REPORT

BOOSTING THE INDIAN MEDICAL DEVICES INDUSTRY

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Acronyms

Acronyms	Full Form
AAAN	Action Agenda for Aatma Nirbhar
AAMI	Advancement of Medical Instrumentation
ABIMED	Brazilian Association of Medical, Dental, Hospital and Laboratory Equipment Industries
ABIMO	Associação Brasileira da Indústria de Artigos e Equipamentos Médicos e Odontológicos
ABRAIDI	Associação Brazileira de Importadores e Distribuidores de Produtos para Saúde
AC	Anesthetics and Cardio-Respiratory Medical Devices
ACIC	Atal Community Innovation Centre
ADI	Absolute Data Insights
AED	Automated External Defibrillator
AERB	Atomic Energy Regulatory Board
AG	Aktien gesellschaft
AHSN	Academic Health Science Networks
AI	Artificial Intelligence
AIA	Automated Immunoassay Analyzer
AIIMS	All India Institute of Medical Sciences
AIIP	ASEAN-India Innovation Platform
AIM	Atal Innovation Mission
AIMED	Association of Indian Medical Device Industry
AIMS	Anesthesia Information Management System
ALISEI	Advanced Life Science in Italy
AMD	Advanced Micro Devices
AMMI	Association of Malaysian Medical Industries
AMSL	Allengers Medical Systems Limited
AMTZ	Andhra Pradesh MedTech Zone
ANSM	The National Agency for the Safety of Medicines and Health
ANVISA	The National Health Surveillance Agency Brazil
AOI	Area of Innovation
AOPL	Allengers OEM Private Limited
APAC	Asia Pacific
APAP	Automatic Positive Airway Pressure
APMTZ	Andhra Pradesh MedTech Zone
APTT	Activated Partial Thromboplastin Clotting Time
AR	Augmented Reality
ARIIS	Health Industry Alliance for Research and Innovation
ASEAN	Association of South-East Asian Nations.
ASI	Annual Survey of Industries
AST	Antibiotic Susceptibility Testing

Acronyms	Full Form
ATMP	Advanced therapy medicinal product
ATPC	Advanced Technology Platform Centre
TU	Simplified Expanded Access Program France (Authorization Temporaire d'Utilisation)
AUSTRADE	Australian Trade and Investment Commission
AWAK	AWAK Technologies
BARC	Bhabha Atomic Research Centre
BBB	BSC BioNEST Bio-Incubator
BBIF	Biotechnology Business Incubation Facility
BCIL	Biotech Consortium India Limited
BDS	Bachelor of Dental Surgery
BDSP	Business Development Service Provider
BDTD	Biomedical Device and Technology Development
BEP	Biomedical engineering program
BIO	Biotechnology Industry Organization
BIRAC	Biotechnology Industry Research Assistance Council
BIS	Bureau of Indian Standards
BMBF	Bundesministerium für Bildung und Forschung
BME	Biomedical Engineering
BN/Bn/bn	Billion
BNCT	Boron Neutron Capture Therapy
BPAP	Bilevel Positive Airway Pressure
BPI	Public Investment bank France (Banque publique d'investissemen France)
BRIC	Brazil, Russia, India, China, and South Africa
BSL	Bio Safety Levels
BTG	British Technology Group
BW	Baden-WürRemberg
CAGR	Compound Annual Growth Rate
CD	Consumables and Disposables
CDRH	Centre for Devices and Radiological Health
CDSCO	Central Drugs Standard Control Organization
CE	European Conformity
CEA	French Alternative Energies and Atomic Energy Commission
CETP	Common Effluent Treatment Plants
CFC	Common Facility Centre
CFDA	China Food and Drug Administration
CGPDTM	Controller General of Patents, Designs, and Trademarks
CHER	Centre for Health Equity Research
CHF	The Swiss Franc
CII	Confederation of Indian Industry
CIPET	Central Institute of Plastics Engineering & Technology
CKD	Chronic Kidney Disease
CLRI	Central Leather Research Institute
CMDT	The Consortium for Medical Device Technologies
CNRS	Scientific Research National Centre

Acronyms	Full Form
COVID	Coronavirus disease
CPAP	Continuous positive airway pressure
CPCB	Central Pollution Control Board
CR	Computed radiography
CRIUM	Central Research Institute of Unani Medicine
CSF	Cerebral Spinal Fluid
CSIR	Council Of Scientific and Industrial Research
CSIS	Strategic Council for the Healthcare Industries (Conseil stratégique des industries de santé: CSIS)
CT	Computed Tomography Scan
CTP	Computed Tomographic Perfusion
CVD	Cardiovascular Disease
DBT	Department of Biotechnology
DCA	Drugs and Cosmetics Act
DEITY	Department of Electronics and Information Technology
DEKRA	German Motor Vehicle Inspection Association
DG	Directorate-General
DGFT	Director General of Foreign Trade
DGR	Diagnosis-Related Group
DHB	District Health Boards
DGCI&S	Directorate General of Commercial Intelligence & Statistics
DICOM	Digital Imaging and Communication in Medicine
DIMDI	German Institute of Medical Documentation and Information
DIPP	Dept of Industry Policy and Promotion
DNA	Data Not Available
DOP	Department of Pharmaceuticals
DPIIT	Department of Promotion for Industry and Internal Trade
DPR	Detailed Project Reports
DR	Digital Radiography
DRG	Diagnosis Related Groups
DSCR	Debt service coverage ratio
DSIR	Department of Scientific and Industrial Research
DSM	DSM Biomedical USA
DSS	Decision Support System
DST	Department of Science and Technology
DTML	Dynamic Techno Medicals Private Limited
EC	European Commission
ECG	Electrocardiogram
ECRI	Emergency Care Research Institute
EE	Electronic Equipment
EEPC	Engineering Export Promotion Council
EFPIA	European Federation of Pharmaceutical Industries and
EFTA	European Free Trade Association

Acronyms	Full Form
EH	Express Healthcare
EIU	Economist Intelligence Unit
EKF	Entwicklung, Konstruktion und Fertigung
ELISA	Enzyme-Linked Immunoassay
EMC	Electromagnetic compatibility
EMERGO	EMERGO By UL
EMI	electromagnetic interference
EMN	European Metropolitan Region Nuremberg
EMR	Electronic medical records
EMS	Emergency Medical Responders
ENT	Ear, Nose and Throat
EODB	Ease Of Doing Business
EPCG	Export Promotion Capital Goods Scheme
EPF	Swiss Federal Institute of Technology (École Polytechnique Fédérale De Lausanne)
EPFL	Swiss Federal Institute of Technology in Lausanne
EPO	European Patent Office
EPR	Extended Producer Responsibility
ER	Emilia-Romagna's Cluster Heath & Wellbeing Italy
ERP	External Research Program
ESDM	Electronics System Design and Manufacturing
ESG	Enterprise Singapore
ESI	Early-Stage Investigators
ESRD	End Stage Renal Disease
EST	Electrical Safety Training
ETEX	ETEX Healthcare Pvt. Ltd.
ETH/ETHZ	Institute of Technology in Zurich
ETO	Ethylene Oxide Sterilization
ETP	Effluent treatment Plant
EU	European Union
EUR	Euro
EXACT	EXACT Sciences
FAP	Foreign Average Pricing
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FEZ	Free Economic Zone
FFR	Fractional Flow Reserve
FPD	Flat panel detector
FTZ	Free Trade Zone
FY	Financial Year
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
GE	General Electric
GFR	General Finance Rule
GLOBOCAN	Global Cancer Observatory

Acronyms	Full Form
GMP	Good Manufacturing Practices
GMR	Global Manufacturing Revenue
GN	GN Resounds
GPO/GPOs	Group Purchasing Organization
GRIPS	GRIPS Development Forum
GSDX	Gold Standard Diagnostics
GSK	GlaxoSmithKline (GSK Pharmaceuticals Ltd,)
GST	Goods and Services Tax
GSTN	Goods and Services Tax Number
GVA	Gross Value Added
GW	GW Plastics USA
HBD	Health Big Data
HBV	Hepatitis B virus
HCV	Hepatitis C Virus
HD	Hemodialysis
HI	High Income
HIV	Human Immunodeficiency Virus
HLL	Hindustan Latex Limited
HMD	Hindustan Syringes & Medical Devices Ltd
HP	Hewlett-Packard Development Company, L.P.
HR	Human Resources
HS	Harmonized System of Nomenclature
HSA	Health Science Authority
HSN	Harmonized System of Nomenclature code
HT	High Tension
HUG	Geneva University Hospital
IA	Intravenous Access
IAB	Italian Angels for Biotech
IARC	International Agency for Research on Cancer
IBEF	India Brand Equity Foundation
IBM	International Business Machines Corporation
IBSC	Indian Biomedical Skill Consortium
IC	Integrated Circuit
ICCU/ICU	Intensive Coronary Care Unit
ICMR	Indian Council of Medical Research
ICT	Information and Communications Technology
ID/AST	Antibiotic susceptibility testing (ID/AST)
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IGST	Interstate Goods and Services Tax
IHPL	Innovation Healthcare Private Limited, Integris Health Private Limited (IHPL)
IIPME	Industry Innovation Program on Medical Electronics
IISC	Indian Institute of Science
IIT	Indian Institutes of Technology
IITP	Innovation Imaging Technologies Private Limited

Acronyms	Full Form
IKP	IKP Knowledge Park Hyderabad
ILO	International Labour Organization
IMD	International Institute for Management Development
IMDRF	International Medical Device Regulators Forum
INC	Incorporated
INMETRO	The National Institute of Metrology, Standardization and Industrial Quality Brazil
INN	Innovation National Network
INR	Indian Rupee
INSEAD	European Institute of Business Administration (Institute Européen d'Administration des Affaires)
IOL	Intra Ocular Lens
IOT	Internet Of Things
IP	Intellectual Property
IPC	Intellectual Property Corporation
IPR	Intellectual property rights
IRDPP	Industrial R&D Promotion Program
IRHPA	Intensification of Research in High Priority Area
IRIS	IRIS India Pvt Ltd
IRR	Internal Rate of Return
ISIC	International Standard Industrial Classification
ISO	International Organization for Standardization
IT	Information Technology
ITC	International Trade Centre
ITI	Industrial Training Institutes
ITPL	Isothermal Technology Private Limited
IV	Intravenous
IVD	In Vitro Diagnostic
JCI	Joint Commission International
JETRO	Japan External Trade Organization
JJI	Johnson & Johnson Innovation LLC
JJMI	Johnson & Johnson Medical India
JMS	JMS Co. Ltd.
JPY	Japanese yen
JV	Joint Venture
KAIST	Korea Advanced Institute of Science and Technology
KBIC	Kobe Biomedical Innovation Cluster
KFDA	Korea Food & Drug Administration
KIHT	Kalam Institute of Health Technology
KMU	Small and medium-sized businesses- Innovativ (Kleine und mittlere Unternehmen)
KSIDC	Kerala State Industrial Development Corporation
LC	Labour Compensation
LFB	LFB Biomanufacturing France
LG	LG Electronics Inc
LINAC	Linear Accelerator

Acronyms	Full Form
LLC	Limited Liability Company
LLP	Limited Liability Partnership
LP	Labour Productivity
LSAC	American Lebanese Syrian Associated Charities
LSP	Life Sciences Park
LSSSDC	Life Sciences Sector Skill Development Council
LTD	Limited
LVIS	Live Visualization Corporation
MCA	Ministry of Corporate Affairs
MCO	Medium Cut-Off
MD	Medical Device, Doctor of Medicine, Managing Director
MDDC	Medical Device Development Centre
MDI	Medical Device Industry
MDR	Medical Device Regulations
MDSAP	Medical Device Single Audit Program
MEDPAC	Medicare Payment Advisory Commission
MEDTECH	Medical Technology
MEITY	Ministry of Electronics & Information Technology
MEMS	Micro Electromechanical Systems
METEAN	Medical Technology Test and Demonstration Centre
MFG	Manufacturing
MIF	Medical Innovation Fund
MII	Medical Informatics Initiative
MN/Mn/mn	Million
MIT	Massachusetts Institute of Technology
ML	Machine learning
MNBIO	Minnesota Biotechnology Association
MNC	Multi-National Companies
MOD	Ministry of Defense
MOE	Ministry of Education
MOH	Ministry of Health
MOH&FW	Ministry of Health &Family Welfare
MR	Mixed Reality
MRI	Magnetic Resonance Imaging
MRP	Maximum Retail Price
MS	Master of Science
MSDE	Ministry of Skill Development & Entrepreneurship
MSME	Micro Small and Medium Enterprises
MTAL	Medical Technology Association of India
MTRC	Med Tech Reimbursement Consulting
NA	Not Available
NABA	Nuova Academia Di Belle Arti
NABCB	National Accreditation Board for Certification Bodies
NABL	National Accreditation Board for Testing and Calibration Laboratories

Acronyms	Full Form
NASSCOM	National Association of Software and Service Companies
NB	Nota Bene
NBM	National Biopharma Mission
NCATS	National Centre for Advancing Translational Sciences
NCI	National Cancer Institute
NCL	National Chemical Laboratory
NEI	National Eye Institute
NHA	National Health Authority
NHGRI	National Human Genome Research Institute
NHLBI	National Heart Lung and Blood Institute
NHM	National Health Mission
NHS	National Health Service
NHSA	National Healthcare Security Administration
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAD	National Institute of Allergy and Infectious Diseases
NIAID	National Institute of Allergy and Infectious Diseases
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NIBP	Non-invasive Blood Pressure
NIC	National Industrial Classification
NICHD	National Institute of Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIDCD	National Institute on Deafness and Other Communication Disorders
NIDCR	National Institute of Dental and Craniofacial Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIDHI	National Initiative for Developing and Harnessing Innovations
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NIHLBI	National Heart Lung and Blood Institute
NIM	National Institute Management
NIMH	National Institute of Mental Health
NINDS	National Institute of Neurological Disorders and Stroke
NIPER	National Institute of Pharmaceutical Education and Research
NITI	National Institution for Transforming India
NL	Netherlands
NM	Nuclear Medicine
NMDPC	National Medical Devices Promotion Council
NMI	Natural, Medical Sciences Institute
NMPA	National Medical Products Administration
NOC	No Objection Certificate
NOK	Norwegian krone
NOS	National Occupational Standards

Acronyms	Full Form
NPCMS	National Product Classification for Manufacturing Sector
NPPA	National Pharmaceutical Pricing Authority
NRW	North Rhine-Westphalia
NSDA	National Skill Development Agency
NSDC	National Skills Development Corporation
NSQC	National Skills Qualifications Committee
NSQF	National Skills Qualifications Framework
NUB	Neonatal Uterine Bleeding
NUS	National University of Singapore
NV	Naamloze Vennootschap
NXP	Next Experience (formerly Philips Semiconductors)
NZ	New Zealand
OCD	Obsessive-compulsive disorder (OCD)
OECD	Organization for Economic Co-operation and Development
OEM	Original Equipment Manufacturer
OHDSI	Observational Health Data Sciences and Informatics
OHS	Occupational Health and Safety
OOP	Out-Of-Pocket
OPS	Operationen- und Prozedurenschlüssel
OR	Operating Room
PACS	Picture Archiving and Communication System
PACT	Partnerships for Capability Transformation
PAMDRAP	Philippine Association of Medical Device Regulatory Affairs Professionals
PAP	Positive Airway Pressure
PC	Printed Circuit
PCB	Printed Circuit Board
PCR	Polymerase Chain Reaction
PDP	Productive Development Partnership
PE	Private Equity
PET	Polyethylene Terephthalate
PGI	Post Graduate Institute
PHC	Primary Health Care
PIA	Promotion of Investments Act
PICA	Percutaneous transluminal coronary angioplasty
PL	Production Linked Incentive
PLC	Public Limited Company
PLI	Production Linked Incentive
PMA	Preferential Market Access
PMC	Pre-market Consultation
PME	Patient Monitoring Equipment
PMJAY	Pradhan Mantri Jan Arogya Yojana
PMKK	Pradhan Mantri Kaushal Kendra
PMNDP	Pradhan Mantri National Dialysis Program

Acronyms	Full Form
PMP	Price Maintenance Premium
POC	Point-Of-Care
PP	Polypropylene
PPE	Personal Protective Equipment
PPP	Purchasing Power Parity
PRC	People's Republic of China
PRISM	Promoting Innovations in Individuals, Start-ups and MSMEs
PRO	Producer Responsibility Organizations
PROMÉXICO	a trust fund of the Federal Government Of Mexico
PSG	Polysomnography
PT	Prothrombin Time
PTCA	Percutaneous Transluminal Coronary Angioplasty
PTFE	Polytetrafluoroethylene
PVC	Polyvinyl Chloride
PVT	Private
QA	Quality Assurance
QCI	Quality Council of India
QP	Qualification Pack
RCA	Revealed Comparative Advantage
RCB	Regional Centre of Biotechnology
RCN	Research Council of Norway
RDI	Recognition of In-house R&D Units
RI	Reverse innovation
RIBA	Robot for Interactive Body Assistance
RIS	Regional Innovation System
ROI	Return on Investment
ROS	Radiology Oncology Systems
RPM	Remote Patient Monitoring
RRC	Reagent Rental Contract
RRT	Renal replacement therapy
RT	Radiotherapy
RTPCR	Reverse Transcription–Polymerase Chain Reaction
SABIC	SAUDI Basic Industries Corp
SAG	Scientific Advisory Groups
SAMEER	Society for Applied Microwave Electronics Engineering & Research
SCTIMS	Sree Chitra Tirunal Institute for Medical Sciences
SCTIMST	Sree Chitra Tirunal Institute for Medical Sciences & Technology
SEED	Sustainable Entrepreneurship and Enterprise Development
SERB	Science and Engineering Research Board
SG	Singapore Government
SGD	Singapore dollar
SI	Surgical Instruments
SINAEMO	Sindicato da Indústria de Artigos e Equipamentos Odontológicos, Médicos, Hospitalares do Estado de São Paulo

Acronyms	Full Form
SINTEF	Stiftelsen for industriell og teknisk forskning
SIVA	Selskapet for Industrivekst
SKKU	Sungkyunkwan University
SKW	South Korean Won
SME	Small and Medium Enterprises
SMTI	Swiss Medical Technology Industry
SP	Sao Paulo
SPECT	Single-Photon Emission Computed Tomography
SPF	Specific Pathogen-Free
SPHN	Swiss Personalized Health Network
SPIC	Southern Petrochemical Industries Corporation Ltd
SPV	Special Purpose Vehicle
SRI	Shriram Institute for Industrial Research
SS	Stainless Steel
SSDC	Sector Skill Development Council
SSN	Servizio Sanitario Nazionale
STAR	Science, Technology and Research
STD	Sexually transmitted diseases
STP	Science Technology Park
SW	Social Welfare
SWOT	Strength, Weakness, Opportunity, and Threat
TAG	Technical Advisory Group
TAITRA	Taiwan External Trade Development Council
TB	Tuberculosis
TBIU	Technical Business Incubation Unit
TDDP	Technology Development and Demonstration Program
TFT	Thin Film Transistor
TIFAC	Technology Information Forecasting and Assessment Council
TMC	Texas Medical Centre
TMT	Treadmill Test
TPU	Thermoplastic Polyurethane
TS	Technical Specification
TUV	Technischer Überwachungsverein
TV	Television
UAE	United Arab Emirates
UCL	University College London
UCPMP	Uniform Code of Pharmaceutical Marketing Practices (UCPMP)
UDI	Unique Device Identification
UG	Undergraduate
UK	United Kingdom
UL	Underwriters' Laboratories
ULC	Unit Labour Cost
ULCAB	Unit labour cost between country A and B
UN	United Nations

Acronyms	Full Form
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNIDO	United Nations Industrial Development Organization
UPI	Unified Payments Interface
US	United States
USA	United States of America
USD	United States Dollar
USFDA	United States Food and Drug Administration
UT	Union territories
VC	Venture Capital
VR	Virtual Reality
WAK	Wearable artificial kidneys
WGHPL	Wipro GE Healthcare Private Limited
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization
YA	Output for Country A
YB	Output for Country B
YEIDS	Yamuna Expressway Industrial Development Sector
ZIM	Zentrales Innovations Program Mittelstand

1. Executive Summary[1]

1.1. Global Scenario

1.1.1 Health Infrastructure

Growth in the medical devices market, among others, is a function of the degree of government expenditure in healthcare. The high-income countries in 2019 spent about USD 6328 per capita and 12.53 per cent of GDP with government spending covering 62 per cent of health expenditure. In contrast, the upper middle- income countries spent around 10 percent while the lower middle-income countries spent around 5 percent of the per capita health expenditure of that of the high-income countries. Percentage of "Out of Pocket Expenditure" of the lower middle-income countries is around 3.5 times that of the high-income countries.

1.1.2 Market

The global medical device market is poised to grow at a CAGR of 9.21 per cent[2]. Electronics and Equipment is the biggest segment followed by Disposables & Consumables. The Disposables & Consumables segment is expected to grow at the fastest rate of 10 percent, followed by Surgical Instruments at 9.49 percent between 2020 and 2030.

1.1.3 Lead Firms

Globally the industry is controlled by a handful of enterprises. Among the top 30 companies in 2020, more than 60 percent (19) belong to USA followed by 4 firms from Japan, 3 from Germany, 1 each from Switzerland, UK, Sweden, and Netherlands and together they command around 58 percent of the global medical device market in 2020. It is interesting to note that 19 of the top 30 medical device companies in the world belong to USA and together they contribute about 42 per cent of the overall market.

At a therapeutic level, the lead players in diagnostic imaging are Siemens, General Electric and Philips, capturing nearly 62 percent of the global market. In cardiology, the leaders are Medtronic, Abbott Laboratories and Boston Scientific with close to 42 percent share. The top 3 players in Orthopedics, all of whom are from USA are Johnson & Johnson, Stryker and Zimmer, control 57 per cent of the overall orthopedic related medical device market. The IVD market is led by Roche, Abbott Laboratories, Danaher, and Siemens Healthineers with close to 36 per cent share of the global market.

1.1.4 Clusters

Medical device firms are many a times operating in clusters. This is necessitated due to the various cross-functional support required by the units, including the presence of hospitals and doctors for conceptualizing and testing and quality raw materials. USA has over ten clusters. Europe too has a number of medical device clusters in Germany Netherlands, France, Italy, Switzerland, etc. India has over ten clusters. Medical devices clusters are also present in Japan, China, South Korea, Brazil, Australia etc.[3]

1.1.5 R&D

The top 20 companies account for two-thirds of the global R&D budget of the private sector of USD 20 bn. The average R&D spending of the top 20 is around 6.3 per cent (2020) and the industry average is around 3.9 per cent. While the average R&D spending by the top 10 companies has remained almost the same between 2017 and 2020, that of the next 10 companies has increased substantially from 1.2 per cent in 2015 to 8.1 per cent in 2020.

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[1] Detailed sources are mentioned in the following chapters.

[2] Source ADI Market Research

[3]Sources: China: Torsekar P. Mihir, China Climbs the Global Value Chain for Medical Devices", 2018, China, Journal of International Commerce and Economics, France: https://www.mddionline.com/business/seven-most-important-medtech-clusters-europe, Germany: (1) Lovisa Jacobsson, Jan Klütsch, Nahua Kang, Richard Probst, "The medical technology cluster in Tuttlingen", January 2017, (2) "Medical Technology Clusters in Germany", 2020, Germany, GTAI, Japan: eu-japan.eu/northern-osaka-biomedical-cluster, Malaysia: (1) miti.gov.my/miti/resources/12._Medical_Devices_Industry_.pdf and (2) The Edge Markets: Special Report: Medical Devices Industry is Penang's (Malaysia) Hidden Gem: theedgemarkets.com, Oct 2020, South Korea: Daegu Medical Cluster – A hub for Medical R&D Industry, Switzerland: mddionline.com/business/seven-most-important-medtech-clusters-europe, USA: austrade.gov.eu

1.1.6 Patent

While the number of patents filed by leading countries in the field of medical devices has largely grown modestly from 2011 to 2020 across most leading countries, China's patent filing rate has grown at a CAGR of over 24 per cent between 2011-2020. USA, which is the other major country which files a lot of patents yearly in medical technology, filed 44972 patents in 2020.

1.1.7 Disease Pattern

Major cause of death in USA and Germany are cardiovascular (31 to 34 per cent) and cancer (21 to 28 per cent). The other important areas are Alzheimer's (9 to 13 per cent) and kidney issues (3 to 4 per cent). Causes of death in India are one of the highest for cardiovascular and neoplasm (cancer) as in USA and Germany (the developed world). Although the severity of these two diseases is much higher in the other countries, the growth trend is significant in India. Also, developing countries like India and China suffer more acutely from chronic respiratory diseases. Here, while the trend growth (in percentage) is negative in China, it is significantly positive in India. Another area of concern for India and Brazil is diabetes. While in USA and Germany the death rate due to diabetes has gone down between 2009 and 2019, however for Brazil and India, it has increased during the same period.

1.1.8 Trade

Global exports of medical devices have grown at a CAGR of 8.68 per cent from USD 308.6 bn in 2015 to USD 467.9 bn in 2020. In 2019, Equipment & Electronics was the most traded category contributing nearly 37 per cent of the overall trade in medical devices but it fell to the second position in 2020 as Consumables and Disposables became the highest traded medical devices taking 42 per cent of the trade share. IVD and Implants are the smallest categories contributing an average of 7.5 per cent. The Consumables and Disposables and IVD segments have grown the fastest among all segments, growing at a CAGR of 15.20 per cent and 11.08 per cent respectively. For 2020, this may be partly attributed due to the COVID impact and unpreparedness of most countries to tackle it. IVD segment grew by 24 per cent while the Consumables and Disposables increased by 40 per cent. Surgical Instruments, Equipment & Electronics and Implants grew at a CAGR of 4.33 per cent, 4.68 per cent and 1.60 per cent respectively.

1.1.9 Best Potential Entrepreneur - Strategy of Champions

Strategies adopted by firms to achieve global leadership in their areas of specialization were continuous innovation in the area of specialization, diversification in related segments by collaboration (acquisitions) of specialized companies, overall support framework of the country in terms of incentivizing innovation and other economic incentive packages, promotion and collaborative policies with start-ups in related field and presence of a strong national patent regime.

1.1.10 Promotion of Industry by Countries-

The kind of support being provided by governments of various countries ranges from providing support for innovation through funding & innovation parks, to support for branding & networking, support for data interface, support for lead by medical sector, promoting national industry through various means including global investment, skilling, strengthening factor conditions, price reduction steps, support for start-ups and regulatory support for national industry and all supporting industries.

Table 1.1 Types of Support from Different Governments

Type of Support	BZ	CH	FR	GR	IT	JP	ML	NW	SN	SK	SZ	US
Innovation	✓		✓	✓	✓		✓	✓	✓	✓	✓	✓
Networking		✓	✓	✓				✓	✓		✓	✓
Park		✓						✓		✓	✓	
Start-up				✓	✓				✓			✓
Factor Conditions								✓	✓			✓
Lead by Hospitals in R&D		✓							✓	✓		✓
Branding R&D			✓	✓					✓		✓	
Promoting National Industry	✓	✓					✓		✓			

Note: BZ = Brazil, CH = China, FR = France, GR = Germany, IT = Italy, JP = Japan, ML = Malaysia, NW = Norway, SN = Singapore, SK = South Korea, SZ = Switzerland, US = United States of America

1.2. Indian Scenario

1.2.1 Health Statistics

India also has a public-funded universal healthcare system providing access to healthcare to poorest of the poor in the country. India's share of government health expenditure in total GDP has increased from 1.15% in 2013-14 to 1.28% in 2018-19 and is expected to reach 2.5% of GDP by 2025 as prescribed by the National Health Policy of 2017. In per capita terms, the government health expenditure has significantly grown from Rs 1042 in 2013-14 to Rs.1815 in 2018-19, with more emphasis on the primary healthcare sector. The out-of-pocket expenditure as a share of total health expenditure has come down to 48.2% in 2018-19 from 64.2% in 2013-14[4]. As on 2021-22, nearly 70 percent of the population is protected by health insurance coverage including state government schemes, social insurance schemes, and private insurance.

1.2.2 Market

Medical device is a sunrise sector of the Indian economy. The size of the Indian medical devices market is estimated at USD 11 Billion in 2020, expected to grow to USD 50 Billion by 2030 with CAGR of 16.4%.

1.2.3 Trade

1.2.3.1 Exports from India

India exported USD 2.9 billion worth of medical devices in FY 2021-22, a growth of 15.47 per cent over 2020-21. This growth rate is 5 percentage points higher than for the year 2020-21 over the year 2019-20. The CAGR for the period 2019-20 to 2021-22 is 8.43%. In 2021-22, USA (21.6%) was the top export destination of India, followed by China (5%), Germany (4.4%), France (3.1%) and Singapore (2.8%). The situation was identical for the year 2020-21, with top 5 exporters being USA (23.7%), China (5.3%), Germany (5.3%), France (3%) and Singapore (3%). The top 5 export destinations in 2021-22 accounted for around 36.9 percent of India's exports.

In 2021-22, 'disposables and consumables' contributed towards 47.14% (50.97% in 2020-21) of medical device exports. Electronics and equipment also had a fair share of 39.8% (38.9% in 2020-21), with an export value of USD 1.16 billion in FY 2021-22, showing substantial growth of 18.10% in 2021-22, as compared to negative growth of 1.42% in 2020-21. IVD reagents contributed to 6% of export of medical devices in 2021-22, with a growth rate of 68.65% in 2021-22, with USA being the top export destination. India exported USD 135.2 mn worth of implants, (USA being the top importer) growing by 36.83% in 2021-22 (4.98% in 2020-21). Quantum of surgical instruments exported is relatively low at

[4] National Health Accounts Estimates for India 2018-19, Ministry of Health and Family Welfare, Government of India, 2022

USD 71.21 mn as of FY 2021-22.

1.2.3.2 Imports by India

India is a net importer of medical devices, with total imports of USD 8.5 bn in 2021-22, a growth of 36.8% over 2020-21. This growth rate is 30.08 percentage points higher than for the year 2020-21 over the year 2019-20. The CAGR for the period 2019-20 to 2021-22 is 13.47%. In 2021-22, China is the top source of imports (19.4%), followed by USA (17.2%), Germany (9.2%), Singapore (8.5%), and Japan (4.0%). The situation was similar in 2020-21, with top import destinations being China (17.8%), USA (15.8%), Germany (10.7%), Singapore (8.3%) and Japan (3.8%). Together, the top 5 import destinations accounted for 58.3 percent of India's imports in 2021-22 (56.4% in 2020-21).

In 2021-22, import dependency on equipment and electronics grew by 52.47%, as compared to a negative growth of -2.14% in 2020-21. It comprised 63.7% of total medical devices exports in 2021-22 (57.18% in 2020-21). India imported USD 1.6 bn worth of disposables and consumables in 2021-22, consisting of 19% of medical devices import (23.57% in 2020-21). Imports grew significantly by 36.66% in 2020-21, moderating to 10.39% in 2021-22. India's import dependance on 'IVD reagents' sky-rocketed by 65.4 percent to USD 872 mn in 2020-21, moderating to 1.23% in 2021-22. A sharp fall can be seen in the import growth rate of implants (-45.68%) and surgical instruments (-42.47%) in 2020-21. The import demand increased in 2021-22, with growth rates for implants (87.50%) and surgical instruments (63.12%).

1.2.4 Foreign Direct Investment (FDI)

FDI per annum increased from Rs 942 crores in 2014-15 to Rs 1545 crores in 2021-22. In between it saw two peaks in the years 2016-17 (Rs 3212 crores) and 2019-20 (Rs 2196 crores). The cumulative FDI during these years stood at Rs 11157 crores during 2014-15 to 2021-22. However, there was a quantum jump in FDI in 2022-23. FDI during the first three quarters of the year was Rs 2,798 crores. The cumulative FDI during the years 2014-15 to December 2022 stood at Rs 13955 crores.

1.2.5 Human Resources

HR requirements and skills vary depending on the sub-sector, e.g., disposables, implants, equipment, IVD, imaging, IT enabled products, etc. or on the department like materials management, production, testing and quality control, R&D, clinical trials, market research, marketing and sales and servicing, management, regulatory, Intellectual Property (IP), legal requirements etc. Around 80 per cent of the respondents[5] felt the need for skill development. The requirement is relatively high for high tech products like electronics / implants / equipment / surgical instruments, etc. as compared to low tech consumables/disposables and IVD. Over 80% of the respondents felt the need for HR related to quality assurance. More than 70% of the respondents felt the need for HR in the areas of assembly workers and export-import specialists. Around 60% of the respondents felt the need for HR in the areas of microbiology, biomedical engineering, production chemists.

Such shortfall will get augmented as India implements Ayushman Bharat and PLI schemes. There is relative over emphasis on biomedical engineering, whereas the requirements are much more on various specialized branches including biomedical, polymer, mechanical, electrical, electronics, mechatronics, clinical engineering, microbiology/biomaterials, pharmacy, M.B.B.S./BDS, IT, management – general/sales/marketing who have hands-on experience in various types of devices. Stakeholders suggested that reviewing the curriculum with interaction of industry/Industry Associations with the Academic Institutions and promoting cross- disciplinary studies along with promotion of online training courses will help.

1.2.6 Clusters and Parks

10 medical device clusters are present in Andhra Pradesh, Haryana, Gujarat, Karnataka, Tamil Nadu, Telangana, Maharashtra, and West Bengal. The Ahmedabad and Vadodara clusters in Gujarat manufactures a wide variety of implants, equipment, and disposables, with Surat cluster having most implant manufacturers. Faridabad cluster in Haryana produces an array of consumables and disposables. Bengaluru cluster in Karnataka majorly focuses on medical electronics. The Baruipur cluster in West Bengal specializes in manufacturing of surgical equipment. Implant and medical electronics manufacturers are clustered both in Chennai and Mumbai, with Mumbai cluster also having IVD and disposable production units. Both Hyderabad and Vishakhapatnam clusters manufactures a

[5] Primary Survey

wide range of medical devices.

DoP has given AMTZ a grant of Rs 25 crores for its CFC. Under the “Scheme for Promotion of Medical Device Parks” of the DOP, support of Rs 100 crore each has been approved for creation of common facilities in four medical devices parks in Uttar Pradesh, Tamil Nadu, Madhya Pradesh, and Himachal Pradesh.

Despite recent experiences in accelerating domestic production of medical devices, most imports of medical devices are largely high-value and low-volume devices while the domestic production are largely low-value and high-volume diagnostic tools. However, in recent years, Indian medical devices manufacturing industry is improving its coverage even among sophisticated and high-end segment. Indian industry has begun manufacturing more sophisticated devices like electro-diagnostic apparatus, used in medical, surgical, dental, or veterinary sciences, orthopedic appliances, splints and other fracture appliances, artificial parts of the body etc. (Datta and Selvaraj, 2019).

Labour Cost (2252 USD/annum) of Indian Manufacturing Sector is among the lowest in the world as per the ILO 2018 data. In fact, Labour Cost (2547 USD/annum) of Indian Medical Devices Industry is also among the lowest and is significantly cheaper from other fast-developing countries like China (9274 USD/annum), Brazil (8038 USD/annum), Mexico (7415 USD/annum) and Vietnam (3090 USD/annum). Unit Labour Cost (0.12) of Indian Manufacturing Sector is one of the lowest in the world after Indonesia (0.09) and Japan (0.03). Percentage of high skilled workforce (13%) in Medical Devices Industry is third highest in Manufacturing Sectors after Petroleum Products Industry (15%) and Pharma Industry (14%). However, the percentage of low to medium skilled workforce (65%) is lowest in Manufacturing sector after Pharma Industry (61%). More than 8% of the Medical Device Industry receives foreign investment, second highest after Automobile Industry (11%) in the Manufacturing Sector and 30% more when compared to Pharma Industry (6%). Although less than Pharma, average GVA and Profit of Medical Devices Industry is 20% higher, on an average, than most industries in Indian Manufacturing Sector.

The industry is particularly benefitting because of two flagship schemes of the Department of Pharmaceuticals – PLI and Medical Devices Park. It is also benefitting local manufacturers with special purchase policy. The Industrial land bank portal will make investment easier too. A number of medical devices arks are also opening up in various parts of the country. However, comparatively low R&D base is one of the major weaknesses of the Indian medical devices manufacturing industry. Our estimate from Annual Survey of Industries (2017-18) shows that only 8% of factories manufacturing medical devices and equipment have R&D units (whereas 15% of pharmaceuticals, medicinal chemical & botanical products manufacturing factories have R&D units). If this is taken care of India will be more confident a manufacturing base for innovative products.

With a rising domestic demand, the support through various programs of the various Ministries, especially the Department of Pharmaceuticals, the Indian medical device industry is all poised to grow.

1.2.7 Addressing Demand Supply Gap in Select Medical Devices

Going, among others, by global levels, demand supply gap exists among others in some critical high value equipment. Department of Pharmaceuticals, through its flagship PLI scheme have squarely addressed the same. 26 Projects have committed investment of Rs 1205.52 crores for manufacturing some of the most critical equipment including radiotherapy, CT, MRI, Cath lab products, USG, anesthesia, dialysis, and patient monitoring equipment, etc. DoP has come out with a fresh guideline for investment for “Category A” and “Category B” applicants in August 2022. It has been found that there will also be shortage of requisite HR in imaging professionals, among others.
Philips Global Services has committed investment of Rs 103.46 crores for producing MRI coils. Besides, Siemens Healthcare, Allengers Medical Systems and Trivitron Healthcare have also committed investment of Rs.167.21 crores for MRI, CT, and other equipment.[6] MEITY is supporting creation of a 1.5T Indian MRI by SAMEER Mumbai in collaboration with various national and internationally acclaimed institutes.[7] Siemens, Allengers Medical Systems, M/s Allengers OEM Private Limited, Wipro GE and Trivitron have committed investment of Rs.217.43[8] crores for CT and other equipment. Panacea Medical Technologies has committed investment of Rs. 24.50 crores for teletherapy

[6] In MRI along with other products like CT, USG, PET, X-ray equipment, Cath Lab, etc.

[7] https://www.cdac.in/index.aspx?id=lu_SMR-TID-EOI-2021-22-1

[8] Investment of Rs 217.38 crores also include also include items like MRI, USG, PET, X-ray equipment, Cath Lab etc.

equipment.

Bio India Investment Technologies, Wipro GE Healthcare, Trivitron Healthcare and Allengers Medical System have committed investment of Rs. 403.32 crores[9] for making Cath Labs, stents, PCTA balloon catheters and other equipment. Nipro India and Poly Medicure have committed investment of Rs 252 crores for manufacturing dialysis equipment in India. Allied Medical has committed investment of Rs 22.89 crores[10] for anesthesia equipment. WIPRO GE Healthcare, BPL Medical Technologies, Deck Mount Electronics have also committed investment of Rs 75.11 crores[11] for anesthesia and other equipment. Allengers OEM has committed investment of Rs 40 crores for X-ray equipment. Besides, Allengers Medical Systems, BPL Medical Technologies and Trivitron Healthcare have committed to invest Rs 86.55 crores[12] for X-ray and other equipment.

1.2.8 CFC Support

Common testing facility was a unanimous demand of 70% of the respondents, 64% suggested for calibration facility, 47% were interested in training facility and 45% suggested for mould preparation facility. Other requirements included presence of a multi-disciplinary institution for supply of required HR, wastage handling facility, linkage to hospitals, as also for the presence of a large medical device firm. Among various testing facilities, 74% suggested for microbiology/bio-compatibility testing, 58% for material characterization testing, 49% for product life cycle testing, 47% for physical and physico-chemical testing for plastic raw materials and products, 43% for critical care product testing, e.g., implants; 42% for software validation and 40% for electronics product testing. Various suggestions were made by users and experienced stakeholders too. Accordingly, the suggestive common facilities that can be supported for medical devices clusters are:

- Electra-magnetic interference & Electra-magnetic compatibility center; medical grade molding/milling/injection molding/machining/tooling center; 3D design, prototyping, and rapid tooling facility; common pilot scale production facilities, sterilization/ETO/gamma center; radiology tube/flat panel detectors/MRI magnets/piezo electrical crystals/power electronics facility; clinical trial facility, calibration/validation of manufacturing equipment, clean room, etc.
- Testing facilities for biomaterial, biocompatibility, raw material, components, products including electronic, toxicity, radiation, material characterization, software, etc.
- Essential support system including solid waste management/ETP/STP/Electronic Waste management unit, common warehouse, weighbridges, exhibition/seminar hall, skill development Centre. Etc.

1.2. Views of Stakeholders Based on Primary Research

The major issue of sourcing raw material from India is lack of quality or availability of raw material, its high cost as well as need for high technology requirement. Supplier integration program, low-cost finance, and space for vendors in the medical device parks were suggested with export promotions. Eco system support in the form of linkage with hospitals, availability of quality raw material, incentives for exports, single window clearance, tax holiday, cheaper finance, power subsidy, land on long lease rental, import duty waivers. Global collaboration in R&D will also help over time to brand Indian R&D efforts. Start-ups can play an enhanced role in leap frogging technology and degree of support may be linked to the degree of deep-tech intensiveness of the product. Some stakeholders suggested when price starts to fall, manufacturers stop making the product and shifts to a new technology. So, the benefit which less endowed persons could have received, once the price has fallen, gets lost. It was also suggested that innovators sometimes get engrossed in technology and the concept of innovation gets lost. Industry felt that target need not be patent, but product creation. Indian companies must go for substitutes and at lower cost. There can be an exclusive committee to define MRP with due representation from medical device industry. Respondents felt that cash flow challenges sometimes happen from delayed payments by hospitals supplies. Unlike exports that are paid on time through L/C, local procurement should not be held back due to delays of, e.g., installation sites not being ready etc.

Almost all respondents have ISO 13485 and over 50 per cent have MDR 2017 (CDSCO India). Some

[9] Investment of Rs 125.32 crores by Allengers Medical Systems, Wipro GE Healthcare and Trivitron Healthcare also include products like MRI, CT, USG, X-Ray, PET, etc.

[10] DoP

[11] Investment of Rs. 75.11 crores also include patient monitoring equipment, dialyzers, etc.

[12] Along with CT, MRI, Cath Lab, and USG

also have EU MDR, US FDA, MDSAP, WHO GMP, ANVISA, KFDA (Korea), ISO 15917. There is a high need for getting EU MDR, US FDA and MDSAP. However, the major challenges are high cost of annual certifications and multiple country compliances. Investments of INR 10 to 15 crore can be done in peso electric crystal cutting, if someone can develop not only algorithms but complete drawing, development of PC layout, etc. Around 70 to 75 per cent of the respondents felt that product understanding, knowledge of regulatory issues and willingness to innovate are the most critical sectoral issues for this industry. Other issues like understanding of competitors, investment capacity, knowledge of distribution network, IPR understanding were considered as less important. Entrepreneurs are high onthe prospects of the industry, given its growth rate and thus 92 per cent of the respondents suggested that they will/most probably will suggest budding entrepreneurs to take up this business. Two-thirds of the respondents felt that that NoC from the state pollution control board is required. Other rules that may apply include Biomedical Waste Management Rules, 2006. About a quarter of the respondents were of the opinion that they do not require anything from the mentioned regulations.

1.4. Way Forward

1.4.1 Vision

Vision@2047 is to ensure that India has a strong, fair, competitive, and green industry that derives its strength from digital transformation of healthcare, well functional integrated supply chains, and an approach that caters to the entire lifecycle Medical Devices products, right from production to distribution, consumption, and disposal, in a responsible manner.

The strategy is to derive maximal dividend from our Medical Devices sectors by bridging the gaps and facing the challenges for becoming a recognized centre for high value production and quality research. The Vision@2047 has been divided into three tenures viz. Near term (FY 2022 – 2027), Medium term vision (FY 2027 – FY 2037), Long term (FY 2037 – FY 2047).

1.4.2 Objectives

The objectives are:

- Establish 50 Medical Devices Clusters/Parks
- Focus on with AI & ML in Pharma & MD
- Do 10-12 innovation every year
- Introduce innovative pricing framework
- Increase spending by Government to enhance opportunities in research projects
- Enable recruitment of international faculty and international collaboration for strengthening expertise in
- Funding of research projects of high-risk nature through development of dedicated institutes for high priority areas like NCDs
- Position India as originator of tech such as Robotics, 4D, Organ Bioprinting, Laser Physics, etc.

2. Objective and Methodology

2.1. Objective of the Assignment

Department of Pharmaceuticals (DoP) has launched the Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices. A need was felt for a mechanism to further boost the manufacturing capability of the domestic manufacturers of medical devices. Accordingly, this study aims to accomplish the following:

- Describe the Indian medical device sector
- Describe the global medical device sector
- Identifying the best practices/eco-systems developed by countries which leading the global medical device sector
- Benchmarking the Indian medical device sector and do gap analysis
- Identify characteristics of the best potential entrepreneurs – strategy of champions
- Industry analysis
- Economic evaluation of the industry
- Identify the need for common facility centers including common testing facilities and others
- SWOT analysis
- Suggestions
- Way Forward

2.2. Methodology

The methodology involves the following two steps:

2.2.1 Secondary Research

A list of secondary sources along with the information extracted from them is given below.

Data available on the internet: A rigorous internet search was carried out on gathering data on the global medical device industry. The search included reports and papers published by experts and reports by various agencies on the topic. The data collected through this research has been considered from only authentic sources and sources have been mentioned thereof. Around 300 references were consulted.

Central Government agencies: Central government websites and repositories often include data based on social surveys and industry statistics. As the report includes industry-specific data analysis, websites of Central Government Ministries and departments have been referred to.

Department of Pharmaceuticals (DoP): Several data on initiative by DoP, status of PLI and other schemes, etc. were collected from DoP.

Department of Promotion for Industry and Internal trade (DPIIT): The DPIIT website has provided data related to Foreign Direct Investment (FDI) in the medical device sector. Annual data has been taken from the DPIIT website on total FDI in India and FDI done in the medical devices industry.

State Government Agencies: The websites of industry departments of various state governments were searched to collate the schemes offered by different state governments. These schemes have been analyzed in the report. Presentations made by State Governments to various Ministries and NITI Aayog were also consulted.

Global Agencies: Data collated from websites of global agencies include white papers and government statistics published by international organizations such as:

World Bank: Data on Health-related expenditure has been collated from World Bank website. This data includes expenditure incurred by countries on healthcare (both public and private) as compared to the GDP of the country. Furthermore, data on availability of healthcare infrastructure has also been taken from the World Bank website.

World Health Organization (WHO): The WHO website has provided annual data on causes of death across the countries which has helped us analyses the disease intensity of countries as compared to the medical devices industry landscape.

Intracen: The Intracen website has been used to pull out global as well as country specific trade data.

European Commission (EC): The EC website has published data on R&D Investment Scoreboard across the world to benchmark the performance of industries against major global counterparts. This includes a database of 2500 top companies across countries and industries showing their turnover and expenditure on Research and Development.

Literature Review: Publications and reports published by various non-government agencies were reviewed and data has been collated from the same. Third-party perspective includes market derivation through investor analysts' report, broker reports, academic commentary, and health management publications.

Other information sources: To analyze the national and global scenario of the medical devices market, we have also taken support of external databases and publications. Data of Indian companies has been sourced from commercial information sources like Tofler.in. A report on "Global Medical Devices Market, 2015-2030" by Absolute Market Insights was sourced for analyzing global market scenario.

Industry Associations: In order to get specific data on enterprises and obtain data sets on business-related topics, the following Industry Associations were approached:

- Association of Indian Medical Device Industry (AIMED)
- Association of Diagnostic Manufacturers of India
- Medical Technology Association of India (MTAL)
- Confederation of Indian Industry (CII)
- Orthopedic Products Manufacturer Association
- Ophthalmic Products Manufacturer Association
- Syringes and Needle Manufacturer Association

2.2.2 Primary Research

To understand the medical device industry in India better primary research was conducted.

