee implants suitable for an Indian body structure.

With a vision of skilling resources, the company has entered in a PPP (public-private partnership) in 2015 with the National Institute of Pharmaceutical Education and Research (NIPER) in Ahmedabad for a postgraduate training program for future medical devices industry regulators.

28 Medtronic website, as accessed in May 2021

29. 70 years of Johnson & Johnson in India, Johnson & Johnson website, November 2017

Trivitron Healthcare

Trivitron Healthcare, a domestic company, started as a medical device trading company in 1997. It has now evolved into a medical equipment manufacturing company with a turnover of USD 95 million (in 2020).

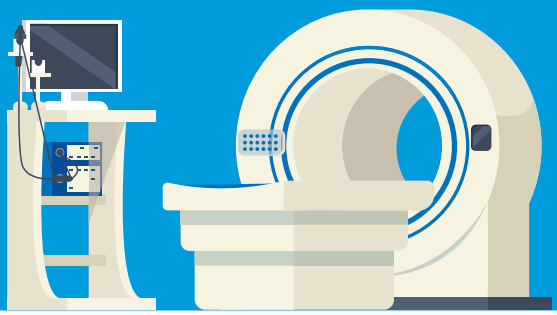
The company has its presence in complex device-segments such as in-vitro diagnostics, imaging, intensive care, renal dialysis segments, etc. It markets medical devices to hospitals, individual healthcare providers, independent clinics and laboratories, extended care facilities etc.

In 2010, the company entered a joint venture with Aloka Japan (now Hitachi) enabling it to manufacture over 1,000 ultrasound machines per year.

The company manufactures not only for the Indian market but has presence in major African countries, European countries, in the Middle East, and in the U.S.

Trivitron has also been approved under the PLI Scheme for Medical Devices with committed investments of INR 25.3 Crore under the CT Scan, MRI, Ultrasonography, X Ray Equipment, Mammography, C-Arm and Cath Lab project with potential employment generation of 577 personnel.[30]

Trivitron has managed to break into the high-end medical device segment and has proved to be are liable contract manufacturer for leading global healthcare companies.



Transasia Bio-Medicals

Transasia started as a distributor for Japanese automated cell counter machines in the IVD (in-vitro diagnostic device) segment. Over the years, the company has started manufacturing indigenously and has grown into an estimated USD137 million company. It has product-offerings and solutions in biochemistry, haematology, coagulation, erythrocyte sedimentation rate (ESR), immunology, urinalysis, critical care, diabetes management, microbiology, and molecular diagnostics.

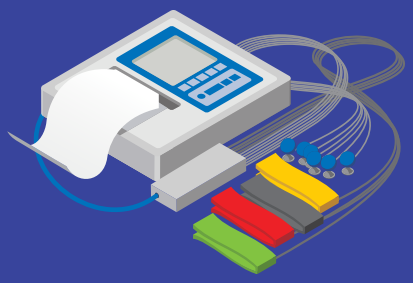
The company aims to pool in latest technologies from their global subsidiaries and manufacturers in India to offer customised, low cost solutions.

Their ECL 760® coagulation analyser employs technology from their Czech Republic subsidiary and is three times faster and is delivered at a cost that is 30 per cent lesser compared to imported analysers.

Their complete range of clinical chemistry instruments and reagents are designed and developed in India out of which EM 200® is their flagship instrument.

In 2006, Transasia was recognised as India's largest IVD company and has retained that position till date.

The company has been able to meet domestic diagnostic needs for affordable and quality products.

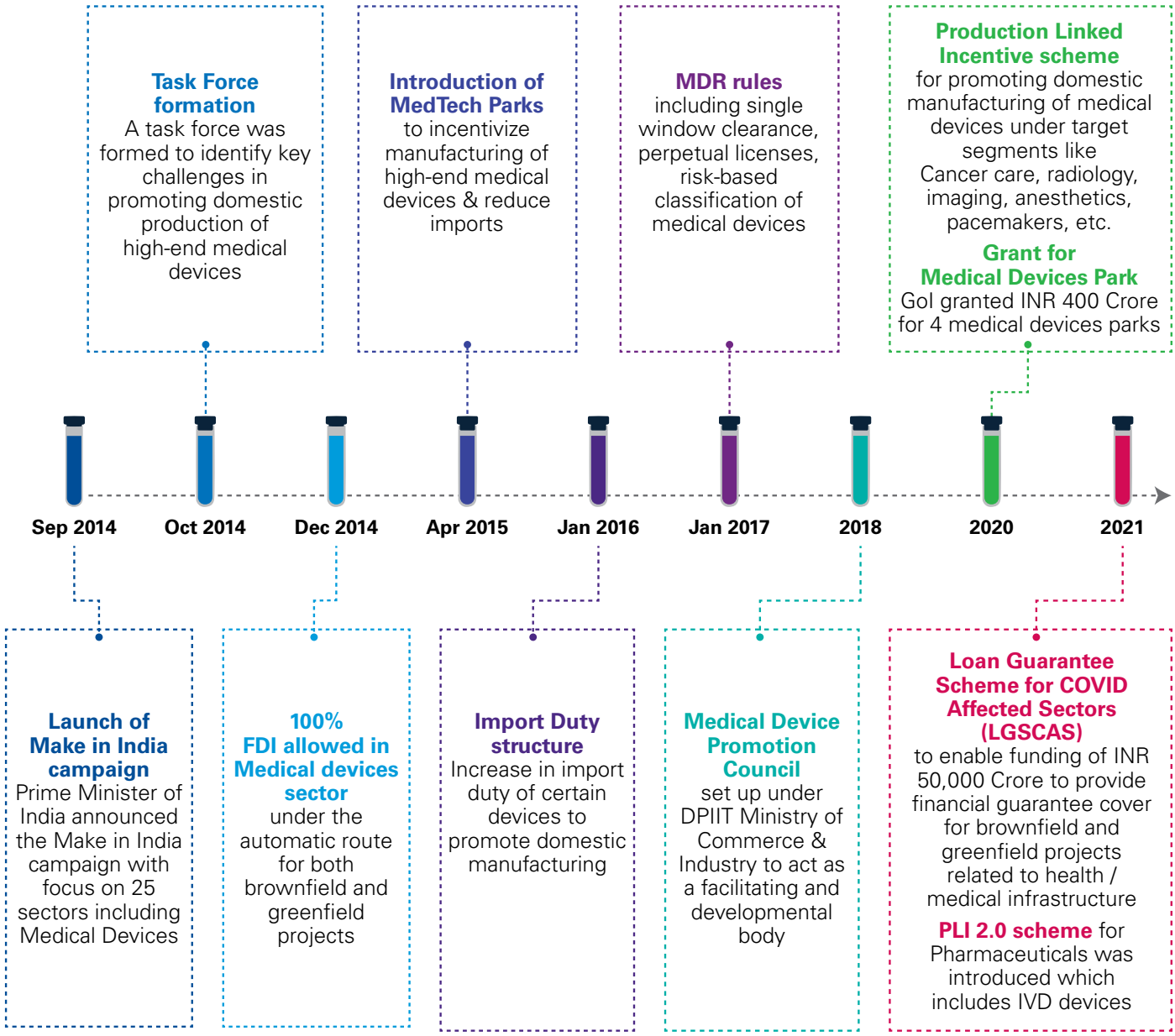


30. Medical Devices sector, Invest India, as accessed in February 2022

Key policy interventions

The government has been proactively taking steps to attract investments from MNCs and private players for setting up innovation and manufacturing base in India.