Objective: Objective of the primary research was to undertake an industry and trade analysis, identify strengths and weaknesses, forecast growth rate perceptions of the industry and the facilitating factors for the same, ascertain the import substitution and export promotion status and requirements, Human resource situation of the industry, R&D efforts, issues therein and way forward, technology and transfer of technology, quality assurance systems, need and benefits of CFC and Med Device Parks, pricing issues and government & regulatory support.

Methodology: As part of primary research, a questionnaire was developed to be administered to industry stakeholders and firms. Also, key informants were identified, and interviews were conducted with them by the lead researchers.

The sample framework of the primary research is as follows.

- **Industry Questionnaire –** Stratified chain sampling within the strata was used for identifying the firms from the industry.

Table 2.1 Sample Mix

#	Stratification – Project Classification	Target	Achieved
1	Cancer Care/ Radiotherapy Medical Devices	5	5
2	Radiology and Imaging medical device (Ionizing, Non-Ionizing and Nuclear Imaging Devices	10	10
3	Anesthetics and Cardio-Respiratory medical device including Catheters of Cardiorespiratory Category and Renal Care	10	10
4	All implants including implantable Electronic Devices	15	15
5	IVD	15	15
6	Consumables/ Disposables	20	43

7	Electronics		5
8	Instruments		14
9	Others		12

- **Key Informant Interviews –** Since the study covered different dimensions of the industry and had a geographical spread across several countries, it was essential to get a nuanced and in-depth understanding of issues involved in the promotion of Indian medical device industry. For this purpose, key informants were identified, and the interview schedule was administered to them. Key informants included top luminaries and senior professionals from the industry, senior researchers involved with the industry, senior policy makers and regulators, industry associations, healthcare providers' associations, Med Tech Parks, R&D institutes, and relevant chambers. In all, 20 key informants were interviewed.
- Visit to MedTech Park AMTZ and MedTech Park Sultanpur in Telangana
- Support taken from Industry Association including Confederation of Indian Industry (CII) and AIMED for pursuing respondents to fill up questionnaires.
- Discussions with IVD manufacturers association

2.2.3 Cost-Benefit Analysis Methodology

In this study we have compared Indian Medical Device Industry with the Indian Manufacturing Sector with respect to Labour Cost, Labour Productivity and Unit Labour Cost to observe the manufacturing competitiveness. We have accounted the Indian Manufacturing Industries based on the National Industrial Classification Code (NIC Code) which is equivalent to ISIC Rev.4 Classification. The Manufacturing Industry comes under the Section C of the NIC 2008 Codes which ranges from the code division 10 to 33. Unfortunately, the NIC Classification does not specify Medical Devices Industry under any particular division, making it difficult to classify from other industry divisions. We extracted medical device products from the NIC Code List taking Table 1 from Datta and Selvaraj 2019[13] as a reference and created a pseudo division, 34[14], for the purpose of the study.

Owing to the variances in classification and limited data availability for the Medical Device Industry of different countries we were not able to compare Indian Medical Device Industry with other countries' counterparts. Instead, we compared Indian manufacturing sector with manufacturing sector of selected developed and fast-developing countries to assess the competitiveness. We assume that the results will be close to those of the Medical Device Industry as well.

2.2.3.1 Definitions

- Labour productivity (LP) is defined as the ratio of output (Y) volume (from GDP data) per unit of labour (L), i.e., persons employed, or hours worked) or LP=Y/L
- Unit labour cost (ULC) is the ratio of nominal labour compensation (LC) and output (Y) produced with that compensation in a production process or ULC=LC/Y,
- Relative Unit Labour Cost of country A with respect to country B (ULCAB) is defined as ULCAB = (LCA/LCB)/(YA/YB)

2.2.3.2 Data

2.2.3.2.1 India Data

The microdata of Annual Survey of Industries (ASI) by Ministry of Statistics and Program Implementation has been the primary source of the study. For this study we obtained data for the financial year 2017-18. ASI covers organized manufacturing[15]

[13] Datta, P., & Selvaraj, S. (2019). Medical Devices Manufacturing Industry. Economic & Political Weekly, 54(15), 47.

[14] The National Industrial Classification (NIC, version 2008) system is used to identify any particular industry from the ASI data set. But unlike other economic activities, the manufacturing of medical devices and equipment is not classified together under a single division (two-digit level). So, we teased out all possible manufacturing activity (5-digit level) that may produce medical devices and equipment under one pseudo-two-digit classification (36 in the list). We also removed these 5-digit activities from their original two-digit code (for example 26600 from two-digit division 26; 30922 from two-digit division 30 etc.) to avoid double counting.

[15] factories which employ 10 or more workers with power and 20 or more workers without power. Data is available for more than 5000 products classified under National Product Classification for Manufacturing Sector (NPCMS). Since this data is plant level data, we had to clean the data before aggregating to industry level. All data presented in

Given the vastness of the Indian Manufacturing Sector, Indian Medical Devices Industry has primarily been put against the auxiliary industries to medical devices i.e., Chemical Industry, Pharma Industry, Electronic Industry, Electrical Industry, Machinery Industry and Refurbish Industry. The calculations made for Indian Manufacturing Sector follows the formulas presented in the Tabulation Program of ASI and the indicators are based on the ASI Schedule for 2017-18. The accuracy of the data has been obtained by using the multiplier set by the ASI in Block A of microdata.

We have taken Block A of ASI 2017-18 data as the reference point of analysis. Block A has a sample size of 66688 factories, out of which 61500 factories come under NIC Section C i.e., Manufacturing Sector. As a first step, we calculated the number of factories segregated through the code division 10-34. We then merged Block A to Block B to find out the number of factories which have received foreign investment and factories that have R&D units.

Secondly, we derived total invested capital for the number of operational factories across code divisions 10-34. The total invested capital is the sum of total fixed assets (Block C) and total working capital (Block D). We then calculated the total workforce along with the total workforce pay-out in the operational factories across the code divisions 10-34 from Block E. Total workforce comprises of workers employed directly as well as contractually to work in the factories. Apart from that, it also includes the supervisory and managerial employees and other paid and unpaid staffs. Similarly, the total pay-out was calculated for the different sections of the workforce in the operational factories.

Thirdly, we calculated the total input/expense of the operational factories in 2017-18 from Block F, H & I. The total input/expense is the sum of raw material expenses, operational expenses, R&D expenses, imported products and materials consumed (fuel, indigenous materials and imported materials) for manufacturing of the products. Lastly, we calculated the total revenue generated by the operational factories in 2017-18 from Block G & J. The total revenue is the sum of value of products and by products sold by the operational factories. It also includes the income generated from other sources like services, rent, etc.

Based on the above calculated data, we were able to draw the Gross Value Addition (GVA) and Profit made by different divisions of the Manufacturing Sector. We also were able to estimate the economic contributions of those divisions in the Manufacturing Sector. Furthermore, we arrived to understand the competitiveness of Indian Medical Devices Industry with different divisions of Manufacturing Sector in terms of Productivity and Unit Labour Cost.

2.2.3.2.2 Global Data

The data for labour cost, labour productivity and total workforce of the manufacturing sector of different countries were obtained from the International Labour Organization. The data was collected for the year of 2018 to have a standard comparison with Indian Manufacturing Sector. We selected 17 countries comprising of both developed and fast-developing nations – USA, UK, Germany, France, Italy, Norway, Sweden, Japan, South Korea, China, Singapore, India, Brazil, Bangladesh, Indonesia, Vietnam, and Mexico. Similarly, latest data related to the Infrastructure and Business Environment in India were collected from the TheGlobalEconomy.com research platform.

Firstly, we collected the Labour Cost *(Annual Mean nominal monthly earnings of employees by sex and economic activity)* data from the ILO Stat website for all the 17 selected countries for the year of 2018. However, for China and Bangladesh we only got the Labour Cost data for 2016 and 2017 respectively. In order to have a uniform comparison we calculated the Labour Cost of China and Bangladesh for the year of 2018 by taking inflation into the account. For China, we took 2% and 1.59% as the rate of inflation for 2017 and 2018, and for Bangladesh we took 5.70% as the rate of inflation for 2018. The rate of inflation was based on the data available in the World Bank Database.

Secondly, we collected the Labour Productivity (Annual Output per worker at GDP constant 2011 international $ in PPP) data and the Total Workforce (Annual Employment by sex and economic activity – ILO modelled estimates) from the ILO Stat website for all the 17 selected countries for the year of 2018. Thirdly, we collected the data for Competitiveness, Road Quality, Railway Quality, Port Quality, Airport Quality, Innovation Index and Tax Rate on Profit for the year of 2020 while R&D Expenditure was collected for 2018 and Average Business Credit Interest Rate and Ease of Business Index was collected for 2020. We selected 9 countries comprising of both developed and fast-developing nations – USA, UK, Germany, France, Japan, South Korea, China, Singapore, and India. Lastly, we put the collected data in a tabulated format to derive and analyze the competitiveness of the selected 17 countries with respect to the Labour Cost, Labour Productivity, Unit Labour Cost, Infrastructure.

3. Global Scenario[16]

3.1. Health Scenario

Growth in the medical devices market, among others, is a function of the degree of government expenditure in healthcare. The high-income countries in 2019 spent about USD 6328 per capita and 12.53 per cent of GDP with government spending covering 62 per cent of health expenditure. In contrast, the upper middle- income countries spent around 10 percent while the lower middle-income countries spent around 5 percent of the per capita health expenditure of that of the high-income countries. Percentage of "Out of Pocket Expenditure" of the lower middle-income countries is around 3.5 times that of the high-income countries.

Table 3.1 Healthcare Indicators for High, Upper Middle and Lower Middle-Income Countries

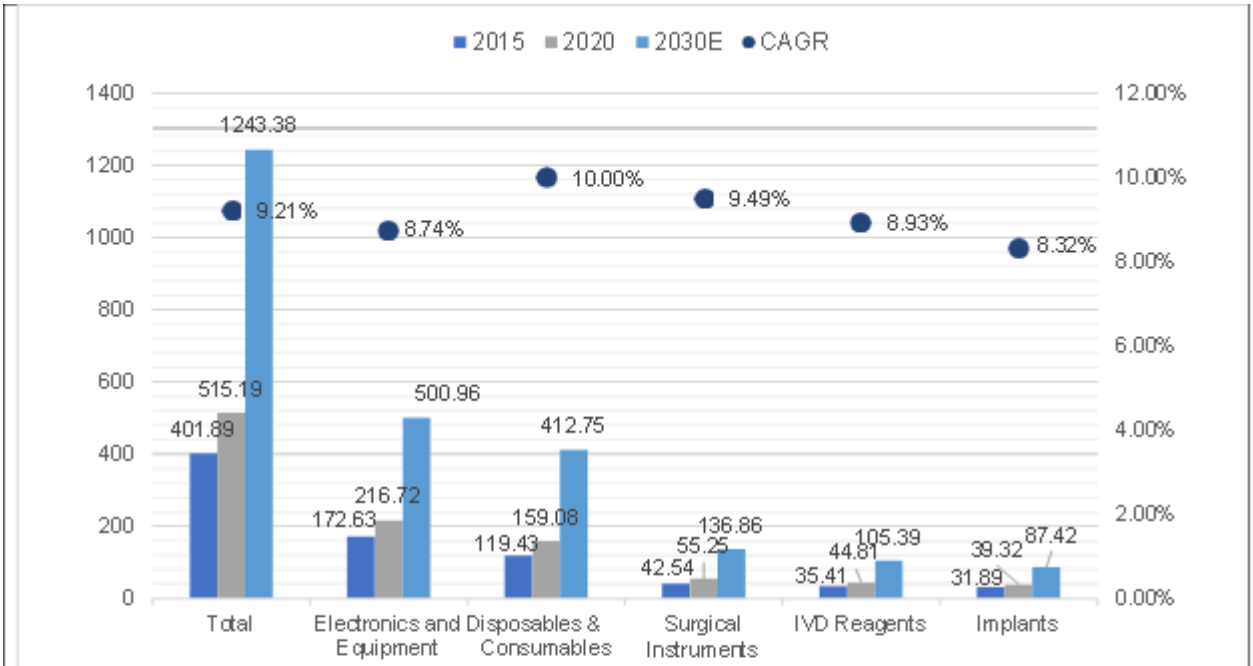
Indicators	Year	High Income Countries	Upper Middle-Income Countries	Lower Middle-Income Countries
Current health expenditure (% of GDP)	2015	12.16	5.12	4.06
	2019	12.53	5.33	3.71
Current health expenditure per capita, PPP (Current international USD)	2015	5271.25	510.2	257.41
	2019	6328.25	616.90	281.75
Domestic general government health expenditure (% of current health expenditure)	2015	62.01	53.91	35.85
	2019	61.74	52.69	39.00
Domestic general government health expenditure per capita, PPP (Current international USD)	2015	3378.81	265.72	91.54
	2019	3970.64	320.09	108.08
Out-of-pocket expenditure (% of current health expenditure)	2015	14.04	35.77	52.92
	2019	13.61	34.98	48.23
Physicians (per 1,000 people) *	2015	5.48	DNA	DNA
	2019	5.82	DNA	DNA
Nurses and midwives (per 1,000 people) *	2015	9.74	DNA	DNA
	2019	10.29	DNA	DNA
Hospital beds (per 1,000 people) *	2015	2.61	DNA	DNA
	2019	2.46	DNA	DNA
Source: https://data.worldbank.org ; DNA – Data Not Available Note: *UK data has been taken as reference as HI countries data was not available for the year 2019				

3.2. Market

The global medical device market is poised to grow at a CAGR of 9.21 per cent between 2020 and 2030 and is projected to grow from USD 515 billion in 2020 to USD 1243 billion by 2030. Electronics and Equipment are the biggest segment followed by Disposables & Consumables. The Disposables & Consumables segment is expected to grow at the fastest rate of 10 percent, followed by Surgical Instruments at 9.49 percent between 2020 and 2030.

[16] Apart from sources mentioned, various aspects of this chapter have also been drawn from references mentioned in bibliography numbers 152 to 171

Figure 3.1 Global Devices Market



	2015 (in USD Bn)	*2020 (in USD Bn)*	*2030E (in USD Bn)*	*CAGR (2020- 2030)*
Total	**401.89**	**515.19**	**1243.38**	**9.21%**
Electronics and Equipment	172.63	216.72	500.96	8.74%
Disposables & Consumables	119.43	159.08	412.75	10.00%
Surgical Instruments	42.54	55.25	136.86	9.49%
IVD Reagents	35.41	44.81	105.39	8.93%
Implants	31.89	39.32	87.42	8.32%
Source: Absolute Data Insights				

The following countries covered by the Study command around 80 per cent of the global market.

3.3. Lead Global Manufacturers

Globally industry is controlled by a handful of enterprises. Among the top 30 companies in 2020, more than 60 percent (19) belong to USA followed by 4 firms from Japan, 3 from Germany, 1 each from Switzerland, UK, Sweden, and Netherlands and together they command around 58 percent of the global medical device market in 2020. It is interesting to note that 19 of the top 30 medical devices companies in the world belong to the US and together they contribute about 42 per cent of the overall market.

Table 3.2 Contribution of Top Medical Devices Companies in the World

	2017		2018		2019		2020	
	Sales (USD Bn)	Market Share	Sales (USD Bn)	Market Share	Sales (USD Bn)	Market Share	Sales (USD Bn)	Market Share
Top 10	172.80	39%	184.21	40%	186.90	38%	188.49	37%
Top 20	243.40	56%	257.85	56%	262.35	54%	262.75	51%
Top 30	275.30	63%	293.34	64%	300.71	61%	300.34	58%
Total	438.31	100%	458.05	100%	480.95	100%	515.19	100%

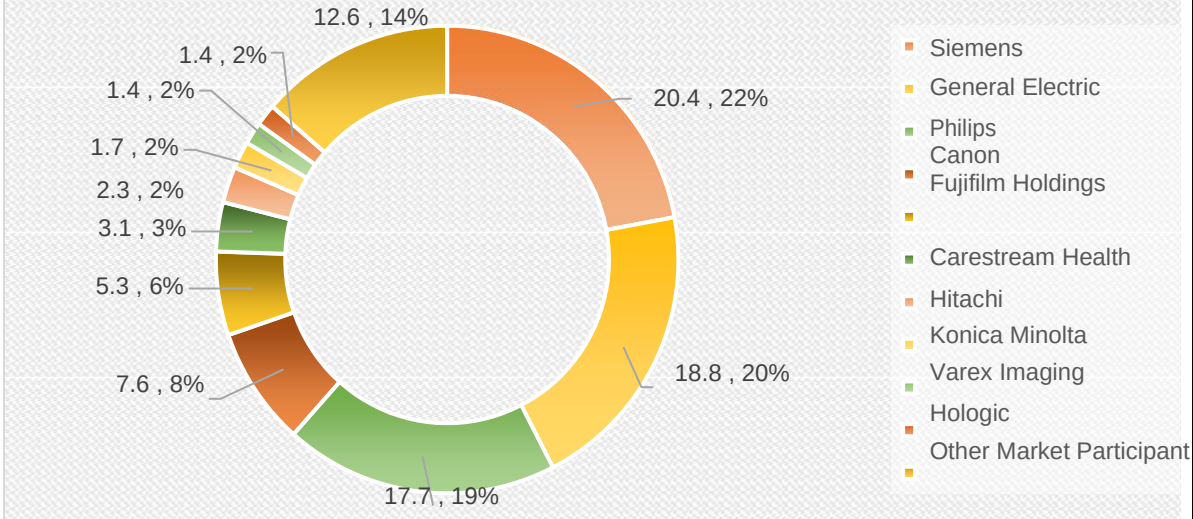
Source: https://www.mpo-mag.com/issues/2018-07-01/view_features/the-2018-top-30-global-medical-device-companies
https://www.mpo-mag.com/issues/2017-07-01/view_features/top-30-global-medical-device-companies-461934/
https://www.mpo-mag.com/issues/2019-07-25/view_features/the-2019-top-30-global-medical-device-companies-400900/; https://www.mpo- mag.com/issues/2020-07-01/view_top30/the-top-30-679842/
Absolute Data Insights

3.3.1 Global Leaders in Select Therapeutic Areas

3.3.1.1 Diagnostic Imaging

The market size of the diagnostic imaging segment in 2020 was USD 92.5 bn[17] and the top 3 players Siemens, General Electric and Philips had a very strong hold on the market capturing nearly 62 percent of the global market. The Japanese and US companies dominate the top 10 segment with 4 companies each. The top 10 players in the diagnostic imaging segment control close to 86 per cent of the global diagnostic imaging market.

Figure 3.2 Global Leaders in Diagnostic Imaging by Revenue (USD bn, %) – 2020



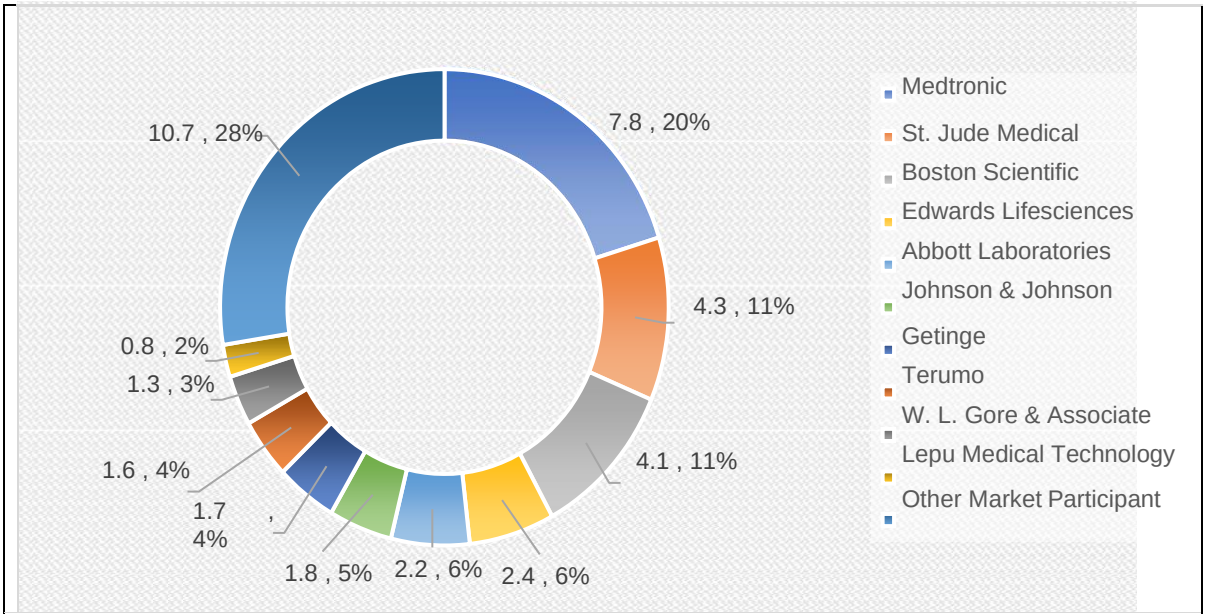
Source: Absolute Data Insights

3.3.1.2 Cardiology

USA dominates the cardiology related medical devices as 70 percent of the top 10 players belong to USA. The global cardiology related medical device market in 2020 was USD 38.7 bn[18]. Medtronic, Abbott Scientific and Boston Scientific are the leading players in the global cardiology market with close to 42 percent share. The top 10 players in cardiology related medical devices control 72 per cent of the global market.

[17] Source: Absolute Data Insights

Figure 3.3 Global Leaders in Cardiology by Revenue (USD bn, %) – 2020

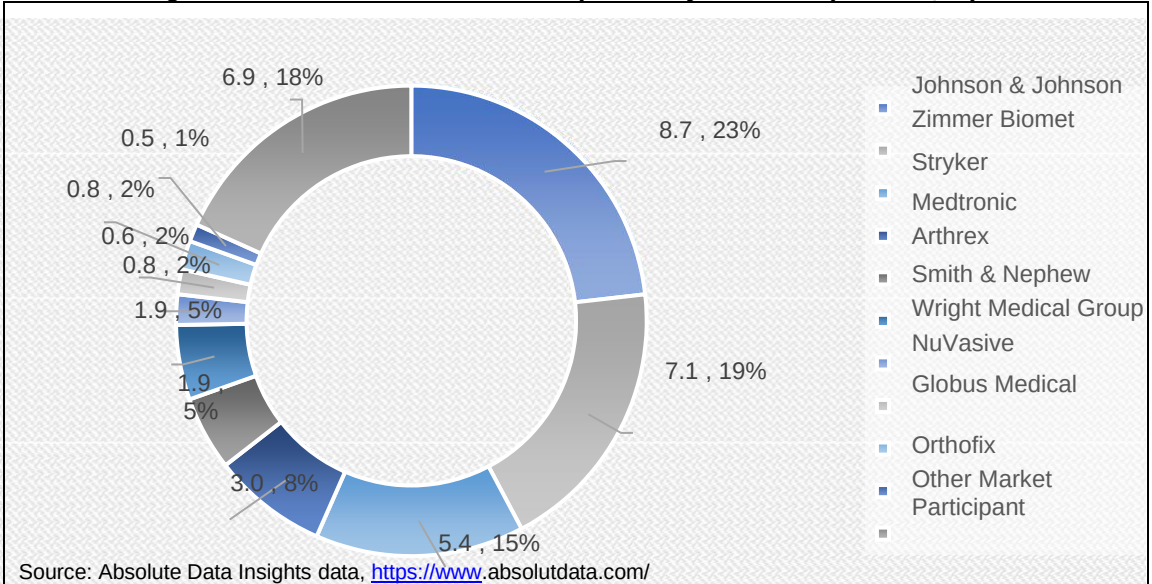


Source: Absolute Data Insights

3.3.1.3 Orthopedics

The top 3 players in Orthopedics, all of whom are from USA – Johnson & Johnson, Stryker, and Zimmer control 57 per cent of the overall orthopedic related medical device market (in 2020) which was USD37.5 bn[18] in 2020. The top 10 players in orthopedics related medical devices segment control close to 82 per cent of the market. This segment is again dominated by companies from the USA with 9 out of the top 10 companies originating there.

Figure 3.4 Global Leaders in Orthopedics by Revenue (USD bn, %) – 2020

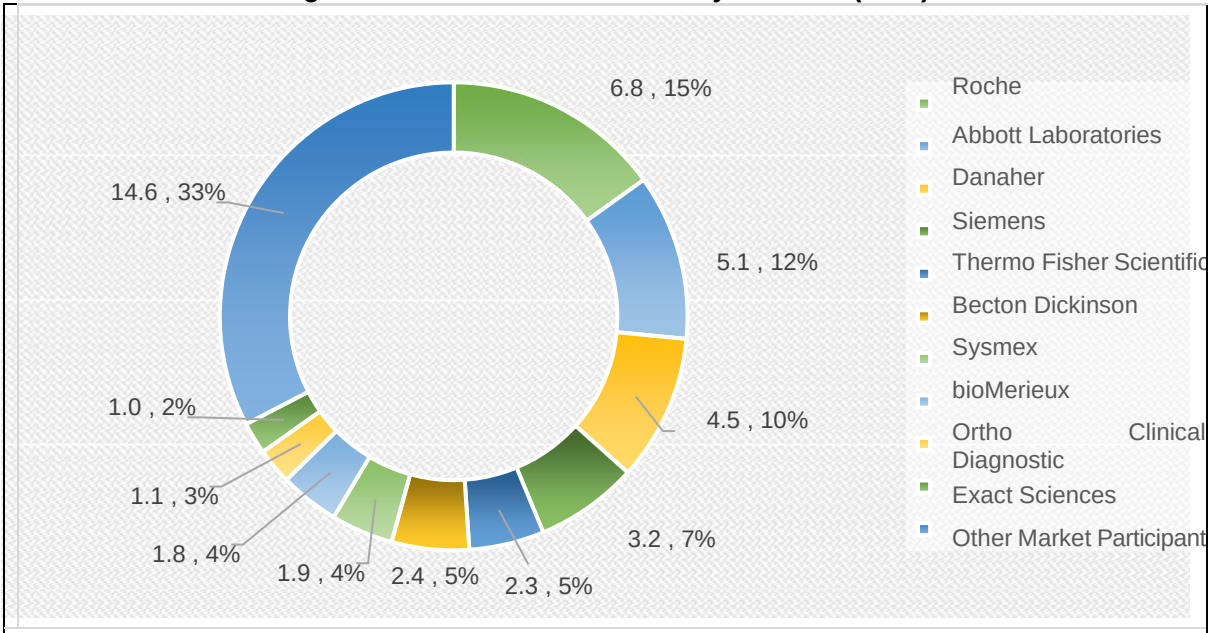


Source: Absolute Data Insights data, https://www.absolutdata.com/

3.3.1.4 IVD

The IVD market was USD 44.81 bn[18] in 2020. Roche, Abbott Laboratories, Danaher, and Siemens Healthineers are the leading players in this segment, and they control 36 per cent of the global IVD market. The top 10 players in the Diagnostic imaging segment control more than two-third of the global IVD market. 60 percent of the top 10 players in IVD belong to USA, followed by one company each from Switzerland, Germany, France, and Japan.

Figure 3.5 Global Leaders in IVD by Revenue (2020)



Source: Absolute Data Insights data, https://www.absolutdata.com/

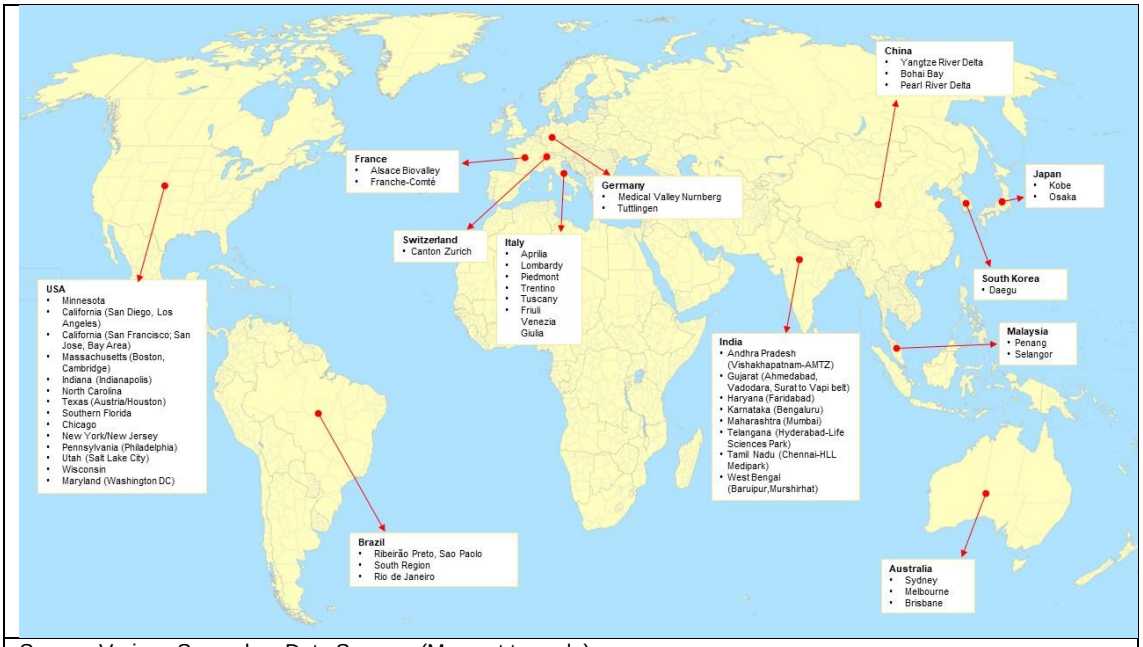
3.3.2 Leading Medical Device Clusters in the World[18]

Medical device firms are many a times operating in clusters. This is necessitated due to the various cross-functional support required by the units, including the presence of hospitals and doctors for conceptualizing and testing and quality raw materials. USA has over ten clusters. Europe too has a number of medical device clusters in Germany Netherlands, France, Italy, Switzerland, etc. India has over ten clusters. Medical devices clusters are also present in Japan, China, South Korea, Brazil, Australia etc.[19]

[18] This analysis is based on information available with us and may not be exhaustive.

[19]Sources: China: Torsekar P. Mihir, China Climbs the Global Value Chain for Medical Devices", 2018, China, Journal of International Commerce and Economics, France: https://www.mddionline.com/business/seven-most-important-medtech-clusters-europe, Germany: (1) Lovisa Jacobsson, Jan Klütsch, Nahua Kang, Richard Probst, "The medical technology cluster in Tuttlingen", January 2017, (2) "Medical Technology Clusters in Germany", 2020, Germany, GTAI, Japan: eu-japan.eu/northern-osaka-biomedical-cluster, Malaysia: (1) miti.gov.my/miti/resources/12._Medical_Devices_Industry_.pdf and (2) The Edge Markets: Special Report: Medical Devices Industry is Penang's (Malaysia) Hidden Gem: theedgemarkets.com, Oct 2020, South Korea: Daegu Medical Cluster – A hub for Medical R&D Industry, Switzerland: mddionline.com/business/seven-most-important-medtech-clusters-europe, USA: austrade.gov.eu

Figure 3.6 Some Medical Device Clusters in the world

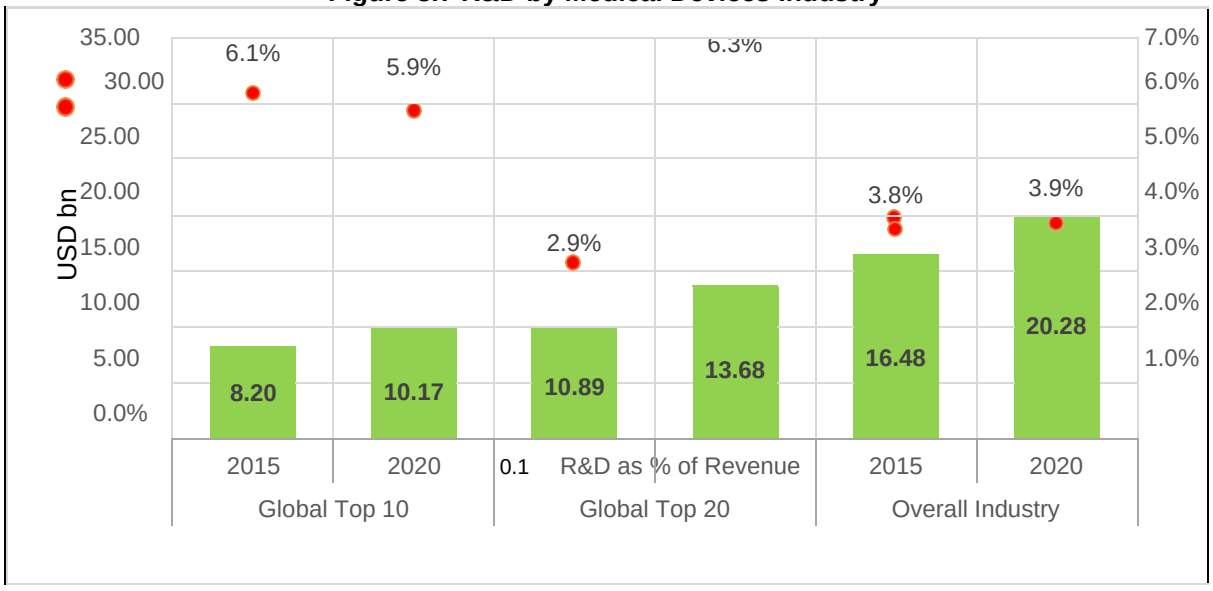


Source: Various Secondary Data Sources (Map not to scale)

3.4. Research & Development

The top 20 companies account for two-thirds of the global R&D budget of the private sector of USD 20 bn. The average R&D spending of the top 20 is around 6.3 per cent (2020) and the industry average is around 3.9 per cent. While the average R&D spent by the top 10 companies has remained almost the same from 2017 to 2020, that of the next 10 companies has increased substantially from 1.2 per cent in 2015 to 8.1 per cent in 2020.

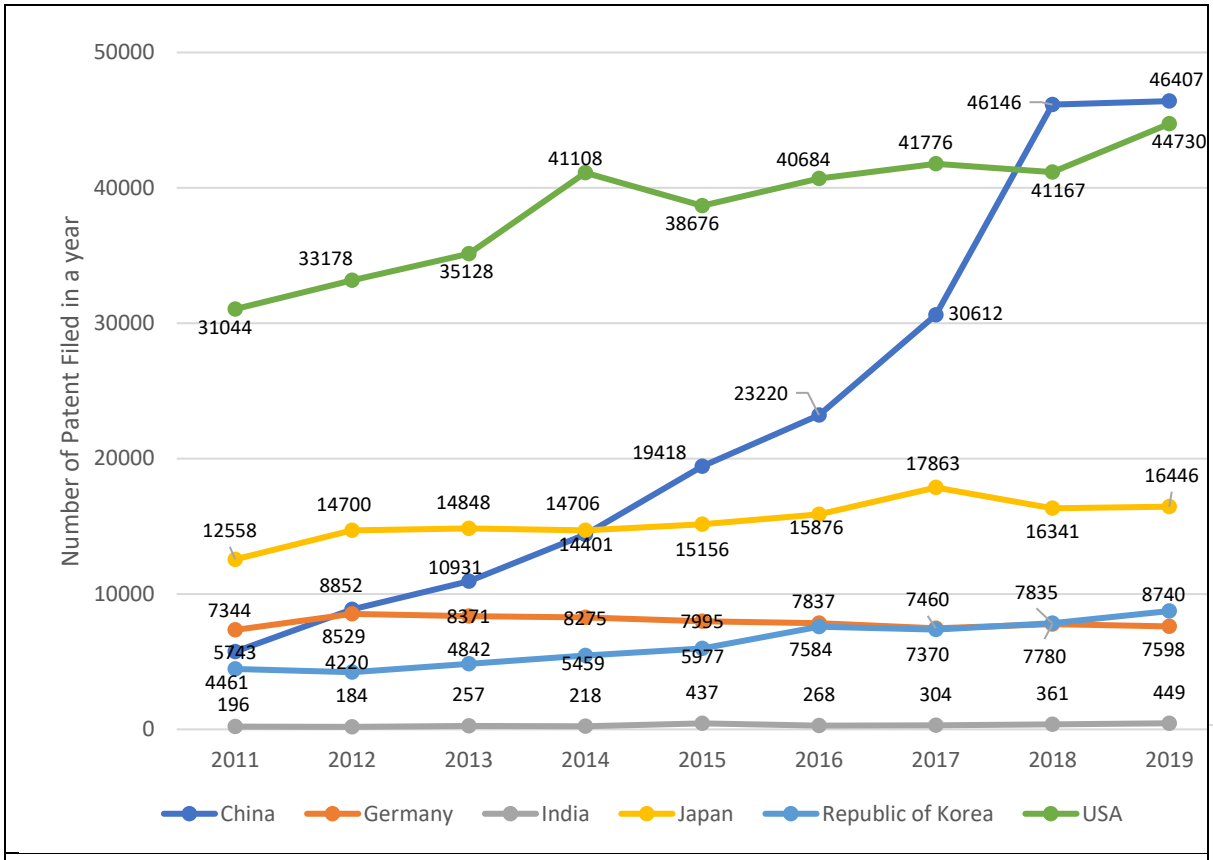
Figure 3.7 R&D by Medical Devices Industry



3.5. Patent

While the number of patents filed by leading countries in the field of medical devices has largely grown modestly from 2020 across most leading countries, China's patent filing rate has grown at a CAGR of over 24 per cent between 2011-2020. USA which is the other major country which files a lot of patents yearly in medical technology filed 44972 patents in 2020.

Figure 3.8 Number of Patents Filed in Medical Technology by Leading Countries and India



Source: WIPO statistics database. Last updated: January 2021 for code - –3 (Medical technology)

3.6. Major Mergers & Acquisitions (M&A)

Mergers, acquisitions, and specialization by selling off units also made the companies move up and down the rankings. Some of the major M&A deals during 2016-2020 are as follows

- Danaher bought Cytiva
- Teladoc acquired the digital disease management company Livongo
- Illumina reacquired its former cancer blood test developer Grail
- Stryker acquired Wright Medical
- Becton Dickinson's acquired C.R. Bard
- Essilor's acquired Luxottica
- Abbott Labs union with St. Jude Medical
- Abbott sold optics division to Johnson & Johnson
- Terumo Corporation bought (partially) Vascular Closure and Electrophysiology products of Abbott
- Danaher finalized its shedding of Fortive
- Medtronic plc purchased Covidien
- Acelity sold advanced wound care and specialty surgical firm to 3M
- Johnson & Johnson continued its move toward surgical robotics with its purchase of Auris Health.
- Danaher bought BioPharma unit of GE
- Medtronic plc acquired Mazor Robotics
- Stryker acquired K2M
- ResMed acquired MatrixCare
- Stryker acquired Entellus Medical
- Boston Scientific acquired Augmenix and NxThera
- RTI Surgical acquired Paradigm Spine
- Boston Scientific acquired Claret Medical & VENITI
- ResMed acquired Propeller Health
- Stryker acquired Hyperbranch Medical Technology & Invuity

3.7. Disease Pattern

A study of the cause of death in USA and Germany shows that the major reasons are cardiovascular (31 to 34 per cent) and cancer (21 to 28 per cent). The other important areas are Alzheimer's'(9 to 13 per cent) and kidney issues (3 to 4 per cent). Causes of death in India are one of the highest for cardiovascular and neoplasm (cancer) as in USA and Germany (the developed world). Also, India and China suffer more acutely from chronic respiratory diseases. Here, while the trend growth (in percentage) is negative in China, it is alarmingly positive in India. Another area where India and Brazil are much higher than the other countries is in the area of diabetes. while the death rate due to diabetes has gone down or stagnated in Germany and USA, between 2009 and 2019, however, in India and Brazil, it has increased over the same period.

Table 3.3 Cause of Death

Cause of Deaths	Brazil		China		Germany		India		USA	
	2009	2019	2009	2019	2009	2019	2009	2019	2009	2019
Cardiovascular	31.8%	29.4%	39.7%	43.0%	41.2%	33.5%	22.9%	28.5%	33.3%	30.7%
Chronic respiratory	5.2%	5.4%	12.4%	10.1%	6.0%	6.2%	10.5%	12.5%	7.6%	8.0%
Cancer	16.0%	18.3%	22.4%	24.4%	26.7%	27.6%	6.5%	9.1%	23.4%	21.2%
Diarrheal	0.6%	0.5%	0.2%	0.1%	0.4%	0.5%	10.8%	7.8%	0.5%	0.4%
Tuberculosis	0.6%	0.4%	0.6%	0.4%	0.0%	0.0%	6.1%	5.0%	0.0%	0.0%
Neonatal Disorders	3.1%	1.7%	1.3%	0.5%	0.2%	0.2%	8.7%	5.0%	0.6%	0.5%
Cirrhosis and Chronic Liver	2.4%	2.2%	2.3%	1.9%	2.5%	2.5%	3.8%	3.9%	1.6%	1.9%
Diabetes	5.0%	5.2%	1.4%	1.7%	2.3%	2.2%	2.2%	3.1%	2.5%	2.5%
Nephropathy	2.9%	3.7%	1.9%	2.1%	3.2%	3.5%	2.3%	2.8%	3.5%	3.6%
Road Injuries	4.5%	2.9%	3.2%	2.6%	0.6%	0.4%	2.4%	2.5%	1.8%	1.7%
Alzheimer	1.7%	3.1%	3.0%	3.8%	4.0%	9.0%	1.2%	2.0%	9.7%	12.9%
Source: WHO The Global Health Observatory; https://data.worldbank.org										

3.8. Trade Data

Global exports of medical devices have grown at CAGR of 8.68 per cent from USD 308.6 bn in 2015 to USD 467.9 bn in 2020. In 2019, Equipment & Electronics was the most traded category contributing nearly 37 per cent of the overall trade in medical devices but it fell to second position in (31 per cent) 2020 as Consumables and Disposables became the highest traded medical devices taking 42 percent of the trade share. IVD Reagents and Implants are the smallest categories contributing an average 7.5 per cent each in 2020.

The Consumables and Disposables and IVD Reagents segment has grown the fastest from all segments, growing at CAGR of 15.20 per cent and 11.08 per cent respectively. For 2020, this may be partly attributed due to the COVID impact and unpreparedness of most countries to tackle it. Surgical Instruments, Equipment & Electronics and Implants grew at a CAGR of 4.33 per cent, 4.68 per cent and 1.60 per cent respectively.

3.9. Relative Competitive Advantage Status

One way to identify comparative advantage of output of a product as compared to another country is its revealed comparative advantage (RCA)[20]. A country with a revealed comparative advantage in product is considered to have export strength in that product. The higher the value of a country's RCA for product, the higher its export strength in product. In general, this is done by taking total exports in the denominator and total medical devices in the numerator.

A comparison of RCA of select countries has been done for the major product areas. USA has a natural comparative disadvantage in consumables and disposables, and it has increased over the years. However as expected it is in lead in the other high-tech areas including Electrical & Equipment, Implants and IVD Reagents. India has the highest RCA for electronics and equipment. RCA for the other relatively high-tech products is less than 1, especially in Implants and Surgical Instruments, which is these are at a relatively disadvantageous position. The situation for consumables & disposables and IVD reagents is quite similar, although the growth rate in IVD Reagents is very high. China is doing well in consumables and disposables although the trend is in the negative as they are moving away from low-value products. In the equipment and electronics area, they have moved to a significant competitive advantage. A case in point is also Singapore. It has clearly disengaged itself from Consumables & Disposables with very low RCA and with a clear competitive advantage in Electronics and Equipment, Implants and IVD Reagents. The trend is increasing in all three items.

Table 3.4 Relative Competitive Advantage of Select Countries

Country	Category	2015	2016	2017	2018	2019	2020
USA	Consumables/Disposables	0.48	0.49	0.42	0.42	0.42	0.29
	Equipment & Electronics	1.31	1.32	1.17	1.17	1.16	1.40
	Implants	1.65	1.56	1.40	1.44	1.41	1.73
	IVD Reagents	1.33	1.34	2.54	2.53	2.65	2.73
	Surgical Instruments	0.78	0.77	0.68	0.67	0.67	0.79
India[21]	Consumables/Disposables	1.60	1.56	1.56	1.45	1.41	1.03
	Equipment & Electronics	0.95	0.97	0.87	0.97	1.01	1.19
	Implants	0.34	0.38	0.43	0.51	0.48	0.66
	IVD Reagents	0.40	0.46	0.90	0.90	0.91	1.05
	Surgical Instruments	0.57	0.56	0.53	0.47	0.48	0.54
China	Consumables/Disposables	1.03	1.03	1.00	0.97	0.94	0.68
	Equipment & Electronics	1.68	1.69	1.65	1.52	1.56	1.85
	Implants	0.21	0.25	0.26	0.29	0.34	0.28
	IVD Reagents	0.11	0.12	0.34	0.36	0.33	0.62
	Surgical Instruments	0.17	0.17	0.16	0.51	0.51	0.59
Singapore	Consumables/Disposables	0.39	0.36	0.32	0.30	0.29	0.20
	Equipment & Electronics	1.56	1.60	1.53	1.53	1.55	1.86
	Implants	0.79	0.88	0.95	1.04	1.17	1.80
	IVD Reagents	1.16	1.28	1.38	1.71	1.50	1.40
	Surgical Instruments	0.92	0.78	0.88	0.70	0.76	0.87
Source: Intracen data							

3.10. Science Parks

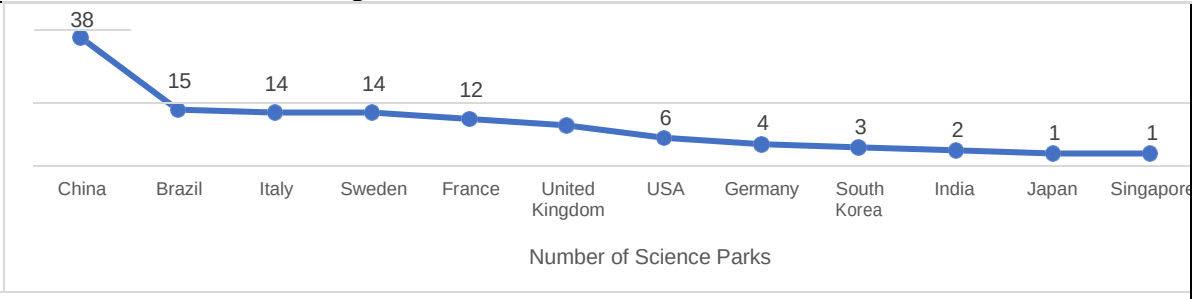
This section is based on the information analysis of the International Association of Science Parks. A science technology park (STP) is an organization managed by specialized professionals which stimulates and manages the flow of knowledge and technology amongst universities, R&D institutions, companies, and markets; it facilitates the creation and growth of innovation-based companies through incubation and spin-off processes; and provides other value-added services together with high-quality space and facilities. There is a clear move towards the presence of a host of related technologies including ICT, robotics, software and hardware engineering, electronics, biotechnology, health, and pharmaceuticals. Most of these scientific parks are owned by scientific organizations and these tend to have facilities for small batch production, and training resources for human resources. The number of science parks in select member countries which are registered with the International Association of

[20] It is calculated as the ratio of exports of a sub product to its total exports of principal products with respect to medical device products with respect to the same ratio for the entire world as a whole. For example, the formula for calculating the RCA of IVD for USA would be ((Export of IVD from USA/Total Exports of medical device from USA)/(Exports of IVD in the world/Total Exports of medical device in the world)) If a nation has RCA >1 for a product, it may be concluded that it is a competitive producer and exporter of that product relative to a country producing and exporting that good at or below the world average.