Figure 14: Evolving regulatory policies in India – key government Interventions[31]



Policies have evolved over the years reflecting the government's intention to provide an enabling business environment to the players in the medical devices sector.

31. Medical Devices Reforms and Landscape in India Report, WHO, 2020

Key highlights of regulatory policies:

- **Simplification of licensing requirements[32]:** Licenses for import, manufacturing or sale of medical devices have been made perpetual in nature, i.e., medical device licenses that are granted have been made valid in perpetuity, if license fees are paid every five years from the date of issue, unless the license is suspended or cancelled by the licensing authority.
- **Affordable healthcare pricing[33,34,35]:** The MRPs (Maximum Retail Price) of all the medical devices are monitored by the government under the provisions of the Drug Prices Control Order (DPCO), 2013 to ensure that no manufacturer / importer increases the MRP of a drug more than 10 per cent of MRP during preceding 12 months. Some of the key interventions done recently by the government to facilitate availability & affordability:
  - NPPA (National Pharmaceutical Pricing Authority)capped the trade margin at 70% on Price to Distributor (PTD) for pulse oxymeters, digital thermometers, BP monitoring machines, glucometers, nebulizers and oxygen concentrators.
  - The Government has notified the ceiling prices of non-scheduled Medical Devices Orthopedic knee implants.
  - NPPA has also fixed ceiling prices for scheduled Medical Devices such as drug eluting stents, coronary stents, condoms and Intra uterine devices (IUD).
- **Harmonisation with global standards for medical device regulation:** The government of India has approved Memorandum of Understanding (MoU) to be signed between Central Drugs Standard Control Organisation (CDSCO) and the United Kingdom Medicines and Healthcare Products Regulatory Agency (U.K. MHRA) on cooperation in the field of medical product regulation.

Other major initiatives[36,37]

- **Dedicated project development cells:** Empowered Group of Secretaries and Project Development Cells have been set up across the ministries / departments of Government of India for attracting investments into the country. The project development cells expedite investments through focused coordination between the central government and state governments supporting the pipeline of investible projects in India and support faster issue resolution.
- **Medical Device Parks[38]:** Under the umbrella for Development of Pharmaceutical Industry by the central government, a sub-scheme termed as "Assistance to Medical Device Industry for Common Facility Centre" has been rolled out with a financial outlay of INR 100 crore for 2018-2020. The sub-scheme provided a one-time grant-in-aid of INR 25 crore or 70% of the project cost, whichever was less, to be released for creation of identified infrastructure and common facilities to a State Implementing Agency (SIA) set up for the purpose. The Department of Pharmaceuticals (DoP) had approved the proposal of Andhra Pradesh Medtech Zone Ltd. (AMTZ), Andhra Pradesh, for the establishment of Common Facility Centre for testing & research of Superconducting Magnet Coils of MRI.

  Recognizing the need for higher levels of investments for the creation of testing and laboratory facilities, the sub-scheme "Assistance to Medical Device Industry for Common Facility Centre" was revised and renamed as "Promotion of Medical Device Parks" and was approved by the Government of India on 20th March 2020. These parks intend to provide common testing and laboratory facilities/centre at one place reducing the manufacturing cost significantly and help in creating a robust ecosystem for medical device manufacturing in the country. The total financial outlay of the scheme is INR 400 crore Under the scheme, final approvals have been provided to the proposals from Himachal Pradesh, Uttar Pradesh, Madhya Pradesh and Tamil Nadu.

32. All medical devices in India to be regulated as "drugs"- Medical Devices (Amendment) Rules, 2020, Arogya Legal, February 2021
33. Capping of Trade Margin by the Union Government, PIB press release, July 2021
34. Capping of Trade Margin on Oxygen Concentrators, PIB press release, June 2021
35. Price Control on Devices Notified as Drugs, PIB press release, March 2020
36. Medical devices industry in India, IBEF, as accessed in May 2021
37. Medical Devices sector, Invest India, as accessed in February 2022
38. Public Notice and Approach paper on draft National Medical Device Policy 2022, Department of Pharmaceuticals, GoI, March 2022

- **Phased manufacturing programme (PMP):** In 2021, the government launched Phased manufacturing programme (PMP) to promote domestic manufacturing of medical X ray machines and specific sub-assemblies, parts and sub-parts by notifying enhanced Basic Custom Duty for next three financial years.
- **Standing Forum of Medical Devices Associations:** On 25th August 2021, the Department of Pharmaceuticals (DoP) constituted a Standing Forum of Medical Device Industry Associations with the objective of deliberating upon issues pertaining to the sector and arriving at well-rounded inputs from the industry for Policy and Program formulation. The Standing Forum provides a platform to the various Medical Device Associations to deliberate on various issues in the sector with all the stakeholders including regulators. The forum then comes up with workable solutions for these issues with consensus of the associations.
- **Production Linked Incentive scheme for Medical Devices[39]:** In March 2020, the government approved Production-Linked Incentive (PLI) scheme to encourage domestic manufacturing of medical devices with financial implications worth INR 3420 Crore for the period FY21-FY28. As part of this scheme, an incentive at 5 per cent of incremental sales over the base year 2019-2020 will be provided to segments of medical deices such as cancer-care, radiaotherapy, radiology, imaging devices, anaesthetics, cardiorespiratory devices (including catheters of cardiorespiratory category and renal care devices and implants including implantable electronic devices such as cochlear implants and pacemakers). The PLI scheme received 28 applications in the 1st round of which 13 were approved by the government with a total committed investment of INR 798.93 Crore (USD 106.3 Mn). In the 2nd round, 14 applications were received of which 8 have been approved with a total committed investment of INR 260.40 Crore (USD 34.66 Mn). Commissioning of the approved projects will seminally help in strengthening the domestic supply chains, provide adequate infrastructure for the healthcare sector, reduce the cost of manufacturing and focus on bolstering R&D and skill development within the sector. The expected employment generation from this scheme is about 4212 personnel.
- **Production Linked Incentive Scheme for Pharmaceuticals (PLI 2.0):** In the year 2021, the government announced PLI 2.0 scheme with a financial outlay of INR 15000 Crore for the period FY21-FY 29. This scheme aims to enhance India's manufacturing capabilities by increasing investment and production in the pharmaceutical sector. It includes a broad range of product segments ranging from biopharmaceuticals, APIs, and in vitro diagnostic devices. The scheme received 278 applications against which 55 (5 in vitro diagnostic devices) applicants have been selected, leading to investments to the tune of INR 15,000 Crore (USD 2 Bn). Commissioning of the approved projects is estimated to generate employment for 100,000 personnel. The scheme is also expected to contribute to product diversification of high value goods within Pharmaceuticals & Medical Devices, leading to incremental sales of INR 2,94,000 Crore (USD 39.13 Bn), and total incremental exports of INR 1,96,000 Crore (USD 26.09 Bn) during FY23-FY28.
- **Loan Guarantee Scheme for COVID Affected Sectors (LGSCAS):** The government launched LGSCAS to give financial guarantee cover of INR 50,000 crores for brownfield and greenfield projects related to health and medical infrastructure. This scheme has been rolled out in an effort to ramp up the nation's readiness to contain impact from COVID.
  Target projects include (1) hospitals / dispensaries / clinics / medical colleges / pathology / labs / diagnostic centers; (2) facilities for manufacturing of vaccines / oxygen / ventilators / priority medical devices; (3) public healthcare facilities. Maximum loan per project is capped at INR 100 crores.
  The interest rate for loans processed under the scheme will be capped at 7.95 per cent per annum till the availability of the guarantee cover.
  The scheme will be applicable to all eligible loans sanctioned during the period from May 7, 2021 till March 31, 2022 or till guarantees for an amount of INR 50,000 crores are issued under the scheme, whichever is earlier.