[21] Calculated from INTRACEN Data

Science Parks, is as follows.

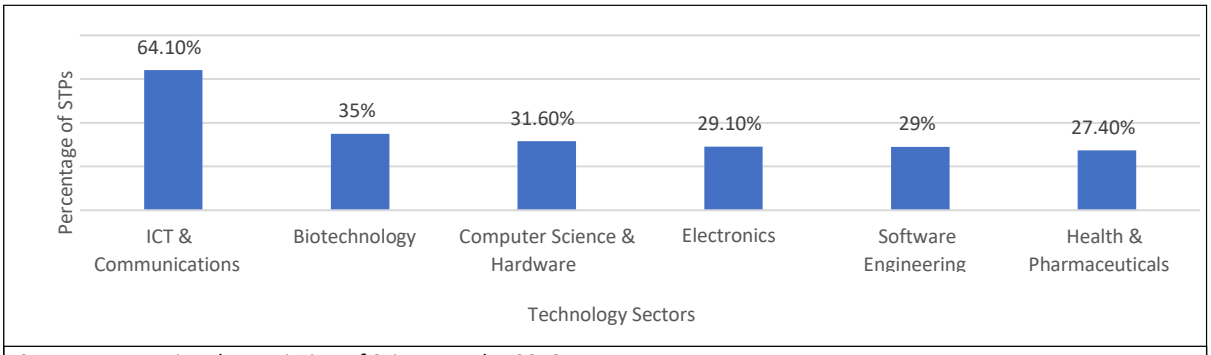
Figure 3.9 Number of Science Parks– 2018



Source: International Association of Science Parks, 2018

As per data available from International Association of Science Parks, in 2018, the major technology sectors in science technology parks across countries is ICT & Communications (64 per cent). However, there are about 35 per cent parks have biotechnology as focus and about 27.4 per cent parks have health & pharmaceuticals as focus areas.

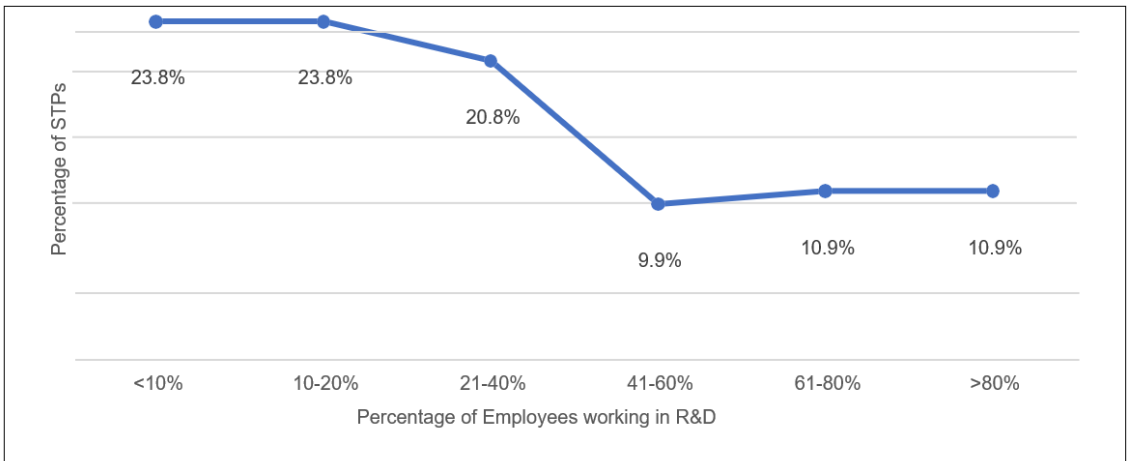
Figure 3.10 Main Technology Sectors of STPs in 2018



Source: International Association of Science Parks, 2018

Research and Development is a vital activity for the great majority of STPs/AOIs, research and technological institutes and universities being some of the main elements present within the parks/area's premises. 21.8 per cent of STPs in 2018 had more than 60 per cent of their employees working in R&D and a further 9.9 per cent with somewhere between 41 and 60 per cent.

Figure 3.11 Percentage of employees working in R&D in STPs/AOIs (2018)



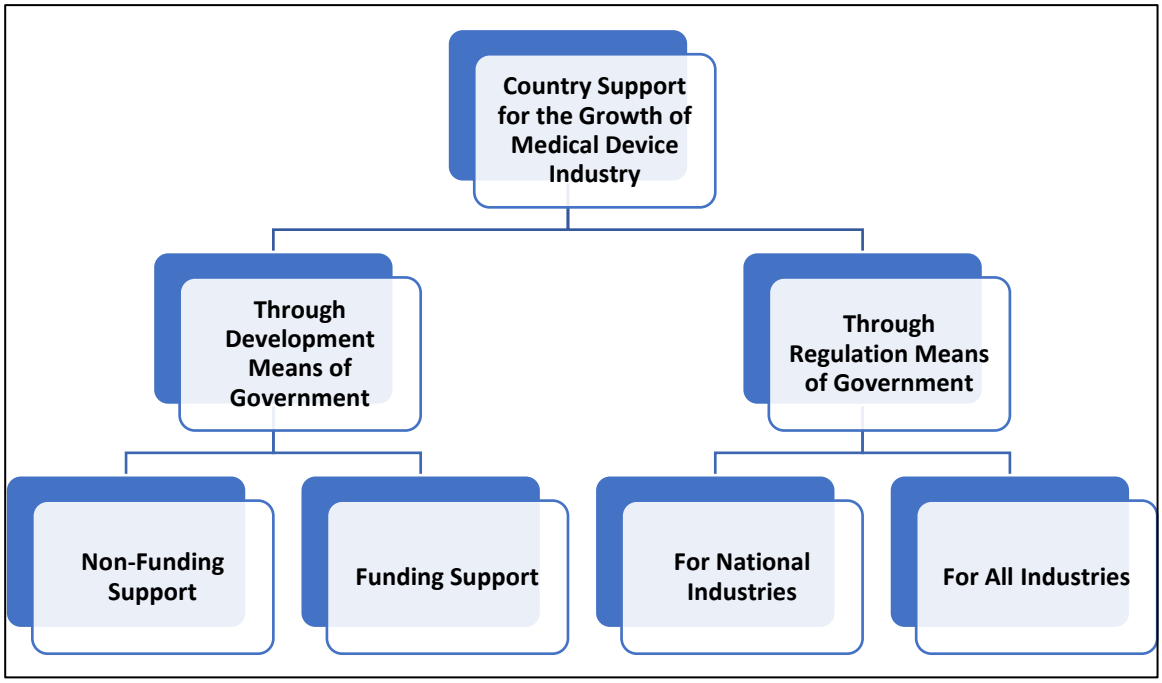
Source: International Association of Science Parks 2018

3.11. Role of Government

Countries provide support mainly in two forms, through funding & non-funding measures and through

regulatory support.

Figure 3.12 Different Type of Support provided by Governments



Source: Study Team

3.11.1 Role of Government of Various Countries[22]

Governments and other agencies provided a range of support to the industries. A snapshot of the same is as below:

- **Brazil** – Among others, support provided include quicker granting of patents and approval of clinical trials, enhanced validity of registration - especially for essential products, promoting regulatory convergence with International Medical Device Regulator Forum (IMDRF), etc. Of special interest is Productive Development Partnership (PDP). Here foreign companies can enter into partnership of five years with local unit to supply for public purchase with a reserved market share and a definite technology transfer post that time period.
- **China** – Among others, support provided include restrictive procurement policies, targeted export promotion, expedited regulatory approvals for deemed innovative devices, mergers, and acquisitions of specialty foreign firms, etc. China Strategic Alliance of Medical Device Innovation of institutions in the medical device domain was created in 2009. This was a sectoral alliance at the national level. Soon similar types of networks were established at regional, provincial, and city-level alliances in thematic areas. Large firms were promoted to create Centre of Excellence with Government support. “Made in China 2025” initiative obliged hospitals to use domestically produced devices to the extent of 50 percent by 2020 and 95 percent by 2030. Innovative products having a Chinese patent were given faster approval at discounted price. China has launched five industrial parks in 2020 (area of around 60 square kilometer), which will specialize in various aspects including high-end medical equipment.

- **France** – France exhibits significant contribution of both public and private sector in R&D, networking, promotion of start-ups and creating appropriate factor conditions at the cluster level. A fund for €25 billion public investment in the French research system over the next 10 years, including €5 billion in health sciences is a major support. A €10 billion fund for future investments for 2021- 25 will support strategic sectors including the top two priority sectors in health: bio-production of innovative therapies and digital healthcare. Research tax credit amounts to 30 per cent of R&D expenditure. Expenditures subcontracted to public bodies are considered at a rate of 200 per cent, remuneration for young doctoral students is considered at a rate of 400 per cent,

[22] Further details with sources available in Chapter 4

and depreciation of research material is taken into account at a rate of 175 per cent. Public-Private Partnerships are promoted through placement (12 to 24 months) of private R&D personnel in public laboratories with 80 per cent of the salary covered by the State. Four research centers (CEA, CNRS, Inserm and Pasteur Institute) are in the World's Top 25, a brand that attracts talent.

- **Germany** – Innovative medical devices can quickly go to clinical practice in general. New (in Germany) Methods of Treatment and Screening (NUB) is a payment scheme for remunerating cost-intensive, innovative services and technologies. Horizon 2020 program (EU) offers grant up to 100 per cent of R&D project expenditure with a total budget of 77 billion euro. Central Innovation Program for SMEs (ZIM) reimburses cost of joint R&D by SMEs with grants up to 55% for a maximum of Euro 385,000 per project. Innovative cluster networks of stakeholders – firms and their support institutions including hospitals, universities, research institutions are promoted. Cluster promotion teams help obtain funding for joint R&D projects, provide share facilities, and organize training. German notified bodies like TÜV and DEKRA has set in motion international standards as a branding tool. Apprenticeship based training give medical technicians access to different recognized trades. 20 per cent of German companies take part in the dual vocational training system, thereby turning apprentices into specialists and more than seventy percent are absorbed post apprenticeship. The Joint Task for Improving Regional Economic Structures defines maximum possible investment and wage linked incentives rates for all regions eligible for funding throughout Germany.

- **Italy** – Among others, support provided include tax credit for fundamental/industrial/ developmental R&D done on its own or jointly with universities/research institutes/similar organizations/other enterprises and for expenditure on salary, depreciation, expert cost, patent etc. for an amount of at least 30,000 Euros per year. Besides several venture capitals and business angels have also been created to finance new enterprises in life sciences. Various regional level incentives are also provided to the units including non-repayable grants for R&D from 15 to 80 per cent, private-public equity financing up to 1.5 million euros and high involvement of human resources in the R&D area of the medical devices sector.

- **Japan** – At one point of time, price maintenance premium (PMP), a mechanism designed to accelerate introduction of innovative pharmaceutical products, used parameters like number of local clinical trials and product launches give support to Japanese companies. However, of late clinical data of abroad are being accepted. The reimbursement price of existing products always decreases. This necessitates innovation to maintain profits. Also, in the past (2013), growth strategy measures such as accelerating regulatory approvals and eliminating so-called "medical device lags" and "drug lags" was addressed. A variety of financial support is also provided by various provincial governments to industries including medical devices.

- **Malaysia** - Among others, support provided include promotion of medical tourism. Malaysia Healthcare Travel Council (MHTC), supports healthcare and travel industry by creating specialized public-private partnerships in Malaysia and nearby countries where there is demand, e.g., Indonesia, Vietnam, Myanmar, etc. Other supports include organizing medical visas, guest lounge at international airports of Malaysia, tie up with 21 elite (accredited globally) and 59 ordinary hospitals and providing fiscal incentives including income tax exemption for establishing new healthcare facilities or renovating/modernizing existing facilities to promote healthcare travel. Promotion of Investments Act (PIA) 1986 targets foreign investments by providing certain reliefs from income taxes and investment tax allowances and targets electromedical equipment, cardiovascular devices, orthopedic devices, IVD, wound care management products, products from convergence of technology, etc. among others. Tax incentives to promote R&D in the domestic medical device industry is also provided.

- **Norway** - Among others, support provided include promotion of networks of firms and support stakeholders (hospitals, finance, knowledge and research institutions, regional institutions) to facilitate commercialization. Network managers are supported to expedite the process. R&D support comes through grants to start-ups and SMEs. Investinor (government supported) provides venture capital to Norwegian companies aiming for international growth and expansion. Argentum, created by Ministry of Trade and Industry has invested in life science companies in Sweden and Norway since 2007.

- **Singapore –** Among others, support provided include creating a country brand as a destination to high-value production hub, promoting research through branding like getting accredited through JCI, collaboration with Centre for Integration of Medicine and Innovative Technology in Boston, USA, etc. National Research Foundation launched Singapore Health Technologies Consortium (HealthTEC) 2019. It connects academics and industry partners, provide seed funding, and facilitates licensing of locally developed technologies. The country is working towards making manufacturing a seamless process for investors and start-ups by providing a single-window support to find R&D resources, build and staff a manufacturing facility, develop a sales organization and then navigate through all the regulatory red tape and manage it. Apart from funding, Government agencies provide high value R&D for own researchers as well as from abroad - MIT and Harvard and global supply chain. Singapore is also investing in partnerships between OEMs and suppliers of automation and advanced manufacturing technologies through the SGD 250 million Partnerships for Capability Transformation (PACT) program. It also provides regulatory support to cut down registration time, with regulating bodies providing pre-registration consultancy.

- **South Korea** - Government is in constant pursuit to reduce device approval time. It also adopted a "negative regulatory approach" for products that require lesser safety checks. Preferential market entry permission was also planned for AI, 3D printing and robotics. Korea also promotes creating research-oriented hospitals and establishing industry-hospital cooperation bodies. It will also support heavily (USD10.3 billion) in R&D of medical device over the next six years. Korea also promotes MD parks.

- **Switzerland** - Large companies like Novartis and Roche are divesting non-core areas and simultaneously focusing on innovative products. Various research centers are now doing collaborative research to utilize their specialization. Swiss government allocated USD 70 million to build a national coordinated data infrastructure to support research by hospitals, universities, and other research institutions. The country is also promoting innovation parks. Swiss Innovation Agency has an annual budget of around 200 million Swiss francs. Besides there is complete exemption from corporate and capital taxes for ten years for start-ups and newly established foreign companies. Also, the firms gain a lot while operating in deep and wide clusters.
- **United States of America (USA)**– USA has made very high Public Investment in R&D with the lead role played by national-level health institutes. During the last 20 years (1998-2018), the National Institute of Health (NIH) alone has spent USD 433 billion through its various specialized institutions. The fund support tripled from USD 9.8 billion in 1999 to USD 28 billion (more than INR 22 million crores) in 2019. NIH provides these funds to around 25 national and therapeutic level specialized institutes. These Institutes in turn provide funds to various public and private institutes and businesses, especially small businesses. Around 80 per cent of NIH support to NIHLBI goes for funding research grants. US medical devices giants have grown in clusters in conjunction with other life sciences clusters and are characterized by the presence of lead firms, other life sciences (biotechnology/pharmaceuticals) firms and support firms, a large number of research-active universities and institutions, hospitals of repute, public and private sector in R&D and specialization. While the large firms do invest heavily in R&D, smaller firms, start-ups, and doctors (20% of patents) are doing the research focused on specialized therapeutic areas. Long term supply contracts with large institutional purchasers - Group Purchasing Organizations (GPOs) produce cash flow.

Broadly, countries provided support in two forms – financial and non-financial including regulatory support. A snapshot of the same is as below

3.11.2 Government Support (Financial)

3.11.2.1 Tool 1 – Substantial R&D Support

Almost all the countries invested a substantial amount in R&D. Although annual R&D expenses in the medical devices sector could not be ascertained, however, the amounts run into billions of USD and Euros. During the last 20 years (1998-2018), the National Institute of Health (NIH) alone has spent USD 433 billion in terms of research grants through its various specialized institutions. The fund support tripled from USD 9.8 billion in 1999 to USD 28 billion (INR 22 million crores) in 2019. NIH provides these funds to around 25 national and therapeutic level specialized institutes. These Institutes in turn provide funds to various public and private institutes and businesses, especially small businesses. The Swiss Innovation Agency (Innosuisse) has an annual funding budget of around 200 million Swiss francs. South

Korea plans to invest USD10.3 billion in medical device R&D over the next six years. Singapore's Research, Innovation and Enterprise plan has allocated SGD 3.2 billion to advanced manufacturing and engineering research through 2020. The French government has set up a fund for €25 billion in public investment in the French research system from 2021 to 2030, including €5 billion in health sciences. A €10 billion fund for future investments for 2021-25 will support strategic sectors including the top two priority sectors in health: bio-production of innovative therapies and digital healthcare.

3.11.3 Government Support (Non-Financial)

3.11.3.1 Tool 1 – Branding

To become a global preferred destination for doing R&D, countries which are traditional leaders in this area have established a brand for their globally acclaimed research organization. Countries which are planning to leapfrog are creating the brand image by linking up with globally acclaimed research organizations (e.g., Stanford India Bio Design).

3.11.3.2 Tool 2 – Park

While science parks are an order of the day, countries like China, Norway, South Korea, Switzerland, etc. have promoted R&D/innovation-oriented parks too. In 2020, China launched 5 innovation parks for promoting medical devices with each specializing in certain areas. The parks will also get integrated with biomedical big data facilities.

3.11.3.3 Tool 3 – Networking

Creation of formal networks and supporting formal networks of industry/academia/hospitals is a powerful tool for promoting R&D and innovation. This model was seen as getting implemented in France, Germany, Norway, Switzerland, and Singapore. Joint research is an effective globally acceptable norm in high tech products.

3.11.3.4 Tool 4 - Promoting National Industry

These are being done in developing economies, e.g., China, Singapore, etc. through various innovative tools like

- Focused export promotion and creation of hospitals (China in Africa)
- Investments in lower-tier hospital infrastructure
- Support large firms to create Centre of Excellence
- Made in China 2025 initiative - hospitals to use 95 percent domestically produced devices by 2030
- Promote high tech manufacturing as done in Singapore
- Promoting a high-value manufacturing Hub with single window support

3.11.3.5 Tool 5 - Global investment

Promoting national industry by attracting global investment is another tool being used in developing medical devices economies like China, Singapore, etc. through various innovative tools like

- Presence of Free Trade Zones that encourages foreign investment
- Restrictive procurement policies at times allowing only high-tech devices not produced in the country (China)
- Promoting foreign investment in electronics and equipment through incentives like customs duties reduced price for industrial land, preferential tax
- Presence of backward linkage in areas where FDI came
- Mergers and Acquisitions by local firms

3.11.3.6 Tool 6 - Support for Start-up

India is well informed and well-composed to promote start-ups. Government of India and State Governments have taken several steps for the same. Deep tech start-ups get special support in Singapore. JETRO operates Global Acceleration Hub in 12 countries and AUSTRADE has built launching pads in five countries for Australian Start-ups. In USA start-ups do the R&D and production is picked up by firms in an open innovation system running there.

3.11.3.7 Tool 7 – Strengthening Factor Condition

These are found in a traditional cluster. These include the following tools:

- Support partnerships between foreign corporations and local suppliers to develop supply chain

- Growth of clusters of medical devices in conjunction with other life sciences cluster
- Presence of large firms, supply chain and involvement of universities and medical centers in research

3.11.3.8 Tool 8: Promote Medical Tourism

- Create a special cell to promote
- Creating representative offices in countries where there is demand
- Organizing medical visas
- Tie up with hospitals
- Provide fiscal incentives including income tax exemption for establishing new healthcare facilities or renovating/modernizing existing facilities

3.11.3.9 Tool 9 - Regulatory Support for National Industry

These include tools like

- Promoting patents
- Legislation compelling purchase of certain types of equipment from domestic manufacturers
- Clinical trials in the host country
- Faster Approval for host country patented products

3.11.3.10 Tool 10: Regulatory Support for all Industries

These include tools that promote innovation as well as production and are found in developed as well as developing nations

- Extending registration validity timeframes
- Regulatory convergence based on IMDRF
- Expedited registration process for essential products
- Reserved market share for foreign companies if they agree to transfer technology
- Shortened approval time for clinical trials
- Expedited regulatory approvals for innovative devices
- Fast track for clinical trials for innovative products
- Quick entry for innovative devices in clinical practice
- Decreasing reimbursement price of existing products necessitates innovation
- Paid Pre-market Consultation (PMC) Scheme by Singapore's Health Science Authority (HSA) on regulatory requirements
- Relaxation in registration for new products
- Joint purchase for hospitals by institutional purchasers

3.11.4 Synopsis of Country Support

Table 3.5 Support Provided by Various Governments to their respective Medical Device Industry

	Country	Action for Promotion of Medical Device Industry	Nature of Activities for Promoting Med Tech Industry
1	Brazil	Investment in R&D for healthcare IT – increased role of IoT and AI	Government funding support for innovation
2	Brazil	Promoting patents	Regulatory support for national industry
3	Brazil	Extending registration validity timeframes	Regulatory Support for all industries
4	Brazil	Regulatory convergence based on IMDRF	Regulatory Support for all industries
5	Brazil	Expedited registration process for essential products	Regulatory Support for all industries
6	Brazil	Reserved market share for technology transfer	Regulatory Support for all industries
7	Brazil	Shortened approval time for clinical trials	Regulatory Support for all industries
8	China	Launched five industrial parks in 2020, in a bid to build itself into an innovation highland for the biomedical industry with global knowledge.	Government support for innovation through parks
9	China	Support creation of networks at national and regional levels of university, hospital, and industry	Government support for networking
10	China	Investments in lower-tier hospital infrastructure	Government support for promoting national industry
11	China	Promote exports to Africa	Government support for promoting national industry

	Country	Action for Promotion of Medical Device Industry	Nature of Activities for Promoting Med Tech Industry
12	China	Created hospitals with country staff	Government support for promoting national industry
13	China	Support large firms to create Centre of Excellence	Government support for promoting national industry
14	China	Made in China 2025 initiative - hospitals to use 95 percent domestically produced devices by 2030	Government support for promoting national industry
15	China	Presence of Free Trade Zones has encouraged foreign investment	Government support for promoting national industry through global investment
16	China	Restrictive procurement policies allowing only high-tech devices not produced in China	Government support for promoting national industry through global investment
17	China	Promoting foreign investment in electronic and equipment through incentives like customs duties reduced price for industrial land, preferential tax	Government support for promoting national industry through global investment
18	China	Presence of backward linkage in areas where FDI came	Government support for promoting national industry through global investment
19	China	Mergers and Acquisitions by local firms supported by Government	Government support for promoting national industry through global investment
20	China	Price cuts through group purchase	Price reduction steps
21	China	Urged all public hospitals to remove price mark-ups of high value medical consumables	Price reduction steps
22	China	Standardize bidding classifications and codes of high value consumables	Price reduction steps
23	China	"Two Invoices" system	Price reduction steps
24	China	Expedited regulatory approvals for innovative devices	Regulatory Support for all Industries
25	China	Legislation compelling purchase of certain types of equipment from domestic manufacturers	Regulatory support for national industry
26	China	Clinical trials in China	Regulatory support for national industry
27	China	Faster Approval for Chinese Patented Products	Regulatory support for national industry
28	France	Huge Public support for R&D	Government funding support for innovation
29	France	Research Branding	Government support for branding
30	France	Promotion of health big data (HBD)	Government support for data interface
31	France	G5 Health Forum of principal French companies in the fields of health and life sciences.	Government support for networking
32	France	Fast track for clinical trials for innovative products	Regulatory Support for all Industries
33	Germany	Scheme for remunerating cost-intensive, innovative services and technologies	Government funding support for innovation
34	Germany	Grant up to 100% of R&D project expenditure with a total budget of 77 billion euro for SMEs	Government funding support for innovation
35	Germany	Reimburses cost of joint R&D by SMEs with grant up to 55% for a maximum of Euro 385,000 per project	Government funding support for innovation
36	Germany	Sizeable R&D Incentive for SMEs - grant up to 50 percent of project costs	Government funding support for innovation
37	Germany	Setting International Standards as a Branding Tool	Government support for branding
38	Germany	Notified body of country origin – a branding tool	Government support for branding
39	Germany	Innovative Cluster Networks	Government support for networking
40	Germany	Apprenticeship training - 323 courses - more than 70% taken on as employees	Government support for skilling
41	Germany	Loan support to Start-ups	Government support for Start-ups
42	Germany	Quick entry for innovative device in clinical practice	Regulatory Support for all Industries
43	Italy	Tax credit on research	Government funding support for innovation
44	Italy	Preferential tax policy on revenue generated by intellectual property rights	Government funding support for innovation
45	Italy	State level grants for up to 100 million Euros and up to 80 per cent	Government funding support for innovation
46	Italy	Recognition of the status of “innovative” SMEs	Government support for Start-ups
47	Italy	Special support to “innovative” to start-ups	Government support for Start-ups
48	Japan	Decreasing reimbursement price of existing products necessitates innovation.	Regulatory measure for innovation
49	Malaysia	Provides reliefs from income taxes and investment tax allowances.	Government funding support for innovation
50	Malaysia	Extends a full tax exemption incentive of 15 years for firms with ‘pioneer status’	Government funding support for innovation

	Country	Action for Promotion of Medical Device Industry	Nature of Activities for Promoting Med Tech Industry
51	Malaysia	Tax incentives to promote R&D in domestic medical device industry	Government funding support for innovation
52	Norway	R&D Support	Government funding support for innovation
53	Norway	Presence of highly developed research parks	Government support for innovation through parks
54	Norway	Promotion of networks	Government support for networking
55	Norway	Cluster level associations	Government support for networking
56	Norway	Creating Appropriate Factor Conditions	Government support for strengthening factor conditions
57	Norway	Regional institutions are set up to facilitate commercialization	Government support for strengthening factor Conditions
58	Singapore	Promote R&D status	Government funding support for innovation
59	Singapore	Substantial R&D Support	Government funding support for innovation
60	Singapore	Branding in Research through global collaboration	Government support for branding
61	Singapore	Centre of Regulatory Excellence (CoRE), promoted by Medical School	Government support for lead by medical sector
62	Singapore	Health Technologies Consortium (HealthTEC) of academics and industry provide seed funding and facilitates licensing of locally developed technologies	Government support for networking
63	Singapore	MedTech Manufacturing Consortium helps local firms	Government support for networking
64	Singapore	Promote advanced manufacturing	Government support for promoting national industry
65	Singapore	Promoting a High Value Manufacturing Hub with single window support	Government support for promoting national industry
66	Singapore	Special support to early-stage Deep Tech start-ups	Government support for Start-ups
67	Singapore	Support partnerships between foreign corporations and local suppliers to develop supply chain	Government support for strengthening factor conditions
68	Singapore	Paid Pre-market Consultation (PMC) Scheme by Singapore's Health Science Authority (HSA) on regulatory requirements	Regulatory Support for all Industries
69	South Korea	Public R&D Support	Government funding support for innovation
70	South Korea	Park for R&D	Government support for innovation through parks
71	South Korea	Creating research-oriented hospitals to establish "industry-hospital cooperation organizations"	Government support for lead by medical sector
72	South Korea	Relaxation in Registration for New Products	Regulatory Support for all Industries
73	Switzerland	Substantial R&D Support	Government funding support for innovation
74	Switzerland	Exemption from Taxes	Government funding support for innovation
75	Switzerland	Attractive destination for professionals	Government support for branding
76	Switzerland	National Data Infrastructure	Government support for data interface
77	Switzerland	Promotion of Innovation Park	Government support for innovation through parks
78	Switzerland	Setting up Innovation Parks	Government support for innovation through parks
79	Switzerland	Research centers doing collaborative research to utilize specialization	Government support for networking
80	Switzerland	Operating from a cluster with strong eco system	Government support for networking
81	USA	High Public Investment in R&D	Government funding support for innovation
82	USA	R&D involves research through specialized medical institutes	Government support for lead by medical sector
83	USA	Joint R&D	Government support for networking
84	USA	Innovation by start-ups, small firms, and physicians and production by large firms	Government support for Start-ups
85	USA	Growth of clusters of medical devices in conjunction with other life sciences cluster	Government support for strengthening factor conditions
86	USA	Presence of large firms, supply chain and involvement of Universities and Medical centers in research	Government support for strengthening factor conditions
87	USA	Joint Purchase for hospitals by large institutional purchasers	Regulatory Support for all Industries
Source: Study Team Analysis			

In summary, the kind of support being provided by governments of various countries ranges from

providing support for innovation through funding & innovation parks, to support for branding & networking, support for data interface, support for lead by the medical sector, promoting national industry through various means including through global investment, skilling, strengthening factor conditions, price reduction steps, support for start-ups and regulatory support for national industry and all supporting industries.

3.12. Best Potential Entrepreneur – Strategy of Champions

Some firms have a clear advantage in certain domains. For example, Johnson and Johnson (USA) is clearly a leader in orthopedic implants, Roche (Switzerland) in IVD, Siemens Healthineers (Germany) in Diagnostic Imaging and Medtronic (USA) in Cardiac Devices. If we look at the strategies adopted to achieve the global leader status in specific segments, we find certain common themes.

The first being continuous innovation in area of specialization. This is reflected in the significant R&D investments made by these companies in their areas of specialization. Second is diversification in related segments by collaboration (acquisitions) of specialized companies. These companies have collaborated with and acquired other companies which have been able to create a niche through their specialization. The third important factor is the overall support framework of the country in terms of incentivizing innovation and other economic incentive packages. The next significant factor is the promotion and collaborative policies with start-ups in related fields and lastly a strong patent regime. A combination of these five factors has helped these countries emerge as leaders in their specific domain areas. This is further expanded below in a company/country wise analysis.

3.12.1 Johnson and Johnson (J&J) – leader in Orthopedic Implants

J&J is a leader in orthopedic implants. Reasons of its excellence, include among others, its capacity for collaborations through mergers and acquisitions, commitment to innovation, excellent change management capacities including innovative business model, a strong ecosystem, and the general support system of the country.

3.12.1.1 Focus on Innovation, Quality and Reliability

J&J opened a biotech incubator (JLINX) in Belgium, with investment from Bioqube Ventures. JLINX acts as an eco-system support unit by making available capital, HR for R&D, infrastructure, etc. to research scientists and early-stage entrepreneurs during a very early phase of product development. Its innovation arm, Johnson & Johnson Innovation LLC (JJI), created the Centre for Device Innovation, which promotes medical device development in partnerships and acquisitions of small-scale start-ups. This is in addition to two life sciences start-up incubators, TMCx and TMCx+. J&J also established the J&J Institute for Professional Medical Resources. National Institute of Pharmaceutical Education and Research (NIPER), Ahmedabad (NIPER-A) has also signed an MoU with J&J to develop an ecosystem for the development of the medical devices sector in India.

3.12.1.2 Change Management Systems

J&J also modifies its business model. For example, in 2016, it streamlined its consumer and medical devices operations when it created a Medical Device Management unit with three global franchises (Ethicon Surgical, Biosense Webster Cardiovascular, and DePuy Synthes Orthopedics), a single research and development segment, and one supply chain unit.[23] J&J started a “Supplier Diversity Program” in 1998 to promote suppliers from businesses with diverse backgrounds and ownership.

3.12.1.3 Mergers and Acquisitions

Like many champions, J&J also does strategic M&A and collaboration. J&J acquired DePuy Synthes and merged them together as a single company doing orthopedics business. Another example is the USD 3.4 billion purchase of Auris Health.[24]

3.12.2 Roche – leader in IVD

Roche preempts patients’ needs. This has led Roche to become the biggest market leader in IVD segment. The key reason being its extensive work in R&D. In 2020 the company has spent over USD 11 billion[25] in R&D. The major cause of this success is also attributable to Roche’s constant nature of collaborating and funding medical researchers and institutes to develop, acquire and later industrialize

[23] https://www.mpo-mag.com/heaps/view/3670/1/253220

[24] https://www.mpo-mag.com/heaps/view/3670/1/253220

[25] https://www.evaluate.com/vantage/articles/data-insights/other-data/roche-remains-big-pharmas-biggest-rd-spender

medical solutions.

3.12.2.1 Revolutionizing Medical Industry

Roche was among the first companies that foresaw the future of industrial production of standardized medicines. Founded in 1896, it was the first company to mass produce synthesized vitamins in 1934. In 1968, Roche forayed its way into Diagnostics market by setting up laboratories across Europe and in 1986 it acquired Biomedical Reference Laboratories to become one of the biggest diagnostic companies in the US. Roche has made 41 acquisitions and 27 investments by spending over USD 75.73 billion on the acquisitions.

- Acquired Biomedical Reference Laboratories to expand Diagnostic Market in 1986
- Roche acquired Syntex in 1994 to produce therapeutic solutions
- In 1996 Roche entered into a collaboration agreement with Gilead Sciences
- In 1998 Roche acquired Boehringer Mannheim and became the market leader in the global diagnostic market
- In 2005, GlycArt Biotechnology (a Swiss firm) was acquired by Roche which gave them access to various approved technologies.
- In 2008 Roche acquired Ventana Medical Systems specializing in instrument reagent systems.
- In 2009, Roche acquired Genentech

3.12.2.2 Entering Newer Areas

Here there is some limited evidence of strategizing growth through Collaborations/Acquisitions

- 1968-69: Opens Roche Institute of Molecular Biology and Basel Institute for Immunology to research and develop IVD reagents
- 1979: Roche launched the world's first automated laboratory diagnostics device: Cobas Bio 1992: Develops HIV test kits and PCR test kits
- 1995: Develops Accutrend and Accu-Chek, kits for convenient diabetes management
- 2007: CINtec Histology was developed to provide objectivity to diagnostic interpretation that helps all pathologists identify more cervical diseases.
- 2018: Roche launches CoaguChek Vantus to monitor coagulation levels wirelessly 2020: Launch of 15 new diagnostic solutions for COVID-19

3.12.2.3 Policy Interventions[26]

Through various industry fora like IFPMA, EFPIA, PhRMA, AdvaMed, etc. Roche promotes policy interventions which are good for the industry.

3.12.2.4 Ecosystem Support

With support from the Government and favorable ecosystem, Roche has paved its path of success for itself and others in Switzerland. These include among others R&D support and support to start-ups and an advanced patent system.

3.12.3 Medtronic – leader in Cardiac Devices[27,28,29]

As of 2020, 30 per cent of the turnover of Medtronic is in the area of cardiac devices. It spent a whopping 15 billion USD during the last 7 years in R&D. However, this is a journey of 7 decades starting in 1949 in Minnesota as a repair shop for medical electronics. Analysis of the ecosystem suggests the factors that made Medtronic a leader in cardiac devices include among others are its quest for specialization in its area of strength, collaborations in new areas, a strong ecosystem, and the general support system of the country.

3.12.3.1 Continuous Innovation in the field of Specialization[30]

[26] https://www.roche.com/sustainability/impact/public-policy

[27] https://www.medtronic.com/us-en/about/history.html

[28] https://www.medtronic.com/us-en/healthcare-professionals/external- research-program/guidelines.html

[29] The Minnesota Medical Devices Cluster, Michael E. Porter, Project Adviser: Professor Jorge Ramirez-Vallejo Harvard Business School May 6, 2011

[30] The Minnesota Medical Devices Cluster, Michael E. Porter, Project Adviser: Professor Jorge Ramirez-Vallejo Harvard Business School May 6, 2011

As early as the 1930s, the University of Minnesota was becoming specialized as a cardiac care center. The first successful open-heart surgery took place there in 1952. Pacemakers of those times were huge box types running with electricity. These were being used for post-operative care of heart surgeries. Often, sudden power cuts endangered the lives of postoperative open-heart surgery in 1957. At the request of a heart surgent at the University of Minnesota Earl Bakken created a battery-operated pacemaker. In less than a month it started saving lives. Since then, innovation in the cardiac threptic division has been almost continuous.

1957: First implantable pacemaker 1958: First implantable pacemaker
1977: Prosthetic heart valve
1977: Created a heart-valve division
1977: Medtronic-Hall mechanical heart valve to the market that same.
1996: Implantable Cardioverter Defibrillators
2010: Transcatheter Heart Valves
2011: Revo MRI SureScan (2011) for patients with pacemaker
2016: Micra - world's smallest pacemaker, implanted directly in the patient's heart (result of a decade-long effort called "deep miniaturization.".

3.12.3.2 Entering Newer Areas
Here there is some limited evidence of strategizing growth through Collaborations/Acquisitions

- 1983: Neurostimulation in collaboration with French doctors.
- 1999: Acquiring spine leader Sofamor Danek Group to augment its growing spine and biologics business.
- 2001: Medtronic bought diabetes market leader MiniMed, where a team of biomedical engineers had developed a continuous glucose monitor.

3.12.3.3 Eco System
This included support from networks like Medical Alley (a trade association), MNBIO (biotechnology trade association) and Life Science Alley. The Mayo Clinic and The University of Minnesota Hospital serve the dual purpose of buyer as well as talent supplier. Other factors included state Investment in education infrastructure, presence of complimentary clusters which include among others IT, analytical instruments, presence of large firms, R&D centers, hospitals, and educational institutions that provide sophisticated demand for goods and services, etc. Medtronic also promotes External Research Program (ERP) and evaluates each ERP submission for, among other factors, scientific merit, strategic interest, and degree of new scientific and clinical evidence. Medtronic receives many requests for support of ERP proposals and as a result, not all submissions can be supported.[31]

3.12.3.4 Overall Support Conditions: These include innovation by start-ups, small firms and physicians, public Investment in general R&D which facilitated growth of the industry in general, etc.[32]

3.12.4 Siemens Healthineers – leader in Diagnostic Imaging[33]
Siemens Healthineers is a global leader in the medical devices space. It develops, manufactures, and sells a wide range of products in more than 180 countries worldwide. The company started its operations in mid-19th century as a part of Siemens AG and the company in its current form was created in 2016. The company has a long history and proven track record of developing and introducing technologies in the areas of diagnostic /medical imaging. The imaging segment contributed ~ 63 percent of the company's revenue in 2020. The company invests about 9 percent of its annual revenue on R&D with nearly 15 percent of workforce engaged in R&D.

3.12.4.1 Continuous Innovation in field of Specialization
Siemens manufactured X-ray tubes as early as in 1896 only a year after discovery of X-ray by Wilhelm Conrad Röntgen. Since then, the company has been at the forefront of innovation in the field of diagnostic imaging and is widely accepted as one of the global leaders in this space.

- 1953: First company to use the ultrasound technique for echocardiography 1960: First "real-time" ultrasound unit
- 1975: Launched computed tomography scanner

[31] https://www.medtronic.com/us-en/about/history.html

[32] http://grants.nih.gov/grants/new_investigators/index.htm#earlystage, www.nih.gov and www.nhlbi.nih.gov/

[33] https://www.siemens-healthineers.com/investor-relations

- 1983: First magnetic resonance imaging (MRI) scanner
- 1999: The company developed and integrated an image processing software for company's various imaging devices thus providing a single interface for all of company's imaging devices
- 2000: Combined positron emission tomography (PET) with computed tomography (CT)
- 2010: Launched Biograph MMR.

3.12.4.2 Entering Newer Areas

The company has used acquisitions effectively to grow in the diagnostic imaging space. The pace of acquisitions has really grown since 2005 with the company acquiring 10 companies overall with nearly 50 percent of these acquisitions coming in diagnostic imaging space.

- 2005: Acquired CTI Molecular Imaging
- 2012: Siemens acquired Penrith Corporation, manufacturer of ultrasound imaging systems
- 2016: Acquisition of NEO New Oncology AG helped expand molecular diagnostics portfolio
- 2020: Will acquire a lead firm in radiation - Varian Medical Systems

3.12.4.3 Eco System

Erlangen, Nuremberg (company headquarter) that houses the Medical Valley European Metropolitan Region Nuremberg (EMN) is a leading international medical technology cluster. In 2010, German Ministry of Education and Research chose Medical Valley EMN as a 'Centre of Excellence for Medical Engineering'. 2 university hospitals, 8 other universities and 21 research institutes promote R&D for the development of medical devices sector which in turn helped save costs for the medtech firms in the area. Nuremberg region also has another cluster in the pharma space which is closely related to the medical devices. Besides, there are several large medical devices companies that have a base in the Nuremberg region. Besides the larger players, there are nearly 500 small & medium scale medical device companies.

3.12.4.4 Overall Support Conditions

In general, the firms in this area were supported through huge national and EU funding, presence of innovative networks, promotion of start-ups, easy reimbursement for innovative medical device, setting of International Standards as a branding tool, promotion of apprenticeship-based training, R&D incentive and product linked incentives created the support eco system for the company to flourish.[34]

[34] https://www.nrwinvest.com/en/nrw-as-location/how-to-do-business-in-nrw/incentive-programs/cash-incentives-for- investment-projects/, https://www.gtai.de/gtai-en/invest/investment-guide/incentive-programs/r-and-d-incentives/r-d-grants-in-germany-72756, https://www.bmbf.de/de/kmu-innovativ-561.html

4. Country Analysis

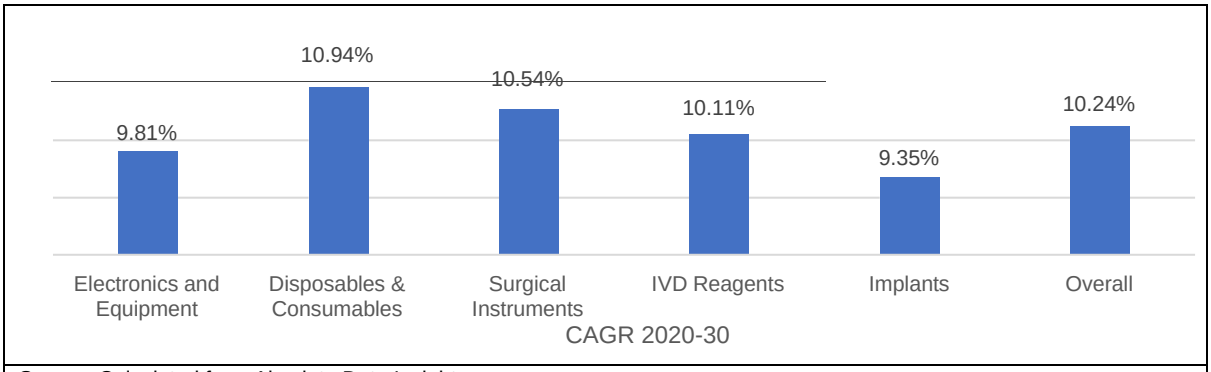
4.1. Brazil

Health expenditure in the country (as percentage of GDP) as of 2019 was 9.59 percent, which is closer to the amount spent by high income countries. However, the hospital infrastructure in terms of beds available was closer to the middle-income countries. The number of physicians in the country in 2019 was significantly lower than the number of physicians in high income countries. The number of hospital beds per 1000 people is also much less than the high-income countries, but comparable to middle-income countries.

4.1.1 Industry Structure

The medical device sector has been the main growth area in Brazil post 2017 when it started registering GDP growth post- recession. More than 50% of the companies are medium size enterprises. Brazil's market size for medical device in 2020 was approximately USD 8.68 bn. Medical devices market is expected to grow at 10.24% over the next decade and is expected to be USD 23.02 bn by 2030. Among the segments, the Disposables and Consumables segment is expected to grow at the fastest pace at about 10.94% over the next decade. Fast increase in healthcare expenditure, number of hospitals, automation, and adoption of systems with AI and machine learning and enhanced healthcare facilities are expected to bring growth in the market in the coming years. IVD Reagents and Surgical Instruments are expected to grow fast too, at 10.11% and 10.54% respectively.[35]

Figure 4.1 Brazil Medical Devices Segment Growth Rates (2020-30)



Source: Calculated from Absolute Data Insights

While exports of medical devices from Brazil grew only at CAGR of 2.13% between 2016-20, the imports of medical devices grew by over 8.64% over the same period. Imports of IVD Reagents grew by 34.17%, while exports of the same grew by 48.10% over the period 2016-20

4.1.2 Major Companies[36]

Some of the lead firms are General Electric, Johnson & Johnson, Medtronic, Baxter International, Koninklijke Philips Electronics NV., Geratherm, Edwards, Terumo, Fresenius Medical Care AG & Co., Boston Scientific Corporation, Cardinal Health, St. Jude Medical Inc., Siemens Ltd, and Hitachi Medical Corporation, among others. Adavium is a leading domestic medical devices manufacturer of Brazil[37].

4.1.3 Innovative Cluster Network[38]

Associação Brazileira de Importadores e-distribuidores de Produtos para Saúde (ABRAIDI), is a non-profit Brazilian Association of Importers and Distributors of Health Products. ABRAIDI[39] is represented at the Brazilian Alliance of the Innovative Industry in Health and the Coalition Health Institute. An issue of bother is that ANVISA technicians, generally limited in number, need to visit on certain occasions the country of origin to validate and approve a product, barring simple products like scissors, syringes, etc.

[35] Source: Absolute Data Insights

[36] https://www.kenresearch.com/healthcare/medical-devices/brazil-medical-device-market-outlook/303834-91.html

[37] medgadget.com

[38] https://www.flandersinvestmentandtrade.com/export/sites/trade/files/market_studies/Medical-Equipment%20Brazil-2020.pdf

[39] Abraidi.com.br

4.1.4 Leading Clusters

Medical equipment manufacturers are mostly clustered in Sao Paulo (68%), with the region of Ribeirão Preto being the major centre for medical equipment production. Other clusters are in the region of South (17%) and Rio de Janeiro (6%).[40]

4.1.5 Country Efforts to Promote Medical Devices Industry[41+42]

Some of the steps taken by the Government to promote the industry include:

- Reducing the number of years, it takes to grant patents
- Cutting down approval time for clinical trials
- Enhancing validity time of registration from 5 to 10 years
- Gradually adopting best practices of International Medical Device Regulator Forum ("IMDRF")
- Faster registration for products of national interest
- Through Productive Development Partnership (PDP), foreign companies allowed collaboration with local firms to supply for public purchase for a period of 5 years with protected market share with compulsory technology transfer post contract period.
- Investments to digitize the public basic healthcare system for healthcare IT by Ministry of Health.
- Post COVID 19 telemedicine is picking up and hence there will be enhanced role of AI.

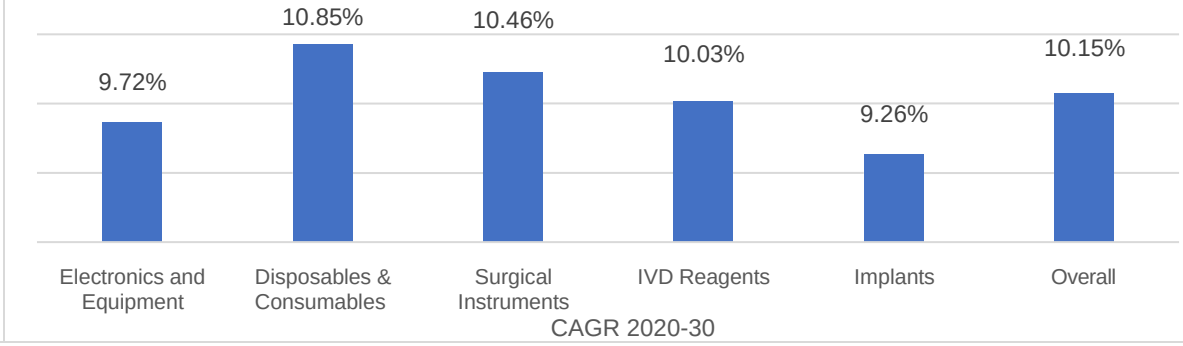
4.2. China[43]

Health expenditure (as percentage of GDP) as of 2019 was just 5.35 percent, which is much lower as compared to high income countries. The number of physicians per 1000 people in China in 2015 was much less than that in UK (high income country). The per capita spending on health by government in China is higher than middle-income countries but much less than high-income countries. Out of pocket expenditure on healthcare is also comparable to middle-income countries but almost 3 times as compared to high-income countries.