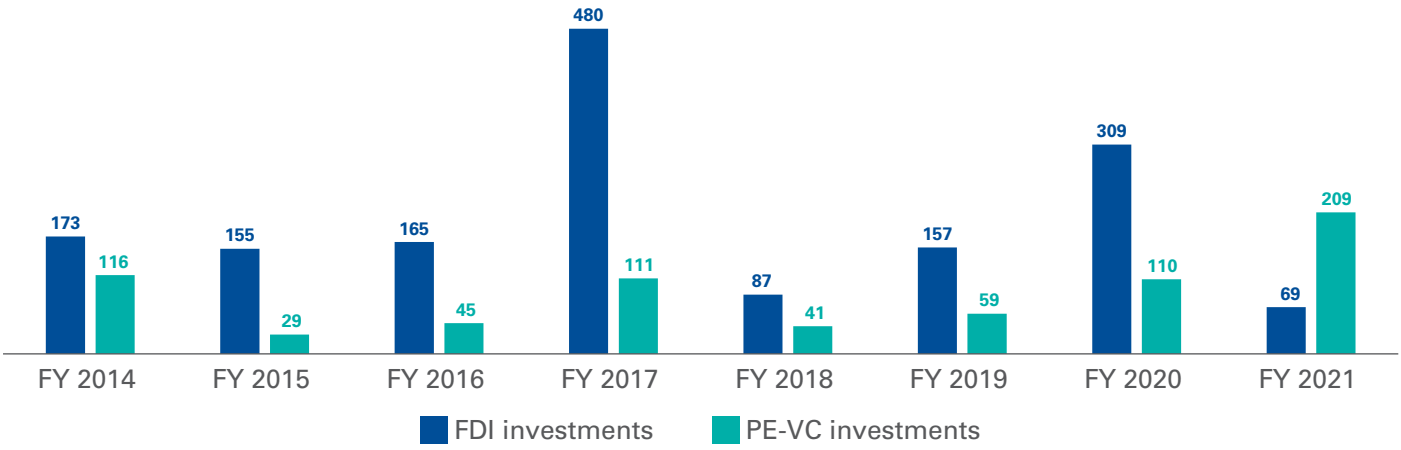
39. Status of Production-Linked Incentive Schemes, PIB press release, December 2021

Investment scenario

Investment scenario in the Indian medical devices sector

The medical devices sector has seen a surge in FDI (Foreign Direct Investment) inflows since the announcement of Make in India campaign in 2014. The spike in FDI in FY 2017 correlates with amendments made in Medical Device Rules (MDR) such as single-window clearance (Sugam), perpetuality of licenses for notified devices, risk-based classification of devices, etc. indicating increase in investor-confidence arising from government's effort to improve transparency in regulations. A significant drop in FDI was observed in FY 2018, which is believed to be due to factors such as price-caps on equipment like stents and knee implants towards the end of FY 2017. A similar trend was seen in PE-VC investments as well.

Figure 15: FDI & PE-VC investments in Indian medical devices sector (in USD million)[40,41]



40. Year end press reviews, Department for Promotion of Industry and Internal Trade, 2021

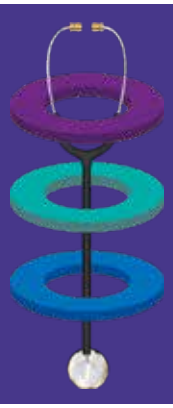
41. VC Edge database, as accessed in May 2021

Table 3: Key highlights of PE-VC deals in medical devices sector over the years[42]

Medical Devices Company	Investors	Investment (USD million)	Year	Highlights of the deal
Molbio Diagnostics	Motilal Oswal	32.74	March 2020	Motilal Oswal has invested in Molbio's Truenat™ which can detect 22 (44 in pipeline) infectious diseases
Translumina	Everstone	78.65	August 2019	Translumina is a domestic manufacturer and distributor of cardiac stents and cardiovascular medical devices and has sourced its technology from German Heart Centre. Everstone's partnership is intended to help the Company to acquire global assets, augment the company's R&D efforts, bolster its local manufacturing capabilities, and enhance its distribution ecosystem.
Healthium MedTech	Apax Partners	300	April 2018	Healthium manufactures and sells a broad range of medical devices and consumable products. Apax aims to bring its strong experience in Medical devices companies globally to further expand Healthium's product-portfolio while leveraging its pan-India market reach and its capabilities in developing and manufacturing quality products at affordable prices.
Ascent Meditech	Leapfrog	21.16	July 2018	Ascent Meditech deals majorly in the orthopaedics and wound care market. The investment by Leapfrog aimed to help Ascent tap into growing Medical devices sector.
Tynor Orthotics	Light-house, Others	21.12	June 2018	Tynor Orthotics is a manufacturer of artificial support devices for various body parts. The investment is aimed to help Tynor achieve sales of over INR500 crore by 2022.
Sahajanand Medical Technologies (SMT)	Samara Capital, Others	36	January 2018	SMT manufactures minimally invasive coronary stent systems. The company plans to use a major portion of the funds on R&D to expand its product line in the cardiovascular segment.

The investment trends over the years indicate that they are highly correlated to the changing dynamics in the regulatory & macro environment.

Stability & transparency in policies would boost investor-confidence and attract significant investments much needed for establishing manufacturing & R&D base in India.



42. VC Edge database, as accessed in May 2021

Key focus areas to faciliate growth

Key areas for India to focus on to facilitate rapid growth in the sector

Over the last few years, the government has introduced policies to encourage indigenous manufacturing in the medical devices sector. While the sector has immense potential in India, some of the most prevalent challenges will need to be addressed to expedite growth.

KPMG in India's survey with industry leaders highlighted some of the key areas that need to be focused on.[43]

- Improving Ease of Doing Business and establishing a predictable policy regime
- Simplification of the regulatory structure
- Establishing a robust supplier ecosystem
- Aligning public procurement policy to local manufacturing capabilities
- Structuring duties on imported devices and components to make local products price competitive

90%
of the industry leaders believe that lack of predictability in policies act as a barrier to operate in the Indian market

85%
of the leaders considered the 'Pricing Policy Framework' as a challenge in attracting global companies

75%
of the respondents considered the absence of an established supplier base / ecosystem as a gap

Ease of Doing Business and predictable policy regime:

Over the years, India has improved in 'Ease of Doing Business' ranking. India was ranked 63rd in 2020, an improvement from 77 in 2019 and 134 in 2014 when Make in India Campaign was introduced.[44] Recent efforts by the government such as single window clearance, providing perpetual licenses, etc. are a step in the right direction. However, compared to its peers in the APAC region, India still lags in 'Ease of Doing Business' and has significant room for improvement to be a preferred destination for manufacturing and R&D.

Figure 16: India's Ease of Doing Business Ranking - comparison with other emerging markets[45]

Ease of Doing Business Rank 2020	New Zealand (1)	Singapore (2)	Hong Kong (3)	Malaysia (12)	China (31)	India (63)	Vietnam (70)	Indonesia (73)
Ease of Doing Business Rank 2014	Singapore (1)	Hong Kong (2)	New Zealand (3)	Malaysia (6)	China (96)	Vietnam (99)	Indone-sia (120)	India (134)

43. KPMG in India analysis
44. Ease of Doing Business, Make in India Website, as accessed in March 2021
45. Ease of Doing Business Report, World Bank, 2020

The regulatory policies in Indian medical devices sector have evolved and have undergone several changes over the years. While the policies are intended to encourage indigenous manufacturing, several changes (such as price caps on medical devices, changes in import duties and tax rates, etc.) have affected the predictability of policies.Since medical device manufacturing requires high upfront investments, global companies look for a more stable policy regime before committing their investments. The government could look at having an inclusive approach by taking feedback from the industry and laying out a clear long-term roadmap for the sector.

Regulatory structure:

The Ministry of Health & Family Welfare, Government of India has notified the Medical Devices Rules, 2017 (MDR), under the provisions of the Drugs and Cosmetics Act, 1940 (DCA) in order to have comprehensive regulatory provisions for import, manufacture, sale, and distribution of medical devices based on risk-based criteria. Under these rules, the Class A and Class B medical devices (devices of relatively lower risk grade) are licensed by concerned State Licensing Authorities on the basis of conformity assessment done by Notified bodies which are registered by CDSCO. The Class C and Class D medical devices (relatively complex devices with higher risk grade) are licensed by the Central Licensing Authority based on the conformity assessment done by Medical Device Officers of CDSCO. However, the current structure involving regulatory authorities across the Centre & states has further scope for harmonization of processes & timelines in order to improve the overall predictability levels in these processes and to attract global players in the industry.

Supplier ecosystem for device-manufacturing:

The medical devices sector has high import-dependence in sourcing components for manufacturing of sophisticated devices. Most of the imported components like displays, magnets, other capital-intensive equipment require high initial investments to be manufactured indigenously. To develop the supplier ecosystem, the device-component market needs to be sufficiently incentivized to facilitate indigenous manufacturing and to establish economies of scale. Learnings can be drawn from the Indian auto sector which has a robust domestic supply market for auto-components. The PLI scheme for the auto sector, under the Department of Heavy Industries, is applicable to both automobiles and auto-component manufacturers. A robust domestic supply market for critical components in the medical devices sector can be established by incentivizing component manufacturers, thereby reducing dependence on imports in the long run.

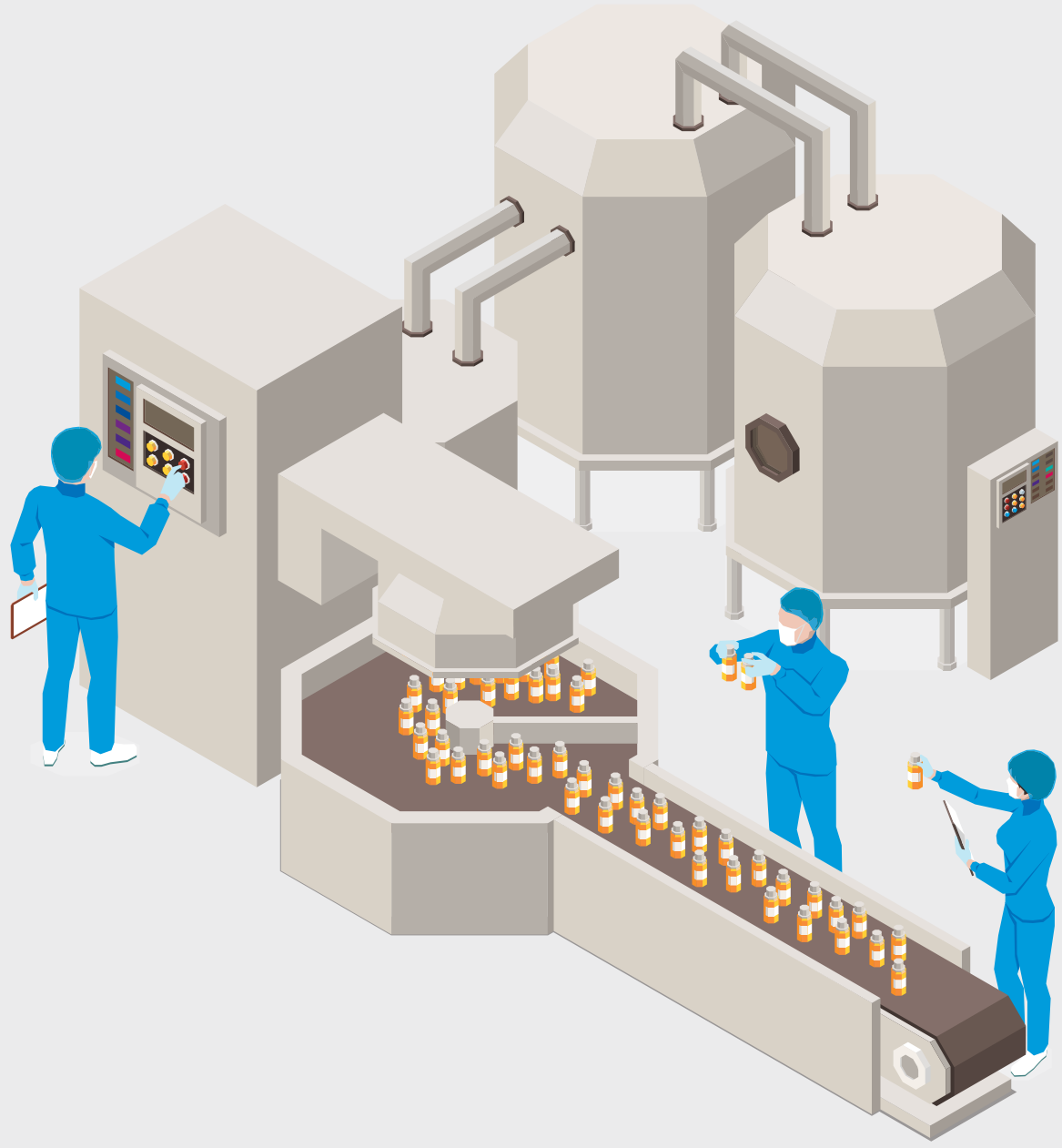
Public procurement policy:

The government is a major buyer of medical devices in India with its network of medical colleges and public healthcare centers. Public procurement policies for medical devices are designed to provide preferential market access to locally manufactured devices. These policies were introduced with the intent of encouraging domestic manufacturing by giving them preferential market access. However, in case of majority of sophisticated devices, domestic manufacturing capabilities are not fully evolved. Public Procurement Policy should encourage competitiveness amongst manufacturers by emphasizing on meeting critical quality parameters, pricing and safety requirements.

Moreover, having a systematic review of local capabilities and allowing exemptions for those products which have no or low local capabilities to meet the stipulated local requirements can ensure availability of high-quality critical devices as part of public procurement. Steps have been taken in this direction, for having a balanced procurement approach by allowing relaxations / exemptions for an identified list of medical devices which do not have sufficient local manufacturing capacity.

Duty structure to make local devices price-competitive:[46]

The import duty on majority of finished devices ranges from zero to 7.5 per cent, which is the lowest amongst BRIC countries. The budget in February 2022 has attempted to correct the situation by revising the duties on certain devices. For example, duty exemptions have been removed on devices like artificial kidneys, disposable sterilized dialyzer and micro-barrier of artificial kidney. The duty on X-ray machines for medical, surgical, dental or veterinary use has been increased from 7.5 per cent to 10 per cent. However, in order to promote demand for domestic devices, the duties on critical components and finished devices could be reviewed and structured in such a way that locally manufactured devices can be priced competitively in the market after adding applicable duties and taxes.



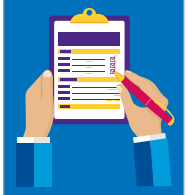
46. Medical Devices sector, Invest India, as accessed in February 2022

What India can learn from other countries to realise its potential in the medical devices sector

Comparison of key policy parameters with other countries

A comparison of key policy parameters with some of the other emerging markets (Comparators) and evolved markets (Leaders) for areas for improvement that can enable growth in the medical devices sector.