4.2.1 Industry Structure[44]

China's medical devices market is the largest in Asia and it is estimated to grow at a CAGR of 10.15 per cent over the next decade.

Figure 4.2 China Medical Devices Segment Growth Rates (2020-30)



Source: Absolute Data Insights

While imports of medical devices from China grew only 10.81% between 2016-20, the exports of medical devices grew by over 18.31% over the same period. Imports and exports grew substantially in Surgical Instruments, IVD Reagents and Disposables and Consumables. Imports of Surgical instruments grew by 127.66% and that of IVD Reagents grew by 24.77%, while exports of both these product categories grew by 54.02% and 81.96% respectively over the period 2016-20. China has made considerable progress in moving away from low-tech medical devices like disposables towards the medium

[40] "The Life Sciences Industry in Brazil – Working Paper Nr. 5/2012", Pedro Gouveia, Fraunhofer MOEZ, 2012

[41] export.gov

[42] https://www.trade.gov/country-commercial-guides/brazil-healthcare

[43] Apart from sources mentioned specifically, various parts of this section have been derived from a mix of sources as mentioned from bibliography numbers 13 to 25

[44] Source: Absolute Data Insights

to high-tech devices including therapeutic devices and diagnostic equipment.

4.2.2 Leading Companies

The leading domestic players in this industry are Mindray, DaAn, Fosun, Shinva, Naton, United Imaging, Kerunxi, Neusoft, Nurotron, Wangdon, Lepu, Microport, Wego, Double engine. With the support of government policy encouraging medical device innovation several domestic manufacturers including Shenzhen Mindray, Edan Instrument, Shandong Shinva, etc. are manufacturing high-quality products and are now competing with global suppliers in medium to high-level technology niches. Establishment of wholly owned subsidiary and joint ventures are preferred route for foreign investment. China also houses almost all the leading medical devices MNCs of the world.

4.2.3 Leading Clusters[45]

- Yangtze River Delta: Shanghai, Suzhou, Wuxi, Nanjing, and Ningbo are the main cities in this cluster. Their major products are disposable medical devices and consumables. It has lot of SMEs here.
- Bohai Bay: The main regions are Beijing, Shandong, and Tianjin. Major products here are MRI, digital ultrasound, accelerators, computer navigation and positioning medical equipment.
- Pearl River Delta: It includes the cities of Guangzhou, Shenzhen, Dongguan and Zhongshan, among others. It specializes in R&D of high-tech medical equipment. This is made possible as Shenzhen specializes in electronics, computer, communications, mechanical and electrical integration. Major products are patient monitoring, ultrasound, MRI and other imaging instruments like gamma knife, large X knife stereotactic radiotherapy equipment, tumor hyperthermia equipment, etc.

4.2.4 Country Efforts to Promote Medical Devices Industry

Some of the steps taken by the Government to promote the industry include:

- **FTZ**: FTZs have promoted US investment for sells in China and abroad.[46]
- **Protection**: In 2019, procurement policies that required hospitals to justify purchase (plus lengthy audits) of foreign medical devices, encouraged hospitals to procure from domestically manufactured medical devices. At the provinces and municipalities level Sichuan, Zhejiang and Jiangxi put legislations that required mid-level and high-level health care institutions to source certain devices from domestic companies.[47]
- **Targeted Export Promotion:** China made special effort to promote Chinese devices, especially in Africa. In 2019 China exported devices worth USD 460 million (an increase of 28% over 2018) comprising of disposables as well as advanced equipment. To make Chinese products more demanding, China also created hospitals, which were handed over[48] to the host country, but often remained administered and staffed by Chinese personnel. Importantly, on the price front, those were 10 to 70 percent of the product cost of MNCs.[49]
- **Selective Opening up:** After some prolonged period of promoting national industry, under the PRC Foreign Investment Law[50] manufacturing of mostly electronic and equipment g was opened for foreign companies with reduction or exemption of customs duties for imported self-use equipment, potential reduction of the price for using industrial land, etc. In certain regions additional preferential tax reduction is made available[51].
- **Regulatory Push**: In 2014, the China Food and Drug Administration (CFDA) introduced faster regulatory approvals for deemed innovative products. This included devices that will better safety

[45] Torsekar P. Mihir, China Climbs the Global Value Chain for Medical Devices", 2018, China, Journal of International Commerce and Economics

[46] www.mpo-mag.com/issues/2019-07-25

[47] Protected at Home, China's Medical Device Industry Looks Abroad, Dec 2019, cfr.org

[48] China officially hands over 7-year hospital project to Kenya | CGTN Africa

[49] Torsekar P. Mihir, "China's Changing Medical Device Exports", 2018, China, Journal of International Commerce and Economics

[50]China Foreign Investment: Expert Q&A Series – Medical devices industry, Global Publication, January 2020 - https://www.nortonrosefulbright.com/en/knowledge/publications/fdc8ef3b/china-foreign-investment-expert-qa-series-spotlight-on-medical-devices)

[51]China Foreign Investment: Expert Q&A Series – Medical devices industry, Global Publication, January 2020 - https://www.nortonrosefulbright.com/en/knowledge/publications/fdc8ef3b/china-foreign-investment-expert-qa-series-spotlight-on-medical-devices)

and performance of existing products, ones with novel technology at world level and those patented in China. Of the 222 products that applied (2014 to mid-2019), 65 products were approved of which 64 were domestically produced including high-end consumables, such as branched aortic stent grafts and interventional artificial heart valves. In another CFDA policy, classes 2 and 3 devices needed to carry out clinical trials in China regardless of the origin of the device. This must have discouraged imports too.[52]

- **Mergers and Acquisitions**: Mindray acquired Datascope to lead information monitoring. To strengthen orthopedics MicroPort acquired Wright Medical OrthoRecon. To strengthen cardiology Lepu took over Winmedic, Star, Shaanxi Qinming, etc. Other marketing strategies included setting up foreign subsidiaries (Mindray), share in ME online store (Yuwel), developing tier 2 and 3 city markets (Lepu), optimizing product structure (Weigao).[53+54]
- **Promoting Networks** - In 2009, the Ministry of Science and Technology organized institutions in medical device domain into China Strategic Alliance of Medical Device Innovation, a sectoral alliance at the national level. Soon different types of networks were established at regional, provincial, and city-level alliances emerged in thematic areas too. These included Optical Strategic Alliance of Medical Device Innovation by Eye Optical Research Institute of Wenzhou Medical University, Peking University, etc., Minimally Invasive Interventional and Implanted Strategic Alliance of Medical Devices Innovation by MicroPort Scientific Corporation, Ruijin Hospital of Shanghai JiaoTong University, etc.[55]
- **Promoting Large Firms to create Centre of Excellence**: Ministry of Science and Technology supported Mindray to build National Engineering Research Centre for Diagnostic Instruments and Lepu to build the National Engineering Research Centre for Heart Disease. [56]
- **China's "Made in China 2025" initiative** urges front-ranking Chinese hospitals to enhance sourcing domestically produced devices by 50 percent by 2020 and 95 percent by 2030. China is also focusing on developing high-performance devices such as diagnostic imaging, robotic surgery, high-value implantable and fully degradable cardiovascular stents, biological 3D printing, etc.[57]
- **Price Control**: Cutting high prices of high-value medical consumables was promoted (in 2019) through group purchase and urging all public hospitals to remove price mark-ups of high-value medical consumables[58], curbing price increase by medical reimbursement, promoting a UDI (Unique Device Identification) system and standardizing the bidding classifications and codes of high-value consumables and promoting "two invoice" "system[59], (2018), which enabled manufacturers to directly bid for procurement instead of going through multiple distributors.[60]
- **Technology Transfer:** Encouraged international players to have local legal entities either wholly owned or through a JV in China for registration and licensing which helps in technology transfer to local Chinese firms.[61]
- **Faster Approval for Chinese Patented Products** - Under Order 650, which mandate clinical trials for all class II and III medical devices in China, with few exceptions, enhances license getting time and adds costs to foreign firms. Fast-track Green Channel for both domestic and foreign companies need a Chinese patent and products qualifying for the Green Channel are given priority in the registration review and are exempt from the USD 90,000 registration fee.[62]
- **Investments in lower-tier hospital infrastructure**: To reduce overcrowding in higher class

[52] Dorcas Wong, "China Medical Devices Industry: Key Market Entry Consideration",2020, China

[53] Cheong Teng Sok, "Building an innovation system of medical devices in China: Drivers, barriers, and strategies for sustainability",2020, China, Article (P-1 to P-14)

[54] Torsekar P. Mihir, China Climbs the Global Value Chain for Medical Devices", 2018, China, Journal of International Commerce and Economics

[55] Cheong Teng Sok, "Building an innovation system of medical devices in China: Drivers, barriers, and strategies for sustainability",2020, China, Article (P-1 to P-14)

[56] Cheong Teng Sok, "Building an innovation system of medical devices in China: Drivers, barriers, and strategies for sustainability",2020, China, Article (P-1 to P-14)

[57] China's Medical Device Market: A Must Win Proposition, Allen D, Reachfurther, March 30, 2020

[58] China's Central Government Introduces Major Policy Incentives and Restrains to the Medtech Industry, Wnag, K, (www.mondaq.com)

[59] Dr. Urs Mattes, Switzerland Global Enterprise, "The Chinese Medtech Sector", April 2017

[60] China's Medical Device Market: A Must Win Proposition, Allen D, Reachfurther, March 30, 2020

[61] Cheong Teng Sok, "Building an innovation system of medical devices in China: Drivers, barriers, and strategies for sustainability",2020, China, Article (P-1 to P-14)

[62] Torsekar P. Mihir, "China's Changing Medical Device Exports", 2018, China, Journal of International Commerce and Economics

hospitals, China is investing heavily in improved infrastructure at lower-class hospitals, as well as promoting skill of its medical and para medical staffs at these facilities.

- **Presence of Backward Linkage**: Provinces of Guangdong and Jiangsu and the municipalities of Beijing and Shanghai have comparative advantage in manufacturing electronics and electrical equipment, industrial machinery and IT and very well-developed transportation networks and above all huge presence of high-end hospitals. These places attracted high FDI.
- **Specialized and Big Parks**: Shanghai launched five industrial parks in 2020, which will promote biomedical innovation research (at Zhangjiang), precision medicine and equipment (at Lingang), high-end medical equipment. These parks are huge covering an area of more than 60 square kilometers.

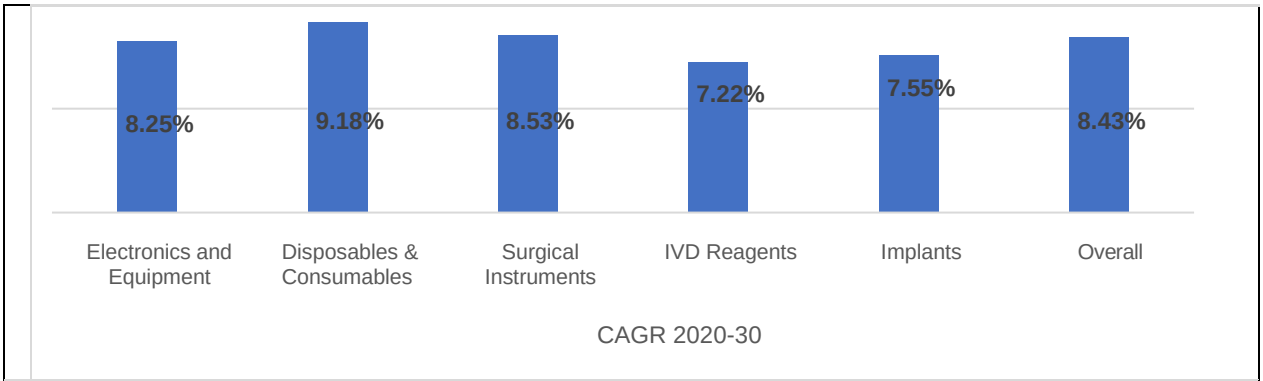
4.3. France[63]

The health expenditure in the country (as percentage of GDP) as of 2019 was 11.06 percent, which is slightly lower than the spending ratio in 2015. The out-of-pocket expenditure in France is very low, owing to the universal service provided by the French government. The number of hospital beds (per 1000 people) in 2015 was higher than the high-income countries.

4.3.1 Industry Structure

France is the second largest medical device market in Europe. The market was valued at USD 24.66 bn in 2020. It is expected to grow at nearly 8.43% over the next decade and will be USD 55.39 bn by 2030[64]. Around 1300 companies along with 350 subcontractors and 350 specialist distributors, of which 92% are SMEs make up the French medical device industry. The Medical device industry employs more than 85000 people[65]. The French medical device industry is a pioneer in developing and producing In Vitro Diagnostic (IVD) devices. Around 90% of the sector, produces 7000 out of the 40000 IVD devices produced in Europe, making France the second largest producer in Europe.

Figure 4.3 France Medical Devices Segment Growth Rates (2020-30)



Source: Absolute Data Insights

IVD Reagents saw the maximum growth in imports between 2016 and 2020 at CAGR of 21.45 per cent and as well as in exports (12.50 per cent). Imports of surgical instruments showed a negative growth of 1.78 per cent between 2016 and 2020 and similarly, exports of Implants saw a negative growth of 1.79 per cent during the same period.

Dominance of French medical device in Europe is because of its R&D led industry. 76% of the businesses conduct R&D. Together the industry engages nearly a third of its workforce (30,000 people) in research and development. A major part of the EUR 6.7 billion annual R&D investment comes from the Government. Besides EUR 800 million is made available through R&D tax credit per year. Over fifty per cent of the health-tech companies originate from public or academic research.[66]

4.3.2 Major Companies

[63] Apart from sources mentioned specifically, various parts of this section have been derived from a mix of sources as mentioned from bibliography numbers 26 to 31

[64] Source: Absolute Data Insights

[65] Medical Devices in France, businessframe.fr

[66] Healthcare made in France: Excellence in Patientcare, French Healthcare

Some of the major French companies include BioMérieux, Zimmer Biomet Robotics (formerly Medtech SA), Essilor Luxottica, Guerbet, Poeitis, Alcis and Carmat. France also has subsidiaries of Roche (Switzerland), Bayer (Germany), Johnson & Johnson (United States), Becton Dickinson (United States), Thermo-Fischer (United States), etc.

4.3.3 Lead Clusters[67]

The two most prominent clusters of France are the Alsace Biovalley cluster (150 firms) specializing in robotics related research (e.g., keyhole surgery), implantable, tools for simulation and modelling, drug delivery system, etc. and the Franche-ComtÃ which mostly works in the areas of keyhole surgery and implants. The ecosystem is supported by the University of Strasbourg (a world-class research center), the bio-cluster that supports in creating collaborative projects and grants for R&D. Presence of eco-system players specializing in micro-mechanics, micro-robotics, micro-fluids, optics, and IT also help.

4.3.4 Innovative Cluster Network

Medicen[68] includes majority of life science innovation stakeholders. The cluster majorly focuses on development of IVD, Medical Imaging, Digital Health, and Techno-therapy devices. It has 475 member companies with 441 SMEs. It provides a range of services to international companies including entry to European and third country markets, public support (regional/national programs, innovation vouchers, etc.), access to private funding (connecting to investors, seed-capital, venture-capital, crowdfunding, etc.) and location promotion. Innovation is led by leading institutions such as the Paris Hospitals and other reputed institutions. Medicen has supported more than 292 collaborative innovation projects with a total investment of EUR 1.05 billion and has helped bring 62 new products to market in the fields of imaging, medical devices, and biological solutions. Medicen has received funding close to EUR 2.5 billion from the French Government, public investment bank, the National Research Agency, the European Regional Development Fund, and the Invest for the Future program.

4.3.5 Country Efforts to Promote Medical Devices Industry

France exhibits significant contribution of both public and private sector in R&D, networking, promotion of start-ups and creating appropriate factor conditions at the cluster level. Some interesting statistics is as follows:

- **Public support for R&D**: The French government setup a fund for €25 billion public investment in French research system from 2021-2030, including €5 billion in health sciences. A €10 billion fund for future investments for 2021-25 will support strategic sectors including the top two priority sectors in health: bio-production of innovative therapies and digital healthcare.
- **Health Data Hub**[69]: Promotion of health big data (HBD) for the medical and medico-research fraternity is being promoted by various Governments like EU, France, USA, Germany, China, etc. HBD supports clinical decision-making, disease surveillance, and population health management. These include among other the Health Data Hub by France, the Observational Health Data Sciences and Informatics (OHDSI) collaboration by the USA, the national Medical Informatics Initiative (MII) by Germany, etc.
- **Research Branding**: Four research centers (CEA, CNRS, Inserm and Pasteur Institute), in World's Top 25, a brand that attracts talent.
- **Networking**[70]
    - **G5 Health Forum**: It is a forum of the principal French companies in the fields of health and life sciences. The forum is the voice of the leaders (bioMérieux, Guerbet, Ipsen, Laboratories Théa, LFB, Pierre Fabre, Sanofi, Servier) of the French healthcare industry. France is the destination of these companies to do R&D. They have 33 R&D sites and 56 production sites in France.
    - **CSIS**: This is a very active platform for interaction between industry and the government. For example, at the 8th CSIS held in July 2018, 48 new measures were identified, 85 per cent of which are already effective including simplified expanded access program (ATU), health data hub and fast track clinical trials.
    - **Global Disease Pattern and Future Potential**: A € 50 million program called AKEOME is

[67] https://www.mddionline.com/business/seven-most-important-medtech-clusters-europe

[68] https://medicen.org/en/our-missions/

[69] Projects to Promote Data Sharing in Healthcare Marc Cuggia1 , Stéphanie Combes2 1 INSERM, UMR 1099, Rennes, France and Université de Rennes 1, LTSI, Rennes, France 2 Lab Santé, Sous-direction de l'observation de la santé et

[70] diplomatie.gouv.fr

implemented by a French company for healing diabetic foot ulcers. The program received the support of BPI France in 2016.

- **Fast track for clinical trials**[71]: France maintains two fast tracks (from 2018) to speed clinical trials for new and already known medicinal products.

4.4. Germany[72]

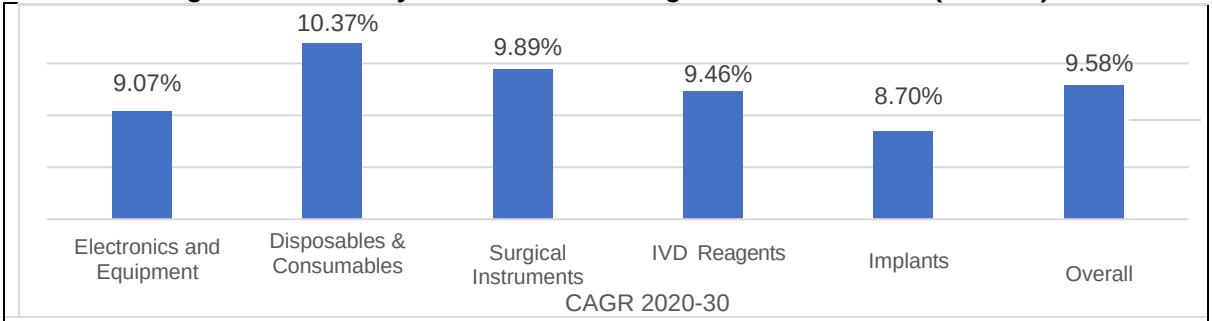
While the health expenditure of Germany (% of GDP) was lower than that of high-income countries, but the domestic per capita health expenditure by government in PPP terms was much higher than that of High-income countries. The per capita spend by government on healthcare in 2019 was USD 5238 (PPP) as compared to 3971 (PPP) done by high-income countries. The number of beds available per 1000 people in Germany (8.13) was much higher than that available in high income countries (2.61).

4.4.1 Industry Structure[73]

The German medical device market grew at a CAGR of 5.5 percent between 2015 and 2020 to become a USD 52.31 bn market in 2020. However, the German medical device market is expected to grow at a much higher rate of 9.58% over the next decade to become a USD 130.6 bn by 2030.[74]

SMEs (more than 20 employees) and subgroups of large firms make for 95% of the medical device industry of Germany. Around 1,200 SMEs employ over 125,000 people and 11,300 smaller businesses employ around 75,000 people. 95 per cent of all companies employ less than 250 employees. Germany excels in making in diagnostic imaging, precision medical, surgical instruments, optical technologies, etc. German devices get 33 per cent of their revenue from devices that are less than 3 years old.

Figure 4.4 Germany Medical Devices Segment Growth Rates (2020-30)



Source: Absolute Data Insights

In EU, Germany is the largest exporter and importer of medical devices.

During 2016 to 2020, while imports grew at an estimated rate of 8 per cent, imports grew at 5 per cent. IVD reagents recorded the highest growth rate both in exports and imports. Germany being a major producer of surgical instruments, it recorded a growth of 8 per cent during that period.

4.4.2 Major Companies

Some of the major German companies include Siemens, B. Braun, Fresenius, Carl Zeiss, Dragerwerk, Paul Hartmann, Karl Storz, Eppendorf, Brainlab[75] and other global players including Philips (NL), Hitachi (Japan) and Toshiba (Japan), GE Medical, Medtronic, Agilent, 3M Healthcare, Hollister, Abbott, and Johnson & Johnson, etc.

4.4.3 Lead Clusters[76+77]

[71] Zachary Brennan, "France to Maintain Fast Track Schemes for Clinical Trials", 11 November 2019, Regulatory Affairs Professional Society (RAPS.org)

[72] Apart from sources mentioned specifically, various parts of this section have been derived from a mix of sources as mentioned from bibliography numbers 32 to 46

[73] "Healthcare Resource Guide" U.S. Commercial Service, USA Department of Commerce, https://2016.export.gov/ and others

[74] Source: Absolute Data Insights

[75] EU R&D Scorecard

[76] Lovisa Jacobsson, Jan Klütsch, Nahua Kang, Richard Probst, "The medical technology cluster in Tuttlingen", January 2017

[77] "Medical Technology Clusters in Germany", 2020, Germany, GTAI

- Tuttlingen is the lead Surgical instruments cluster in the world producing minimally invasive instruments, implants, lab Equipment, therapeutical devices, lubricants, polymers, fully Integrated OR Systems, surgery carts, disinfection, catheters, software, and a lot more. Various factor conditions support this development:
    - The State of Baden-Württemberg (BW) which houses the cluster, has the highest R&D intensity in Germany. 30 per cent of all German patent applications are from BW. The region is also blessed with strong R&D institutes including the NMI Natural, Medical Sciences Institute at the University of Tübingen, the Hahn Schickard Society for Applied Research and the Fraunhofer Society. Besides, there are 9 universities, 5 private higher education institutions, 6 colleges of education, 46 universities of applied sciences.
    - More than 600 med-tech companies (90 percent SMEs) including Aesculap, Karl Storz, Allgaier, Avellanus, Mahe Medical, etc. have a global market share of 55% in surgical instruments. The small companies increased their competitiveness in the global market through high specialization and virtual horizontal integration (e.g., by using shared showrooms). Offering their products collectively, they address global customer needs from "one hand" and mitigate potential shortcomings in sales know-how.
- Medical Valley Nurnberg, Germany: It started with the discovery of x-ray technology in the near-by area and with the establishment of Siemens. And now has 180 medical technology companies and houses pioneers in the areas of CT, MRI, lithotripsy, endoscopy, sensors, medical information systems, high tech implants, etc. The ecosystem is supported by highly specialized SMEs from electronics, IT, communication, optical engineering, and new materials. It also has 40 hospitals, 20 research institutes such as Fraunhofer Institute for Integrated Circuits (that has Medical Technology Test and Demonstration Centre and the Max-Planck- Institute for the Science of Light. This collaboration helps save costs for the firms. It also gave birth to 100 medtech start-ups.[44]

4.4.4 Innovative Cluster Networks

Medical Mountains is a cluster organization that helps network among medtech companies, universities, research institutes, politics, and international med-tech actors in Tuttlingen. The organization aims to increase the competitiveness of the cluster by fostering innovation and reducing costs. The cluster established a purchasing pool and help conduct clinical evaluations for certain standard products.

4.4.5 Country Efforts to Promote Medical Devices Industry

Germany practices several means to promote the entry of new/innovative medical devices. These include the following:

- **Innovative device**[78]: Innovative medical devices can generally be applied quickly to clinical practice.
- **New code for OPS**[79]: One can apply for a new OPS code for a "New to Germany" medical device, requiring a different procedure than the existing device, through the German Institute of Medical Documentation and Information (DIMDI) jointly with German medical society.
- **New Methods of Treatment and Screening (NUB)** [80]**:** This is a payment scheme for remunerating cost-intensive, innovative services and technologies.
- **Funding:** EU's Horizon 2020 program offers grant up to 100% of R&D project expenditure with a total budget of 77 billion euro. In Germany the Central Innovation Program for SMEs (ZIM) reimburses cost of joint R&D by SMEs with grant up to 55% for a maximum of Euro 385,000 per project.[81]
- **Innovative Cluster Networks**: Promoting networks of firms and eco system players have created a major difference in the performance of the firms. The network managers link to funding for joint R&D projects, share facilities and do capacity building/training. The "go-cluster" excellence program brings together around 100 such networks across the country. [82]
- **Setting International Standards as a Branding Tool:** Setting and continuous adhering to highest quality standards through industry-regulatory and German notified bodies like TÜV and DEKRA have ensured high quality standards through adoption of industry norms like ISO 13485, ISO 14155

[78] aim.oges.com

[79]"Reimbursement of Medical Devices in Germany", 2020/2021,Germany, Assessment in Medicine

[80] "Reimbursement of Medical Devices in Germany", 2020/2021,Germany, Assessment in Medicine

[81] "Medical Technology Clusters in Germany", 2020, Germany, GTAI

[82] "Medical Technology Clusters in Germany", 2020, Germany, GTAI

and have created a quality brand for the country.

- **Apprenticeship based training:** Apprenticeship based training give medical technicians access to three hundred plus different recognized trades. 20 per cent of German companies take part in the dual vocational training system, thereby turning apprentices into specialists and more than seventy percent are absorbed post apprenticeship.
- **R&D Incentive**[83]**:** For industry, approximately EUR 5 billion annually is reserved for R&D projects in the form of non-repayable project grants supporting up to 50 percent of project costs. Cooperation between project partners, especially between enterprises and research institutions, is usually required[84]. With the funding initiative KMU-innovativ, the BMBF supports top-level research in German SMEs. The funding amount approved is estimated at over 1,266 million euros for more than 1,700 individual and joint projects, in which around 2,900 small and medium-sized companies are involved. The KMU-innovativ funding initiative represents around a quarter of the BMBF's'SME funding[85].
- **Investment Incentive:** The Joint Task for Improving Regional Economic Structures" (Gemeinschaftsaufgabe, **GRW**) defines maximum possible incentives rates for all regions eligible for funding throughout Germany which are published for each funding period in form of the Ministry's "incentives map." Calculation is based on actual investment costs (e.g., for buildings or machinery) or (assumed) wage costs for two subsequent years.[86]
- **Loan support to Start-ups**: "NRW.BANK offers a wide range of financial support for business start-ups …. Loan support is given for 25,000 to 10 million euros….to up to 100 percent of the eligible investment costs or working capital. ….. This promotion program is offered jointly by NRW.BANK and KfW " [87]

4.5. Italy[88]

Health expenditure (as % of GDP) as well as the government health expenditure per capita, PPP in Italy is significantly lower than the high-income countries. Even though the country has a well-organized national health service where services are provided largely for free but the out-of-pocket expenses (as % of current health expenditure) is also significantly high when compared with other high-income countries. However, the number of hospital beds (per 1000 people) is higher than in other high-income countries.

4.5.1 Industry Structure

The medical device market was valued at approximately USD 11.89 bn in 2020 and is expected to grow at a CAGR of ~9 percent to reach USD 28.03 bn by 2030.[89] The medical devices industry of Italy has about 4000 companies which constitute 53% producers and 5% service providers, and 90% of them being SMEs. This sector employs about 76,400 people, 9,200 of whom in R&D. While almost all the top product categories across segments are growing between 8% to 9.7% (between 2020 and 2030), with Implants having the lowest growth rate of 8.08% and Disposables and consumables having the highest growth rate of 9.74%. Despite high production capacity imports are significant too.[90]

[83]https://www.gtai.de/gtai-en/invest/investment-guide/incentive-programs/r-and-d-incentives/r-d-grants-in-germany-72756

[84]https://www.gtai.de/gtai-en/invest/investment-guide/incentive-programs/r-and-d-incentives/r-d-grants-in-germany-72756

[85]https://www.bmbf.de/de/kmu-innovativ-561.html

[86] https://www.gtai.de/gtai-en/invest/investment-guide/incentive-programs

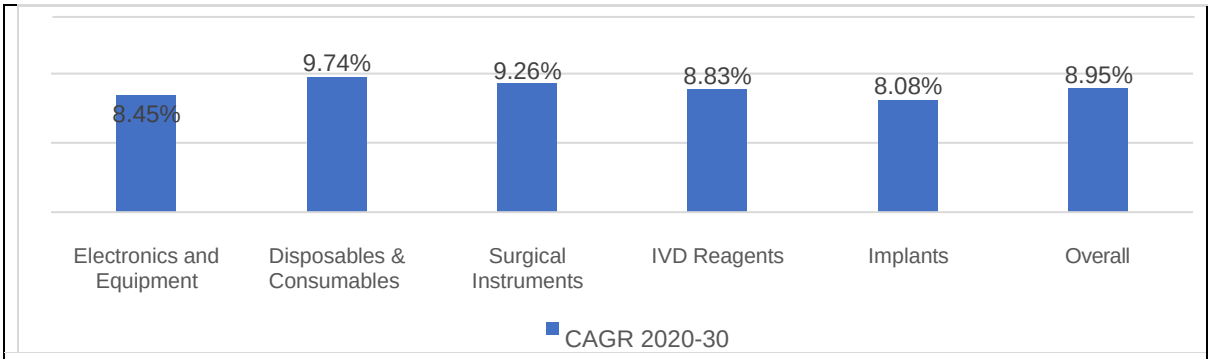
[87]https://www.nrwinvest.com/en/nrw-as-location/how-to-do-business-in-nrw/incentive-programs/cash-incentives-for-investment-projects/#:~:text=Cash%20Incentives%20Program%3A%20GRW&text=The%20program%20is%20issued%20by,so%20called%20%22incentives%20map.%22

[88] Apart from sources mentioned specifically, various parts of this section have been derived from a mix of sources as mentioned from bibliography numbers 47 to 56

[89] Source: Absolute Data Insights

[90] "Life Science in Italy", 2019, Italy, ALISEI

Figure 4.5 Italy Medical Devices Segment Growth Rates (2020-30)



Source: Absolute Data Insights

4.5.2 Major Companies

The major companies operating in the Italian medical devices industry are Bracco (imaging), DiaSorin (Immunodiagnostics and molecular diagnostics), ElEn (trans catheter mitral bio-prosthesis), Servizi, Lima (Sterilization services), Amplifion (hearing aid), etc.[91]

4.5.3 Lead Clusters

The industry is spread across six clusters – Apulia, Friuli Venezia Giulia, Lombardy, Piedmont, Trentino, and Tuscany.

4.5.4 Innovative Cluster Network[92]

The Emilia-Romagna Cluster Network aims to bring together companies, universities, research centers and regional stakeholders. The cluster forges synergies and set up coordinated and stable networks with public-private agglomerations operating in the same sectors at European and International level. The cluster includes among other prothesis, usable technologies for healthy living and active aging and various pharmaceutical products. The network has 80 members, 50% being firms (SMEs, start-ups, large firms) and 50% being eco system players (research organization and other eco-system actors). Some of the objectives are:

- Support the development of new diagnostic, therapeutic devices and new drugs maximizing efficacy and improving patient's quality of life.
- Support innovation in industrial processes introducing bio fabrication and industrial modernization and reducing the time to market of innovative technologies whose cost / effectiveness ratio has been proven.
- Promote competitiveness of medical devices companies that are already at excellence in the regional industrial sector.
- Promotes innovation with the support of joint projects between companies and support stakeholders including research laboratories, healthcare systems.

4.5.5 Country Efforts to Promote Medical Devices Industry

Some of the steps taken by the Italian government to support innovation are giving special recognition to "innovative" start-ups and SMEs, providing tax credit on research, preferential tax policy on revenue generated by IPRs. Venture capitals finance new enterprises in Life Sciences, e.g., Panakès with 120 million euro is dedicated to biomedical technologies and medical devices. The fund Principia III Health of 206 million euro and Italian Angels for Biotech – IAB, created by a group of entrepreneurs, managers and scientists support ideas and talents in this sector[93]. Various regional level incentives are also provided to the units.

[91] Bell Jamie, "A Closer look at some of Italy's biggest medical device companies", 2020, Italy, NS Medical Devices

[92] "Business Opportunities in Italian Life Sciences: Selected Companies and Clusters", ITA, Italy, 2019

[93] https://www.export.gov/apex/article2?id=Italy-Biotechnology

Table 4.1 Support Extended to Industry by Regional governments in Italy.

Region	Support to Industry
Apulia	Regional grant scheme for innovation and investment for new/existing Large/SMEs/Start-ups for investment projects up to 100 million euro
Friuli Venezia Giulia	Regional tax reduction and grants for creation of new enterprises and implement R&D projects.
Lombardy	5% to 15% non-repayable grant, long-term financing from €50,000 to €2.85M at favorable rates, with a duration from 3 to 6 years. Free financial guarantee to cover up to 70% of financing. Zero-interest- loan and a non-repayable grant (min €25,000 to max €65,000) for start-up.
Piedmont	Funding in the form of soft loans, non-repayable grants or free-of-charge guarantee support for labs and research centers; creating and developing start-ups; technology transfer from research to SMEs through Innovation Hubs; collaborative research
Trentino	Up to 80% local grant on R&D project, —Up to 70% local grant on internationalization and —Up to 60% local grant for researchers hiring and private-public equity financing up to 1.5 million €
Tuscany	Tax credit and fund for 70% of investments within a range of €0.5 million and €1.5 million.
Source: Secondary Research	

However, what is of interest is the ecosystem that works with the medical devices sector to make the industry produce innovations that matter and the high involvement of HR in the R&D area of the medical devices sector. Interestingly, 6.2 per 1000 inhabitants in Piedmont, 10 per cent of the employees of the 370 units in Tuscany and 67 per cent of the units in Trentino are engaged in R&D only. Taken together Lombardy and Piedmont have 674 research organizations.

Table 4.2 Research Organization in Some Regions in Italy

Name of the Region	Firms	National/International Research Centers and Universities	Hospitals	Networks	MNCs	Parks
Apulia	226	2	3	2	DNA	DNA
Friuli Venezia Giulia	150	10	2	4	DNA	1
Piedmont	400	3	DNA	7	21	4
Source: Secondary Research DNA = Data not available						

4.6. Japan[94]

In 2019, Japan spent about 10.74% of the nation's gross domestic product (GDP), on health, which is below the percentage spent by other high-income countries. The domestic general government health expenditure per capita, PPP, rose marginally over the period 2015 to 2019. The number of hospital beds (per 1000 people) was much higher than that of high-income countries on an average.

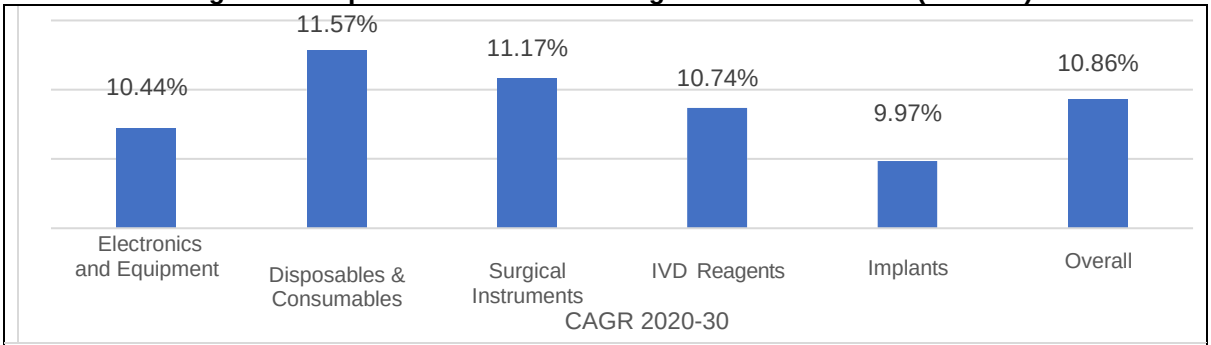
4.6.1 Industry Structure

As of 2020, the medical devices market in thecountry reached USD 18.34 bn and is estimated to reach USD 51.43 bn by 2030, growing at a compound annual growth rate (CAGR) of 10.86%. In recent years, therapeutic equipment and devices had the highest sales share in Japan, both for domestic products and imports.[95]

[94] Apart from sources mentioned specifically, various parts of this section have been derived from a mix of sources as mentioned from bibliography numbers 57 to 65

[95] Source: Absolute Data Insights

Figure 4.6 Japan Medical Devices Segment Growth Rates (2020-30)



Source: Absolute Data Insights

4.6.2 Major Companies

Olympus Corporation and Terumo Corporation are the top two domestic manufacturers. Olympus specializes in endoscopic solutions segment and commanded over about 70 percent of the global market share as of 2020. Terumo's specializes in the cardiac and vascular segment, and hospital equipment.

4.6.3 Lead Clusters in Japan

4.6.3.1 Kobe Biomedical Innovation Cluster (KBIC)[96], Kobe

KBIC is the largest biomedical cluster in Japan. It is a lead cluster in innovation. There are about 370 companies including start-ups as well as multinational healthcare giants and support stakeholders including universities, research institutes, specialized hospitals, and a host of global partners focused on innovation through collaboration. Leading institutes at KBIC include Riken Centre for Biosystems Dynamics Research, Japan's largest comprehensive research organization. Our corporate members range from promising. Interestingly, the cluster has generated numerous start-ups with successful product launches.

4.6.3.2 Northern Osaka Biomedical Cluster[97], Osaka

Northern Osaka Biomedical Cluster has a large number of pharmaceuticals and medical device manufacturers and research institutes. This mixture of complementary technologies help. The national center providing advanced and specialized medical care and conducts research focusing on the cardiovascular system related circulatory condition will move to NohBIT and become a key part of the city.

4.6.4 Innovative Cluster Networks

In Kobe, the "Pro-Cluster Kobe" provides a variety of R&D and commercialization support regarding intellectual property, funding, law marketing.

4.6.5 Country Efforts to Promote Medical Devices Industry[98]

Pricing[99]: All medical devices need to be approved for getting listed for reimbursement. Price Maintenance Premium (PMP) accelerated the introduction of innovative pharmaceutical products and medical devices to the Japanese market. Once, PMP calculation factors, such as the number of local clinical trials and product launches, used to "favor" Japanese companies wishing to qualify for the premium. However, of late clinical data of abroad are being accepted. In addition, approval times are also getting reduced. Japan used to do price revision every two years and is now proposed to go to annual price revision. Hence units anticipate further lowering of profit. Further downward pressure is expected by use of Foreign Average Pricing (FAP) policy[100]. FAP often does not take care of the highest

[96] https://www.eu-japan.eu/japanese-clusters/kobe-biomedical-innovation-cluster

[97] https://www.eu-japan.eu/northern-osaka-biomedical-cluster

[98] www.meti.go.jp/covid-19/pdf/pamphlet.pdf.,**Error! Hyperlink reference not valid.**www.jetro.go.jp/en/invest/region

[99] https://2016.export.gov/industry/health/healthcareresourceguide/eg_main_108592.asp

[100] It is a price reduction mechanism based on the average selling price to hospitals/clinics and a price reduction rule to set a ceiling relative to the foreign average price (FAP).

price and the multiplier value of FAP is also coming down over years[101].

Reimbursement Price Promotes R&D/New Products: Japan follows strong reimbursement price control measurements for existing products - reimbursement price of existing products always decreases. This necessitates innovation to maintain profits.

- Government of Japan/ Prefectures Support to Industries in General[102][103]
  - Government of Japan: Financial assistance, including safety net loans up to Rs 280 million yen. Industries suffering 20% or more loss gets full support and those between 5 to 20 per cent gets 80% support.
  - Government of Japan: Recapitalization of SMEs by low-interest loans at 0.5% to 2.95% rate of interest
  - Aichi: Subsidies up to 10 billion yen for industries investing in cutting-edge high- tech fields.
  - Nagano: Subsidies between 5%-20% of value up to 1 billion yen for companies setting up manufacturing, information services and science R&D centers depending on investment value and number of new employees.
  - Miyazaki: Subsidies up to 5 billion yen for agro, food processing, forestry & fisheries, electronic components, and services industries
  - Medical industries (Medical Devices, Pharmaceuticals, R&D, etc.) [104]
    - Sapporo, Hokkaido: R&D subsidies for biomedical R&D establishment: 1 million yen per employee up to 12 million yen for 2 years if 5 or more employees and capital investment subsidy up to 100 million yen for minimum investment of up to 1 billion yen in fixed assets
    - Chiba city, Chiba: Subsidy system for establishment of enterprises up to 500 million yen/year for 5 years and 600,000 yen per employee moving into the city) and 1/½f rent, up to 10mn yen for a year plus amount equivalent to corporate tax for 5 years.
    - Kanagawa: Subsidy for companies operating in special zone for medical industries up to 10% of investment, up to 1 billion yen.
    - Kumamoto: Subsidy for companies with more than 50% foreign ownership wishing to establish business up to 150 million yen, 5% of investment and 500,000-to-700,000-yen times the number of employees or making large-scale investments up to 20 billion yen and hiring 200 plus employees, subsidy up to 5 billion yen max, 8~15% of investment amount plus 500,000~700,000 yen times the number of employees.

4.7. Malaysia[105]

In 2019, Malaysia spent about 3.83% of its gross domestic product (GDP), which is marginally above the lower middle-income countries. Out of pocket expenditure is almost equal to that of middle-income countries,

4.7.1 Industry Structure

Malaysia is the largest producer of catheters and medical gloves and accounts for 80% and 60% of the supply respectively[106]. Other major export categories in Malaysia are medical instruments, apparatus and appliance, syringes, needles, and sutures, electromedical equipment, ophthalmic lenses including contact lenses, dental instruments and appliances, medical and surgical X- ray apparatus, and medical furniture.[107] Malaysia is moving towards high tech products.[108]

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[101] http://www.mitc.com/wp-content/uploads/2015/04/2015-Medical-Devices-Resource-Guide-Japan-and-China.pdf?29e721

[102] 1 INR = 0.67 yen

[103] www.meti.go.jp/covid-19/pdf/pamphlet.pdf., www.jetro.go.jp/ext_images/en/invest/pamphlets/canada2018_2.pdf, www.jetro.go.jp/en/invest/region

[104] Basically, medical devices, pharma, and R&D. Each prefecture has different standards, depending on their cluster. Sapporo defines it as biotechnology, Miyagi as generic R&D, Ibaraki as Life science as part of the Tsukuba Life Science Promotion Association, Saitama as Medical, health and beauty, Chiba as Food and Health Lifestyle-Oriented Industries (including devices and products), Kanagawa as preventative medicine/advanced medical related industry, Aichi as medical robots, and Kumamoto as part of food and pharma industries.

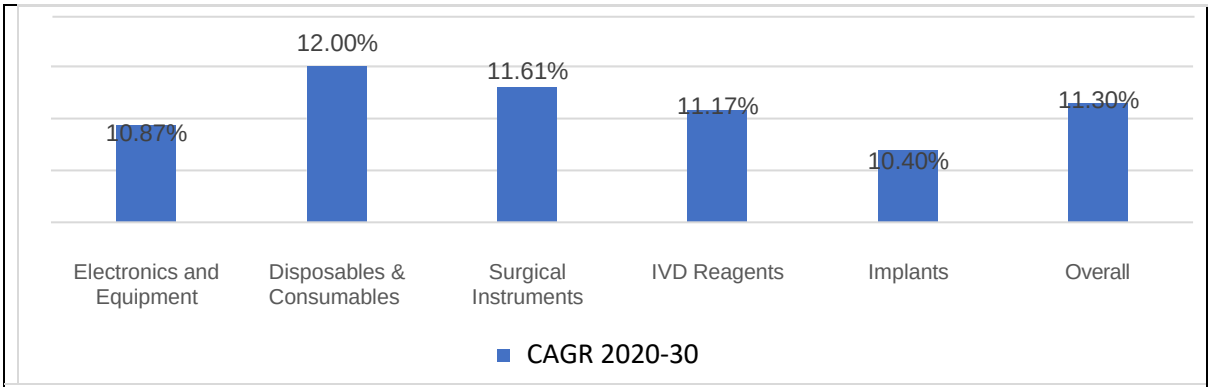
[105] Apart from sources mentioned specifically, various parts of this section have been derived from a mix of sources as mentioned from bibliography numbers 74 to 80

[106] https://andamanmed.com/target-markets/malaysia/

[107] https://2016.export.gov/industry/health/healthcareresourceguide/eg_main_108601.asp

[108] https://www.mida.gov.my/mida-news/medical-devices-industry-is-penangs-hidden-gem/

Figure 4.7 Malaysia Medical Devices Segment Growth Rates (2020-30)



Source: Absolute Data Insights

4.7.2 Major Companies[109]

Over 200 medical devices manufacturers, mostly SMEs, produce catheters and medical gloves. Also manufacturing cardiac pacemakers, stents, orthopedic implantable devices, electromedical, therapeutic and monitoring devices. Some of the major local producers include Aibo Orthopedics, Straits Orthopedics, Vigilenz Medical Devices, Granulab (M), Hospitech Manufacturing Services, OSA Technology, Top Glove and Kossan Latex Industries (M), etc.

Of MNCs, there are currently more than 30 companies that are producing high value-added medical devices by making Malaysia their offshore location for manufacturing operations, such as Agilent, B. Braun, St. Jude Medical, C.R. Bard, Symmetry Medical, Teleflex, Resmed, Ciba Vision, Kelpac Medical, Ambu, Toshiba Medical Systems and Haemonetics. Apart from that, B. Braun has it's APAC regional headquarters and a Centre of Excellence for Intravenous Access (IA) in Malaysia.

4.7.3 Lead Cluster[110]+[111]

Penang is the largest medical device cluster in Malaysia. The cluster specializes in producing high-end medical devices such as cardiovascular products and orthopedic implants and tools. Penang is home to one-third of the medical devices' companies in Malaysia – B-Braun, Boston Scientific, Abbott Laboratories, Integer, Haemonetics, Japan Lifeline, Tecomet and the likes of other well-established players. A well- developed supply chain (certified with ISO 9001, ISO 13485, ISO 14000, ISO/TS 16949, and FDA) supports the manufacturers.

The success of Penang cluster is largely because of Penang's vast Electrical and Electronics industry which houses the global leaders - Intel, Bosch, Clarion, Advanced Micro Devices (AMD), HP, Osram Opto Semiconductors, Hitachi, and National Semiconductor. The already successful E&E cluster helped in creating a space for competitive pricing of electronic components which are used in medical devices and helped attract foreign investments because of established infrastructure. Apart from that, the availability of a high skilled talent pool is another factor of cluster's success.