Table 4: What India can learn from other countries to realise its potential in the medical devices sector[47,48,49,50,51,52,53]

Key parameters	India	Comparators (Emerging markets – E.g.: Malaysia, Indonesia, Vietnam, China, Philippines)	Leaders (Evolved Markets – E.g.: Singapore, Japan, South Korea, Ireland, France, U.S.)	Key takeaways for India
 **Regulatory structure**	• Multiple regulatory authorities across Centre and states govern medical devices policies. Class A and Class B devices are licensed by concerned State Licensing Authorities, while Class C and Class D devices are licensed by the Central Licensing Authority after the conformity assessment done by Medical Device Officers of CDSCO.	• Single central authority governing regulatory policies for medical devices • High predictability and transparency as policies are consistent in the long run and harmonised across the nation		Countries having single central authority / better coordination between state and centre for overlooking all affairs related to medical devices, provide better predictability for doing business
 **Affordable pricing**	• To ensure patient affordability, the government has capped ceiling prices / trade margins for certain 'essential' devices • However, the treatment / procedure fees vary across hospitals	• Vietnam, Malaysia, Indonesia do not have price-control mechanisms for devices or medical procedures • There are varying procedure fees across hospitals • China manages price control on devices through public hospitals and national group purchase policies	• Price cap exists for medical procedures • In Japan and France, there are price caps for both medical procedures and devices • Fixed fees defined for medical procedures based on "diagnosis groups"	Price caps for devices as well as for medical procedures can ensure affordable healthcare services to patients. However, this will need robust data systems, well-defined treatment guidelines and patient records to be established

47. Healthcare sector report, IBEF, June 2020
48. KPMG in India analysis
49. ASEAN Medical Device and Pharmaceutical Regulations, Pacific Bridge Medical, accessed in May 2021
50. Regulatory, Pricing and Reimbursement, Pharma Boardroom, as accessed in May 2021
51. Snapshot: medicine and medical device pricing in Singapore, an extract from Lexology, as accessed in May 2021
52. China Extends 15% Profits Tax to Qualifying Investors in its Western Regions, China Briefing, May 2020
53. The Global MedTech Hub, Irish MedTech Association, 2020

Key parameters	India	Comparators (Emerging markets – E.g.: Malaysia, Indonesia, Vietnam, China, Philippines)	Leaders (Evolved Markets – E.g.: Singapore, Japan, South Korea, Ireland, France, U.S.)	Key takeaways for India
 **Medical reimbursement schemes**	• Higher share of out-of-pocket spend as only 47 per cent of the population is covered under health insurance	• Patient reimbursements are managed through universal healthcare schemes as well as private health insurance schemes	• In Japan, South Korea and U.K., patient reimbursements are managed through universal healthcare schemes as well as private health insurance schemes • In U.S., the prevalence of private insurance schemes is relatively high	India has rolled out a universal healthcare scheme under PMJAY. However, it needs to cover majority of its citizens under this scheme to increase access to healthcare services to its population
 **Device registration timelines**	• The average registration timelines range from 45 to 180 days depending on the criticality of devices	• The average registration timelines range from 45 to 90 days	• The average registration timelines range from 30 days to a few months depending on the category of devices	Timelines for registration in India are comparable with other countries. However, predictability in registration timelines can be improved
 **Financial benefits for domestic manufacturing and R&D**	• The Government of India (GoI) has rolled out multiple initiatives to incentivise domestic manufacturing of medical devices, such as, PLI scheme, grants for Medical Device Parks, concessional loans as part of LGSCAS, etc. The GoI could also focus on incentivising R&D to boost local innovation in the medical devices sector .	• China has identified medical devices sector as an "Encouraged Industry" has reduced corporate tax from 25 per cent to 15 per cent. It also provides tax-benefit extensions for investments made in development of medical devices	• Ireland has the lowest corporate tax rate of 12.5 per cent to facilitate local businesses. It provides additional tax credit of 25 per cent for R&D activities	Countries that are leaders in the medical devices market have concessional tax rates targeted at incentivizing both R&D and manufacturing in the sector

Case Study of Ireland: Medical Devices sector fostering on the back of strong R&D[54,55]

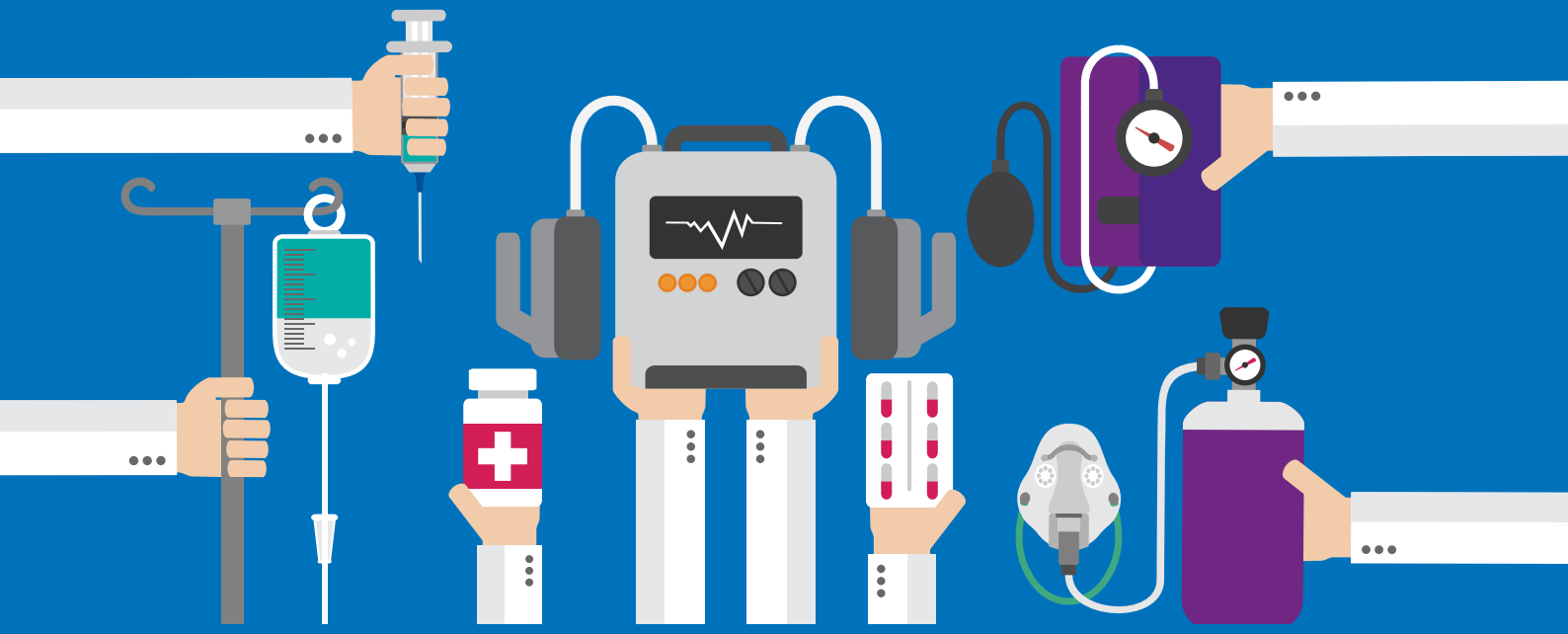
Sector Profile

- Irish Medical devices market is a major exports hub with proximity to EU markets
- The government strives to collaborate with the industry players and look for new ways to enhance competitiveness, develop new capabilities and generate growth that is sustainable

Snapshot of the Irish medical devices sector

There are 450 Medical devices companies including:

- 9 of the world's top 10 medical devices companies have a base here
- 60 per cent of the companies are homegrown
- 4 out of 5 are start-ups or SMEs
- Annual exports of € 12.6 billion and growing with direct exports to more than 100 countries
- 50 per cent of the companies located here are in the contract research and manufacturing business space



54. The Global MedTech Hub, Irish MedTech Association, 2020

55. The Irish Advantage website, as accessed in September 2021

Key Initiatives taken to enable growth in the medical devices sector:

Focus on R&D and Innovation

- Ireland is ranked no.1 globally for exchange of technology and ideas, Its clinical research facilities support patient-focused research
- 70 per cent of medical device companies in Ireland engage in R&D activities
- Majority of the recent investments in the industry has come from the existing companies investing in innovation and R&D
- The government also supports investments in R&D through the Science Foundation Ireland.
- Active collaboration between companies is one of the key reasons behind Ireland's growth in the medical devices sector. Over 25 per cent of the companies in Ireland have a shared services mandate, helping the sector develop world-class operations and technology solution development

Manufacturing Expertise

- Ireland is a preferred location for top MNCs for the production of complex high margin medical devices, medical grade / heavily regulated products and development of critical elements of IoT products.
- Ireland has established cross sectorial 'Manufacturing Forums' to enable collaboration across stakeholders to develop infrastructure, manufacturing competencies and skills sets.
- • The country has attracted leading companies through its efficient skill base, thriving R&D sector with the ability to bring innovative products to the market quickly and its proximity to EU market consisting of over 500 million potential customers.

Skilling Resources

- Ireland has established "national medical technology innovation training programme" in which academia, clinicians and industry can collaborate to develop novel medical technologies. The programme drives partnership between universities and hospitals across the country.
- Government funded initiatives such as Irish Medical devices Association's Skillnet Network and Springboard educate graduates about employment opportunities in the sector.

Financial Incentives

- Lowest corporate tax rate of 12.5 per cent in Europe
- R&D tax credit of 25 per cent

Regulatory and IP Advantages

- Quicker product approvals

Case Study of Malaysian Medical Devices sector[56,57]

Sector Profile

- The government views Medical devices as one of the leading industries that can revitalise manufacturing sector in the country
- In the South East Asian region, Malaysia currently holds a strong position in terms of a top outsourcing destination for many MNCs, though it needs to keep pace with the upcoming hubs in APAC such as Vietnam and Philippines to maintain its leadership

Snapshot of the Malaysian Medical Devices Sector

There are more than 200 Medical devices companies including:

Large scale manufacturing is dominated by the 30 MNCs having a footprint in the country

90 per cent of the medical devices manufactured in the country are exported with 50 per cent of these going to US, Germany, Japan and China

Malaysia supplies 60 per cent of the world market for medical gloves and 80 per cent for catheters

Key Initiatives taken to enable growth in the medical devices sector:

Increased Healthcare Expenditure

- Continued expansion in the central government's budget allocation on healthcare (expected to reach USD20.8 billion by 2023, which is ~5 per cent of the projected GDP)

Ease of Business

- Developed and integrated logistics and supply-chain network that connects the country with the markets across APAC
- Large footprint of third-party players which act as key partners managing functions from order collection to packaging to distribution
- High success in attracting foreign investments on account of competitive costs, supportive infrastructure, and a large talent pool

Collaboration

- InvestPenang initiative by the government to allow companies to network with other companies both in the medical devices and other high-tech industries

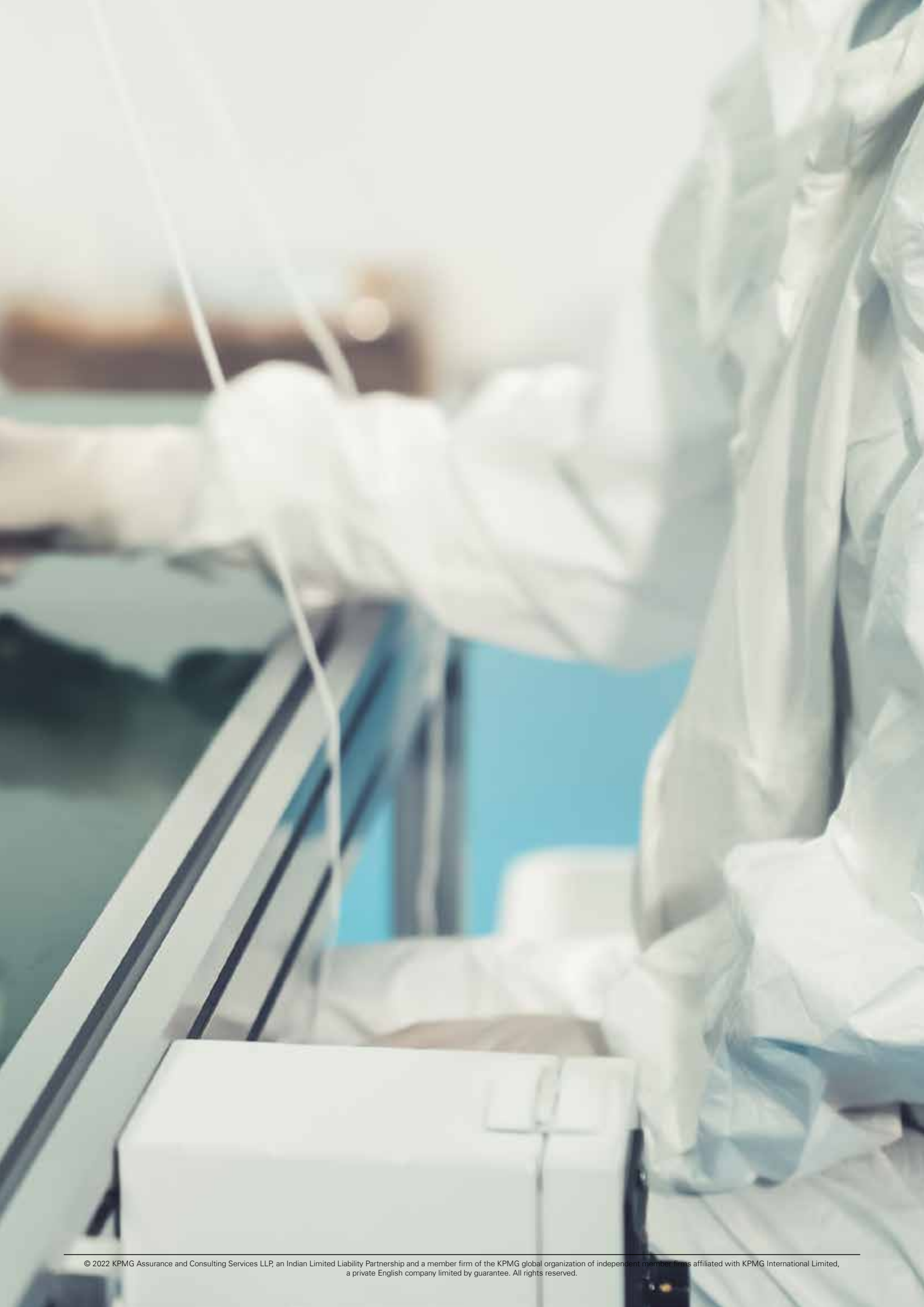
Contribution by MNCs

- MNCs have played a major role in the development of the sector by acting as the training ground that started the medical devices industry in Malaysia
- Set-up of massive manufacturing plants (375,000 sq. ft.) by leading companies in Batu Kawan for catering to APAC markets