Another major medical device cluster in Malaysia is Selangor cluster. The cluster specializes in producing latex products i.e., medical gloves, catheters, and condoms because of its proximity to raw materials. Some of the major companies present in the cluster are Hartalega Holdings, Supermax Corp., and Top Glove.

4.7.4 Innovative Cluster Network

The Association of Malaysian Medical Industries (AMMI) is the biggest medical device manufacturer

[109] https://www.miti.gov.my/miti/resources/12._Medical_Devices_Industry_.pdf

[110] The Edge Markets: Special Report: Medical Devices Industry is Penang's (Malaysia) Hidden Gem: theedgemarkets.com, Oct 2020

[111] https://www.miti.gov.my/miti/resources/12._Medical_Devices_Industry_.pdf

association and includes not only the equipment producers but also their supplier eco system platers.[112]

4.7.5 Country Effort to Promote Medical Device Industry

- Promotion of Investments Act (PIA) provides reliefs from income taxes and investment tax allowances to electromedical equipment, cardiovascular devices, orthopedic devices, IVD, wound care management and products from convergence of technology. The Safeguards Act 2006 gives full tax exemption incentive of 15 years for firms with 'pioneer status' and 10 years for companies with 'investment tax allowance' status. In addition to research grants, tax incentives to promote R&D is applicable for expenses made for raw materials, technical services, travelling and transportation costs, salary and allowances of research personnel, maintenance costs of research buildings and equipment, and rental of equipment, machinery or buildings used for research.

- Malaysia provides a variety of support for promotion of medical tourism. "..In 2005, the Ministry of Health established an agency called the Malaysia Healthcare Travel Council (MHTC), designated to facilitate and promote the country's healthcare travel industry by establishing public-private partnerships at home and abroad…"[113], The supports include (a) creating representative offices in countries where there is demand (e.g. Indonesia, Vietnam, and Myanmar), (b) organizing medical visas, (c) guest lounge at international airports of Malaysia, (d) tied up with 21 elite (accredited globally) and 59 ordinary hospitals and (e) providing fiscal incentives, etc.

4.8. New Zealand[114]

New Zealand spends around 9.74% of its GDP towards healthcare which is around 80% of the value of high-income countries. Per capita current health expenditure (PPP) was USD 4439.35 in 2019.

4.8.1 Industry Structure[115]

New Zealand's Medtech is the largest secondary sector generating USD 1.9 bn in revenue employing 7500 persons. The country's medical devices market is estimated to grow at a CAGR of 8.58% during the years 2020-2030. The expected growth rates are uniform across categories are 9.72% for disposables and consumables, 8.88% for surgical instruments, 8.46% for IVD reagents, 8.16% for electronics and equipment and 7.7% for implants.

New Zealand healthcare industry is presently focusing on the production and procurement of medical devices for oncology, obesogenic and diabetic care including remote management and telehealth solutions, cardiovascular treatments, mental health, and renal problems.

4.8.2 Major Companies

Some of the major medical device companies in New Zealand are Orion Health, Fisher & Paykel Healthcare, Atlantis Healthcare, KonnectNET, Intrahealth Systems, Biomatters, MedTech Global, Sysmex, Dynamic Controls, Howard Wright, MoleMap NZ, AFT Pharmaceuticals and Aroa Biosurgery.

4.8.3 Lead Cluster[116]

Auckland and Canterbury are the two biggest medical device clusters in New Zealand, housing 139 companies together. Auckland is the tech powerhouse of New Zealand and houses 60% of the firms and employs 50% of the country's workforce. The cluster is blessed with the presence of support of five institutions and R&D centers.

4.8.4 Innovative Cluster Network[117]

The Consortium for Medical Device Technologies (CMDT) links NZ Universities and Crown Research Institutes (CRIs) and agencies with companies, healthcare providers, regulatory and industry bodies, the Health Innovation Hub, and the Commercialization Partner Networks. It helps companies to link with their research partner and the eco system.

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[112] https://andamanmed.com/target-markets/malaysia/

[113] www.aseanbriefing.com

[114] Apart from sources mentioned specifically, various parts of this section have been derived from a mix of sources as mentioned from bibliography numbers 81 to 86

[115] thefreelibrary.com

[116] aucklandnz.com

[117] cmdt.org.nz

4.9. Norway[118]

Although health care expenditure in 2019 was 10.52% of the country's GDP, slightly lower than average of high-income countries.

4.9.1 Industry Structure[119]

Estimates indicate that the total Norwegian market for medical devices was over USD 2 billion in 2015 including USD 2.8 billion in imports and USD 2.3 billion in exports. 227 firms (67% being start-ups) employ 5000 persons. As health and social welfare is predominantly publicly financed, 90% of the medical device purchases are made by various public healthcare authorities. It is research led industry. In 2015, the industry accounted for one third of total country R&D expenditure of USD 7.5 billion. Half of these expenditures were executed in university hospitals. More than 50% came from the Ministry of Health and Care Services and less than 25% came from the Ministry of Education and Research. About 70% of the R&D funding for medical and health sciences to universities came from General University Funds.

4.9.2 Major Companies

Some of the major Norwegian medical device companies are PharmaLex, Invitrogen, CIMON Medical, Epiguard and Bulbitech. Norway also houses international companies like GE Healthcare (USA), Abbott Rapid Diagnostics AS (USA), Merck AS (USA), Zimmer & Peacock AS (USA/UK) and Siemens Healthineers (Germany).

4.9.3 Lead Cluster[120]

Norway Health Tech, formerly known as Oslo Medtech, is a cluster of 140 medical companies, 2 hospitals (Oslo University Hospital and Akershus University Hospital), finance, knowledge and research institutions focusing on medical technology and eHealth. The cluster is a pioneer in remote diagnostics sensors & wireless products. The cluster's main goals are to facilitate cooperation between research, the health sector and industry, facilitate testing, (coordinates a network of 7 Nordic testbeds).

4.9.4 Innovative Cluster Network

In 2017 the Norway Health Tech cluster launched a project named Nordic Proof to connect the Nordic test facilities into a network.

4.9.5 Country Efforts to Promote Medical Devices Industry

- **Creating Appropriate Factor Conditions**
  - Regional institutions are set up to facilitate commercialization of products and services based on research results in hospitals and universities. These institutions build expertise for intellectual property rights, standardization, and commercialization, and bring together research knowledge, technology competence and commercial stakeholders.
  - Knowledge and research within OSLO life science sector is normally produced in11 research institutes and centers of excellence, 3 universities and 5 hospitals. Medinnova, SINTEF/Unimed and the Research Foundation of the Norwegian Radium Hospital commercializes ideas. Two highly developed research parks are also present in the region.[121]

- **Promotion of Networks**
  - Norway has promoted a number of networks to promote its medtech clusters that facilitate innovation, procurement processes and projects, clinical trials and testing, business plans and strategies and help companies to reach global market. Some of the well-known networks (number of companies/institutes) include Oslo Medtech (140), Arena Helseinnovasjon (11), MedITNor (30), Oslo Cancer (60), MedCoast (15).

- **R&D Support:** Support comes through start-up grants, cluster program which funds three clusters Oslo Cancer Cluster, Oslo Medtech Cluster and Norwegian Smart Care Cluster. Innomed competence network provides funding to the 'pre-projects' –usually between 200 000 and 500 000

[118] Apart from sources mentioned specifically, various parts of this section have been derived from a mix of sources as mentioned from bibliography numbers 87 to 96

[119] Source: Absolute Data Insights

[120] European Cluster Collaboration Platform

[121] https://www.urenio.org/e-innovation/stratinc/files/Cluster_document_OSLO.pdf

NOK per project.

- **Venture Capital:** 15 VC and PE exist in Norway. Sarsia Seed has had the highest number of seed stage investments in this sector during the last couple of years. Birk Venture in Norway is also a recently established fund committed to the life science sector. NeoMed Management is another important Norwegian fund committed to the Life Science industry with a strong focus on Medtech.[122] Like any other private institute, Investinor (government funded) investment company invests venture capital into highly competitive and promising Norwegian companies aiming for international growth and expansion. Investinor manages NOK3.7 billion (460 million Euro). Another similar organization is Argentum established by the Norwegian Ministry of Trade and Industry. Which has invested in 16 life science companies in Sweden and Norway since 2007.[123]

4.10. Philippines[124]

The current health expenditure as percent of GDP was 4.08% as compared to 3.71% of lower middle-income countries. The per capita current health expenditure also increased significantly during the period 2015 to 2019.

4.10.1 Industry Structure

The market size is estimated at USD 1.48 billion in 2020 and is expected to see a growth at the rate of 10.61 per cent CAGR to USD 2.45 billion by the end of 2025. Local production the Philippines is limited to prototype units and disposables. The import of medical devices in Philippines has merely grown by 0.5% annually between 2016 and 2020, while the export has grown significantly at 7% annually in the same period.

4.10.2 Major Companies

Since Philippines imports almost all of its required medical device, no major medical device manufacturers are producing devices in Philippines. However, some of the major foreign companies present include GE Medica, Smith and Nephew, Siemens, Fujirebio, Fukuda, Fukugawa, Hitachi, etc.

4.10.3 Lead Clusters

No formal clusters are present in Philippines for medical devices development and manufacturing. Some trading and service providers associations like the association of IVD Distributors (IVD-Dap) and Philippines Association of Medical Devices Regulatory Affairs Professionals (PAMDRAP) respectively are present.

4.11. Singapore[125]

Singapore's healthcare expenditure was 4.08% of GDP in 2019 and could go up to 9% by 2030. This increase is largely attributed to rising government spending on healthcare, as well as the local population's consumption of healthcare services. Out-of-pocket expenses incurred as percentage of health expenditure in Singapore is comparable to the amount spent in middle income countries and is nearly 2.5 times that of high- income countries.

4.11.1 Industry Structure

The medical devices market in Singapore was USD 0.47 bn in 2020 and was expected to grow at 11.16% over the next decade to reach USD 1.36 bn by 2030. The industry currently employs around 9,000 people in Singapore. Ministry of Health is a major buyer.[126] Singapore is a major supplier of global market for contact lenses (10%), microarrays (over 70%), thermal cyclers and mass spectrometers (around 50%)[127]. Some of the top products that are expected to see a high growth rate between 2020 and 2030 are diagnostic and laboratory disposables antibodies & handheld surgical devices patient

[122] sariaseed.com, neomed.net, birkeenture.com

[123] Investinor.no

[124] Apart from sources mentioned specifically, various parts of this section have been derived from a mix of sources as mentioned from bibliography numbers 97 to 99

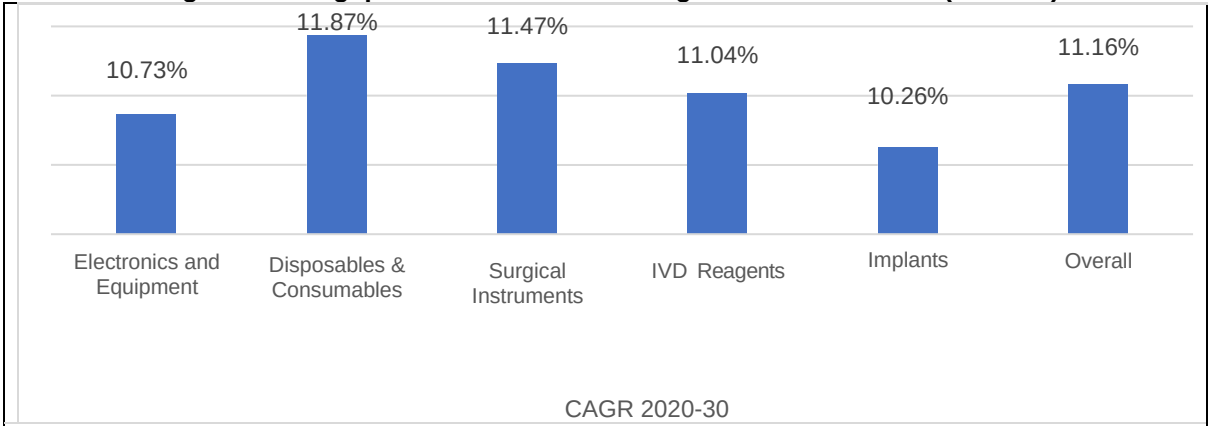
[125] Apart from sources mentioned specifically, various parts of this section have been derived from a mix of sources as mentioned from bibliography numbers 100 to 121

[126] Absolute Data Insights

[127] https://www.aseanbriefing.com/news/singapore-an/

monitoring surgical sutures and staplers.

Figure 4.8 Singapore Medical Devices Segment Growth Rates (2020-30)



Source: Absolute Data Insights

4.11.2 Major Companies

Major companies include QT Vascular, Biosensors International, Becton Dickinson, Optimal Medical Products Pte Ltd, B. Braun Singapore Pte Ltd, Alcare Pharmaceuticals, and Kingston Medical Supplies Pte Ltd.[128]

4.11.3 Lead Cluster

Singapore is a regional hub for medical device industry with more than 60 multinational medical device companies having a base here. Singapore's medical device cluster has developed vastly in recent years including the hosting of a collection of start-ups. The growing sectors are cardiovascular, eye care, diagnostic, imaging, scientific instruments, and orthopedics.[129]

Apart from providing opportunities within, Singapore is also positioning itself as the hub for medical technology manufacturing for the western manufacturers to supply to the entire Asia Pacific. One needs to find R&D resources, build, and staff a manufacturing facility, and develop a sales organization. And then navigate through all the regulatory red tape and manage it. Singapore provides the location where one could invest, with available talent pool, infrastructure, technological advantages, and a progressive environment designed to support medical technology manufacturing.

4.11.4 Innovative Cluster Network

The Joint Commission International (JCI) has accredited 23 Singapore hospitals and healthcare facilities. Renowned global healthcare research stalwarts like American Association for Cancer Research, Duke University, Healthcare Information and Management Systems Society have established presence in Singapore.[130]. National Research Foundation launched Singapore Health Technologies Consortium (HealthTEC) [131] in 2019 to connect academics and industry partners and provide with seed funding and facilitates licensing of locally developed technologies.

4.11.5 Country Efforts to Promote Medical Devices Industry

- Singapore is working on a dual strategy of creating scope for advanced manufacturing to take advantage of high margin products and simultaneously promoting the R&D status to leapfrog to the global leadership club.

- Going Global in Research - Branding
    - Joint Commission International (JCI), a global leader in health accreditation, has accredited 23 Singapore hospitals and healthcare facilities. American Association for Cancer Research, Duke University, Healthcare Information and Management Systems

[128] researchandmarkets.com

[129] https://www.aseanbriefing.com/news/singapore-an/

[130] https://www.trade.gov/country-commercial-guides/singapore-healthcare

[131]https://www.nrf.gov.sg/programmes/technology-consortia/health-technologies-consortium

Society, and JCI have established a presence in Singapore.
    - Agency for Science, Technology, and Research (A*Star) has implemented medical-technology (MedTech) initiatives. Its Biomedical Engineering program (BEP) – a collaboration with the Centre for Integration of Medicine and Innovative Technology in Boston, Mass. trains engineers and clinicians to collaborate in developing and providing cost-effective innovative medical products through research projects.[132]

- **R&D Support**
    - Ministry of Health, in partnership with A*STAR and several other governmental bodies, invested USD 53 million in clinical and translational research and USD 10.6 million for development of new clinical services. Singapore's Research, Innovation and Enterprise plan has allocated SGD 3.2 billion to advanced manufacturing and engineering research through 2020.
    - Besides there is a robust start-up ecosystem. "Since the launch of SEEDS Capital, an investment arm of ESG and DxD Hub, the number of Singapore-based MedTech companies has spiked by 250 per cent in just four years (2014 – 2018) to more than 250 MedTech companies"[133]. Over half of them are start-ups. SEEDS Capital has co-invested more than SGD 90 million in over 20 MedTech start-ups since 2018.More recently on 14 July 2020, SEEDS Capital and Advanced MedTech Holdings co-invested USD 10 million to fund ABM Respiratory Care (ABM), a medical device company developing novel integrated airway clearance and ventilation solutions. "The funding will accelerate the global commercialization of the Alpha, the world's first telehealth ventilator developed by ABM in Singapore. The investment represents one of SEEDS Capital's largest investment in the medical device sector to date…."[134]. In April 2019, SG Innovate named five new co-investors[135] to focus on early-stage Deep Tech start-ups in various fields, including MedTech. The government-owned investment firm has already invested SGD 40 million in around 70 local and foreign deep tech start-ups, which have also gone on to attract SGD 450 million of funding from the market. To date, SG Innovate and its partners have completed 22 co- investment deals. The total value of investments that would be made alongside these co-investors is estimated to reach up to SGD 80 million by 2022

- **Promoting a High Value Manufacturing Hub**
    - To promote high value manufacturing Singapore is making the experience a seamless process for investors and start-ups by providing a single window support to find R&D resources, build and staff a manufacturing facility, and develop a sales organization and then navigate through all the regulatory red tape and manage it. Government agencies provide not just funding, but also top-notch R&D from their own researchers as well as from MIT and Harvard and access to a ready-made global supply chain.
    - MedTech Manufacturing Consortium helps local firms to develop their capabilities and technologies and train manpower. The Centre of Regulatory Excellence (CoRE), promoted by Duke-NUS Medical School promotes collaboration between academia, industry, and regulatory agencies.
    - Singapore is also investing in partnerships between OEMs and suppliers of automation and advanced manufacturing technologies. The SGD 250 million Partnerships for Capability Transformation (PACT) [136] program was introduced to encourage partnerships between foreign corporations and local suppliers by aiding with knowledge transfer, upgrading supplier capabilities, and developing collaborative processes.

- **Regulatory Support to Cut Down Registration Time[137]**
    - Under the Pre-market Consultation (PMC) Scheme, one can consult Singapore's Health Science Authority (HSA) on regulatory requirements during the medical device development or seek feedback on device dossier before submission. This will expedite device registration and facilitate early access of medical devices. The PMC Scheme will also help the manufacturer to adhere to regulatory requirements in Singapore. The support

[132] https://www.aseanbriefing.com/news/singapore-an/

[133] https://www.singaporemedtech.com/articles/industry-articles/key-drivers-of-growth-in-singapore-s-medtech-industry

[134] https://www.singaporemedtech.com/articles/industry-articles/key-drivers-of-growth-in-singapore-s-medtech-industry

[135]https://www.nrf.gov.sg/programmes/technology-consortia/health-technologies-consortium

[136]http://www.enterprisesg.gov.sg/

[137] hsa.gov.sg/medical-devices/consultation-schemes

includes:

- "Development Consultation" during a medical device's' development phase with respect to concept feasibility, invention and prototyping, design validation (pre-clinical) and clinical consultation with a fee of USD 500 (for 2 hours) and
- Pre-submission Consultation to seek feedback on their device dossier before registration application so as to ensure that supporting documents are complete and appropriate at fees of USD 200 (for 1 hour).

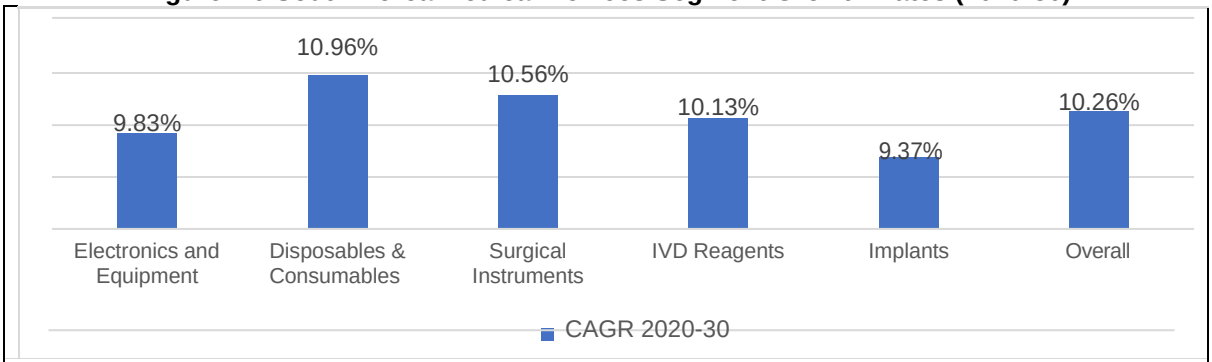
4.12. South Korea[138]

Healthcare spending totals 8.16% of GDP (in 2019) per capita spending on healthcare (PPP) was USD 3521 in 2019 as compared to nearly USD 6328 for high income countries. The number of hospital beds per 1000 people in South Korea in 2015 was over four times the number of hospital beds in high-income countries.

4.12.1 Industry Structure[139]

The market size for the medical device sector in 2020 was approximately USD 7.12 bn. The market is expected to grow at a CAGR of 10.26 percent and be 18.92 bn by 2030. Nearly 80 percent of South Korean medical device manufacturers are small- and medium-sized enterprises (SMEs) with less than USD 1 million in revenue and as of 2018.

Figure 4.9 South Korea Medical Devices Segment Growth Rates (2020-30)



Source: Absolute Data Insights

The total exports and imports of medical devices are growing at CAGR of 19.53 per cent and 9.14 per cent respectively in the period 2016-2020. IVD Reagents was the fastest growing category both in terms of exports and imports in South Korea in the review period 2016-2020.

4.12.2 Major Companies

In 2019, Osstem Implant was the leading medical device manufacturer in South Korea followed by Samsung Medison. Some of the other leading firms are Dentium, Vatech, Siemens Healthineers, GE Ultrasound Korea, Medytox, Samsung Electronics, Magagen Implant, Abbott Korea, etc. [140]

4.12.3 Lead Clusters

Daegu leads Medicine and Information technology. The eco system consists of five medical schools, more than 3,500 clinics, and hosts the Daegu High-tech Medical Cluster, which provides R&D support for cutting-edge technology for medical devices. Highlights of the Medivalley cluster are as follows.

- Key facilities for medical devices, including the Pohang Accelerator Laboratory and Gyeongju Proton Accelerator Research Centre
- The best preclinical and clinical facilities and medical devices outside the country's'capital region.
- A host of medical universities from the Daegu-Gyeongbuk region, including 5 medical, 2 oriental

[138] Apart from sources mentioned specifically, various parts of this section have been derived from a mix of sources as mentioned from bibliography numbers 66 to 73

[139] Source: Absolute Data Insights

[140] South Korea: Leading Medical Device Manufacturers, Statista 2019

medical, and 4 schools of pharmacy
- 3,466 medical institutions and 5,236 pharmacies
- Facilities for the development of the robot industry, led by Korea Institute for Robot Industry Advancement
- Large-scale projects, including a regional 3D Convergence industry development project.
- Co-development of imaging device, next-generation display, and component industries
- Related industry facilities, including mechatronics, mould, nano and advanced materials and IT
- Joint research agreements with national research institutions, including Korea Research Institute of Bioscience and Biotechnology and National Cancer Centre
- Global networks with Kobe Medical Foundation, New Jersey Medical Cluster, etc.
- Joint research agreements with local universities, including Kyungpook National University
- Agreements with related organizations, including Korea Drug Research Association and Korea Medical Devices Industry Association
- The largest cluster of universities outside the capital region (annually, over 85,000 graduates from universities and colleges in Daegu-Gyeongbuk)
- Customized manpower training projects optimized on-site
- Programs to avoid job mismatching, including a recruiting tour and a company visit project
- Tax benefits – Corporate tax and income tax 100%exemption for 3 years and 50% for the next 2 years, property tax 100% exemption for 10 years and 50% exemption for the next 3 years, even more for Foreign-Invested Companies.
- R&D budget support for drug and advanced medical device research and development
- Interest-free instalments for 5 years on land purchase, 3% discount on pre-payment
- Exceptional deregulation to provide better environments for doing business
- Total firms – 60 plus.

Medical Device Development Centre

- Support for imaging-based fusion diagnosis and treatment device (IT) development with a focus on three major diseases: cardio-cerebrovascular, geriatric, and cancer diseases
- One-stop total solution services for commercialization
- R&D Support for IT-based Fusion Diagnosis and Treatment Device Commercialization
    - Research Equipment Support
        - Image fusion equipment
        - Research equipment (reliability test equipment, etc.)
    - Skill and Reliability Solution
        - Product technology analysis and developed technology application test
    - R&D Support
        - Reliability improvement
        - Product technology
    - Academic and Research Network
        - Other support through network of industries, academia, research centers and hospitals

Table 4.3 Support Projects – Medical Device Development Centre in Medivalley

Support Projects	Support Content
Joint R&D for Key Technology Development	Support for products that have great potential but have been delayed for release or have seen low sales due to technological problems
Customized Collaborative R&D	Support for products that feature excellent technological quality but have failed to access the market due to the lack of the credibility of hospitals
Prototype Production	PCB engineering/manufacturing & part installation (SMT)
Test and Evaluation	Main targets: surgical devices, diagnostic devices, medical simulators, in vitro diagnostic devices, syringes and needles, u-healthcare devices
Human Resource Matching for companies	- Matching a professional expert of the Centre to a company (1:1) - Comprehensive consulting from the conception of an idea to the commercialization of a product
Exchange Lab Operation	- Joint research and close cooperation among companies, hospitals, research centers, etc. - Support for joint R&D and equipment utilization

Customized Education	- Education course development for each medical device development stage - Support with the Centre's experts and professional instructors
Source: www.medivalley.re.kr	

Laboratory Animal Centre

- An animal testing system for synthetic drug and IT medical device development
- Support for customized animal testing through three strategies of differentiation Bio-imaging analysis / Advanced fusion microsurgery / Customized animal models
- Support Area: Optimization of Candidate (Animal in-vivo assessment) in new drug development; and evaluating the performance and biological stability through animal test in Medical Device Development
- 4 rabbit rooms, 4 guinea pig rooms, 1 SPF room (Rabbit 138, Guinea pig 512 Mouse 2,800) for Medical Device testing.

Table 4.4 Support Projects – Laboratory Animal Centre in Medivalley

Support Projects	Support Content
Medical Device Performance	In vivo performance assessment of prototypes Material assessment / Imaging-based material assessment •Material insertion test Telemetry test
Assessment Study monitoring	Evaluation of approval test Monitoring Consulting on items of safety assessment Manual/SOPs establishment and supplementation
Preliminary Biological Stability Assessment of Medical equipment	Cytotoxicity Genotoxicity (Micronucleus, Ames) Blood compatibility Material monovalency Acute/subacute systemic toxicity Sensitization test Elution test Irritation test Telemetry test
Source: www.medivalley.re.kr	

4.12.4 Country Efforts to Promote Medical Devices Industry

- **Relaxation in Registration for New Products**: The South Korean Government is in constant pursuit to reduce the device approval time. It made an announcement to reduce time significantly in 2018. It also adopted a "negative regulatory approach" for products that requires lesser safety checks. Here, a new product will be assessed after its introduction in the market. For example, the period for entry to market for IVD devices will be shortened from 390 days to 80 days and that for patient treatment from 490 days to 390 days and preferential market entry permission for AI, 3D printing, and robotics technologies used for IVD.[141]

- **Role of Hospitals in R&D**: Korea also promotes crating research-oriented hospitals. Government is promoting hospitals to establish "industry-hospital cooperation organizations[142]. For such hospitals the Government will get rid of institutional barriers.

- **Park for R&D**: Medical cluster project of the Government of Korea is promoting Parks for promoting R&D. For example, the Medivalley project in Daegu has core facilities and R&D centers of medical device or drug companies. Facilities include the Medical Device Development Centre (MDDC), which will provide comprehensive solutions including applied R&D support, prototyping, effectiveness evaluations etc.

- **Public R&D Support**: South Korea will invest USD10.3 billion in medical device R&D over the next six years.

[141]http://www.businesskorea.co.kr/news/articleView.html?idxno=23796

[142]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6313395/

4.13. Sweden

The country saw an increase in domestic general government health expenditure per capital (PPP terms) between 2015 and 2019 and it was much higher as compared to other high-income countries. Per capita spending on healthcare was USD 6223 in 2019 which is close to the average for high income countries.

4.13.1 Industry Structure

The market size of healthcare and services sector of Sweden is EUR 14 billion which includes medtech industry with a share of EUR 2.1 billion in 2014. Swedish medtech industry has over 629 companies (40% SMEs) working mainly in the areas of medical research, precision and optical instruments, orthopedic articles and implants, and x-ray and radiation equipment. More than 56,000 people are employed in the industry with 43% in research, 15% in product development and 40% manufacturing.

Swedish medtech industry functions on the solely through public private collaborations. Procurement and outsourcing are among the most common ways of public private collaboration in Sweden. Solutions and products that are being developed through public private collaboration on innovation have to be subjected to a public procurement process once the outcome is matured and ready to be applied in the public sector.

Swedish medtech industry is currently focusing in the areas of e-health, telemedicine, non-invasive surgical equipment, orthopedic and prosthetic equipment and home health care and assistive technologies equipment and supplies.

4.13.2 Major Companies

Some of the major Swedish medical device companies are ArjoHuntleigh, Getinge, Osstell AB and Spectronic. Major international brands also have set up their facilities in Sweden such as Cochlear Bone Anchored Solutions (Australia), Abbott Scandinavia AB (USA), Liko (USA), Medtronic AB (Ireland) and B. Braun Medical AB (Germany).

4.13.3 Innovative Cluster Network

Swedish Medtech is the largest medtech cluster in Sweden and has almost 200 companies. The cluster's major goal is to ensure a well-functioning partnership between the industry and healthcare to realize sustainable care and care for the future. The cluster also focuses to strengthen the medical technology companies' 'onditions for developing innovative solutions in Sweden in collaboration with healthcare, academia, and patients.

The cluster paves improved business condition for their companies through close collaboration with the public health sector on various matters such as public procurement and structural collaboration within healthcare and other institutions to improve the healthcare system.[143]

Innovation Engines is a strategic project of the cluster body with the goal of increasing the pace of development work in healthcare. The purpose of the project is to make better use of the knowledge and experience available in healthcare to strengthen the sector's' role as an engine for the development of new methods and products. The project hosts a vast network of law corporations, business and technology consulting organizations, product development companies, research and medical institutes, an exhibition center, standards and certification agencies and public affair firms. The network works in a symbiosis which enables medtech companies to successfully transform an idea into product and easily make it accessible to public.

4.14. Switzerland[144]

While the out-of-pocket expenditure (as a % of current health expenditure) is nearly double that of other high-income countries, the quality of service provided more than makes up for it. Domestic general government health expenditure per capita, PPP for Switzerland is also lower as compared to other high-income countries. The number of physicians per 1000 people in Switzerland (4.19) in 2015 was lower than that in high-income country (5.48)

[143] swedishmedtech.se

[144] Apart from sources mentioned specifically, various parts of this section have been derived from a mix of sources as mentioned from bibliography numbers 128 to 131

4.14.1 Industry Structure

The Swiss medical device industry in 2019 was CHF 17.9 billion[145] and the industry has been growing at over 6.5% over the last few years. The industry growth rate has been significantly higher than the overall growth rate of Switzerland's GDP and the at present it forms 2.6% of the country's GDP. There are around 1400 firms across various areas such as manufacturers, suppliers, service providers and companies involved in trade and distribution of the goods. In addition to global corporations, SMEs dominate, with over 90 per cent employing less than 250 people and 20 per cent employing less than 50 people. Micro enterprises (fewer than 10 employees) are the majority. The industry provides employment to close to 63,000 personnel across various functions and this figure corresponds to nearly 1.2% of the total workforce of the country. [146]

The Swiss medical devices industry exports have grown by an average of 3.2% per year and in 2019 was CHF 12 bn, which was nearly 5% of the total exports of Switzerland. Major export destinations are USA, Germany, Netherland, Belgium, China, etc. The top 10 destinations covered around 80 per cent of the exports.

The country is at the forefront of patent applications in the European region. Swiss companies filed 770[75] medical device patent applications in 2019 and the country ranks third behind Germany and the Netherlands among European counterparts in patent filings in this space.

4.14.2 Major Companies

Roche Diagnostics, Sonova, Straumann, Ypsomed are the leading Swiss companies in medtech space. Besides these, leading players in this industry such as J&J Medical, Medtronic, Zimmer Biomet, Jabil, Dentsply, Sirona, Biotronik have a presence in the country. These companies are the top medical devices employers in the country employing nearly 16000 people.

4.14.3 Lead Clusters

The Jura region is home to a cluster of tech companies that act as suppliers of specialized know-how. Lake Geneva and Zurich regions are considered the base of medical device companies in the country due to their proximity to the two Swiss Federal Institutes of Technology, EPF Lausanne and Swiss Federal Institute of Technology in Zurich (ETHZ), both of which have a strong focus on the medical device industry. As an important financial center, Zurich has easy availability of venture capital and private equity funds.

4.14.4 Innovative Cluster Networks

There is a unique system of transfer of expertise and cooperation among partner firms in the Swiss medtech industry which encourages innovation. Over 90% of the medical devices firm collaborate with universities, hospitals, or companies from related sectors, such as mechanical engineering or pharmaceuticals.[147]

4.14.5 Country Efforts to Promote Medical Devices Industry[148]

Switzerland practices several means to promote the entry of new/innovative medical devices. These include the following:

- **Specialization** [149] : Large companies like Novartis and Roche are divesting non-core areas and simultaneously focusing on "...highly innovative products...which also impacts operations in Switzerland..." [150] They are even cutting the workforce in manufacturing and investing in research.

- **Collaborative Effort:** Various research centers are now doing collaborative research to utilize their specialization**. "...**Federal Institute of Technology in Lausanne (EPFL), the University of Geneva (UniGE) and the Geneva University Hospital (HUG) have joined forces, aiming to create Switzerland's first high-throughput DNA sequencing platform[151] University. Hospital of Bern, the

[145] The Swiss medical Technology Industry 2020, Swiss Medtech

[146] s-ge.com

[147] s-ge.com

[148] Select portions from s-ge.com

[149]Hug,Sebastien; "How Switzerland is leading Innovation going forward", October 28, 2018, IndiaMed Today (swiss-medtech.ch)

[150]Hug,Sebastien; "How Switzerland is leading Innovation going forward", October 28, 2018, IndiaMed Today

[151] https://www.unige.ch/communication/communiques/en/2017/cdp100517

Swiss Institute for Translational and Entrepreneurial Medicine is offering R&D labs for joint use by industry and academia. " [152] . Donations are coming from entrepreneurs. " Wyss Zurich R&D center was supported by a USD 120 mn by Mr Hansjörg Wyss" that brought together the University of Zurich and ETH Zurich launched at the center "...to drive translational research in the fields of regenerative medicine and robotics" Also "94% of the medical equipment manufacturers in Switzerland collaborate with partners – whether they are universities, hospitals, or companies from related sectors, such as in mechanical engineering or pharmaceuticals [153] .

- **National Data Infrastructure**: In 2017, Swiss government launched the "Swiss Personalized Health Network" [154] (SPHN) initiative and dedicated USD 70 mn to build a national coordinated data infrastructure for research hospitals, universities, and other research institutions. This will not be a centralized data-base but a dynamic network of existing data sources" [155]

- **Promotion of Innovation Park**: Switzerland promotes Innovation Park, including two hubs close to the two Federal Institutes of Technology in Zurich and Lausanne and the three network locations in Aargau, Basel, and Biel [156]

- **R&D Support**: Annual budget of Innosuisse[157] is around 200 million Swiss francs. It also promotes cooperation between science and the market with innovation projects, networking, training, and coaching. An Innovation Park was launched at the start of 2016, which includes two hubs close to the two Federal Institutes of Technology in Zurich and Lausanne and the three network locations in Aargau, Basel, and Biel.

- **Operating from a Cluster with strong ecosystem**: Leading firms gain a lot as they operate from clusters having internationally renowned "...healthcare companies, teaching hospitals, technical colleges, and university.... with access to a skilled, international, and diverse talent pool " [158]

- **Setting up Innovation Parks –** The Swiss Innovation Agency (Innosuisse) specifically promotes cooperation between science and the market with innovation projects, networking, training, and coaching. An Innovation Park was launched at the start of 2016, which includes two hubs close to the two Federal Institutes of Technology in Zurich and Lausanne and the three network locations in Aargau, Basel, and Biel. The agency has an annual funding budget of around 200 million Swiss francs – the majority going to innovative projects.

- **Exemption from Taxes** - Start-ups and newly established foreign companies are eligible for partial, or in some cases complete, exemption from corporate and capital taxes at cantonal level for a period of up to ten years.

- **Simple Procedures to Protect Intellectual Property** –There is a one central, internationally valid registration procedure provides access to international systems for the protection of intellectual property (European Patent Office EPO, World Intellectual Property Organization WIPO). Local representatives in other countries are not required.

- **Invite Experienced Specialists from Abroad** – One of the major challenges that the Swiss medical device companies face is access to qualified specialists. To overcome this challenge, Switzerland promotes itself as an attractive destination for highly qualified foreign workers. The country ranks at the top of the most attractive destinations for highly qualified foreign workers in the IMD World Talent Ranking, 2019.

- **Free trade agreements with the EU/EFTA and 40 other countries** – Switzerland has signed a

[152]Hug,Sebastien; "How Switzerland is leading Innovation going forward", October 28, 2018, IndiaMed Today

[153]Switzerland Global Enterprise, November 2020

[154]Hug,Sebastien; "How Switzerland is leading Innovation going forward", October 28, 2018, IndiaMed Today

[155]Hug,Sebastien; "How Switzerland is leading Innovation going forward", October 28, 2018, IndiaMed Today

[156]Switzerland Global Enterprise, November 2020

[157] The Swiss Innovation Agency

[158]Switzerland Global Enterprise, November 2020

free trade agreement with EU and other important countries including China and Japan. The mutual recognition of conformity and quality control makes it easier for Swiss medical device companies to access these international markets.

4.15. United Kingdom[159]

The total expenditure on healthcare as a proportion of GDP has been hovering at ~10% between 2015 & 2019, below the average of 12.5% for high-income countries. In 2019 the UK spent USD 5087 per person on healthcare, which was lower than the high-income group countries. The country also fares poorly in terms of out-of-pocket expenditure and hospital infrastructure (hospital beds per 1000 people) when compared with other high-income countries.

4.15.1 Industry Structure[160]

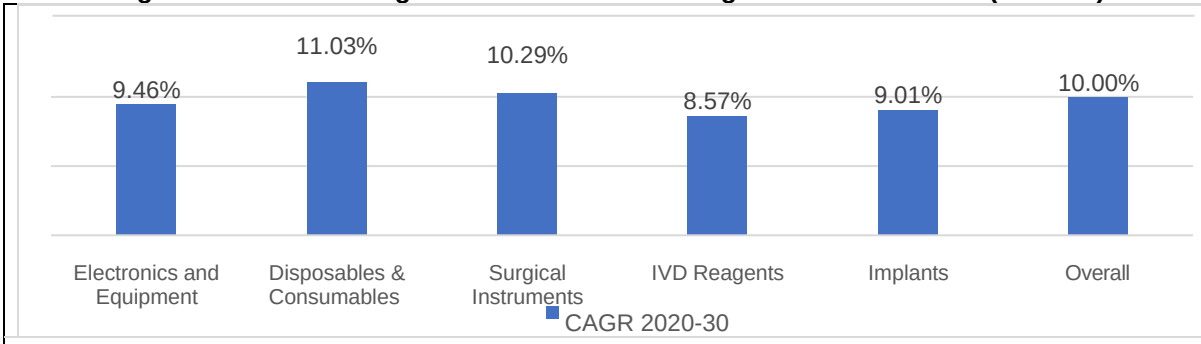
The UK medical devices market is the third largest in Europe, behind Germany and France, and the sixth largest in the world. It was valued at USD 37.27 bn in 2020 and is expected to grow to USD 96.64 bn by 2030, growing at a CAGR of 10%.

The UK medical technology sector is comprised of just over 2150 companies providing jobs to 86,000 people and 98% of them are small to medium sized companies.

The largest purchaser of medical products in the UK is the public healthcare segment, the National Health Service (NHS). The NHS serves 84% of the population and is planned and commissioned by 191 clinical commissioning groups (CCGs), 152 acute hospital trusts, 10 ambulance trusts, and 54 mental health trusts. The NHS annual spending on MedTech amounts to £6 bn, of which £3 bn is spent on research and development of complex medical devices such as hip joints, cardiac devices, etc.

The industry has been developing and producing radiotherapy equipment, neurology and cardiovascular devices, single-use technology, in vitro diagnostic technology, and orthopedic devices.

Figure 4.10 United Kingdom Medical Devices Segment Growth Rates (2020-30)



Source: Absolute Data Insights

4.15.2 Major Companies

Some of the major medical device companies in the UK are Smith & Nephew, Livanova, Puretech Health, Lumiradx and Quotient. Apart from these, companies like Roche (Switzerland), Johnson & Johnson (USA), Zimmer Biomet (USA) and Becton, Dickinson, and Company (USA) operate in UK as well.

4.15.3 Lead Clusters[161]

MedCity is the largest cluster organization for the world-leading health and life sciences sector in UK, which is a part of The Golden Triangle. The cluster has a strong footprint for academic medical research and product development in collaboration with 5 world-class institutions (University of Cambridge, University of Oxford, Imperial College London, University College London, and King's'College London) along with 994 medtech companies. MedCity spots opportunities for industry and researchers to work together. MedCity has 140 special clinics, 39 acute trusts, 32 CCGs and 32 research, technology and trial centers. The cluster also has a talent pool of more than 185,000 life-sciences students – the largest

[159] Apart from sources mentioned specifically, various parts of this section have been derived from a mix of sources as mentioned from bibliography numbers 132 to 137

[160] Source: Absolute Data Insights

[161] medcityhq.com

life-sciences talent pool in Europe.

4.15.4 Innovative Cluster Network

Academic Health Science Networks (AHSNs) created a MedTech Innovation National Network (INN) to speed up innovations and their adoption by the NHS. It specializes in devices and IVD.[162]

4.15.5 Country Efforts to Promote Medical Devices Industry

4.15.5.1 UK Government's Support to Industries in General

- Enterprise Investment Scheme[163] (EIS): is a venture capital scheme designed to help companies raise money by offering tax reliefs to individual investors who buy new shares in the company. EIS enables businesses to raise up to INR 515 million each year, and a maximum of INR 1237 million in the company's lifetime. Businesses must not have gross assets worth more than INR 1547million before any shares are issued and must have less than 250 full-time employees.
- Seed Enterprise Investment Scheme[164] (SEIS): The SEIS is designed to help businesses raise up to INR15.5 million worth of investment. The business should have been operating for less than two years and have less than INR 20.6 million of assets. The SEIS scheme is designed to help companies raise money by offering tax relief to individual investors who buy new shares in your company.
- Research and Development tax reliefs[165]: Companies which focus on science and technology can reduce their corporation tax by claiming an R&D tax credit equivalent to 230% of qualifying costs. To qualify, firms must have fewer than 500 employees and an annual turnover of less than INR 8.7 billion. Additionally, if the firm is loss making, it can claim a tax credit worth up to 14.5% of the surrender-able loss.
- Start Up Loans[166]: The Start Up Loans Company, subsidiary of the British Business Bank, supports businesses by providing them finance under UK government's Start Up Loans program. The loan amount is generally up to INR 2.6 million.
- There are a lot of schemes targeted at SMEs (startups and established) located in various parts of UK and providing different types of business support such as business consultancy, training, and grants for equipment purchase (up to INR 5.1 million). These schemes often run-in collaboration with leading local educational institutions or local business promotion councils. Some examples of such schemes are ALPHAS Project (South East Midlands), Building Legacies (London Area), Business Development Grant Scheme (Scarborough), Business Growth Grant (Leicestershire), Coventry and Warwickshire Green Business Program, D2N2 Capital Growth Fund (Derbyshire and Nottinghamshire), Enterprise M3 Funding Escalator (Surrey or Hampshire), Innovation Bridges - South East Midlands among others.

4.15.5.2 Life Science industries (Medical Devices, Pharmaceuticals, R&D, etc.)

- The UK government has announced plans for an INR 288 billion[167] hospital building program through NHS initiative in September 2019, which will include funding to invest in new diagnostics and technology.
- Medical Research Council Grant[168]: provides research grants in the field of medical to the tune of INR 103 million (maximum). Under the research grant support is provided for a period of up to five years, which can include salary of research team, equipment costs, travel costs and other related expenses.
- Scotland Government's Support[169]: With support of Scottish government's Advancing Manufacturing Challenge Fund (AMCF)[170], (total investment of INR 1.62 billion between 2020-2023), four leading Scottish universities Heriot-Watt, Edinburgh, Glasgow, and Robert Gordon,

[162] greybearconsultancy.co.uk

[163] https://www.gov.uk/guidance/venture-capital-schemes-apply-for-the-enterprise-investment-scheme

[164] https://www.gov.uk/guidance/venture-capital-schemes-apply-to-use-the-seed-enterprise-investment-scheme

[165] https://www.gov.uk/guidance/corporation-tax-research-and-development-rd-relief

[166] https://www.startuploans.co.uk/

[167] https://www.gov.uk/government/news/new-hospital-building-programme-announced

[168] https://mrc.ukri.org/funding/

[169] https://www.medicaldevice-network.com/features/scotland-towards-a-med-tech-manufacturing-powerhouse/

[170] https://www.scottish-enterprise.com/support-for-businesses/develop-products-and-services/innovation-support/advancing-manufacturing-challenge-fund

have come together to create the Medical Device Manufacturing Centre (MDMC). The MDMC supports Scottish small and medium sized companies (SMEs) with the development, manufacturing, and commercialization of medical devices.

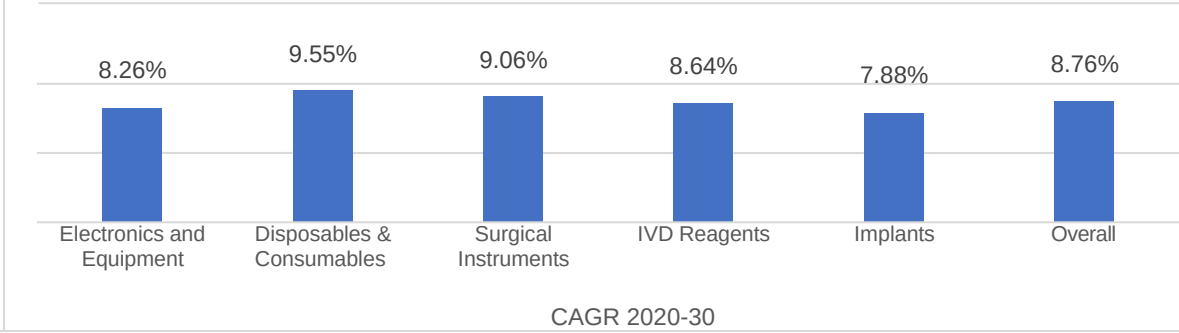
4.16. United States of America[171]

In the USA, 90% of the population has private health insurance, compared to 99% to 100% of the population in the other industrialized countries[85]. The health expenditure (% of GDP) in US substantially higher than that in other high-income countries, 16.77% of GDP (in 2019) for US as compared to 12.53% of GDP for other high-income countries. Healthcare is very expensive, which is evident from the fact the current per capita health expenditure is nearly double that of the other high-income countries.

4.16.1 Industry Structure

The United States remains the largest medical device market in the world at USD 180.32 billion - 35 percent of the global medical device market in 2020. The medical device market in the US is projected to register a Compound Annual Growth Rate (CAGR) of 8.8% from 2020-2030, with a value of USD 418 bn by 2030. US medical device companies are highly regarded globally for their innovative and high technology products. R&D spending continues to represent a high percentage of medical device industry expenditures, averaging 7 percent of revenue.[172]

Figure 4.11 USA Medical Devices Segment Growth Rates (2020-30)



Source: Absolute Data Insights

US medical device exports has grown 5.62% annually between 2016 to 2020 and imports has grown by 7.70% annually. IVD was the fastest growing segment in both exports and imports while the Implants segment was the slowest.