56. Malaysia's Healthcare Sector: A Rising Giant in ASEAN, ASEAN Briefing, September 2020

57. Medical Devices sector, InvestPenang website, 2021

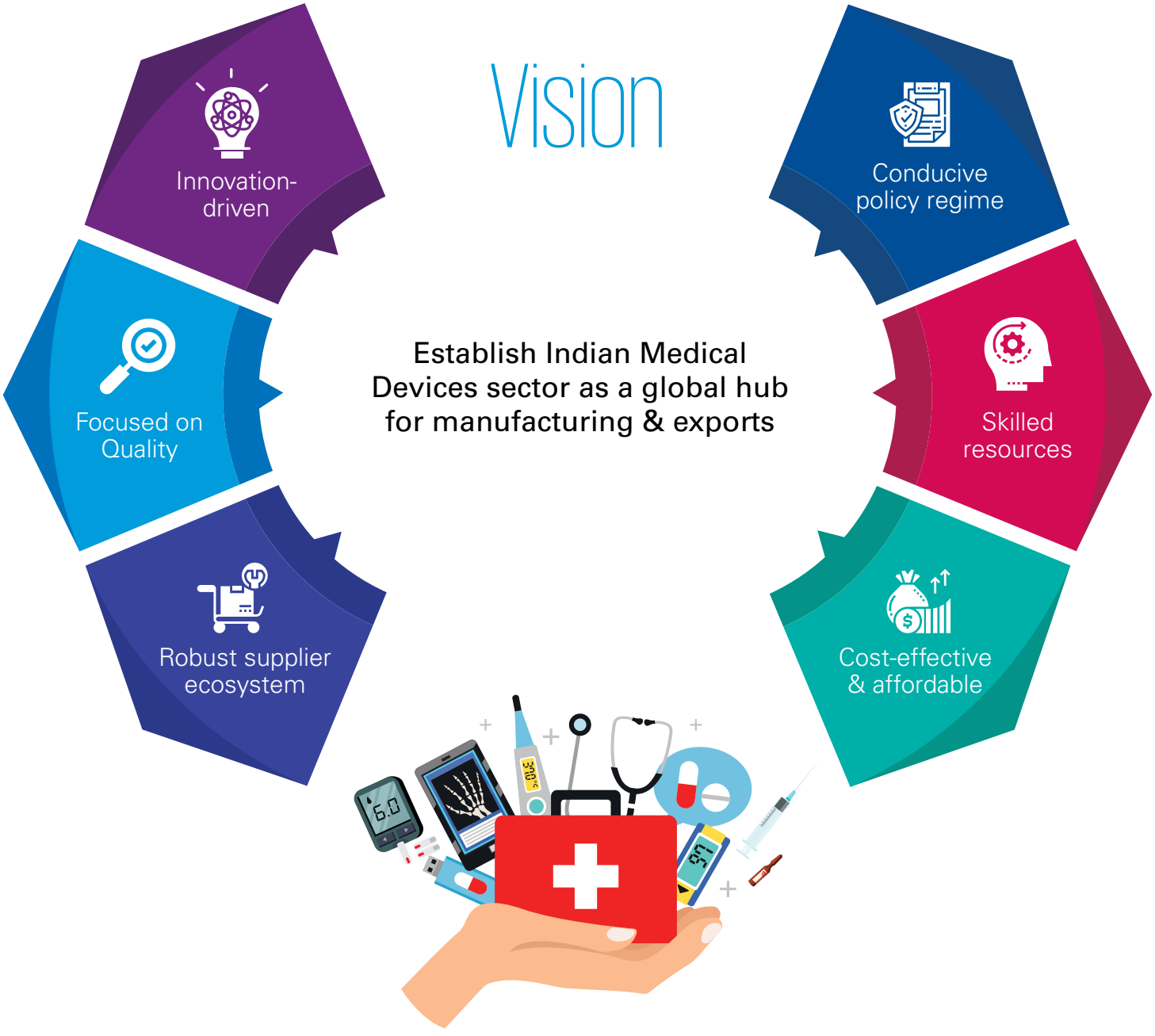
Vision and future policy roadmap



Realising the potential and way forward

Indian medical devices sector has the potential to establish itself as a global hub for manufacturing and exports backed by capabilities to innovate, produce high quality devices at competitive prices, supported by a robust regulatory regime.

Figure 17: Long term Industry vision for the Indian medical devices sector



To realise the vision, specific interventions are needed which can support the medical devices sector, its ecosystem and the macro environment

Key Recommendations

A. Establish a predictable regulatory environment:

- Establish a long-term policy roadmap of 10-15 years for the sector detailing the growth plans along with implementation plan of identified actions. This will provide the necessary long term visibility to potential investors and manufacturers in India.
- Establish a single central authority to regulate medical devices for harmonizing policies across the nation to improve process-predictability
- Introduce a feedback mechanism for an inclusive and consultative approach with industry leaders while defining policies

B. Harmonise quality standards to match global requirements:

- The apex standard making organization of India i.e., Bureau of Indian Standards, should focus on harmonizing the Indian Standards with globally acceptable quality standards so that domestic device manufacturers attain global competitiveness in the crowded market. Deploying different quality standards for the domestic market, especially vertical standards, needs to be critically examined as India aims to be a net exporter of medical devices in the long run. Having harmonized standards for domestic and export markets can help indigenously manufactured medical devices compete against their global counterparts and make indigenous devices more acceptable in the global market (in terms of quality). It can enable global companies to form partnerships with Indian manufacturers to produce devices for local and global markets.

C. Align public procurement policy to local production capabilities:

- India is a growing market for healthcare needs and the domestic industry is evolving in its capabilities to service this market. Government of India (GoI) is simultaneously working on multiple objectives of ensuring availability of products at the right prices while developing local manufacturing capabilities and capacities. With a view to encourage domestic manufacturing, GoI brought Public Procurement (Preference to Make in India) Order, which as the name suggests gives preference to products with higher local content (>50 per cent for Class I devices and between 20-50 per cent for Class II devices) in public procurement. As India is largely dependent on imports for its medical device requirement especially for high risk, complex medical devices, this order started creating availability issues for these medical devices. GoI took timely cognizance of this medical device availability issue and has provided relaxation in Global Tender Enquiry (GTE) for device segments with low or no local manufacturing capacity. In order to ensure that critical healthcare needs of the society are serviced, a systematic and exhaustive review of local manufacturing capacity & capabilities could be carried out in consultation with key industry stakeholders to define exemptions in the policy. Good coordination between the government and the industry stakeholders is critical in making the policy effective.

D. Promote innovation in medical devices sector:

Medical Devices is an innovation driven industry where incremental innovation is a norm and newer generation products are usually launched every 2-3 years. While the Hon'ble Prime Minister's clarion call of "Make in India" has been a great trigger to promote manufacturing activities in India, "Innovate in India" is a natural precursor to "Make in India" for medical device Industry and hence needs equivalent focus and support to realize the dream of making India a Global Medical Device Hub. The government could consider focusing on the following initiatives to promote R&D in this sector -

- Establishing 'innovation forums' to facilitate collaboration amongst industry-players, academia and scientists in the medical devices sector
- Innovation Linked Incentive (ILI) scheme on the lines of Production Linked Incentive (PLI) Scheme
- Setting up a seed capital fund of INR1000 Cr. to facilitate R&D on frugal-innovation projects focused on critical device-segments with growing domestic demand, like Biotechnology Industry Research Assistance Council (BIRAC)
- Establishing innovation parks providing infrastructure support to innovation-focused start-ups
- Promoting research & development with commercial viability through Public Private Partnerships (PPP) for prototyping facilities (houses), precision engineering facilities, etc.
- Medical Device Innovation demands interactions with healthcare professionals (HCPs) right from the ideation stage and therefore globally "Co-Invent" or "Co-Innovate" in medical devices is the widely acceptable model. Therefore, it is important to ensure that the proposed Uniform Code for Medical Device Marketing Practices (UCMDMP) doesn't restrict these important interactions for organizations that are heavily investing in R&D in India.