4.16.2 Major Companies

Some of the major US companies include Medtronic, General Electric, Boston Scientific, Becton Dickinson and Thermo Fisher, Stryker Corporation, Baxter International, Edwards Lifesciences, Zimmer Biomet, Varian Medical Systems, etc.

4.16.3 Lead Clusters[173]

Minnesota is one of the world's largest clusters for medical devices particularly in the fields of cardiology, neurology, urology, orthopedic, spine, audiology, and combination devices. It ranks at the top in cumulative premarket approvals granted by the FDA, medical technology patents granted and concentration of medical technology workers in the USA. The cluster houses many champions including Boston Scientific, 3M, and Medtronic. The local eco system of academic institutions and companies, and strong supplier network favorable tax conditions also help.

[171] Apart from sources mentioned specifically, various parts of this section have been derived from a mix of sources as mentioned from bibliography numbers 138 to 151.

[172] commerce.gov.in

[173] austrade.gov.eu

Table 4.5 Details of Key US Clusters

Name of the Cluster	Specialisation	R&D Organisations	Industries	Large Firms	Incentives/Initiatives (1A-Large supplier, 1B-BDSP, 2-Tax support, 3A-Public Scheme, 3B-Private support, 4-
Minnesota (Minneapolis/St. Paul)	Equipment, Surgical Instruments, IVD, Implants, Ophthalmic goods and Dental Instruments	University of Minnesota, The Mayo Clinic, 7 state universities, 17 private colleges and universities including and 24 two-year colleges.	600	Medtronic, 3M, St. Jude Medical, Boston Scientific	1A. Lake Region Medical – a leader in in wire formed medical devices. 1B. United Health Group is developing capabilities in sharing medical data across providers 2. R&D Tax Credit and a Foreign Royalty Deduction, Angel Tax Credit. 3B. In 2013, Mayo Clinic launched a USD 6 billion initiative
California (San Francisco/San Jose/Bay Area)		Stanford University, University of California Berkeley, University of California, University of San Francisco	1,377	Celgene Corp, Presidio Pharmaceuticals Inc., FibroGen, Ion Torrent Systems Inc., Bayer, Pfizer and Nextar.	1B. San Francisco Landing Pad assists companies to explore in-market business development, investment, mentorship and strategic partnership opportunities. 3A. National Institutes of Health (NIH) grant awards of USD 1.2 billion in 2014 (about 15% of total funding).
California (San Diego/Los Angeles/Orange)	Cardiology, neurology, orthopaedics, and ophthalmology	80 independents, university and college research centres.	1,100	Johnson & Johnson, Medtronic, Arena, Alma Life Sciences, BD Biosciences, Cypher Genomics, etc	3A. In 2013, South Californian companies and universities received USD 939 million in NIH funding.
Massachusetts (Boston/Cambridge)		Harvard Medical School, Brigham and Woman's Hospital, Children's Hospital, Dana-Farber Cancer Institute, Beth Israel Deaconess, and the Joslin Diabetes Centre. 122 colleges and universities	450	Novartis, Pfizer, Phillips Healthcare, Thermo Fisher Scientific, Covidien	1B. BDSP - 2 million square feet of R&D lab and biomedical office space has been added in the last seven years. Longwood Medical Area is home to 17 million square feet of clinical, research, and administrative space. MassChallenge is an international start-up accelerator based in Boston 3. Private R&D Support - Biotech and pharma VC funding in Massachusetts reached USD 449.5 million in 2015.

Name of the Cluster	Specialisation	R&D Organisations	Industries	Large Firms	Incentives/Initiatives (1A-Large supplier, 1B-BDSP, 2-Tax support, 3A-Public Scheme, 3B-Private support, 4-
Florida (Southern Florida)	Immune-oncology, infectious disease, ophthalmology, cardiology, neurodegenerative	University of Florida, The University of Miami, University of South Florida and 9 medical schools	620	Johnson & Johnson, Medtronic, Noven, Steripak, Beckman Coulter,	3. Public R&D Support - Over USD1 billion is invested in life sciences R&D by Florida universities annually.
Illinois (Chicago)	Specialised in dental, surgical and medical equipment	Northwestern University, the University of Chicago and the University of Illinois at Chicago	938	Abbott, AbbVie, Argonne National Laboratory, Fermilab, UL	3. Public R&D Support - In 2015, Northwestern University received USD 226.73 million in NIH funding, the University of Chicago received USD170.94 million and the University of Illinois received USD100.78 million. Over the past decade the top seven universities in Illinois have nearly doubled their R&D expenditures.
Indiana (Indianapolis/Warsaw)	Areas of speciality are cardiovascular, urology, diagnostics, and orthopaedics.	Major colleges such as Butler University, Indiana University, Purdue University, Rose-Hulman Institute of Technology, and the University of Notre Dame.	2,000	Boston Scientific, Cook Medical, DePuy, Medtronic, Roche Diagnostics, Zimmer	2. Taxation Support - – Patent Income Exemption program offers a sales tax exemption. An R&D Sales Tax Exemption offers a refund to sales tax on R&D for equipment. A Research Development tax credit is offered based on qualified research expenditure. A Venture Capital Investment tax credit.
Maryland/Washington Dc		Home to a number of colleges but most prominent in the medical field is John Hopkins University	2500	AstraZeneca, Emergent BioSolutions, Brace Pharmaceuticals, Epigenomics	2. Taxation Support - 50% biotech investor incentive tax credit.
New York/New Jersey		9 academic medical centres include Columbia University, Weill Cornell Medical College, New York University, Albert Einstein College of Medicine and the Rockefeller University along with Princeton University and Rutgers College	3100	Actavis, Bayer Healthcare, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, etc	3B. Private R&D support - In April 2015 USD150 million funds for early-stage research under guidance of two VC firms.
North Carolina (Research Triangle)	Genomics/proteomics, gene therapy, medical devices,	Duke University, the University of North Carolina at Chapel Hill,	300	BASF, Bayer, BD, Biogen, GSK, etc	2. Taxation Support - 4% corporate income tax. 3A Public R&D Support - –n 2012, North Carolina spent

Name of the Cluster	Specialisation	R&D Organisations	Industries	Large Firms	Incentives/Initiatives (1A-Large supplier, 1B-BDSP, 2-Tax support, 3A-Public Scheme, 3B-Private support, 4-
	diagnostics and sensors.	and North Carolina State University			US$2 billion on academic life sciences R&D.
Pennsylvania (Philadelphia)	specialties in radiology, physical rehabilitation and pulmonology	1,000 research, testing and medical labs in the state, 25 medical schools. 300 universities	2,000	B. Braun and Johnson & Johnson	2. Taxation Support - R&D tax credits 3. Public R&D Support - University of Pennsylvania and Pittsburgh received NIH funding of USD180 million and USD176 million respectively
Texas (Austin/Houston)	specialties in orthopaedics, wound care, cardiology and diagnostics	200 hospitals and clinics, 208 colleges and universities. Largest medical complex in the world, the Texas Medical Centre (TMC) with 21 hospitals and 8 academic and research institutions	190	GE Medical Systems, Johnson & Johnson, Alcon Research, Flextronics	3A. Public R&D Support - NIH funding in 2014 was USD 972 million (up from USD 957 million in 2013). 3B. Private R&D Dupport - –n 2014, medtech VC funding equalled USD 63.2 million (up from USD 40 million in 2013).
Utah (Salt Lake City)	specialities in arterial and vascular access devices		1,000	MasterControl, Nelson Laboratories, Moog Medical, Medtronic Inc, etc	3B. Private R&D Support - In 2014, Utah companies received USD16.4 million in VC funding. 3A. Public R&D Support - –n 2014, researchers in Utah received USD 176 million in NIH funding.
Wisconsin (Southeast)		73 higher education institutions		Mikrotech, GE Healthcare, Beere Medical, Xact Wire, Phillips Plastics,	3b. R&D Support - USD 934 million was spent on bioscience academic R&D
Source: Report “Medical Technology and Life Sciences, US Clusters”, Australian Trade and Investment Commission (Austrade), 2016					

4.16.4 Innovative Cluster Networks

Cluster based model helps to create connectivity among firms, service providers and universities, research institutions and hospitals.

4.16.5 Country Efforts to Promote Medical Devices Industry

- **High Public Investment in R&D**: During the last 20 years (1998-2018), National Institute of Health (NIH) alone has spent USD 433 billion through its various specialized institutions. The fund support tripled from USD 9.8 billion in 1999 to USD 28 billion in 2019. NIH provides these funds to around 25 national and therapeutic level specialized institutes. These Institutes in turn provides funds to various public and private institutes and businesses, especially small businesses. For example, around 80 per cent of NIH support to NIHLBI goes for funding research grants. Fostering the success of Early-Stage Investigators [174] (ESIs) who are establishing

[174]http://grants.nih.gov/grants/new_investigators/index.htm#earlystage

careers in biomedical research is a high priority of the NHLBI and NIH. These funds are given for up to four years or at times for project life span, especially where it involves clinical trial/studies [175]

- **Growth in Cluster -** –The success story of US medical devices is a story of growth of clusters of medical devices in conjunction with other life sciences clusters. These are characterized by the following conditions:
    - Presence of sufficient number of medical devices firms in a city area
    - Presence of lead firms
    - Presence of other life sciences (biotechnology/pharmaceuticals) firms and support firms
    - Presence of large number of research active universities and institutions
    - Presence of hospitals of repute
    - Public support and private sector initiatives in R&D
    - Taxation support
    - Specialization

- **Innovation by start-ups, small firms, and physicians**: While the large firms do invest heavily in R&D, the role of smaller firms including start-ups and doctors is significant. Most medical devices are replaced by a newer version every 18 to 24 months. Smaller companies are engaged primarily in the development of new medical technologies and are often focused on relatively narrow therapeutic areas. The small firms are engaged primarily in R&D and may be unprofitable for years before making a breakthrough deal or going out of business and are supported by Angel investors. Start-ups are generally acquired by large firms. Physicians are also substantially involved in R&D. They account for 20 per cent of the patents.

- **Joint Purchase**: Conventional market low barrier low margin but one needs volume and hence long-term supply contract with large institutional purchasers is required and these produce cash flow. This facility is provided by Group Purchasing Organizations (GPOs). As a representative of hospitals GPOs will finalize purchasing contracts with manufacturers. All hospitals in the US use GPOs. GPOs get commission on turnover of 1 to 2 per cent and GPO purchase represent 75 per cent of all hospital supply. GPOs give orders to 2 suppliers for a particular supply. The top 5 GPOS account for 90 per cent of total business of the 600 GPOs.

[175] www.nih.gov and www.nhlbi.nih.gov/

5. India Scenario[176]

5.1. Health Scenario

India also has a public-funded universal healthcare system providing access to healthcare to poorest of the poor in the country. India's share of government health expenditure in total GDP has increased from 1.15% in 2013-14 to 1.28% in 2018-19 and is expected to reach 2.5% of GDP by 2025 as prescribed by the National Health Policy of 2017. In per capita terms, the government health expenditure has significantly grown from Rs 1042 in 2013-14 to Rs.1815 in 2018-19, with more emphasis on the primary healthcare sector. The out-of-pocket expenditure as a share of total health expenditure has come down to 48.2% in 2018-19 from 64.2% in 2013-14[177]. As on 2021-22, nearly 70 percent of the population is protected by health insurance coverage including state government schemes, social insurance schemes, and private insurance.[178] In a landmark step, the Government of India introduced the Ayushman Bharat- Pradhan Mantri Jan Arogya Yojana (PMJAY). PMJAY provides cash less and paper less benefit cover of Rs. 5.00 lakh per annum per family on floater basis in the empaneled hospitals across India. At present AB-PMJAY target to cover 10.79 Crore families (covering more than 50.00 crore population in India).

5.2. Disease Pattern

Causes of death in India are highest for cardiovascular and chronic respiratory. Although the severity of cardiovascular and cancer is much higher in the other countries, the growth trend is positive in India. India also has positive growth rate as well as the second highest cause of death through chronic respiratory diseases. The growth rate is high in Alzheimer too. Although on a percentage basis declining, deaths in India are high in the areas of neonatal disorders, diarrheal and tuberculosis.

Table 5.1 Cause of Death - 2009 & 2019

Cause of Death	2009	2019
Cardiovascular	22.9%	28.5%
Chronic respiratory	10.5%	12.5%
Cancer	6.5%	9.1%
Others	9.5%	7.9%
Diarrheal	10.8%	7.8%
Accidental	7.6%	7.3%
Tuberculosis	6.1%	5.0%
Neonatal Disorders	8.7%	5.0%
Cirrhosis and Chronic Liver	3.8%	3.9%
Diabetes	2.2%	3.1%
Nephropathy	2.3%	2.8%
Road Injuries	2.4%	2.5%
Alzheimer	1.2%	2.0%
Organ Diseases	2.1%	1.3%
STD	1.3%	0.6%
Tropical Diseases	0.7%	0.4%
Communicable Diseases	1.4%	0.3%
Source: WHO The Global Health Observatory; https://data.worldbank.org		

5.3. Market

Medical devices is a sunrise sector of the Indian economy. The size of the Indian medical devices market is estimated at USD 11 Billion in 2020179, expected to grow to USD 50 Billion by 2030 with CAGR of 16.4 % .

5.4. Industry

India being an emerging market is also evolving as a potential manufacturing hub for the key global

[176] Apart from sources mentioned specifically, various parts of this section have been derived from a mix of sources as mentioned from bibliography numbers 172 to 309 and primary surveys.

[177] National Health Accounts Estimates for India 2018-19, Ministry of Health and Family Welfare, Government of India, 2022

[178] Health Insurance for India's Missing Middle, NITI Aayog, Government of India, 2021

[179] Report published by NITI Aayog in 2021 on "Investment Opportunities in India's Healthcare Sector"

medical device companies. It has huge market potential and is witnessing a double-digit growth rate. As per "Invest India", there are 750 – 800[180] domestic medical devices manufacturers in India with an average investment of USD 2.3 – 2.7 mn and an average turnover of USD 6.2 – 6.9 mn. Since 1989, the regulations for Medical Devices including IVD in India has been growing consistently under Drugs & Cosmetics Act 1940.

The government issued Medical Device Rules 2017. Two more notifications in February 2020 expanded the coverage of medical devices, advising on the phase wise actions to be taken by the Industry until August 2023. As a result, the number of medical device companies in India is likely to be multiplied manyfold. New Rules shall ensure availability of quality medical devices across the country. The new Rules also aim to promote a culture of self-compliance by manufacturers of medical devices.

Almost all the lead global firms have their Indian subsidiary. The lead 50 medical devices leaders of the world have their Indian subsidiaries. 50 per cent of those are from USA, 20 per cent from Japan, 4 each from France and Switzerland, 3 from Germany and the remaining from UK, China, etc.

Some of the Indian firms in the medical devices space in India are:

Table 5.2 Some Indian Firms in Medical Device Industry

Disposables	**Consumables**	**Electronics**	**Equipment**
G. Surgiwear	BL Lifesciences	Allengers Medical	Cura
HMD	Healthium	BPL	Midmark
Kanam Latex	Polymedicure	ITPL	Phoenix
Medico Electrodes	Romsons	Skanray	Remi
RK	Tynor Orthotics	Trivitron Healthcare	Shivani
Implants	**Diagnostics**	**Instruments**	
Appasamy	Agappe	Alan Electronics	
Aurolab	Meril	Asco	
Biorad Medisys	Mitra Industries	EndoMed Technologies	
Meril	Transasia	HMD	
Pitkar	Trivtron	Quality Needles	
SMT			
Source: AIMED			

The top 30 Indian medical device firms had an estimated turnover of INR 8350 crores in 2019. Turnover of the top 30 Global subsidiaries in 2019 is estimated at INR 21,900 crores.

Table 5.3 Estimaed Turnover of Top Indian and Indian arms of MNC Medical Devices Companies

Cumulative Revenue of MD Firms	**Rs Crore (2019)**
Indian	
Top 10	4600
Top 20	6850
Top 30	8350
Indian Subsidiary of Foreign	
Top 10	15000
Top 20	19200
Top 30	21900

Source: Compiled from Toffler Business Research[181].

[180]https://www.investindia.gov.in/sector/medical-devices

[181] Data for some companies may have turnovers in areas other than medical devices as some of them are also making products other than medical devices

5.5. Trade

5.5.2 Exports from India

India exported USD 2.9 billion worth of medical devices in FY 2021-22, a growth of 15.47 per cent over 2020-21. This growth rate is 5 percentage points higher than for the year 2020-21 over the year 2019-20. The CAGR for the period 2019-20 to 2021-22 is 8.43%. In 2021-22, USA (21.6%) was the top export destination of India, followed by China (5%), Germany (4.4%), France (3.1%) and Singapore (2.8%). The situation was identical for the year 2020-21, with top 5 exporters being USA (23.7%), China (5.3%), Germany (5.3%), France (3%) and Singapore (3%). The top 5 export destinations in 2021-22 accounted for around 36.9 percent of India's exports.

In 2020-21, among the top export destinations, while the growth rate was highest (14.98%) for USA followed by Germany (8.05%); marginal for China (2.17%), France (3.83%); it was significantly negative (-28.87%) for Singapore. The growth in the USA was due to high exports of disposables & consumables, and IVD reagents. The negative growth in Singapore was due to fall in the exports of equipment and electronics, implants, and disposables & consumables. In 2021-22, the growth rate in USA moderated (5.25%), recovered significantly for France (19.32%) and Singapore (10.6%) and increased significantly for China (10.45%). The high growth rate in France was due to high exports of equipment and electronics, disposables, and consumables and IVD reagents and the increase in China was due to high exports of equipment and electronics, disposables and consumables and surgical instruments.

Table 5.4 Major Destinations of India's Exports of Medical Devices

(Value in USD Million)

Country	2019-20	Percent of Total in 2019-20	2020-2021	Percent of Total in 2020-21	2021-2022	Percent of Total in 2021-22	Growth rate in 2020-21 over 2019-20 (%)	Growth rate in 2021-22 over 2020-21 (%)	CAGR 2019-20 to 2021-22 (%)
USA	521.85	22.76	600.01	23.7	631.5	21.6	14.98	5.25	6.56%
China	130.18	5.68	133	5.3	146.9	5.0	2.17	10.45	4.11%
Germany	123.74	5.4	133.7	5.3	127.3	4.4	8.05	-4.79	0.95%
France	72.13	3.15	74.89	3	89.36	3.1	3.83	19.32	7.40%
Singapore	105.16	4.59	74.8	3	82.73	2.8	**-28.87**	10.60	-7.69%

Source: EEPC, DGCI&S

Table 5.5 Exports of Medical Devices as per Product Category

(Value in USD Million)

Category	2019-20	Percent of Total in 2019-20	2020-2021	Percent of Total in 2020-21	2021-2022	Percent of Total in 2021-22	Growth rate in 2020-21 over 2019-20 (%)	Growth rate in 2021-22 over 2020-21 (%)	CAGR 2019-20 to 2021-22 (%)
IVD Reagents	67.58	2.95	104.18	4.12	175.7	6.01	54.16	68.65	37.50%
Disposables & Consumables	1082.53	47.21	1290.26	50.97	1378	47.14	19.19	6.80	8.38%
Equipment & Electronics	998.87	43.56	984.73	38.9	1163	39.79	-1.42	18.10	5.20%
Surgical Instruments	49.77	2.17	53.64	2.12	71.21	2.44	7.78	32.76	12.68%
Implants	94.12	4.1	98.81	3.9	135.2	4.63	4.98	36.83	12.83%

Total	**2292.87**	**100**	**2531.62**	**100**	**2923.16**	**100**	**10.41**	**15.47**	**8.43%**

Source: EEPC, DGCI&S

5.5.2.1 Disposables and Consumables

In 2021-22, 'disposables and consumables' contributed towards 47.14% (50.97% in 2020-21) of medical device exports, with India having comparative advantage in manufacturing high-volume, low-cost medical devices of this category. The growth rate, however, moderated from 19.19% (2020-21) to 6.80% (2021-22).

In 2020-21, the global market benefitted from India's 'disposables and consumables', especially for products like hormone-based contraceptives (USD 188.4 mn), cannula (USD 7.7 mn), fabric garments (USD 6.8 mn), surgical gloves (USD 5.37 mn), and rubber contraceptives (USD 3.84 mn. India's export to USA in disposables and consumables was worth USD 291.23. In a record, India exported hormone-based contraceptives worth USD 107.85 mn to USA in FY 2020-21 - the highest across all categories. The segment contributes significantly to device exports to Germany (30.6%), France (28.7%), China (23.1%), and Singapore (11.4%).

In 2021-22, however growth rate of exports to USA fell (-16.16% in 2021-22 from 50.19% in 2020-21) and in Germany (-18.67% in 2021-22 from 28.51% in 2020-21). Export growth rate to Singapore continued to be negative (-35.63% in 2020-21 and -21.86% in 2021-22). The negative growth rates being due to fall in exports of fabric garments and hormone-based contraceptives to USA and Singapore, and surgical gloves and cannula to Germany. Growth rates recovered in China (-12.24% in 2020-21 to 4.04% in 2021-22) and France (-6.36% in 2020-21 to 21.31% in 2021-22).

5.5.2.2 Equipment and Electronics

In 2021-22, exports under 'electronics and equipment' category had a fair share of 39.8% (38.9% in 2020-21), with an export value of USD 1.16 billion in FY 2021-22, showing substantial growth of 18.10% in 2021-22, as compared to negative growth of 1.42% in 2020-21.

In 2020-21, India's export of equipment and electronics comprised mainly of diagnostic devices/components like X-Ray tubes (USD 132 mn), electrocardiographs (USD 43.56 mn), and endoscopes (USD 29.72 mn). X-Ray tubes were exported to all major countries like USA (USD 38.87 mn), China (USD 42.03 mn), France (USD 18.03 mn), Singapore (USD 15.95 mn), and Germany (USD 8.41 mn). Export growth rate to most major destinations were negative in 2020-21, like that Singapore (-26.23%), USA (-9.07%), China (-1.95%), and Germany (-1.64%) with France (16.18%) being the exception. The negative growth rate was due to the fall in exports of high-end diagnostic devices like MRI apparatus, endoscopes, etc. Strong export demand for device components like X-Ray tubes, radiation-generation units, etc. led to positive growth rate for France.

In 2021-22, however, growth rate bounced back to double digits for USA (12.46%), China (15.48%), Singapore (14.70%), and remained consistent for France (17.28%). Export growth rate remained negative for Germany (-0.72%). The high growth rate for the countries can be attributed to high exports of device components like X-Ray tubes and diagnostic devices like endoscopes, electrocardiographs, etc.

5.5.2.3 IVD reagents, Implants, and Surgical Instruments

IVD reagents contributed to 6.01% of export of medical devices in 2021-22, having CAGR of 37.5% between 2019-20 and 2021-22. Exports have grown consistently by 54.16% in 2020-21 to 68.65% in 2021-22, with USA being the top export destination. USA also imports majority of Indian manufactured implants (USD 29.46 mn) like artificial joints, cardiac catheters, artificial teeth, and defibrillators. In 2021-22, India exported USD 135.2 mn worth of implants, growing by 36.83% in 2021-22 (4.98% in 2020-21). Quantum of surgical instruments exported is relatively low at USD 71.21 mn as of FY 2021-22, with surgical knives, scissors, and blades contributing 46% to export value. USA (USD 22.04 mn) and China (USD 13.22 mn) combined attributes around 49.5 percent of India's surgical instrument exports.

Table 5.6 Top Export Destinations of Medical Devices as per Product Category

(Value in USD Million)

Country	Categories	2019-20	% of Total in 2019-20	2020-2021	% of Total in 2020-21	2021-2022	% of Total in 2021-22	Growth rate in 2020-21 over 2019-20 (%)	Growth rate in 2021-22 over 2020-21 (%)	CAGR 2019-20 to 2021-22 (%)
USA	Equipment & Electronics	283.81	54.385	258.06	43.009	290.22	46.0	-9.07	12.46	0.75%
	Disposables & Consumables	193.91	37.158	291.23	48.538	242.71	38.4	50.19	-16.66	7.77%
	Surgical Instruments	14.34	2.748	13.66	2.277	22.04	3.5	-4.74	61.35	15.40%
	Implants	17.56	3.365	16.86	2.81	29.46	4.7	-3.99	74.73	18.82%
	IVD Reagents	12.23	2.344	20.2	3.367	47.05	7.5	65.17	132.92	56.69%
	Country Total	521.85	100	600.01	100	631.48	100.0	14.98	5.24	6.56%
China	Equipment & Electronics	86.23	66.239	84.55	63.571	97.64	66.4	-1.95	15.48	4.23%
	Disposables & Consumables	34.96	26.855	30.68	23.068	31.92	21.7	-12.24	4.04	-2.99%
	Surgical Instruments	5.26	4.041	11.64	8.752	13.22	9.0	121.29	13.57	35.96%
	Implants	1.44	1.106	1.57	1.18	0.94	0.6	9.03	-40.13	-13.25%
	IVD Reagents	2.29	1.759	4.56	3.429	3.22	2.2	99.13	-29.39	12.03%
	Country Total	130.18	100	133	100	146.94	100.0	2.17	10.48	4.12%
Germany	Equipment & Electronics	83.02	67.092	81.66	61.077	81.07	63.7	-1.64	-0.72	-0.79%
	Disposables & Consumables	31.88	25.764	40.97	30.643	33.32	26.2	28.51	-18.67	1.48%
	Surgical Instruments	2.64	2.134	2.94	2.199	3.18	2.5	11.36	8.16	6.40%
	Implants	3.65	2.95	5.46	4.084	4.95	3.9	49.59	-9.34	10.69%
	IVD Reagents	2.55	2.061	2.67	1.997	4.77	3.7	4.71	78.65	23.21%
	Country Total	123.74	100	133.7	100	127.29	100.0	8.05	-4.79	0.95%
Singapore	Equipment & Electronics	86.97	82.703	64.16	85.775	73.59	89.0	-26.23	14.70	-5.42%
	Disposables & Consumables	13.22	12.571	8.51	11.377	6.65	8.0	-35.63	-21.86	-20.47%
	Surgical Instruments	0.27	0.257	0.2	0.267	0.32	0.4	-25.93	60.00	5.83%
	Implants	4.59	4.365	1.46	1.952	1.64	2.0	-68.19	12.33	-29.04%
	IVD Reagents	0.11	0.105	0.47	0.628	0.53	0.6	327.27	12.77	68.90%
	Country Total	105.16	100	74.8	100	82.73	100.0	-28.87	10.60	-7.69%
France	Equipment & Electronics	42.1	58.367	48.91	65.309	57.36	64.2	16.18	17.28	10.86%
	Disposables & Consumables	22.95	31.818	21.49	28.695	26.07	29.2	-6.36	21.31	4.34%
	Surgical Instruments	1.55	2.149	1.6	2.136	1.77	2.0	3.23	10.63	4.52%
	Implants	2.1	2.911	0.24	0.32	0.49	0.5	-88.57	104.17	-38.44%
	IVD Reagents	3.43	4.755	2.65	3.539	3.67	4.1	-22.74	38.49	2.28%
	Country Total	72.13	100	74.89	100	89.36	100.0	3.83	19.32	7.40%

Source: EEPC,DGCI&S

5.5.3 Imports by India

India is a net importer of medical devices, with total imports of USD 8.5 bn in 2021-22, a growth of 36.8% over 2020-21. This growth rate is 30.08 percentage points higher than for the year 2020-21 over the year 2019-20. The CAGR for the period 2019-20 to 2021-22 is 13.47%. In 2021-22, China is the top

source of imports (19.4%), followed by USA (17.2%), Germany (9.2%), Singapore (8.5%), and Japan (4.0%). The situation was similar in 2020-21, with top import destinations being China (17.8%), USA (15.8%), Germany (10.7%), Singapore (8.3%) and Japan (3.8%). Together, the top 5 import destinations accounted for 58.3 percent of India's imports in 2021-22 (56.4% in 2020-21).

In 2020-21, growth rates were significantly negative for USA (-17.31%), Germany (-8.68%), Singapore (-14.85%) and Japan (-15.38%). However, import growth rate from China (78.55%) was positive. The growth in China was due to high imports of disposables & consumables, equipment & electronics, and IVD reagents. USA experienced highest negative growth, due to fall in imports of implants, surgical instruments, and equipment and electronics.

In 2021-22, import growth rate moderated for China (49.25%), with reduced import dependency on its disposables and consumables. Growth rates moved to the positive quadrant for USA (48.87%), Germany (17.04%), Singapore (40.83%) and Japan (44.77%), with rising import demand for electronics and equipment, surgical instruments, and implants. These are mostly high-end devices which requires R&D and complex manufacturing.

Table 5.7 Major Sources of India's Imports of Medical Devices

(Value in USD Million)

Country	2019-20	Percent of Total in 2019-20	2020-2021	Percent of Total in 2020-21	2021-2022	Percent of Total in 2021-22	Growth rate in 2020-21 over 2019-20 (%)	Growth rate in 2021-22 over 2020-21 (%)	CAGR 2019-20 to 2021-22 (%)
China	622.2	10.64	1110.92	17.8	1658	19.4	78.55	49.25	38.64%
USA	1190.08	20.36	984.08	15.8	1465	17.2	-17.31	48.87	7.17%
Germany	732.07	12.52	668.5	10.7	782.4	9.2	-8.68	17.04	2.24%
Singapore	608.09	10.4	517.77	8.3	729.2	8.5	-14.85	40.83	6.24%
Japan	280.08	4.79	236.99	3.8	343.1	4.0	-15.38	44.77	7.00%

Source: EEPC,DGCI&S

Table 5.8 Imports of Medical Devices as per Product Category

(Value in USD Million)

Category	2019-20	Percent of Total in 2019-20	2020-2021	Percent of Total in 2020-21	2021-2022	Percent of Total in 2021-22	Growth rate in 2020-21 over 2019-20 (%)	Growth rate in 2021-22 over 2020-21 (%)	CAGR 2019-20 to 2021-22 (%)
IVD Reagents	527.2	9.02	871.89	13.97	882.65	10.3	65.38	1.23	18.74%
Disposables & Consumables	1076.23	18.41	1470.77	23.57	1623.55	19.0	36.66	10.39	14.69%
Equipment & Electronics	3646.53	62.38	3568.64	57.18	5441.22	63.7	-2.14	52.47	14.27%
Surgical Instruments	180.1	3.08	103.62	1.66	169.02	2.0	-42.47	63.12	-2.09%
Implants	415.35	7.11	225.63	3.62	423.06	5.0	-45.68	87.50	0.61%
Total	**5845.4**	**100**	**6240.55**	**100**	**8539.5**	**100.0**	**6.76**	**36.84**	**13.47%**

Source: EEPC,DGCI&S

5.5.3.1 Equipment and Electronics

In 2021-22, import dependency on equipment and electronics grew by 52.47%, as compared to a negative growth of -2.14% in 2020-21. It comprised 63.7% of total medical devices exports in 2021-22 (57.18% in 2020-21).

In 2020-21, India imported electronic devices and equipment worth USD 3.56 bn, with China (21.53%)

being the top import destination, followed by USA (15.35%), Germany (13.83%), Singapore (10.30%), and Japan (5.47%). Import growth rate for China (71.07%) was strong due to high import demand for digital thermometers, computed tomography apparatus, oxygen therapy apparatus, etc. Import growth rates plummeted for US (-19.49%), Japan (-17.04%), Singapore (-14.52%), and Germany (-8.32%), showing reduced import dependency on equipment and electronics in 2020-21.

In 2021-22, import growth for equipment and electronics from US (49.40%), Germany (20.26%), Singapore (45.04%), Japan (43.98%) turned significantly positive. Import growth rate for China (79.23%) grew further, maintaining its position as top import destination for equipment and electronics. The positive growth rates being due to rise in exports of digital thermometers, gas analysis apparatus, endoscopes, etc.

5.5.3.2 Disposables and Consumables

India imported USD 1.6 bn worth of disposables and consumables in 2021-22, consisting of 19% of medical devices import (23.57% in 2020-21). Imports grew significantly by 36.66% in 2020-21, moderating to 10.39% in 2021-22. Major products of this import segment include syringes and needles, animal blood used for therapeutic, prophylactic, and diagnostic uses, surgical gloves, opacifiers for X-Rays and diagnostic reagents for patient administration.

In 2020-21, India's import stood at 1.4 billion, with China being the major import destination. India imported USD 26.95 mn worth of fabric garments, mostly from China in 2020-21 as compared to USD 1.48 mn in 2019-20. Import growth rate for China (102.35%) soared in 2020-21, though being negative for USA (-7.48%), Germany (-24.84%), Singapore (-11.62%) and Japan (-20.06%). This negative growth is due to fall in imports of dental cements, microorganism cultures, animal blood, hollow needles, micropores, cannula, etc.

In 2021-22, China (-34.34%) experienced negative growth rate, but growing significantly for USA (59.75%), Japan (45.49%), Singapore (18.91%), and Germany (9.68%). USA moved to position of top import destination. The positive growth rate was due to rise in imports of adhesive tapes, adhesive gauze bandages, icebags, etc.

5.5.3.3 IVD reagents, Implants, and Surgical Instruments

India's import dependance on 'IVD reagents' sky-rocketed by 65.38 percent to USD 871.89 mn in 2020-21, moderating to 1.23% in 2021-22. The CAGR from 2019-20 to 2021-22 was 18.74%. In 2020-21, import growth rates for IVD reagents were exponentially high for China (198.42%) and Japan (57.08%), and moderate for Germany (29.75%), and low for USA (6.73%) and Singapore (2.27%). In 2021-22, import growth rate for IVD reagents dropped for China (9.81%), remained moderate for Japan (43.38%), and turned negative for Germany (-14.49%). Import growth rate from USA (33.43%) shot up significantly, making it the top import destination for IVD reagents in 2021-22.

A sharp fall can be seen in the import growth rate of implants (-45.68%) and surgical instruments (-42.47%) in 2020-21. The import demand improved in 2021-22, with positive growth rates for implants (87.50%) and surgical instruments (63.12%). The positive growth rates being for high import of Implant products like artificial joints, artificial teeth and other dental fittings, and for surgical instruments like surgical knives, scissors and blade. USA remains the top import destination for both implants and surgical instruments across 2019-2020 to 2021-22.

Table 5.9 Analysis of India's Imports to Top 5 Destinations

(Value in USD Million)

Country	Categories	2019-20	Percent of Total in 2019-20	2020-2021	Percent of Total in 2020-21	2021-2022	Percent of Total in 2021-22	Growth rate in 2020-21 over 2019-20 (%)	Growth rate in 2021-22 over 2020-21 (%)	CAGR 2019-20 to 2021-22 (%)
USA	Equipment & Electronics	680.54	57.184	547.9	55.676	818.56	55.9	-19.49	49.40	6.35%

Country	Categories	2019-20	Percent of Total in 2019-20	2020-2021	Percent of Total in 2020-21	2021-2022	Percent of Total in 2021-22	Growth rate in 2020-21 over 2019-20 (%)	Growth rate in 2021-22 over 2020-21 (%)	CAGR 2019-20 to 2021-22 (%)
	Disposables & Consumables	172.34	14.481	159.45	16.203	254.72	17.4	-7.48	59.75	13.91%
	Surgical Instruments	72.17	6.064	42.13	4.281	64.31	4.4	-41.62	52.65	-3.77%
	IVD Reagents	188.54	15.843	201.23	20.449	268.5	18.3	6.73	33.43	12.51%
	Implants	76.49	6.427	33.37	3.391	58.64	4.0	-56.37	75.73	-8.48%
	Country Total	**1190.08**	**100**	**984.08**	**100**	**1464.73**	100.0	**-17.31**	48.84	7.17%
China	Equipment & Electronics	449.19	72.194	768.44	69.171	1377.24	83.1	71.07	79.23	45.28%
	Disposables & Consumables	126.26	20.293	255.49	22.998	167.75	10.1	102.35	-34.34	9.93%
	Surgical Instruments	16.8	2.7	13.81	1.243	31.33	1.9	-17.8	126.86	23.09%
	IVD Reagents	22.14	3.558	66.07	5.947	72.55	4.4	198.42	9.81	48.53%
	Implants	7.81	1.255	7.11	0.64	8.8	0.5	-8.96	23.77	4.06%
	Country Total	**622.2**	**100**	**1110.92**	**100**	**1657.67**	100.0	**78.55**	49.22	38.63%
Germany	Equipment & Electronics	538.53	73.56	493.72	73.855	593.74	75.9	-8.32	20.26	3.31%
	Disposables & Consumables	62.29	8.508	46.82	7.004	51.35	6.6	-24.84	9.68	-6.24%
	Surgical Instruments	29.04	3.967	20.06	3.001	27.11	3.5	-30.92	35.14	-2.27%
	IVD Reagents	66.16	9.037	85.84	12.841	73.4	9.4	29.75	-14.49	3.52%
	Implants	36.05	4.924	22.06	3.3	36.75	4.7	-38.81	66.59	0.64%
	Country Total	**732.1**	**100**	**668.5**	**100**	**782.35**	100.0	**-8.69**	17.03	2.24%
Singapore	Equipment & Electronics	429.85	70.687	367.43	70.96	532.93	73.1	-14.52	45.04	7.43%
	Disposables & Consumables	100.39	16.509	88.72	17.134	105.5	14.5	-11.62	18.91	1.67%
	Surgical Instruments	8.42	1.385	3	0.579	7.99	1.1	-64.37	166.33	-1.73%
	IVD Reagents	41.36	6.802	42.3	8.169	43.27	5.9	2.27	2.29	1.52%
	Implants	28.07	4.616	16.32	3.152	39.52	5.4	-41.86	142.16	12.08%
	Country Total	**608.1**	**100**	**517.8**	**100**	**729.21**	100.0	**-14.85**	40.83	6.24%
Japan	Equipment & Electronics	235.41	84.045	195.3	82.405	281.2	82.0	-17.04	43.98	6.10%
	Disposables & Consumables	31.65	11.3	25.3	10.675	36.81	10.7	-20.06	45.49	5.16%
	Surgical Instruments	1.3	0.464	0.39	0.165	0.87	0.3	-70	123.08	-12.53%
	IVD Reagents	9.67	3.452	15.19	6.409	21.78	6.3	57.08	43.38	31.08%

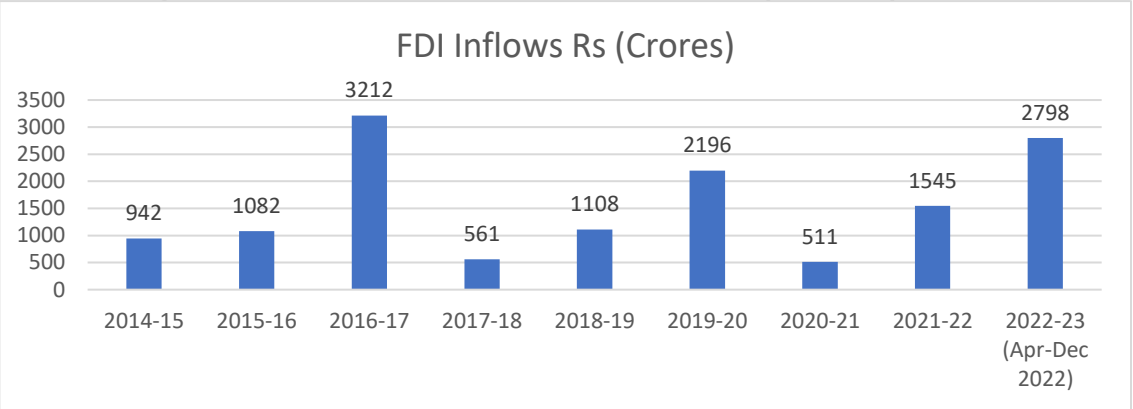
Country	Categories	2019-20	Percent of Total in 2019-20	2020-2021	Percent of Total in 2020-21	2021-2022	Percent of Total in 2021-22	Growth rate in 2020-21 over 2019-20 (%)	Growth rate in 2021-22 over 2020-21 (%)	CAGR 2019-20 to 2021-22 (%)
	Implants	2.05	0.732	0.81	0.342	2.42	0.7	-60.49	198.77	5.69%
	Country Total	**280.1**	**100**	**237**	**100**	**343.08**	100.0	**-15.39**	44.76	6.99%

Source: EEPC,DGCI&S

5.6. Foreign Direct Investment (FDI)

FDI per annum increased from Rs 942 crores in 2014-15 to Rs 1545 crores in 2021-22. In between it saw two peaks in the years 2016-17 (Rs 3212 crores) and 2019-20 (Rs 2196 crores). The cumulative FDI during these years stood at Rs 11157 crores during 2014-15 to 2021-22. However, there was a quantum jump in FDI in 2022-23. FDI during the first three quarters of the year was Rs 2,798 crores. The cumulative FDI during the years 2014-15 to December 2022 stood at Rs 13955 crores.

Figure 5.1 FDI Inflows in Medical Devices in India (Rs. Crore)



Source: DPIIT

5.7. Human Resources

5.7.1 Backdrop

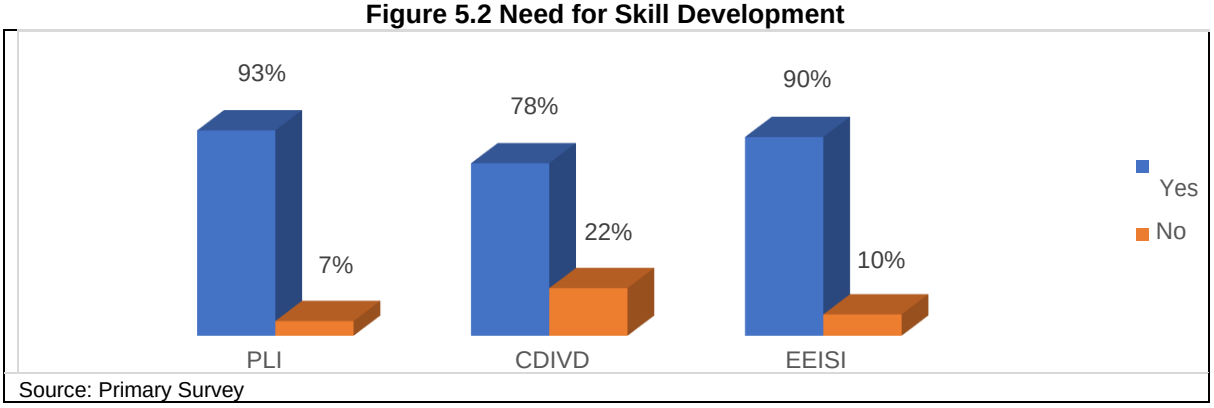
HR requirements and their skills vary depending on the sub-sector, e.g. polymer based and non-polymer-based disposables, implants, electro-medical & medical electronics based, software & IT enabled products etc. It also varies depending on functional responsibilities, e.g. materials management, production, testing and quality control, R&D, clinical trials, market research, marketing and sales and servicing, general management as well as supply chain management, regulatory, Intellectual Property (IP), legal requirements etc. and also depending on the importance of the job functions. Because of the diverse nature of the different areas and roles within the medical device industry, wide range of skills and backgrounds are required to meet the needs of the industry. Broadly the basic education may include Engineering (Graduation/Diploma) & related technical Education (specializations include Biomedical, Polymer, Mechanical, Electrical / Electronics, Mechatronics, clinical engineering etc.), Science including microbiology / Biomaterials etc. (Graduation / Post-graduation/Ph.D.), Pharmacy (Degree / Diploma), M.B.B.S. / BDS, Information Technology, Management (General / Sales & marketing), etc.

5.7.2 Feedback from the Industry on Non-availability of Skilled Manpower

Based on the interactions with different sub-sectors of Indian medical device industry, the feedback on the need for skilled manpower received is as follows:

Around 80 per cent of the respondents felt the need for skill development. The requirement is relatively high for manufacturers making products like electronics and equipment / implants / surgical instruments (EEISI), etc. as compared to consumables/disposables and IVD (CDIVD). The need was particularly high for manufacturing the group of equipment identified for PLI support.

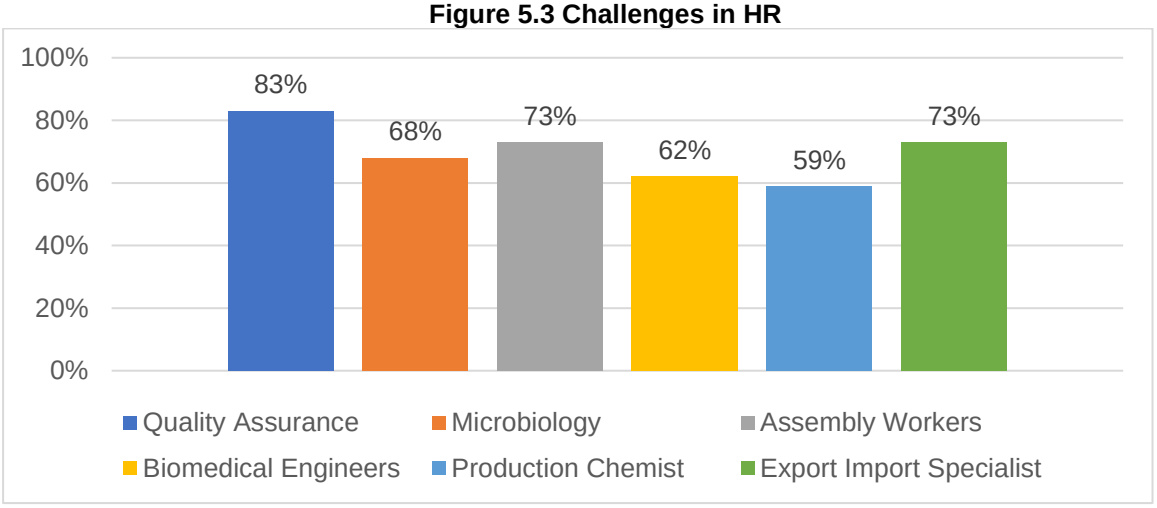
Figure 5.2 Need for Skill Development



Source: Primary Survey

Around 80 to 85 per cent of the respondents felt that there are various challenges in HR including that HR is either not available in good quality or in adequate number or not affordable in the areas of quality assurance, bio-medical engineers, production chemists and microbiology. Around 60 per cent of the respondents felt that such issues are also there for technicians and engineers.

Figure 5.3 Challenges in HR



Over 80% of the respondents felt the need for HR related to quality assurance. More than 70% of the respondents felt the need for HR in the areas of assembly workers and export-import specialists. Around 60% of the respondents felt the need for HR in the areas of microbiology, biomedical engineering, production chemists.

5.7.3 Influence of High Impact Steps

Also, as major schemes like Ayushman Bharat are making its presence felt through investment, need for machinery will increase. Schemes like PLI, Parks and above all the deep thrust and national interest of the Make in India effort will also necessitate more HR in medical devices. Also, as more doctors and nurses will get appointed, demand for medical devices will increase and so also the need for specialized staffs in different areas of medical devices.

5.7.4 Biomedical Engineering (BME)

BME professionals are responsible for developing and advancing the usage of medical devices and clinical services. BME professionals do R&D, safety equipment procurement, installation, integration, regular monitoring, maintenance and repairs, training to health-care professional, etc. BME professionals are employed widely throughout the health technology and health-care industries, in R&D of technologies, devices and treatment modalities, in delivery of healthcare, in academia as well as regulatory agencies.