E. Build supplier ecosystem to support local manufacturing:

Growth in manufacturing of sophisticated devices depends on availability of domestic supplier market for parts and components. An indigenous supply base for critical components can not only build reliability in the supply chain but also reduce the input costs for device manufacturers, making the indigenous devices more price competitive. The government should take measures to extend its support to reduce the cost burden on the manufacturers through initiatives such as -

- Providing concessional power tariffs, cheaper access to land to set up manufacturing units
- Creating common infrastructure facilities which manufacturers can pay per use. Examples of such common facilities include –
  - Component Testing Centre / ESDM / PCB / Sensors facility; Electromagnetic interference & Electromagnetic Compatibility Center; Biomaterial / Biocompatibility /Accelerated Aging Testing Centres; Radiation testing centre;
  - Medical grade moulding / milling / machining / tooling center; 3D designing and printing for medical grade products;
  - Solid waste management / ETP / STP / Electronic waste management unit;
  - Common Warehouse & Logistics facility; etc.
- Providing lower interest rates to manufacturers during the initial years of building supplier ecosystem

F. Build skilled talent pool:

Skill availability is critical, if the government is to realize its vision for medical devices sector in India. The government places immense importance on this sector and has launched the following courses for Medical Devices in National Institute of Pharmaceutical Education and Research (NIPERs)

- M.Tech M.Tech (Medical Device) across NIPERs in Guwahati, Kolkata, Hyderabad and Mohali
- Medical Device M.S. (Pharma) in NIPER Ahemdabad

However, additional efforts as follows are required to ensure India finds its rightful place among global medical device hubs:

- With the evolving domestic industry, the government could consider augmenting the number of institutions offering similar such courses and set up Centres of Excellence providing training and placements to cater to the growing need for skilled resources in the industry.
- Globally medical device research is largely carried out in academic institutions followed by designing and prototyping of medical device by the corporates and therefore, to promote the same culture in India, a robust Industry-Academia Collaboration Model is required which is industry friendly w.r.t. processes implemented.
- Medical Devices Industry is an interdisciplinary industry and therefore it needs competent human resources in many areas like polymer engineering, material science etc. Therefore, availability of skilled talent pool must be looked at by including organizations of repute beyond NIPERs like IITs, NITs, NIDs etc.

G. Establish brand 'India' as a global hub for manufacturing and innovation:

Globally, companies are looking to reduce supply chain risks by exploring alternative supply-base. With the global demand shifting to the emerging economies, companies are looking for an opportunity to establish manufacturing bases closer to these markets. Since India aims to attract global players to manufacture locally, the government can focus on initiatives to promote positive brand image of the country, such as –

- Participation in global platforms showcasing India as a provider of quality goods and services and as a trusted business partner
- Establishing world class clinical practices to ensure safety and quality of "Make in India" devices
- Having a dedicated export promotion council to drive focused initiatives promoting medical devices exports from India

Roadmap for way forward

The current demand and supply dynamics provide tremendous opportunity for indigenous manufacturing of medical devices. India is set to become a major consumption location with high potential for exports.

Its near-term focus should be to become self-reliant and establish itself as an export-hub for the devices where it has evolved manufacturing capabilities. In the long term, it has the potential to become a global leader in exports across all device-segments.

A clear long term vision for the sector along with focused implementation of identified actions can drive collaboration among stakeholders and set the medical devices industry on a rapid-growth trajectory.

Figure 18: Phased-growth vision for medical devices sector in India

Phased Growth Vision for Manufacturing & Innovation in India's MedTech sector				
Device Complexity	Simple Assembly + Simple Electro- Mechanical Assembly	Health IT	Complex Assembly & Complex Electro – Mechanical Assembly	Complex Designing (R&D) & Machining / Manufacturing techniques
Examples	Syringes, IV Catheter, Blood / Urine bags, Sutures, Gloves, Syringe pump, Infusion pump, Patient Monitor, Ventilators, ECG, X-Ray, etc.	Electronic Medical Records (EMR), Electronic Health Records (EHR), Telemedicine, Teleradiology, Body networks, Health Management Information System (HMIS), etc.	Multilumen catheter, Braided catheter, Oxygenators, PET CT, MRI, Digital X-Rays, Linear Accelerators (LINACs), Cath Labs, Heart-Lung machines, etc.	High-end implants
0-2 years	• Focus on indigenous manufacturing to achieve import-independence	• Incentivize Indian IT prowess to develop digital solutions in medical devices sector	• Improve Ease of Doing Business & harmonize policies across center & state regulatory bodies for MNCs to establish manufacturing base in India	
2-5 years	• Promote exports in this segment – initially establishing as export hub in APAC region	• Increase adoption of digital patient-record management	• Skill Development for complex manufacturing & R&D capabilities • Fiscal incentives for manufacturing & exports	• Promote indigenous innovation & incentivize R&D investments
5-10 years	• Establish India as a global hub for exports		• Establish strong local supply-base for the industry • Attract global companies to establish their R&D centers in India	

Methodology

This report is the result of a study undertaken by APACMed team in Partnership with Invest India and KPMG in India. We undertook the following methodology:

Secondary research and analysis based on third party publications, news articles, existing thought leadership reports by industry associations and existing government committee reports

Detailed discussions with senior leaders in the medical devices industry and industry associations

Industry survey based on custom-designed questionnaire

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KPMG entities in India are professional services firm(s). These Indian member firms are affiliated with KPMG International Limited. KPMG was established in India in August 1993. Our professionals leverage the global network of firms, and are conversant with local laws, regulations, markets and competition. KPMG has offices across India in Ahmedabad, Bengaluru, Chandigarh, Chennai, Gurugram, Hyderabad, Jaipur, Kochi, Kolkata, Mumbai, Noida, Pune, Vadodara and Vijayawada.

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About Asia Pacific Medical Technology Association (APACMed):

Founded in 2014 and headquartered in Singapore, APACMed represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations and other key stakeholders associated with the medical technology industry in Asia Pacific.

Providing a unified voice for the medical devices and in-vitro diagnostics industry in Asia Pacific, APACMed works proactively with bilateral, regional and local government bodies to shape policies, demonstrate the value of medical technology and promote regulatory harmonization. We strive to promote digital health innovation and impact policy that advances healthcare access for patients by engaging with medical device associations and companies in Asia Pacific.

APACMed is also host to the annual Asia Pacific MedTech Forum.

www.apacmed.org

About Invest India:

Invest India, set up in 2009, is a non-profit venture under the Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, Government of India. It is the National Investment Promotion and Facilitation Agency of India and acts as the first point of reference for investors in India. Invest India focuses on sector-specific investor targeting and development of new partnerships to enable sustainable investments in India. In addition to a core team that focuses on sustainable investments, Invest India also partners with substantial investment promotion agencies and multilateral organizations. Invest India also actively works with several Indian states to build capacity as well as bring in global best practices in investment targeting, promotion and facilitation areas.

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