Table 5.10 Number of Colleges Offering BME Course at Various Levels

Course	Number of Colleges	Estimated Annual Intake[182]
Diploma / ITI (Medical Electronics)	19	1425
Engineering (B.E. / B. Tech)	161	6440
Masters (M.E. / M. Tech.)	47	940
Source: https://engineering.careers360.com/ , https://collegeindia.in/		

BME is an inter-disciplinary program of biological sciences and engineering. One can do diploma as well as degree in BME. The courses of bio-medical engineering vary. The courses of BE in Bio-Medical Engineering cover among other[183] Sciences - Mathematics, Physics; Biological Sciences: Biology, Human Anatomy & Physiology, Cardiovascular System and Dynamics; Computers and Electronics: Linear Electronics, Analog Integrated Electronics, Digital Logic Circuits, Lasers and Optical Fibers in Medicine, Microcontroller Applications, Microprocessor Architecture & Interfacing, Neural Networks and Fuzzy Logic, Embedded System Design, Programming, IOT, Robotics, Artificial Intelligence; Engineering: Graphics, Mechanics, Basic Electricals Engineering, Prosthetics & Orthotics Engineering, Tissue Engineering, Biomechanics & Design Ergonomics, Control System Engineering; Instrumentation: Analytical Instrumentation, Diagnostic Techniques & Instrumentation, Therapeutic Techniques & Instrumentation, Electronics Measurement & Instrumentation; Bio-electronics: Biomedical Transducers & Biosensors, Medical System Actuators, Biomaterials & Implants, Bio-Potential & Recorders, Bioinformatics, Biological Digital Signal Processing; Imaging: Ultrasonic Imaging and Radiology, Advanced Medical Imaging Techniques, Biological Digital Image Processing; Support Knowledge: Hospital Management & Information System, Clinical Engineering & Patient Safety, Medical Device Safety & Standards, Practical; Social Sciences: Aptitude and Communication Skills, Intellectual Property Rights, Industrial safety and green chemistry, Productivity in management and reengineering, Lean system, Six sigma, Pharmacovigilance and Medical Writing

BME candidates can also specialize in surgical instruments and medical device, tissue engineering, biomaterials, biomechanics, telehealth communication, bio-signal process, medical image, computational modelling, etc. [184] Some of the front ranking industry oriented/linked initiatives in the area of skill development include the following:

5.7.5 Life Sciences Sector Skill Development Council[185]

The Life Sciences Sector Skill Development Council (LSSSDC) is an industry-led organization, setup by National Skill Development Corporation (NSDC) in partnership with various stakeholder organizations representing both industry and government stakeholders. It addresses skill shortfalls in the Life Sciences Sector in India including Pharmaceuticals, Biotechnology & Contract Research complete involved in Manufacturing and Research of biotechnology driven products & services (like vaccine, Agri-Biotech, Medical Devices & Bio-fuels). Its aim, over a 6 years period, is to map all qualifications (job roles) in the sector, enlist Prospective Vocational Training Organizations, train & certify competent Trainers and certify approx. 16.5 million skilled workforces in the sector. Currently LSSSDC has developed National; Occupational Standards for 70 unique qualifications (job roles) covering 89% of employment of the sector. 150 Employer Organizations (Industry/ Institutions) have been engaged by LSSSDC and have given their written inputs and acceptance for the currently published Qualification Packs (QP) and National Occupational Standards (NOS). For providing training It has 8 centers/academy of excellence147 affiliated training institutes, 35 PMKKs and 16 universities.

[182] Considering an average intake per annum of 75 students in Diploma/ITI, 40 students in B.E/ B.Tech, 20 students in M.E/ M.Tech

[183] https://gtu.ac.in/Syllabus/Syllabus.aspx?tp=BE and NIPER

[184] https://www.shiksha.com/engineering/biomedical-engineering-chp#:~:text=Biomedical%20engineering%20courses%20include%20the%20study%20of%20Physics%2C,degree%2C%20diploma%20and%20doctoral%20levels.%20Biomedical%20Engineering%20Specialisations

[185] https://www.lsssdc.in/ as on September 2022

5.7.6 Indian Biomedical Skill Consortium[186]

Andhra Pradesh MedTech Zone (AMTZ) and the Association of Indian Medical Manufacturers of Medical Devices (AiMeD), under the support of the Quality Council of India (QCI), have jointly established “Indian Biomedical Skill Council (IBSC)” to provide a certification system for Biomedical Engineers in the country who serve as the backbone of the healthcare services. IBSC aims at strengthening the Biomedical Skill Sector in the country and with this objective develop job roles and approved by National Skill Development Agency (NSDA) and aligned with National Skill Qualification Framework (NSQF) under Ministry of Skill Development & Entrepreneurship (MSDE). IBSC also signed an MoU with Association for the Advancement of Medical Instrumentation (AAMI) USA for International recognition & equivalence of IBSC Certified professionals…”Certificate Courses offered by Indian Bio Medical Skill Council are in Biomedical Engineering, Biomedical Maintenance, Biomedical Manufacturing, Biomedical Quality Assurance, Biomedical Project Management.

AMTZ has 5 NSDA approved certificate courses in Bio-medical engineering, maintenance, manufacturing, quality assurance and project management. Candidates with diploma in biomedical / medical electronics / electrical / any other related filed or B. E / B. Tech in Biomedical Engineering, Biomedical Instrumentation Engineering / Medical Electronics / any other related field with zero to five years of experience (depending on the course) are eligible to apply. The courses covered are as follows:
Engineering: Anatomy and Physiology, Fundamentals of Electricity and Electronics, Biomedical Instrumentation, Hospital Engineering and Management, Medical Terminology for Engineers
Maintenance: Healthcare Technology Problem Solving and Troubleshooting, Healthcare Safety & Standards, NABH & NABL Accreditation, Facilities / General Management, Radiation Safety
Manufacturing: Operations Management Functions and Strategies, Product Development, Testing, Evaluation, & Modification. Manufacture & Assembly (Design and process), Materials Handling and Inventory Management, Service Delivery Management
Quality Assurance: Medical Device Quality and Regulatory Fundamentals, Risk Management & Risk Analysis, Medical Technology Quality Systems, Design Control & Product Development, Design verification, Validation, clinical evaluation and CAPA
Project Management: Basic Concepts & Application of Project Management, Project Modelling and Management with Applications in MS – Project, People Management in Projects, Scope Management, Applying Project Management Principles to Biomedical Industry

It also does various other training programs including those for lead auditors (ISO 13485-2016), industrial training programs on testing and calibration, laboratory equipment, radiology equipment, OT equipment, etc. and also industrial training and internship.

5.7.7 National Institute of Pharmaceutical Education and Research (NIPER), Ahmedabad

NIPER Ahmedabad offers post graduate master’s degree in medical Devices as well as offers Ph.D. program for medical devices. NIPER-A is collaborating with leading Indian companies for research and development in intraocular lenses, cardiovascular stents, and orthopedic implants to equip students to take up job roles in the industry and as well motivating them to align with make-in-India initiative. NIPER-A signed MoUs with leading industries e.g., Johnson & Johnson, Sahajanand Laser Technologies, and Uthesiya Medicare Pvt. ltd., to develop an ecosystem for development of the medical devices sector in the country.

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Other major Institutions Offering Education / skill development course include the following:

- Various other branches of NIPER
- Various IITs (e.g., at Delhi, Chennai, Mumbai, Gandhinagar, Roorkee, Guwahati, Kharagpur etc.)
- Sree Chitra Institute Biomedical Technology Wing, Trivandrum
- Central Institute of Plastics Engineering & Technology (CIPET), Various Centers
- IISC, Bangalore - Biomaterials Division
- Shriram Institute for Industrial Research (SRI), New Delhi

5.8. Research & Development

Primary data collected showed that among those who disclosed their investment in R&D, 27 per cent touched the global leaders’ ratio of 8 percent and 20 per cent did an average of 4.5 per cent. The overall average for the respondents was 4 per cent. Government of India has been supporting the sector by

[186] This entire section is based on information taken fully from ibsc-amtz.in

investing in research & development under various schemes.

Table 5.11 Government Support in R&D

Source: https://www.indiascienceandtechnology.gov.in/, https://www.birac.nic.in/, http://www.serbficci-iirrada.in/

Scheme	Department
Sustainable Entrepreneurship and Enterprise Development Fund (SEED)	BIRAC
RAPID USAID-TB Diagnostics Programme	BIRAC
Industry Innovation Program on Medical Electronics (IIPME)	BIRAC
National Biopharma Mission - Innovation in India Program (i3)	BIRAC
Sponsored Research Scheme	CSIR
Promoting Innovations in Individuals, Start-ups and MSMEs (PRISM)	DSIR
Industrial R&D Promotion Program (IRDPP)	DSIR
Technology Development and Demonstration Program (TDDP)	DSIR
Technopreneur Promotion Program (TePP)	DSIR
Biomedical Device and Technology Development (BDTD)	DST
Core Research Grant	DST
Grassroots Technological Innovation Acquisition Fund	DST
Medical Innovation Fund (MIF)	ICMR
Industry Relevant R&D	SERB
Scientific and Useful Profound Research Advancement (SUPRA)	SERB
Intensification of Research in High Priority Area (IRHPA)	SERB
Start-up Research Grant	SERB

5.9. Industry Academia Linkages

In India, several academic and research institutes have provided support and worked together to develop, test, and improve medical devices and related technologies to cater India Public Health in the form of research, collaborations, incubations, etc. Some of the major linkages are mentioned in a table below.

Table 5.12 Major Industry Academia Linkages

#	Academia	Some Industry Linkages
1	Stanford-India Biodesign - All India Institute of Medical Sciences (AIIMS)	Brun Health, Consure Medical, HiCARE LIMO, Sohum Innovation Lab, Windmill Health Technologies
2	IKP Knowledge Park	Aindra Systems Pvt. Ltd., Biodesign Innovation Labs Pvt Ltd, BrainSight Technologies Private Limited, Chikitsak LifeSciences Pvt Ltd, Genovel Pharmaceuticals Private Ltd, Innaumation Medical Devices LLP,Sarsuag Enterprises
3	Indian Institute of Science, Bangalore	Wipro GE Healthcare, PathShodh Healthcare, ShanMukha Innovations, Mimyk, SIAMAF Healthcare
4	BARC (Bhabha Atomic Research Centre)	Kavitul Technologies, Aksharaarka Enterprise, Sanjeevani Elecromedicals, Star Automations, Cardea Labs
5	Sree Chitra Tirunal Institute for Medical Sciences and Technology	Axio BioSolutions, Jayon Implants, Neuron Biomed Equipments, Terumo Penpol, Boston Scientific, JJ Orthodontics, Meril Lifesciences, Biopore Surgicals, Neptune Orthopaedics
6	IIT Delhi- BBIF	StellarGene Technologies Pvt Ltd, Ramja Genosensor, ETEX Technologies, Flexmotiv Technologies Pvt Ltd, Fabiosys Innovations, Valetude Primus Healthcare

#	Academia	Some Industry Linkages
7	NIPER	Johnson & Johnson, Sahajanand Laser Technology, Uteshiya Medicare
8	IIT Hyderabad	NeMocare Wellness, Beable Health, Kvayat Medical, Heamac Medical, Aerobiosys Innovation.
Source: Website of these institutes and other sources [187]		

5.10. Reverse Innovation – India Case Studies

Reverse innovation (RI) are innovative techniques and ideas that are developed specifically to meet the needs of emerging countries and are later adopted by other nations, because to their impressive performance[188].

- Portable ECG machine – This was created by GE Healthcare to suit challenges of Indian road conditions especially in rural India. Later it was picked up for distribution by over 100 countries.
- Brilliance – This instrument designed by D-Rev minimized the impact of power fluctuations which reduce the life of bulbs required for phototherapy. This was later picked up by over 50 countries.
- Aravind Eye Care System – Based in India and created by a retired doctor popularly known as Dr Govindappa Venkataswamy (or Dr V)[189]. Following a model of fast- food chain, Arvind succeeded in significant cost cutting and replaced doctors with low-cost trained professionals for routine work. It has drastically reduced the cost of operation in cataract and treated millions of poor patients. It is now going global.

5.11. Cost-Benefit Analysis

5.11.1 Methodology

In this study we have compared Indian Medical Device Industry with the Indian Manufacturing Sector with respect to Labour Cost, Labour Productivity and Unit Labour Cost to observe the manufacturing competitiveness. We have accounted the Indian Manufacturing Industries based on the National Industrial Classification Code (NIC Code) which is equivalent to ISIC Rev.4 Classification. The Manufacturing Industry comes under Section C of the NIC 2008 Codes which ranges from the code division 10 to 33. Unfortunately, the NIC Classification does not specify Medical Devices Industry under any division, making it difficult to classify from other industry divisions. We extracted medical device products from the NIC Code List taking Table 1 from Datta and Selvaraj 2019[190] as a reference and created a pseudo division, 34[191], for the purpose of the study.

Owing to the irregularity of classification and limited data availability for the medical device industry of different countries we were not able to compare Indian medical device industry with other countries' counterparts. instead, we compared Indian manufacturing sector with manufacturing sector of selected developed and fast-developing countries to assess the competitiveness. we assume that the results will be close to those of the medical device industry as well.

5.11.2 Definitions

- Labour productivity (LP) is defined as the ratio of output (Y) volume (from GDP data) per unit of

[187] https://biodesign.stanford.edu/our-impact/companies.html,https://ikpeden.com/startups/,https://iisc.ac.in/, https://technologies.britatom.gov.in/licensees/all, https://www.sctimst.ac.in/About%20SCTIMST/Annual%20Report/resources/Annual_Report_2019_2020_English.pdf,https://fitt-iitd.in/bbif/, http://www.niperhyd.ac.in/, https://www.ncl-india.org/, https://cfhe.iith.ac.in/ and various other secondary sources

[188] https://www.aranca.com/knowledge-library/articles/ip-research/reverse-innovation-in-healthcare-sector.

[189] "Making Breakthrough Innovation" , Porus Munshi, Pg 36, Collins Business2016

[190] Datta, P., & Selvaraj, S. (2019). Medical Devices Manufacturing Industry. Economic & Political Weekly, 54(15), 47.

[191] The National Industrial Classification (NIC, version 2008) system is used to identify any particular industry from the ASI data set. But unlike other economic activities, the manufacturing of medical devices and equipment is not classified together under a single division (two-digit level). So, we teased out all possible manufacturing activity (5-digit level) that may produce medical devices and equipment under one pseudo-two-digit classification (36 in the list). We also removed these 5-digit activities from their original two-digit code (for example 26600 from two-digit division 26; 30922 from two-digit division 30 etc.) to avoid double counting.

labour (L), i.e., persons employed, or hours worked) or LP=Y/L

- Unit labour cost (ULC) is the ratio of nominal labour compensation (LC) and output (Y) produced with that compensation in a production process or ULC=LC/Y,
- Relative Unit Labour Cost of country A with respect to country B (ULCAB) is defined as ULCAB = (LCA/LCB)/(YA/YB)

5.11.3 Data

5.11.3.1 India Data

The microdata of Annual Survey of Industries (ASI) by Ministry of Statistics and Program Implementation has been the primary source of the study. For this study we obtained data for the financial year 2017-18. ASI covers organized manufacturing.[192]

Given the vastness of the Indian manufacturing sector, Indian medical devices industry has primarily been put against the auxiliary industries to medical devices i.e., chemical industry, pharmaceuticals industry, electronic industry, electrical industry, machinery industry and refurbish industry. the calculations made for Indian manufacturing sector follows the formulas presented in the Tabulation Program of ASI and the indicators are based on the ASI Schedule for 2017-18. The accuracy of the data has been obtained by using the multiplier set by the ASI in Block A of microdata.

We have taken Block A of ASI 2017-18 data as the reference point of analysis. Block A has a sample size of 66688 factories, out of which 61500 factories come under NIC Section C i.e., Manufacturing Sector. As a first step, we calculated the number of factories segregated through the code division 10-34. We then merged Block A with Block B to find out the number of factories which have received foreign investment and factories that have R&D units.

Secondly, we derived total invested capital for the number of operational factories across code divisions 10-34. The total invested capital is the sum of total fixed assets (Block C) and total working capital (Block D). We then calculated the total workforce along with the total workforce pay-out in the operational factories across the code divisions 10-34 from Block E. Total workforce comprises of workers employed directly as well as contractually to work in the factories. Apart from that, it also includes the supervisory and managerial employees and other paid and unpaid staff. Similarly, the total pay-out was calculated for the different sections of the workforce in the operational factories.

Thirdly, we calculated the total input/expense of the operational factories in 2017-18 from Block F, H & I. The total input/expense is the sum of raw material expenses, operational expenses, R&D expenses, imported products and materials consumed (fuel, indigenous materials and imported materials) for manufacturing of the products.

Lastly, we calculated the total revenue generated by the operational factories in 2017-18 from Block G & J. The total revenue is the sum of value of products and by products sold by the operational factories. It also includes the income generated from other sources like services, rent, etc.

Based on the above calculated data, we were able to draw the Gross Value Addition (GVA) and Profit made by different divisions of the manufacturing sector. we also were able to estimate the economic contributions of those divisions in the manufacturing sector. Furthermore, we arrived to understand the competitiveness of Indian medical devices industry with different divisions of manufacturing sector in terms of productivity and unit labour cost.

5.11.3.2 Global Data

The data for labour cost, labour productivity and total workforce of the manufacturing sector of different countries were obtained from the International Labour Organization. The data was collected for the year of 2018 to have a standard comparison with Indian manufacturing sector. We selected 17 countries comprising of both developed and fast-developing nations – USA, UK, Germany, France, Italy, Norway, Sweden, Japan, South Korea, China, Singapore, India, Brazil, Bangladesh, Indonesia, Vietnam, and Mexico. Similarly, latest data related to the Infrastructure and Business Environment in India were

[192] Factories which employ 10 or more workers with power and 20 or more workers without power. Data is available for more than 5000 products classified under National Product Classification for Manufacturing Sector (NPCMS). Since this data is plant level data, we had to clean the data before aggregating to industry level. All data presented in this study are accounted only for the factories that were operational

collected from the TheGlobalEconomy.com research platform.

Firstly, we collected the Labour Cost *(Annual Mean nominal monthly earnings of employees by sex and economic activity)* data from the ILO Stat website for all the 17 selected countries for the year of 2018. However, for China and Bangladesh we only got the labour cost data for 2016 and 2017 respectively. In order to have a uniform comparison we calculated the labour cost of China and Bangladesh for the year of 2018 by taking inflation into the account. For China, we took 2% and 1.59% as the rate of inflation for 2017 and 2018, and for Bangladesh we took 5.70% as the rate of inflation for 2018. The rate of inflation was based on the data available in the World Bank database.

Secondly, we collected the labour productivity (annual output per worker at GDP constant 2011 international $ in PPP) data and the total workforce (annual employment by sex and economic activity -- ILO modelled estimates) from the ILO Stat website for all the 17 selected countries for the year of 2018.

Thirdly, we collected the data for competitiveness, road quality, railway quality, port quality, airport quality, innovation index and tax rate on profit for the year of 2020 while R&D expenditure was collected for 2018 and average business credit interest rate and ease of business index was collected for 2020. We selected 9 countries comprising of both developed and fast-developing nations – USA, UK, Germany, France, Japan, South Korea, China, Singapore, and India

Lastly, we put the collected data in a tabulated format to derive and analyze the competitiveness of the selected 17 countries with respect to the labour cost, labour productivity, unit labour cost, infrastructure, and business environment.

5.11.4 Observations

5.11.4.1 Indian Medical Devices Industry with respect to Indian Manufacturing Sector

1. Medical device manufacturers (1080) are 3 times less in numbers when compared to the number of manufacturers in auxiliary industries i.e., pharma (5051), electrical equipment (7622), chemical and chemical products (12568), machinery and equipment (12806), etc.
2. More than 8% of the medical device industry receives foreign investment, second highest after automobile industry (11%) in the manufacturing sector and 30% more when compared to pharma industry (6%). However, the number of recipients is less than third of pharma industry (298).
3. Only 8% of the medical device industry have R&D units which is 82% less when compared to pharma industry (15%) and more than 7 times lesser in numbers of units (medical device industry -88, pharma industry -746).
4. R&D expenses are among the lowest in the manufacturing sector and covers a mere 0.5% (INR 25 Cr) of the total expenses (INR 21986 Cr) of medical devices industry. Pharma Industry on the other hand spends over 17% (INR 1701 Cr) of the total expenses (INR 182832 Cr) towards R&D which is highest in the manufacturing sector.
5. Investments made in medical devices industry (INR 12280 Cr) in 2017-18 are among the lowest in the manufacturing sector. When compared, it comes down to a mere 7% of investments made in pharma industry (INR 179427 Cr) and less than 30% when compared to auxiliary industries.
6. Average capital invested in the medical devices industry reaches approximately to INR 11.37 crore per unit, which is less than a third of average investment made in pharma industry (INR 35.52 Cr) and 40% lower when compared to average investment made in manufacturing sector (INR 18.08 Cr).

Table 5.13 MD vs Manufacturing (Factories, Investment and R&D)

NIC	Industry	Number of Factories	Foreign Investment	R&D Units	R&D (In INR Crore)	Invested Capital (in INR Crore)
20	Chemicals & Chemical Products	12568	4%	5%	341	403007.22
21	Pharmaceuticals, Medicinal Chemical & Botanical Products	5051	6%	15%	1701	179427.84
26	Computer, Electronic & Optical Products	1777	6%	6%	100	43754.25
27	Electrical Equipment	7622	4%	3%	204	108042.04
28	Machinery & Equipment N.E.C.	12806	5%	3%	467	156667.25
33	Repair & Installation of Machinery & Equipment	712	5%	1%	1	5122.80
34	Medical Devices	1080	8%	8%	25	12279.62
-	Registered Manufacturing (aggregate)	220646	2%	2%	5710	3988398.34
Source: Annual Survey of Industries 2017-18, MoSPI						

7. Workforce (99,186) in Medical Device Industry is among the lowest in the Manufacturing Sector, however, the Worker-Manager Ratio (0.20) is highest in the Manufacturing Sector after Pharma Industry (0.22).
8. Percentage of high skilled workforce (13%) in Medical Devices Industry is third highest in Manufacturing Sectors after Petroleum Products Industry (15%) and Pharma Industry (14%). However, the percentage of low to medium skilled workforce (65%) is lowest in Manufacturing sector after Pharma Industry (61%).

Table 5.14 MD vs Manufacturing (Workforce and Pay-out)

NIC	Industry	Workers (in 000)	Managerial Staffs (in 000)	Total Workforce (in 000)	Worker's pay-outs (in INR Thousand)	Managerial pay-outs (in INR Thousand)	Total pay-outs (In INR Thousand)
20	Chemicals & Chemical Products	615	101	829	114320949	116116943	331019662
21	Pharmaceuticals, Medicinal Chemical & Botanical Products	454	102	740	90748200	127085683	333360890
26	Computer, Electronic & Optical Products	129	21	181	24116355	50660116	108642875
27	Electrical Equipment	454	70	599	81992712	77520769	220972321
28	Machinery & Equipment N.E.C.	603	108	848	120608388	137022383	380489523
33	Repair & Installation of Machinery & Equipment	22	3	29	5262634	6360114	15232699
34	Medical Devices	64	13	99	11411607	20005121	46941849
-	Registered Manufacturing (aggregate)	11803	1408	14999	1861032305	1428479035	4571348146
Source: Annual Survey of Industries 2017-18, MoSPI							

9. Domestic raw material expenses (INR 114 Cr) in the medical devices industry are one of the lowest in the manufacturing sector whereas the imported materials (INR 3846 Cr) are 32 times higher.
10. 21% of the total expenses in the medical devices industry goes towards the import of complete build units (INR 4580 Cr) which is highest in the manufacturing sector after the refurbished machinery and equipment industry.

Table 5.15 MD vs Manufacturing (Inputs and Expenses)

NIC	Industry	Imported Inputs (in INR Crore)	Raw materials (in INR Crore)	R&D (in INR Crore)	Purchase of CBUs (in INR Crore)	Total Expenses (in INR Crore)
20	Chemicals & Chemical Products	114089	7609	341	26504	517335
21	Pharmaceuticals, Medicinal Chemical & Botanical Products	26915	4308	1701	9561	182832
26	Computer, Electronic & Optical Products	72106	711	100	30765	150829
27	Electrical Equipment	34551	1626	204	17238	253756
28	Machinery & Equipment N.E.C.	37694	1939	467	19501	274617
33	Repair & Installation of Machinery & Equipment	156	53	1	2376	7547
34	Medical Devices	3846	114	25	4580	21986
-	Registered Manufacturing (aggregate)	1355338	59995	5710	407372	6284833

Source: Annual Survey of Industries 2017-18, MoSPI

11. Although less than pharma, average GVA and profit of medical devices industry is 20% higher, on an average, than most industries in Indian manufacturing sector.
12. The medical devices industry accounts for 0.49% of the revenue of the manufacturing sector whereas pharma industry holds a share of 2.29%. similarly, the medical device industry employs 0.66% of the workforce in the manufacturing sector in comparison to 4.93% of the pharma industry. mdi contributes 0.72% to the GVA of manufacturing sector while pharma industry contributes 7.39%.

Table 5.16 MD vs Manufacturing (Revenue and Economic Contribution)

NI C	Industry	Total Revenue (in INR Crore)	Gross Value Added (in INR Crore)	Profit (in INR Crore)	Economic Contribution by Factories	Economic Contribution by Employment	Economic Contribution by GVA
20	Chemicals & Chemical Products	661499	144164	78623	5.70%	5.53%	10.42%
21	Pharmaceuticals, Medicinal Chemical & Botanical Products	285014	102183	53845	2.29%	4.93%	7.39%
26	Computer, Electronic & Optical Products	176598	25769	11200	0.81%	1.21%	1.86%
27	Electrical Equipment	307386	53630	20577	3.45%	3.99%	3.88%
28	Machinery & Equipment N.E.C.	367173	92556	39744	5.80%	5.65%	6.69%
33	Repair & Installation of Machinery & Equipment	11242	3694	1622	0.32%	0.19%	0.27%
34	Medical Devices	31893	9907	3988	0.49%	0.66%	0.72%
-	Registered Manufacturing (aggregate)	7668217	1383383	563499	100%	100%	100%

Source: Annual Survey of Industries 2017-18, MoSPI

13. Productivity of Indian Medical Devices Industry is significantly less than the average but at par with the Pharma Industry at INR 32 lakh per employee. Moreover, Unit Labour Cost (1471) is second highest in the Manufacturing Sector and notably higher than Pharma Industry (1169).

Table 5.17 MD vs Manufacturing (Productivity and ULC)

NIC	Industry	Productivity	Unit Labour Cost	ULC Compared to MD
20	Chemicals & Chemical Products	7979477	500.41	0.02
21	Pharmaceuticals, Medicinal Chemical & Botanical Products	3851544	1169.63	0.09

26	Computer, Electronic & Optical Products	9756791	615.20	0.08
27	Electrical Equipment	5131655	718.88	0.05
28	Machinery & Equipment N.E.C.	4329871	1036.27	0.06
33	Repair & Installation of Machinery & Equipment	3876415	1355.03	2.61
34	Medical Devices	3221545	1471.84	1.00
-	Registered Manufacturing (aggregate)	5112485	596.14	0.00
Source: Annual Survey of Industries 2017-18, MoSPI				

5.11.4.2 Global Competitiveness of Indian Manufacturing Sector

1. Labour Cost (2252 USD/annum) of Indian manufacturing sector is among the lowest in the world as per the ILO 2018 data. In fact, labour cost (2547 USD/annum) of Indian medical devices industry is also among the lowest and is significantly cheaper from other fast-developing countries like China (9274 USD/annum), Brazil (8038 USD/annum), Mexico (7415 USD/annum) and Vietnam (3090 USD/annum).
2. Annual Output per Worker (19035 USD) in Indian manufacturing sector is one of the lowest in the world after Vietnam (12858 USD) and Bangladesh (10876 USD).
3. Unit Labour Cost (0.12) of Indian manufacturing sector is one of the lowest in the world after Indonesia (0.09) and Japan (0.03).

Table 5.18 India vs Global Manufacturing

Country	Labour Cost (in USD)	Labour Productivity (in USD)	Total Workforce (in thousands)	Total Output (in bn USD)	Unit Labour Cost	ULC Relative to India
Bangladesh	1800.24	10876.20	9623.869	104.67	0.17	14.27
Brazil	8038.92	33044.82	10607	350.51	0.24	6.27
China	9274.44	27534.27	156852	4318.81	0.34	0.70
France	49274.16	105426.82	3269.562	344.70	0.47	12.24
Germany	66308.28	110612.12	8047.863	890.19	0.60	6.08
India	2252.88	19035.57	56124.55	1068.36	0.12	1.00
Indonesia	2089.56	24012.98	18263.22	438.55	0.09	1.79
Italy	30057.6	109188.48	4294.7	468.93	0.28	5.30
Japan	2680.56	77484.57	10896.06	844.28	0.03	0.37
Mexico	7415.4	46369.95	9127.645	423.25	0.16	3.41
Norway	69056.28	124287.07	209.419	26.03	0.56	192.70
Singapore	41635.68	160347.96	356.097	57.10	0.26	41.05
South Korea	41991.84	80096.49	4538.588	363.52	0.52	13.02
Sweden	50526.24	109136.01	498.787	54.44	0.46	76.77
United Kingdom	44779.92	92438.29	2993.965	276.76	0.48	15.80
United States	55546.92	125951.26	16963.24	2136.54	0.44	1.86
Vietnam	3090.24	12858.97	10063.14	129.40	0.24	16.76
Source: International Labour Organization 2018						

4. It is understood that Medical Devices in India is very low in R&D, investment, productivity and very high on raw material imports. This gets further influenced by the following macro parameters[193]:

[193] https://www.theglobaleconomy.com/indicators_list.php

Table 5.19 India vs Global Manufacturing Ecosystem

Country	Avg. Busine ss Credit Interest Rate (2020)	Competitiveness s ss (2019)	Road Quality (2019)	Railway Quality (2019)	Port Quality (2019)	Airport Quality (2019)	Innovation Index (2019)	R&D Expenditure in % of GDP (2018)	Ease of Business Index (2020)	Tax Rate on Profit (2019)
China	4.35%	73.90	4.60	4.50	4.50	4.60	54.80	2.19	77	NA
France	1.24%	78.80	5.40	5.00	5.20	5.50	54.20	2.20	83	28.23
Germany	1.81%	81.80	5.30	4.90	5.20	5.50	58.20	3.09	83	17.83
India	9.15%	61.40	4.50	4.40	4.50	4.90	36.60	0.65	66	NA
Japan	1.47%	82.30	6.10	6.80	5.80	6.20	54.70	3.26	81	NA
Singapore	5.25%	84.80	6.50	5.80	6.50	6.70	58.40	NA	93	30.25
South Korea	2.80%	79.60	5.90	5.90	5.50	5.90	56.60	4.81	91	29.38
United Kingdom	1.64%	81.20	4.90	4.30	5.20	5.30	61.30	1.72	95	32.79
United States	3.54%	83.70	5.50	5.20	5.60	5.80	61.70	2.84	83	52.32

5. It is evident from the above observations that Medical Device Industry is seriously falling short with respect to the R&D expenses (0.5% of total expenses), very low investment, very high dependence on imports of raw materials and built-up units and also low productivity.
6. Besides, there is huge scope for bettering on many areas including rate of interest, competitiveness index, R&D expenditure as % of GDP, etc. Scope also exists for improvement in road, port, and airport quality.

5.11.5 Suggestions

India is expected to become the third largest economy by 2030[194], with an expected GDP growth rate of 7.8 percent in FY 2022-23[195]. The growth in GDP is likely to trickle down to priority sectors like health technology, in particular medicines and medical devices. Backed by growing healthcare needs and government's focus to facilitate growth, the medical devices industry is likely to experience strong growth.

The population in India is expected to reach 1.4 billion by 2025, with an increase in life expectancy to 70+ years in 2022 from 67 years in 2015[196]. This has come with an increased burden of chronic/communicable diseases. By 2051, around 57 percent of the disease burden is expected to be from chronic/communicable diseases (46 percent in 2006).[197] In case of chronic diseases, clinical diagnostics and care are required throughout the patient's life. With the growth in 65+ age-group population, the prevalence of non-communicable diseases is also expected to steepen. These factors can attribute to significant growth in demand for medical devices in India.

India's per capita income is expected to reach USD 2730 by 2025 (USD 1875 in 2016).[198] With the rising income levels, and better health awareness, India's per capita spend on healthcare is projected to be the highest (9.3%) in Asia-Pacific market as compared to China (6.7%), Thailand (5.4%), Malaysia (4.0%), Japan (3.9%), and Australia (1.3%).[199] The share of diagnostic expenditure in the total out of pocket expenditure on health has increased steadily from 1993–94 to 2011–12; the share of has gone up from 2.2% in 1993–94 to 7.6% in 2011–12.[200] The government's expenditure on healthcare as a

[194] India to become 3rd largest economy by 2020: Report, The Times of India article, December 2020

[195] RBI projects India GDP growth rate at 7.8%: Report, Livemint, February 2022

[196] India: Life Expectancy, Statista, May 2022

[197] NCBI Resources, May 2022

[198] India GDP per capita, Trading Economics, February 2021

[199] Healthcare sector reports for all six countries, EIU, 2021

[200] India emerging as a global wellness and ayurveda hub, IBEF Blog, February 2021

percentage of GDP has grown from 1.15% in 2013-14 to 1.28% in 2018-19[201] and is expected to reach 2.5% by 2025 as prescribed by the National Health Policy of 2017. The medical devices industry will experience a boost with rising private and government spending in India.

Despite recent experiences in accelerating domestic production of medical devices, most imports of medical devices are largely high-value and low-volume devices while the domestic production are largely low-value and high-volume diagnostic tools. However, in recent years, Indian medical devices manufacturing industry is improving its coverage even among sophisticated and high-end segment. Indian industry has begun manufacturing more sophisticated devices like electro-diagnostic apparatus, used in medical, surgical, dental, or veterinary sciences, orthopaedic appliances, splints and other fracture appliances, artificial parts of the body etc. (Datta and Selvaraj, 2019[202]).

Labour Cost (2252 USD/annum) of Indian Manufacturing Sector is among the lowest in the world as per the ILO 2018 data. In fact, Labour Cost (2547 USD/annum) of Indian Medical Devices Industry is also among the lowest and is significantly cheaper from other fast-developing countries like China (9274 USD/annum), Brazil (8038 USD/annum), Mexico (7415 USD/annum) and Vietnam (3090 USD/annum).[203] Percentage of high skilled workforce (13%) in Medical Devices Industry is third highest in Manufacturing Sectors after Petroleum Products Industry (15%) and Pharma Industry (14%). However, the percentage of low to medium skilled workforce (65%) is lowest in Manufacturing sector after Pharma Industry (61%). More than 8% of the Medical Device Industry receives foreign investment, second highest after Automobile Industry (11%) in the Manufacturing Sector and 30% more when compared to Pharma Industry (6%). Although less than Pharma, average GVA and Profit of Medical Devices Industry is 20% higher, on an average, than most industries in Indian Manufacturing Sector. [204]

The industry has particularly benefitted because of two flagship schemes of the Department of Pharmaceuticals – PLI and Medical Devices Park. It is also benefitting local manufacturers with special purchase policy. The Industrial land bank portal will make investment easier too. A number of medical devices arks are also opening up in various parts of the country. However, comparatively low R&D base is one of the major weaknesses of the Indian medical devices manufacturing industry. Our estimate from Annual Survey of Industries (2017-18) shows that only 8% of factories manufacturing medical devices and equipment have R&D units (whereas 15% of pharmaceuticals, medicinal chemical & botanical products manufacturing factories have R&D units). If this is taken care of India will be more confident a manufacturing base for innovative products.

With a rising domestic demand, the support through various programs of the various Ministries, especially the Department of Pharmaceuticals, the Indian medical device industry is all poised to grow.

5.12. Relative Competitive Advantage (RCA) Status

A simple way to identify comparative advantage of output of a product as compared to another country is its relative comparative advantage (RCA). It is calculated as the ratio of exports of a sub product to its total exports of principal products with respect to medical device products with respect to the same ratio for the entire world. For example, the formula for calculating the RCA of IVD for USA would be ((Export of IVD from USA/Total Exports of medical device from USA)/ (Exports of IVD in the world/Total Exports of medical device in the world)) If a nation has RCA >1 for a product, it may be concluded that it is a competitive producer and exporter of that product relative to a country producing and exporting that good at or below the world average. A country with a revealed comparative advantage in product is considered to have export strength in that product. The higher the value of a country's RCA for a product, the higher its export strength in the product. In general, this is done by taking total exports in the denominator and total medical devices in the numerator.

A comparison of the RCA of select countries has been made for the major product areas. The USA has a natural comparative disadvantage in consumables and disposables, and it has increased over the years. However, as expected it is in the lead in the other high-tech areas including Electrical & Equipment, Implants and IVD Reagents. India has the highest RCA for electronics and equipment. RCA for the

[201] National Health Accounts Estimates for India 2018-19, Ministry of Health and Family Welfare, Government of India, 2022

[202] Datta, P., & Selvaraj, S. (2019). Medical Devices Manufacturing Industry. Economic & Political Weekly, 54(15), 47.

[203] See section 5.12

[204] See section 5.11

other relatively high-tech products is less than 1, especially in Implants and Surgical Instruments, which is it is at a relatively disadvantageous position. The situation for consumables & disposables and IVD reagents is quite similar, although the growth rate in IVD Reagents is very high. China is doing well in consumables and disposables although the trend is in the negative as they are moving away from low value products. In the equipment and electronics area, they have moved to a significant competitive advantage. A case in point is also Singapore. It has clearly disengaged itself from Consumables & Disposables with a very low RCA and with a clear competitive advantage in Electronics and Equipment, Implants and IVD Reagents. The trend is increasing in all three items.

Table 5.20 Relative Competitive Advantage of Select Countries

Country	Category	2015	2016	2017	2018	2019	2020
USA	Consumables/Disposables	0.48	0.49	0.42	0.42	0.42	0.29
	Equipment & Electronics	1.31	1.32	1.17	1.17	1.16	1.40
	Implants	1.65	1.56	1.40	1.44	1.41	1.73
	IVD	1.33	1.34	2.54	2.53	2.65	2.73
	Surgical Instruments	0.78	0.77	0.68	0.67	0.67	0.79
India	Consumables/Disposables	1.60	1.56	1.56	1.45	1.41	1.03
	Equipment & Electronics	0.95	0.97	0.87	0.97	1.01	1.19
	Implants	0.34	0.38	0.43	0.51	0.48	0.66
	IVD	0.40	0.46	0.90	0.90	0.91	1.05
	Surgical Instruments	0.57	0.56	0.53	0.47	0.48	0.54
China	Consumables/Disposables	1.03	1.03	1.00	0.97	0.94	0.68
	Equipment & Electronics	1.68	1.69	1.65	1.52	1.56	1.85
	Implants	0.21	0.25	0.26	0.29	0.34	0.28
	IVD	0.11	0.12	0.34	0.36	0.33	0.62
	Surgical Instruments	0.17	0.17	0.16	0.51	0.51	0.59
Singapore	Consumables/Disposables	0.39	0.36	0.32	0.30	0.29	0.20
	Equipment & Electronics	1.56	1.60	1.53	1.53	1.55	1.86
	Implants	0.79	0.88	0.95	1.04	1.17	1.80
	IVD	1.16	1.28	1.38	1.71	1.50	1.40
	Surgical Instruments	0.92	0.78	0.88	0.70	0.76	0.87
Source: Calculated from Intracen data; Data is per Calendar Year							

5.13. Permissions for Manufacturing Medical Devices

Following registrations/permissions are required for doing business in medical devices.

Table 5.21 Permissions/Registrations from Union Government

Sl. No	Department	Act and Rule
1	Central Drugs Standard Control Organization, Ministry of Health & Family Welfare	Drugs and Cosmetics Act ,1940 and Rules, 1945 As amended up to the 31st of December, 2016 and Medical Device Rules, 2017
2	National Pharmaceutical Pricing Authority	The Drug Price Control Order, 2013
3	Ministry of Consumer Affairs, Food & Public Distribution	BIS Act, 2016 Section 9 (3) & BIS Rules, 2018
4	Ministry of Consumer Affairs, Food & Public Distribution	Essential Commodities Act, 1955 & DPCO, 2011
5	Ministry of Consumer Affairs, Food & Public Distribution	The Legal Metrology Act, 2009 Section 52(2) (1) and the Legal Metrology (Packaged Commodities) Rules, 2011 (Rules)
6	Atomic Energy Regulatory Board	Atomic Energy Act 1962, Amendments to Atomic Energy Act 2015, Environment Protection Act 1986
7	Ministry of Corporate Affairs	The Companies Act, 2013 Section 3 (2) and the Companies (Incorporation) Rules 2014 and Section 153 and Rules 9(1)
8	Ministry of Finance	The Income Tax Act, 1961 Section 139(A) and The Income Tax Rules 1962 - Rule 114(1) & (2), Section 203(A) and The Income Tax Rules 1962 - Rule 114(A)

Sl. No	Department	Act and Rule
9	Ministry of Finance	The Customs (Import at Concessional Rate of Duty) Rules, 2017, Ntf. No. 50/2017-Cus. Dtd. 30.06.2017
10	Ministry of Commerce	The Foreign Trade (Development and Regulation) Act, 1992 Section 9(A) (4)A and The Foreign Trade (Regulations) Rules, 1993,
11	Ministry of Commerce	The Foreign Direct Investment (FDI) Policy under the Foreign Exchange Management Act, 1999 (FEMA)
12	Ministry of Commerce	The Trade Marks Act 1999, Section 23(2) Rule 62(1), The Copy Rights Act, 1957
13	Ministry of MSME	The Micro, Small and Medium Enterprises Development Act, 2006 Section 2(1)

Table 5.22 Permissions/Registrations from State Government

Sl. No	Department	Act and Rule/Purpose
1	State/ Central Drug Licensing Authority	Drug & Cosmetic Act 1940 and Medical Devices Rules 2017 and sec rule 73 & 83 = Drug Manufacturing License (for Notified Medical Devices)
2	Directorate of Town & Country Planning	Change of Land Use
3	Building Code (State IIDC)	Drawings of Building
4	Chief Inspector of Mines	The Mines Act 1952 - Permission from Mines Department (for Basement)
5	Office of the Joint-Director	The Building and Other Construction Workers Welfare Cess Act, 1996, Section 3(1) and These rules may be called The Building and Other Construction Workers' Welfare Cess Rules, 1998
6	Labour Department	The Contract Labour (Regulations and Abolition) Act, 1970 - Contract Labour License
7	Municipal Corporation	Fire Service Act and Rules – Fire NoC
8	Electrical Inspectorate	Lift and Escalators Act and Rules - Lift Registration
9	State Electricity Authority	Central Electricity Authority (measures Relating to safety and Electric Supply) Regulations, 2010- Regulation 30(1) – Electricity Connection and Independent Feeder
10	Directorate of Urban Local Bodies	Water and Sewage Connection
11	Petroleum & Explosives Safety Organization	The Petroleum Act, 1934 Section 3(1) and The petroleum Rules, 2002- Rule 166. License for Storage of Chemicals and ETO
12	Indian Oil Corporation	The Petroleum Act, 1934 Section 3(1) and The petroleum Rules, 2002- Rule 166. License for Storage of Diesel from Indian Oil Corporation
13	Municipal Corporation	The Petroleum Act, 1934 Section 3(1) and The petroleum Rules, 2002- Rule 166. License for Storage of Diesel from DC
14	State IIDC	Occupation certificate
15	Chief Inspector of Factories	The Factories Act, 1948 & Factories Rules - Factory building plan
16	Labour Department	The Factory Act 1948 and Rules – Factory License
17	Chief Inspector of Factories	The Factory Act 1948 and Rules – Factory Return
18	Labour Commissioner	The Factory Act 1948 and Rules – Maternity Benefit, Workman Compensation, Minimum Wages

Sl. No	Department	Act and Rule/Purpose
19	State Pollution Control Board	Prevention and Control of Pollution) Act, 1974, Section 25/26 and 21/22 - Environment Under Pollution Control - Water and Air respectively
20	Directorate of ESI	The Employees' State Insurance Act 1948
21	Additional Central provident fund Commissioner	The Employees Provident Funds And Miscellaneous Provisions Act, 1952
22	Labour Department	The Payment ff Bonus Act, 1965 Section 38 and Rules
23	Chief Labour commissioner	The Payment of Gratuity Act, 1972 Section 15(1) And Rules
24	Employment Department Haryana	The Employment Exchange Act 1959
25	Excise and Taxation Department	State Act

5.14. Addressing Demand Supply Gap in Select Medical Devices[205]

India's medical devices imports is dominated by electronics & equipment. Again, among electronics & equipment some of the high cost and critical requirements are in imaging devices like CT and MRI, patient monitoring equipment, anesthetics, and dialysis equipment. These are the same products for which the PLI scheme has been created with the intention of promoting their production in the country. PLI scheme has made significant progress with committed investment of Rs 1205.52 crores for 26 and employment of 7411 persons.

5.14.1 MRI[206]

It is estimated that India has around 4050 MRIs[207] (3 per million[208] population), as compared to 55 in Japan, 40 in USA, 30 in South Korea, 9 in Poland and 5.2 in Israel[209].

Table 5.23 MRI Machine per Million Populations in OECD Countries & India

Country	MRI Machine per Million Population
Japan	55
USA	40
Germany, Republic of Korea	30 to 35
Italy, Austria, Iceland	20 to 29
15 European countries and Canada	10 to 19
Israel	5.2
India	3
Source: https://www.statista.com/statistics/282401/density-of-magnetic-resonance-imaging-units-by-country/, Data is for select countries for 2019.	

It is estimated that "…. the overall requirement of MRI India could be approximately 7000 to 8000 machines…"[210] or say 5.5 machines per million[211] population. Towards this end, under PLI Scheme, Philips Global Business Services has committed investment of Rs 103.46 crores for producing MRI coils. Besides, Siemens Healthcare, Allengers Medical Systems and Trivitron Healthcare have also committed investment of Rs.167.21 crores.[212] Some major suppliers of MRI machine to India as well as

[205] This section is derived among other, from numerous issues of Medical Buyer.com.

[206] As per article published in in April 2019 in Indian Radiologist Made in India MRI by Rajesh Harsh, Chief Investigator SCAN-ERA-A National Mission

[207] "…A study conducted indicates that India currently has approximately 3500 MRI machines…" (Source: https://www.indianradiologist.com/index.php/review/made-in-india-mri: Apr 8, 2019). 290 machines were added in 2019 (Source: Medical Buyer, February 27, 2020) and 257 in 2020 (Source: Medical Buyer, MRI Continue to see Subdued Demand…" March 2021). So the total is around 4050, not including machine that might have gone out of service.

[208] "The total population in India is projected at 1,380,004,385 or 1380.04 million for the year 2020. (Source: https://statisticstimes.com/demographics/country/india-population.php, MoSPI, UNWP), so the ratio was estimated at 2.93 = 3 per million

[209] These are for 2019

[210] Source: https://www.indianradiologist.com/index.php/review/made-in-india-mri: Apr 8, 2019

[211] Since the figure of number of machines was suggested in 2019, we have taken the upper limit as better applicable for 2020. Also, the ratio is similar to Israel – a high income country

[212] In MRI along with other products like CT, USG, PET, X-ray equipment, Cath Lab, etc.

the global leaders are Siemens, GE, Philips, Toshiba, Hitachi, etc. [213]

MEITY is supporting creation of a 1.5T Indian MRI by SAMEER Mumbai in collaboration with various national and internationally acclaimed institutes. "…SAMEER and its collaborating institutes have developed all the required sub-modules namely, Coil, FPGA Spectrometer, 16kW Amplifier, Pulse sequence generation module, GUI consisting of Image Reconstruction Module and Image virtualization Module. The MRI Magnet system is at the advanced stage fabrication and expected to be ready by …. August 2022."[214]

"India is currently facing shortage of trained medical imaging professionals…" and tele-medicine can solve the issue to some extent[215]. One can create "Command Centers". Command Centers can accumulate images from various PHCs and diagnostics centers. While AI can solve the standard cases done by low-capacity machine (0.2T to 0.5T), complex issues can be handled by expert radiologists. Also, there is scope for promoting mobile MRIs as well as portable MRIs[216].

5.14.2 CT Scanner[217]

India has an estimated 8000[218] CT Scanners (around 5.8 per million) as compared to an intensity per million of 112 in Japan, 43 in USA, 20 in Ireland, 10 in Israel[219]. The most popular model is the 16-32 slice variety. However, their demand is falling and there is a hike in the 'more than 228 slice' variety. The directive of retiring more than 10 years old machine has also reduced the sales of the refurbished category. Towards this end, under the PLI Scheme Siemens, Allengers Medical Systems, M/s Allengers OEM Private Limited, Wipro GE and Trivitron have committed investment of Rs.217.43[220] crores.

Table 5.24 Comparison of CT Scanners per Million Populations in OECD Countries & India

Country	CT Scan Machine per Million Population
Japan	Above 100
Australia	50 to 100
USA and six European countries	30 to 50
Canada and twelve European countries	15 to 30
Israel	10
Mexico	6
India	5.8
Source: https://www.statista.com/statistics/266539/distribution-of-equipment-for-computer-tomography (Data is for select countries for 2019)	

Some major suppliers are GE, Siemens, Philips, Toshiba, Hitachi, Allengers, Mediray, etc. India now has 3 made in India CT scanners by (a) Allengers along with Cannon[221], (b) Siemens Healthineers (Samotom)[222] and (c) Revolution ACT of Wipro GE[223].

According to industry sources (primary survey), parts of a CT like generator, detectors, tube, software, etc. are available globally. Indian companies mostly integrate them. For CT production one needs a

[213] MRIs continue to see subdued demand Special Feature, Medical Buyer, March 2021, Page 42

[214] https://www.cdac.in/index.aspx?id=lu_SMR-TID-EOI-2021-22-1

[215] Medical Buyer, December 14, 2018

[216] Medical Buyer Issues February 27, 2020 and March 2021

[217] Medical Buyer, Various Issues (Sept 7, 2017; Dec 22, 2017; June 25, 2020; March 27, 2019; ibnmedical.com; Dec 10, 2019; Apr 30, 2019; Dec 12, 2018; Aug 30, 2018; Apr 15, 2018 and others)

[218] Indian J Radial Imaging. 2008 Aug; 18(3): 189–191 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2747440/) published an article by Dr Govindji R. Jankharia mentioned that there were 3000 CT scanners in India (assumed by us as for 2007, the previous year) and predicted doubling the amount in a decade. With India adding around and estimated 750 CT scanners per year during 2018 to 2020 (Medical Buyer issues August 30, 2019, March 16, 2021 and Nov 24, 2021), the number must have gone up from 3000 to 6000 in 2017 and further by another 2250 or to say around 8000 by 2020.

[219] https://www.statista.com/statistics/266539/distribution-of-equipment-for-computer-tomography/

[220] Investment of Rs 217.38 crores also include also include items like MRI, USG, PET, X-ray equipment, Cath Lab etc.

[221] expresshealthcare.in/radiology/allengers-in-association-with-canon-launch-indias-first-made-in-india-32-slice-ct/416542/

[222] siemens-healthineers.com/en-in/press-room/press-releases/pr-20191226001hc.html

[223]health.economictimes.indiatimes.com/news/pharma/wipro-ge-healthcare-launches-made-in-india-ct-system-to-strengthen-access-to-quality-healthcare-across-india/91172912

factory, R&D center, supply chain and team, regulatory team, sales team, servicing team, mechanical support team, etc. In all it is a 5 to 7 years' project and the total investment could be around INR 200 crores. Some respondents felt that while component level manufacturing is fine, focus should be ending product, e.g., CT tube manufacturing is fine, but CT scanner may be prioritized. The need for R&D was also highlighted.

5.14.3 Cath Labs[224]

The Indian market is largely dominated primarily by - Philips, Siemens, GE, etc. [225]. There are about 2000 Cath Labs in India. About 225 Cath Labs gets added to the market every year which still leaves a gap. It is estimated that there is need for 6500 Cath labs[226]. Given the high cost of the Cath Labs, the manufacturers need to focus on innovations to minimize the overall cost while addressing the health issues effectively.[227] Towards this end, under the PLI Scheme, Envision Scientific, Sahajanand Medical Technologies, Innvolution Healthcare, Meril Life Sciences, Bio India Investment Technologies, Wipro GE Healthcare, Trivitron Healthcare and Allengers Medical System have committed investment of Rs. 403.32 crores[228] for making Cath Labs, stents, PCTA balloon catheters, etc.

5.14.4 Teletherapy Equipment

India has an estimated 800[229] machines[230]. Growing number of cancer patients and deaths is a major influencer to propel the market. Some of the major suppliers are Elekta, Varian, etc. India falls short by nearly 650 units[231]. If we add the population growth rate of around 10 million every year it implies a very high requirement of machines every year[232]. Towards this end, under the PLI Scheme Panacea Medical Technologies has committed investment of Rs. 24.50 crores. Also, it was estimated that there will be shortage of supporting human resources to the tune of 2756 radiation oncologists, 1533 physicists and 4737 technologists by the year 2020[233]. Hence it has been suggested that there is need for HR creation and standardization of training[234].

5.14.5 Dialysis Equipment[235]

The global dialysis equipment market is being moved by the high incidence of CKD. Some of the lead manufacturers globally are Asahi Kasei Medical, Japan; B. Braun Melsungen, Germany; Baxter International, USA; Diaverum, Sweden, etc.[236] The Indian market is supplied by Nipro India Corporation, B Braun Medical (India), Fresenius Kabi India, Poly Medicure, etc.[237] Dialysis accessories (such as

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[224] Global Cath Lab Services Market Size By Services, By Type, By Geographic Scope And Forecast Published by: Verified Market Research | Published Date: Jul 2018 | Base Year for Estimate: 2018, https://www.medgadget.com/2020/03/india-coronary-stents-market-growth-with-healthy-cagr-of-14-0-to-reach-us-2049-9-million-till-2027-global-size-trends-insight-share-industry-demand-comprehensive-analysis-and-forecast-to-2027.html, The Economic Times dated April 01, 2019 retrievable at https://health.economictimes.indiatimes.com/news/industry/there-is-a-growing-demand-for-cath-labs-in-tier-3-and-tier-4-cities-in-india-gaurav-agarwal/68663022 , Market Watch, as reported in Transformation on the Cards for Cath Labs, Medical Buyer retrievable at https://www.medicalbuyer.co.in/transformation-on-the-cards-for-cath-labs-2/ , The Economic Times dated April 01 2019 retrievable at https://health.economictimes.indiatimes.com/news/industry/there-is-a-growing-demand-for-cath-labs-in-tier-3-and-tier-4-cities-in-india-gaurav-agarwal/68663022

[225] The Economic Times dated April 01 2019 retrievable at https://health.economictimes.indiatimes.com/news/industry/there-is-a-growing-demand-for-cath-labs-in-tier-3-and-tier-4-cities-in-india-gaurav-agarwal/68663022

[226] Healthworld: India Needs around 6500 Cardiac Cathlab Facilities: Dr C N Manjunath, Nov 28, 2021

[227] ET Healthworld: There is a Growing Demand of Cath Labs in Tier 3 and Tier 4 Cities in India: Gaurav Agarwal, April 1, 2019

[228] Investment of Rs 125.32 crores by Allengers Medical Systems, Wipro GE Healthcare and Trivitron Healthcare also include products like MRI, CT, USG, X-Ray, PET, etc.

[229] Based on an average net increase of 15 machines per year and as on 2020/ The paper mentions population as 1.28 billion (which is year 2013) (Source: Mallick,S and Giridhar,P "Is radiation oncology in India today ready to meet the challenges of increasing cancer incidence? Cancer epidemiology and Cancer control programme, Journal of Cancer Policy 24(2020) 100232)

[230] Journal of Cancer Policy 24(2020) 100232)

[231] Around 1 per million is the standard for developing economies as per WHO (Same as footnote 315

[232] Journal of Cancer Policy 24(2020) 100232

[233] Journal of Cancer Policy 24(2020) 100232

[234] Journal of Cancer Policy 24(2020) 100232

[235] Editorial: Providing Dialysis in India: Many Pieces in the Puzzle, The National Medical Journal of India, Vol 32, No 6, 2019, Pradhan Mantri National Dialysis Programme, Vikas pedia

[236] "Making Dialysis Affordable and Accessible", Medical Buyer, June 2020

[237] Various online sources

blood tubing sets and dialyzers) and dialysis machines account for more than 85 per cent of the Indian renal dialysis equipment market.[238] India is adding 0.22 million ESRD every year amounting to 34 million dialysis per annum[239]. "With…. 4950 dialysis centers, largely in the private sector in India, the demand is met less than half with the existing infrastructure…. High capital cost of machines and operational cost of consumables cause major concern…."[240]. Addressing these concerns, under the PLI scheme of DoP Nipro India and Poly Medicure have committed investment of Rs 252 crores for manufacturing in India.

5.14.6 Anesthetics Equipment[241]

Some of the major players in the global anesthesia and respiratory device market include B. Braun, Becton Dickinson, Drager, GE Healthcare, Philips, Medtronic, Smiths, SunMed, Teleflex, 3M, etc.[242] Some major players in India are Accura Healthcare, Aenomed, Allied Medical, BPL Medical Technologies, Draeger India, DSS Imagetech, EMCO Meditech, Flexicare Medical, GE Helalthcare, Genuine Medica, Heyer Medical, Mindray, Premier Medical System Devices, Skanray, Trivitron Healthcare, etc.[243] Indian health sector bought around 5100 anesthesia devices in 2019[244]. DoP has given thrust for manufacturing anesthetics equipment in India. Towards this end, under the PLI Scheme, Allied Medical has committed investment of Rs 22.89 crores[245]. WIPRO GE Healthcare, BPL Medical Technologies, Deck Mount Electronics have also committed investment of Rs 75.11 crores[246].

5.14.7 X rays

Under the PLI Scheme, Allengers OEM has committed investment of Rs 40 crores under PLI. Besides, Allengers Medical Systems, BPL Medical Technologies and Trivitron Healthcare have committed to invest Rs 86.55 crores[247].

5.14.8 Ultrasound[248]

The Indian ultrasound equipment market mostly includes mid-end and entry-level ultrasound equipment, which are observed to be the general preference in the Indian healthcare industry with majority of market share. Colour Doppler, 3D and 4D ultrasound equipment is also gaining popularity. Some of the major players are GE Philips, Mindray, etc. India has an estimated 60,000[249] ultrasound machines. Under the PLI Scheme, Wipro GE, Allengers Medical Systems, BPL Medical Technologies, and Trivitron Healthcare have committed investment of Rs 136.77 crores.[250] With the introduction of Ayushman Bharat as healthcare is improving in rural India, portable ultrasound scanners are also in demand. Medical device companies can focus on these segments while keeping the cost sensitivity of the Indian market in mind to capture a sizeable portion. Accordingly, it was suggested that companies can focus on portable ultrasound scanners, while keeping the cost sensitivity of the Indian market in mind to capture a sizeable portion, promote products suiting varied requirements of patient and users, need to go for advanced functions to broaden clinical applications. It was also felt that with increased users the need for training is of paramount importance, and e. investments in AI development is desired.

5.14.9 Patient Monitoring Equipment[251]

Cardiac, respiratory and temperature monitoring are on the rise. Some major players are

[238] https://www.globaldata.com/renal-dialysis-equipment-market-in-india-to-reach-us225m-in-2025-says-globaldata/

[239] Medical Buyer, March 27, 2020; https://www.medicalbuyer.co.in/dialysis-industry-has-a-long-way-to-go/

[240] Medical Buyer, March 27, 2020; https://www.medicalbuyer.co.in/dialysis-industry-has-a-long-way-to-go/

[241] Mordon Intelligence; as reported in Medical Buyer and also at https://www.mordorintelligence.com/industry-reports/india-anesthesia-devices-market; includes data for consumables / disposables related to anesthesia equipment.

[242] Select names taken and arranged alphabetically from https://www.fnfresearch.com/anesthesia-equipment-market#:~:text=Some%20of%20the%20market%20players%20dominating%20the%20global,%26%20Co.%20KG%2C%20and%20Aircraft%20Medical%2C%20among%20others

[243] Medical Buyer, September 9, 2020; https://www.medicalbuyer.co.in/anesthesia-equipment-4/

[244] Medical Buyer, January 13, 2020 ; https://www.medicalbuyer.co.in/anesthesia-industry-this-year-and-beyond/

[245] DoP

[246] Investment of Rs. 75.11 crores also include patient monitoring equipment, dialyzers, etc.

[247] Along with CT, MRI, Cath Lab, and USG

[248] Medical Buyer November 2021; https://www.medicalbuyer.co.in/ultrasound-is-making-waves/

[249] Estimated based on 44000 in 2015 (Vijayshankar R Andani, Express Healthcare, 2015) and growth rate of 6.5% (biospectrumindia.com and techsciresearch.com)

[250] Investment of Rs 136.77 crores also includes investment in CT, MRI, X-Ray, PET, Cath Lab etc.

[251] Medical Buyer, March 2022 ; https://www.medicalbuyer.co.in/remote-patient-monitoring-moving-into-the-mainstream/

BPL Group, Schiller, Yonker, Philips Healthcare, GE, Medtronic, etc[252]. The next trend in remote patient-monitoring technology is miniaturization. AI and IoT are inducing entry of non-traditional players. This will also lead to JVs in this segment. Increased usage of IoT and AI are also contributing to this growth. IT companies like Google, Apple, and Amazon are also tapping into the remote patient monitoring (RPM) market. Towards this end, under the PLI Scheme, WIPRO GE Healthcare and BPL Medical Technologies have committed investment for Rs 65.11 crores[253].

5.14.10 IVD

IVD sector in India grew by 15 percent in the past few years and by 30 percent in 2020.[254] Several Indian and foreign companies are active in the equipment and reagent market. These include Transasia Bio Medical, Roche Diagnostics, Beckman Coulter, Abbott Diagnostics, Siemens Healthcare Diagnostics, Sysmex, Qiagen N.V, PerkinElmer, Accurex, Bayer Healthcare, Becton, and Dickinson, etc.[255]

Over the last 5-7 years, organized labs have achieved sizeable growth. [256] Serum Institute of India has invested more than INR 100 crores in MyLab Discovery Solutions to fund advanced automation and increase production capacity of Mylab PathoDetect COVID-19 Qualitative PCR kits. CIPLA has launched ELIFast (IgG Elisa test) for COVID-19 antibody detection. Tata Medical Device company has launched a new test for Covid-19; ready with 10 lakh tests per month capacity.[257]

The price for a similar product in IVD sub-segments is very wide. The price of a product is dictated based on factors like number of tests per hour, range of test parameters, level of automation, number of simultaneous analysis configurations, memory of the device, size and portability, and warranty and service[258].

Strong growth is observed in the Indian IVD Sector due to rise in health awareness and increasing diagnosis affordability. Respondents suggested that manufacturers need to focus on the versatility of their products. Hospitals, clinics, and diagnostic centers prefer to have devices which can perform multiple tests and with less technical assistance as it has a better ROI.

Covid-19 crisis has shown that the Indian medical devices sector can rise to the challenge when imports got disrupted and production had shortages for quantified specific devices. One can also go for the creation of IVD sector manufacturing parks. It will also get a big push with the upscaling of health infrastructure and coverage due to Ayushman Bharat.

5.15. Components of Medical Devices[259]

Some of the front ranking items here are medical plastics, medical ceramics, and medical sensors. The global medical plastics market was estimated at USD 30 Bn in 2019 and was projected to reach USD 54 Bn by 2027.[260] Medical plastics are also preferred to ceramic and steel- based castings and surgical tools due to their durability and cost-effectiveness. However, a challenge here will be in the area of waste recycling. Medical ceramics are raw material for orthopedic, cardiovascular, dental, and hearing implants. The global medical sensors market is predicted at USD 1.2 billion in 2020 and is expected to reach USD 1.7 billion by 2025[261]. Patient monitoring application has the largest share in sensors. The global medical ceramics market is estimated to reach USD 26 Bn by 2025. Stakeholders suggest that growth of these sectors are also imperative. Such component manufacturers should be placed in the appropriate clusters. For example, given the advantage of plastics and ceramics, such component manufacturers can be placed in Gujarat.

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[252] Medical Buyer, December 10, 2019; https://www.medicalbuyer.co.in/patient-monitoring-moving-toward-a-value-based-ecosystem/

[253] Including anaesthetic equipment

[254] https://www.biospectrumindia.com/views/69/19671/indian-ivd-industry-displays-resilience-with-30-cagr.html

[255] https://www.medicalbuyer.co.in/the-indian-ivd-market-to-double-its-global-ivd-market-share-by-2020/

[256] https://health.economictimes.indiatimes.com/news/diagnostics/amid-regulatory-issues-diagnostic-chains-bet-on-mom-and-pop-labs-to-expand-presence/71752714

[257] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/tatamd-launches-new-test-for-covid-19-ready-with-10-lakh-tests/month-capacity/articleshow/79124529.cms?from=mdr

[258] Primary survey

[259] marketresearch.com

[260] Fortunebusinessinsights.com/medical-plastics-market-102136

[261] Marketsandmarkets.com/PressReleases/world-sensors-healthcare-application.asp

Table 5.25 Global Firms in Medical Sensors

Country	Company
Germany	First Sensor, EnviteC
Ireland	Medtronic Plc
Japan	TDK Sensors
Netherlands	NXP Semiconductors
Switzerland	TE Connectivity, Sensirion, Innovative Sensor Technology
USA	Johnson & Johnson, Medtronic, Texas Instrument, Cardinal Health, Tekscan, Amphenol Advanced Sensors, Proteus Digital Health, Cirtec Medical, Keller America, Omni Vision Technologies, Masimo, Stanley Healthcare, Merit Medical Systems
Source: Marketsandmarkets.com/PressReleases/world-sensors-healthcare-application.asp	

Table 5.26 Global Firms in Medical Plastics

Country	Company
Belgium	Solvay
Germany	BASF SE, Evonik, Covestro AG
Saudi Arabia	SABIC
Sweden	Nolato AB
USA	Celanese Corporation, GW Plastics, Eastman Chemical Company
Source: fortunebusinessinsights.com/medical-plastics-market-102136	

Table 5.27 Global Firms in Medical Ceramics

Country	Company
Germany	Ceram Tec, Rauschert, H C Stark, QSIL Ceramics, BCE Special Ceramics,
Japan	KYOCERA, Tosoh, NGK Spark Plug, Kuraray Noritake Dental, Ferro Corporation
Netherlands	CAM Biocreamics, Admatec
Switzerland	Institut Straumann, Noble Biocare Services
USA	3M, Johnson & Johnson, CoorsTek, Zimmer Biomet, Johnson & Johnson, Berkeley Advanced Biomaterials, APC International, TRS Technologies, Washington Mills, CAP Biomaterials, DSM, Cerapedics
Source: fortunebusinessinsights.com	

5.16. Evolving Technologies

Artificial Intelligence (AI), Machine Learning (ML), robotics, IoT, Augmented Reality, Virtual Reality and Mixed Reality (AR/VR/MR) are all evolving technologies that are shaping the world of medical devices. Some of the large manufacturers like GE Healthcare, Medtronic, Philips, etc. are investing in AI and ML. Some of the emerging applications are as follows:

- Disease management for supporting clinical decision, managing implants, inspecting large samples for pathology, etc.

- AI and Internet of Things (IoT) for medical imaging, reduce detection time for MRI, segregate large number of radiographs and make better sense of low quality of images of CTs and in performances of Cath Labs, Nuclear Medicine, ultrasound.

- Augmented and Virtual Reality (AR/VR): AR and VR will have extensive use across specialized services including consultation, diagnosis, training, patient education, and treatment. Some applications of AR/VR include VR based doctor consultation, diagnostics, practicing surgery runs and medical education.

- Digitization of Medical Records: Healthcare digitization is mostly focused on automating individual functionalities, which often results in fragmented data residing in scattered silos. This makes it extremely difficult to carry out advanced AI driven analytics or build meaningful predictive models to deliver deeper insights for the benefit of all stakeholders at an individual or aggregated level. An approach is to address this through a unified ecosystem to ensure availability of quality healthcare

data for the benefit of all stakeholders including providers, receivers, payers, and researchers.

- Block chain in healthcare: Block chain can authenticate data and make claim processing faster and efficient. The use of surgical robotics is coming up.

TIFAC in its "Action Agenda for Aatma Nirbharta (AAAN) (2020)"[262] has proposed for support to industry for promotion of emerging technologies. These include:

Immediate Goals including

- Digital technology platform: Artificial Intelligence (AI), tele-consultation, and remote monitoring and development of Plug/Play model for telemedicine for remote areas and wider population be developed and validated.
- Development /Production facility of IOT sensors for health.

Medium/Long Term Goals including

- Enhanced support for target technologies like robotics, Micro Electromechanical Systems (MEMS), 5G, 3D &4D printing, implantable nano-sensors, lab on chips, bionics, micropower, machine learning, and drones. Indigenization of Digital X Ray & Mammography, Ultrasound, Cath Lab, Computed Tomography, MRI, PET CT, LINAC etc. in its medium/long term goals.

TIFAC has also suggested for setting up of a centralized facility for production of materials for medical devices, preferably in the western part of India. Quality testing which could be leveraged by all smaller companies and start-ups. Apart from that, TIFAC suggested to transform the small and medium companies as feeder entities for the larger companies, including foreign MNCs who are willing to manufacture in India. Many companies have suggested export subsidy to boost the industry towards creating a brand image. Backing this, TIFAC has also proposed creation of about 5-6 medical devices manufacturing park, in the lines of Andhra Pradesh Medtech Zone Ltd (AMTZ). It has also suggested the creation of two specialized parks in IVDs.

There is a global trend in collaboration among IT giants and Medical Device giants.

Table 5.28 Major IT and Medical Device Company Collaborations

Tech Company	Medical Company	Field of Collaboration
Google	iRhythm and UK NHS	Patient Monitoring
	Amwell	Telehealth
	UCL Hospital's Radiotherapy Department	Radiology Imaging
	Alcon	Glucose-Sensing Contact Lenses
	Mayo Clinic	Healthcare
	Vanderbilt University Medical Centre and The University Of North Carolina	Covid-19 Genes
Apple	John Hopkins Medical	Epilepsy
	Biogen	Cognitive Decline
IBM	Pfizer, Memorial Sloan-Kettering Cancer Centre and Manipal Hospitals	Oncology
Microsoft	Nuance	Telehealth
Amazon	Prime Therapeutics and Healthcare Services	Telehealth
Microsoft, Amazon and Tencent	Novartis	Digital Health
Source: Several Secondary Sources		

5.17. Initiatives undertaken by the Government for the MedTech Sector

Government of India has taken a number of initiatives to support the medical device industry in the country. Needless to say, that DoP has taken a number of initiatives too.

[262] Action Agenda for Atma Nirbharta (AAAN), July 2020, TIFAC, DST

5.17.1 Initiatives by DoP

1. In 2019, under the Department of Pharmaceutical's sub-scheme named "Assistance to Medical Device industry for Common Facility Centre", financial assistance of Rs 25 crore was approved to the Andhra Pradesh MedTech Zone (AMTZ) for a superconducting magnetic coil project which has been completed in 2022.

2. In 2020, the above-mentioned sub-scheme was revised with a substantial increase in the outlay. The revised scheme is named "Scheme for Promotion of Medical Device Parks". Under this scheme, financing support of Rs 100 crore each has been approved for creation of common facilities in four medical devices parks coming up in Uttar Pradesh, Tamil Nadu, Madhya Pradesh, and Himachal Pradesh. This is an infrastructure support scheme wherein the common facilities will be accessed by the industrial units in the parks which are being developed by the said State Governments. These parks will come up as manufacturing hubs and provide enabling ecosystem dedicated solely for medical devices.

3. Production Linked Incentive Scheme

- The Union Cabinet approved the proposal on 20.03.2020 with the objective of the Scheme is to boost domestic manufacturing and attract large investments in the Medical Devices Sector.
- The Notification has been issued on 21.07.2020 and Guidelines has been issued on 27.07.2020 and revised guidelines has been issued on 29.10.2020.
- The tenure of the scheme is from FY 2020-21 to FY 2027-28 with total financial outlay of Rs.3,420 crore. The financial incentive is to be given to selected companies at the rate of 5% on incremental sales of medical devices manufactured in India and covered under the Target segments of the scheme, for a period of five (5) years.
- The identified products under this Scheme have been categorized into four Target Segments which is "Cancer care/Radiotherapy medical devices, Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging devices, Anesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care medical devices and All Implants including implantable electronic devices".
- Under the Scheme, 26 applicants have been approved with a total Committed Investment of Rs. 1,205.52 Crores and employment generation of about 7,411.
- Based on the arising needs, the Department has further revised the Guidelines of the PLI Scheme for Medical Devices and issued the same on 18.08.2022. Pursuant to this, the department has invited applications from eligible Category B applicants for Medical Devices listed under the four target segments.

Table 5.29 Rate of Incentive on Incremental Sales of Manufactured Goods

Rate of Incentive on Incremental Sales of Manufactured Goods for respective FY	Incentive rate on Incremental Sales of Manufactured Goods
FY 2022-23 to FY 2027-28 for Category A Applicants	5% up to Rs. 121 crores per applicant
FY 2022-23 to FY 2027-28 for Category B Applicants	5% up to Rs. 40 crores per applicant

Source: Revised Guidelines for the Production Linked Incentive (PLI) Scheme for Promoting: Domestic Manufacturing of Medical Devices, 18th August 2022

Table 5.30 List of applicants under PLI Medical Devices

#	Name of the Applicant	Name of the Eligible Product
1	Panacea Medical Technologies Private Limited	Linear Accelerator (LINAC) ; Rotational Cobalt Machine
2	M/s Siemens Healthcare Private Limited	CT Scan, MRI
3	M/s Allengers Medical Systems Limited (AMSL)	CT Scan, MRI, Ultrasonography, X-Ray, Cath Lab, Mammography and C arm.
4	M/s Allengers OEM Private Limited (AOPL)	Collimators, Flat Panel Detector and Monitors'
5	M/s Wipro GE Healthcare Private Limited (WGHPL)	'CT Scan', 'Cath Lab' and 'Ultrasonography'
6	M/s BPL Medical Technologies Private Limited	Surgical X Ray C-Arm, Fixed LF and HF X Ray Products, X Ray Panels and Ultrasound Products

#	Name of the Applicant	Name of the Eligible Product
7	M/s Trivitron Healthcare Private Limited	CT Scan, MRI, Ultrasonography, X Ray Equipment, Mammography, C-Arm and Cath Lab
8	M/s Philips Global Business Services LLP	MRI Coils
9	Nipro India Corporation Private Limited	Dialyzer
10	Wipro GE Healthcare Pvt. Ltd.	Anaesthesia Unit Ventilators, Patient monitoring system
11	M/s BPL Medical Technologies Private Limited	Anaesthesia Workstation, Automated External Defibrillators (AEDs), ECG, Patient Monitoring, Syringe Pump, Defibrillators, Stress Test System and Oxygen Concentrator
12	M/s Poly Medicure Limited	Dialyzer, Dialysis Machine, Peritoneal Dialysis kits, Fistula, Blood Line, Haemodialysis Catheter and Transducer Protector
13	M/s Allied Medical Limited	Anaesthesia workstation, Anaesthesia Unit Gas Scavengers, Anaesthesia Kits, Masks —Anaesthesia, Anaesthesia Unit Vaporizers, Anaesthesia Unit Ventilators, Automated external defibrillators (AEDs), Oxygen concentrator, Bi- Phasic Defibrillators, Infusion pumps - Syringe and Volumetric, Intensive Care Ventilators, Emergency Ventilators (Portable Ventilators), High Flow Oxygen Devices, Multi-parameter Monitor, Suction Machine
14	M/s. Deck Mount Electronics Limited	Anaesthesia Unit Ventilators, Dialyzer, Oxygen concentrator
15	M/s Microtek New Technologies Private Limited	Oxygen Concentrators
16	Sahajanand Medical Technologies Private Limited (SMTPL)	Heart Valves, Stents, PTCA Balloon, Dilatation Catheter and Heart Occluders
17	Innvolution Healthcare Pvt. Ltd.	Stents, PTCA Catheter
18	Meril Healthcare Private Limited	Hip Implants, Knee Implant and Trauma Implant
19	Meril Life Sciences Private Limited	Heart Valves, Stents, PTCA Balloon Catheter
20	Envision Scientific Private Limited	Stents, PTCA Balloon Catheter
21	Bio India Interventional Technologies Private Limited	Drug Eluting Stents and Drug Eluting Balloons
22	Samvardhana Motherson Maadhyam International Limited	Housing Diamond Emerald Metric 90 DEG, Housing/Centre section Sapphiere, Housing B-130, 180 Degree, Housing anode and SAPPHIRE III, Casting Housing Assembly, FABR Housing Cathode End Std, FABR Housing Anode End Std, B18X Center Section, HousingB-130, 180 Degree, Housing Center B-240, Support Cathode, Anode Outer sealing Ring, Ring Sealing Cathode Inner, Sealing Ring, Shield Cathode, Cover, Collar, Anode Shield, Kovar Bushing, Cathode Can "BULGED "Machined, Cathode Can Machined - 743708, Anode Can, Cathode Can "BULGED "Machined; Housing Aluminium 4131Z.
23	Indovasive Private Limited	Biopsy Kits-Renal, Dialyser Reprocessing System, PCN Catheter / Kit (Abscess Drainage, Catheter / Kit), Ureteral Catheter, Malecot Catheter / Kit, Re Entry Malecot Catheter / Kit, Suprapubic Catheter / Kit, Dual Lumen Ureteral Catheter, IUI Catheter / Kit, Braided Shaft Catheter, (Ureteral Access Sheath), Cysto Catheter /Kit, Urethral Stent, Double J Stent /Kit (Long Term), Double J Stent/Kit (Short Term), Endopyelotomy Stent / Kit, Mono J Stent / Kit, Stone Basket-G Paw, Stone Basket Helical, Stone Basket –Segura, Stone Grasper, Stone Basket - X Circle, Stone Basket -Zero Tip, Stonestop -Retrieval Coil, Perk Basket, URS Forceps, Urethral Dilator / Set, Amplatz Dilator / Kit & Mini Amplatz, Dilator / Kit, Fascial Dilator/Set, Meatal Dilator, Filiform Self Dilator, Nephrostomy Balloon Dilator, Ur eteral Balloon Dilator, Screw Dilator, Ureteral Dilator / Set, S Curve Urethral Dilator / Set, Nottingham One Step Dilator, IP Needle, Chiba Needle, Penile Clamp, Evacuator, Striped Guidewire, Striped Guidewire with Hydrophilic Tip, SS Guidewire, Hydrophilic (Nano Glidewire) Guidewire, PTFE Guidewire, Incontinance Sling-AQUA, Suction And Irrigation System, Thulium Fiber Laser & Laser Probes, Turp Loop/Cutting Electrodes; Endoscopes With Flexible / Fixed Shaft.
24	Omron Healthcare Manufacturing India Private Limited	Automatic Blood Pressure Monitor

#	Name of the Applicant	Name of the Eligible Product
25	Meril Endo Surgery Private Limited	Hernia Surgical Mesh Implants, Endocutter, Linear Stapler, Linear Cutter, Trocar, Litigation Clip, Hemostates
26	Neurovasive Private Limited	Cerebral Spinal Fluid Shunt System (CSF), Flow diverter implants, Embolic liquid , Peripheral Stent, Carotid Stent, Intracranial Stent, Intrasaccular Device

Source: DoP

Out of these 26 projects approved, 14 projects have been commissioned as of December, 2022 with an actual investment of Rs. 638.34 for producing 37 Medical Devices. The details of the commissioned project are as follows:

Table 5.31 Project Commissioned up to December 2022 under the PLI MD

Sl. No.	Name of Company	Target Segment	Products Commissioned
1	Panacea Medical Technologies Pvt. Ltd.	1	• Linear Accelerator (LINAC) • Rotational Cobalt Machine
2	Trivitron Healthcare Pvt. Ltd.	2	• X Ray Equipment • C-Arm • Mammography • Ultrasonography
3	Philips Global Business Services LLP	2	• MRI Coils (Digital / MRI Coils – 1/7/8 ch Analog / MRI Coils – 16 ch Analog /OEM Non- Sentinelle / OEM Sentinelle)
4	Siemens Healthcare Private Limited	2	• CT Scan
5	Wipro GE Healthcare Private Limited	2	• CT Scan • Cath Lab • Ultrasonography
6	Wipro GE Healthcare Private Limited	3	• Patient monitoring System
7	Microtek New Technologies Pvt. Ltd.	3	• Oxygen Concentrators
8	Deck Mount Electronics Limited	3	• Oxygen concentrator
9	Poly Medicure Limited	3	• Blood Line • Dialysis Machine • Dialyzer • Fistula • Peritoneal Dialysis Kits • Transducer Protector
10	Allied Medical Limited	3	• Anaesthesia Unit Gas Scavengers • Anaesthesia Unit Vaporizers • Anaesthesia Unit Ventilators • Anaesthesia Workstation • Anesthesia Kit • Bi-Phasic Defibrillators • Defibrillators / Automated External Defibrillators (AED) • Emergency Ventilators • High Flow Oxygen Devices • Intensive Care Ventilators • Multi-Parameter Monitor • Syringe Pump / Infusion pumps - Syringe and Volumetric
11	Sahajanand Medical Technologies Pvt. Ltd.	4	• Stents • PTCA Balloon Catheter
12	Meril Healthcare (P) Ltd.	4	• Hip Implants • Knee Implant • Trauma Implants
13	Meril Life Sciences Private Limited	4	• Heart Valves • Stents
14	Nipro India Corporation Private Limited	3	• Dialyzer

Source: DoP

4. Phased Manufacturing Program

To promote domestic manufacturing in India, the Department has introduced a Phased Manufacturing Programme for Medical X-Ray Machines and specified sub-assemblies /parts / sub-parts thereof; a

Phased Manufacturing Programme (PMP). The PMP shall enable the Medical X-Ray Machines and related sub-assembly / parts / sub-parts industry to plan their investment in the sector. The following PMP roadmap was notified by the department, with the objective of progressively increasing domestic value addition for establishment of a robust Medical X-Ray Machines manufacturing eco-system in India.

Table 5.32 Proposed Basic Custom Duty Changes in X-ray Machines and Components

#	Item	HS Code	Tariff Rate (%)	Applicable BCD (%) vide Cus. N. No.5012017	Proposed Basic Custom Duty (%)			
					2021-22	2022-23	2023-24	2024-25
1	X-Ray Diagnostic Table	90229040	10	2.5	10	10	10	10
2	Vertical Bucky	90229090	10	2.5	10	10	10	10
3	X-Ray Tube Suspension	90229090	10	2.5	10	10	10	10
4	High Frequency X-Ray Generator (>25 KHz)	<500mA 90221410	10	2.5	10	10	15	15
		>=500mA 90221410	10	2.5	2.5	2.5	2.5	10
5	Medical Grade Monitor	85285900	10	2.5	2.5	2.5	10	10
6	X-Ray Grid	90229090	10	2.5	5	10	10	10
7	Multi Leaf Collimator/Iris	90222900 90229090	10	2.5	5	10	10	10
8	Flat Panel Detector,	90229090	10	2.5	2.5	2.5	10	15
9	X-Ray Tube	90223000	10	2.5	2.5	2.5	10	15
10	Static User Interface	90189099	10	2.5	5	10	10	10

Source: DoP

The duty changes have been made effective from 1st April, 2021.

5. The medical device sector in India has participation both from domestic manufacturers as well as multi-national companies. Therefore, owing to the divergence of views of the industry, a "Standing Forum of Medical Device Industry associations" has been set up by the Department of Pharmaceuticals on 25th August, 2021 which provides a platform to the different associations to deliberate on the common issues of the industry and arrive at a consensus before the same are taken up by the Department for examination. The mechanism has been very much appreciated by the industry.

6. The National Pharmaceutical Pricing Authority (NPPA) monitors the prices of Non-Scheduled Medical Devices and fixed the ceiling prices for Scheduled Medical devices. In view of the extraordinary circumstances arising due to COVID pandemic and with the aim of making these medical devices affordable the prices of (i) Pulse Oximeters, (ii) Blood Pressure Monitoring Machines, (iii) Nebulizers, (iv) Digital Thermometers, (v) Glucometers and (vi) Oxygen Concentrators were brought under price cap using Trade Margin Rationalization

7. Constitution of "National Medical Devices Promotion Council (NMDPC)" under the Department of Pharmaceuticals since 5th August 2022. The council consists of stakeholders from Government and industry and provides a platform to discuss and resolve various regulatory issues for ease of doing business and promotion of the sector.

8. The Scheme "Pradhan Mantri Bharatiya Janaushadhi Pariyojana (PMBJP)" are making available close to 1800 drugs, 285 types of surgical supplies in over 9082 Jan Aushadhi Kendras at highly affordable prices as on 31.03.2023.

5.17.2 Other Schemes of Government of India

Number of other Ministries/Departments of the Government of India has also put in place various

schemes for promoting Medical Devices manufacturing and research and development in the sector and in other high-tech industries.

1. PMJAY: Ayushman Bharat, a flagship initiative of Government of India, was launched as recommended by the National Health Policy 2017, to achieve the vision of Universal Health Coverage (UHC). This initiative has been designed to meet Sustainable Development Goals (SDGs) and its underlining commitment, which is to "leave no one behind." Ayushman Bharat is an attempt to move from sectoral and segmented approach of health service delivery to a comprehensive need-based health care service. This scheme aims to undertake path breaking interventions to holistically address the healthcare system (covering prevention, promotion, and ambulatory care) at the primary, secondary, and tertiary level. Ayushman Bharat adopts a continuum of care approach, comprising of two inter-related components, which are Health and Wellness Centers (HWCs) and Pradhan Mantri Jan Arogya Yojana (PM-JAY). More than 4.21 crore hospital admissions have been done under this scheme since its launch, as on 30th December 2022[263].

2. Government of India launched the Ayushman Bharat Digital Mission (ABDM) in September 2021 "..to develop the backbone necessary to support the integrated digital health infrastructure of the country. It will bridge the existing gap amongst different stakeholders of Healthcare ecosystem through digital highways."[264] The components of Ayushman Bharat Digital Mission include Ayushman Bharat Health Account (ABHA) Number , ABHA App - A personal health record, Health Facility Registry, Healthcare Professionals Registry, Unified Health Interface.

3. The Medical Devices Rules, 2017 were notified under the Drugs and Cosmetics Act 1940 by the Department of Health and Family Welfare. These rules lay out the regulatory framework for medical devices in terms of their quality, safety, and efficacy. This expanded the regulatory oversight to the entire gamut of devices and classified them into four categories based on the level of risk associated with the medical devices.

4. "Health Technology Assessment in India (HTAIn)" scheme of Department of Health Research conducts studies that provide evidence related to cost-effectiveness, clinical- effectiveness and safety of medicines, devices, and health programs to support evidence-based decision making in healthcare services for development of quality and affordable medical devices in the country.

5. Recognizing the importance and need for investments in the sector, 100% FDI through automatic route was allowed in the medical devices sector in 2014.

6. The Department for Promotion of Industry and Internal Trade (DPIIT) came out with the policy of "Public Procurement (Preference to Make in India) in 2017" and designated the Department of Pharmaceuticals (DoP) as the Nodal Department for implementing the provisions related to medical devices. DoP thereafter came out with the definition of Class-I, Class-II, and Non-Local supplier under the said Policy. Initiatives have been taken under the policy to give preference to domestic manufacturers in public procurement of medical devices done by the hospitals of the Central Government. The Public Procurement (Preference to Make in India) policy is an important pillar of the Atmanirbhar Bharat program.

7. To foster Make-in-India product development and nurture the clinical validation ecosystem in the MedTech sector, the Indian Council of Medical Research (ICMR) has established the "Medical Device and Diagnostics Mission Secretariat (MDMS)". This program aims to support and catalyse research, development, and indigenous manufacturing of cost-effective medical devices to strengthen healthcare sector in India and reduce import dependence through a mission mode consortia approach.

8. DST, BIRAC, CSIR, DSIR, ICRM and SERB also has a number of schemes for promoting R&D, product development, proof of concept, fabrication, incubation, etc (Refer to Table 5.12).

[263] https://dashboard.pmjay.gov.in/pmj/#/

[264] https://abdm.gov.in/

5.17.3 Schemes of State Government

Besides, the State Governments have various schemes for establishment of industries. Some of the following schemes are given by the States of Haryana, Telangana, Tamil Nadu, Maharashtra, Andhra Pradesh, Karnataka, Gujarat, Uttar Pradesh, Goa, and Kerala.

Table 5.33 Type of Schemes Provided by Different Indian States to Medical Device Companies

#	Types of Schemes
1	Capital Subsidy
2	Interest Subsidy
3	Stamp Duty
4	Quality Certification
5	Pre-seed grant support for start-ups
6	Seed grant support for start-ups
7	Power tariff subsidy charges
8	Acquisition of foreign technology
9	Land Conversion Charges subsidy
10	Assistance for research from industry
11	Relocation incentives
12	Reimbursement of IPR registration fees (e.g., Patent/design, etc.)
13	Tax rebate on patent acquisition cost
14	Entrepreneur Support Scheme
15	Industry Varsity Linkage Scheme
Source: Compilation of schemes from different Indian State Govt Websites	

5.18. Medical Devices Impact on Environment

Medical Device Industry is multidisciplinary. Depending on nature of product and manufacturing process, various rules under environmental protection act apply to the medical device industry.

The major applicable rules are:

- Biomedical Waste Management Rules, 2016 (read with amendments 2018 and 2019)
- Plastics Waste Management Rules, 2016 as amended in 2018
- Electronic Waste Management Rules, 2016,
- E-Waste Management (read with amendments) Rules, 2018.
- Hazardous Waste Management Rules, 2016 (read with amendments 2017, 2018 and 2019)
- Air and Water Waste Management Rules.
- The Batteries (Management and Handling Rules), 2001

State Pollution Control Boards (PCBs) have been designated with wider responsibilities touching across almost every aspect of implementation of rules.[265]

Government of India appointed a panel to restrict import of refurbished radiology devices. In 2015, the Ministry of Environment, Forests and Climate Change (MoEFCC) issued a circular seeking restriction of import of pre-owned medical equipment over three years old. As per primary survey, some industries are not in favor of allowing imports of refurbished and pre-owned equipment on the following grounds.

- Unreliability of the life of the equipment lead to environmental issues.
- It is a challenge to submit quality assurance reports of radiological equipment's for radiation safety.
- Non-availability of spare parts.
- Such equipment is of doubtful efficacy and quality
- Keeping track of incidents involving pre-owned devices is a big worry
- Can create a serious setback for 'Make in India' program.
- Can lead to loss of job creation owing to the harm caused to local manufacturing, and loss of revenue, owing to reduction of import duty revenue by "reduced cost" while increasing

[265] The details about all the above rules and respective amendments are given on the Central Pollution Control Board website, https://cpcb.nic.in/index.php

the healthcare burden owing to inadequate/ineffective treatments.

5.19. Primary Survey of Industries and Discussion with Key Industry Personnel[266]

5.19.1 Methodology

To understand the medical device industry in India better primary research was conducted.

Objective: Objective of the primary research was to undertake an industry analysis, identify strengths and weaknesses, forecast growth rate perceptions of the industry and the facilitating factors for the same, ascertain the import substitution and export promotion status and requirements, human resource situation of the industry, R&D efforts, technology and transfer of technology, quality assurance systems, need and benefits of CFC and Medical Devices Parks, pricing issues and government and regulatory support. All these were ascertained from the viewpoint of the stakeholders and not necessarily suggestions of this study.

Methodology: As part of primary research, two tools were developed and used. Firstly, a questionnaire was developed to be administered to industry stakeholders and firms. Also, key informants were identified, and an interview was conducted with them by the lead researcher and author of the report.

The sample framework of the primary research is as follows.

- **Industry Questionnaire -** This was administered to the following samples.

Table 5.34 Sample Mix

#	Stratification - Project Classification	Target	Achieved
1	Cancer Care/ Radiotherapy Medical Devices	5	5
2	Radiology and Imaging medical device (Ionizing, Non-Ionizing and Nuclear Imaging Devices	10	10
3	Anesthetics and Cardio-Respiratory medical device including Catheters of Cardiorespiratory Category and Renal Care	10	10
4	All implants including implantable Electronic Devices	15	15
5	IVD	15	15
6	Consumables/ Disposables	20	43
7	Electronics		5
8	Instruments		14
9	Others		12

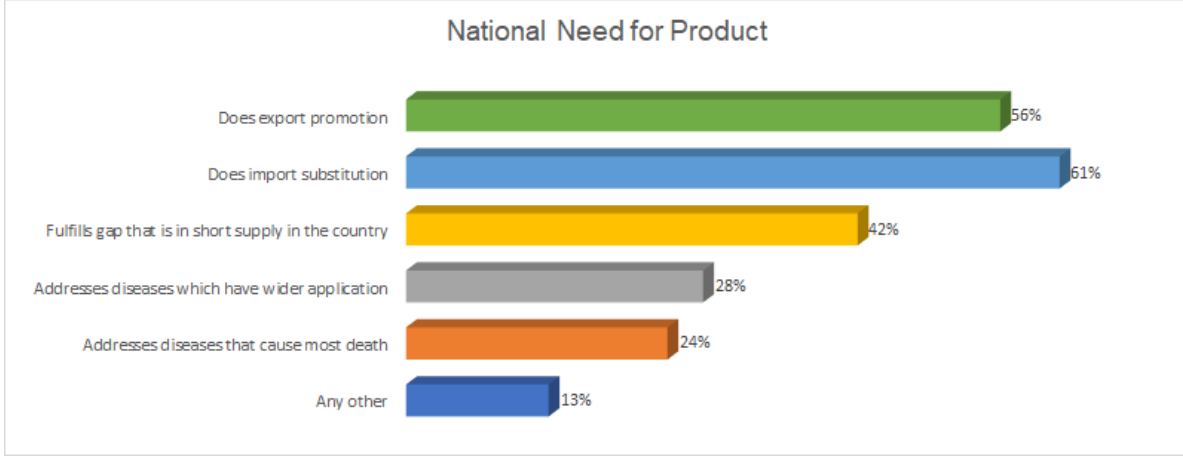
- **Key Informant Interviews -** Since the study covered different dimensions of the industry and had a geographical spread across several countries, it was essential to get an in- depth understanding of issues involved in the promotion of Indian medical device industry. For this purpose, key informants were identified, and the interview schedule was administered to them. Key informants included top luminaries and senior professionals from the industry, senior researchers involved with the industry, industry associations, healthcare providers' associations, Med Tech Park, etc. In all, 20 key informants were interviewed.
- Visit to MedTech Park AMTZ and MedTech Park Sultanpur in Telangana
- Support taken from Industry Association including Confederation of Indian Industry (CII) and AIMED for pursuing respondents to fill up questionnaires
- Discussion with IVD Manufacturers Association

5.19.2 Industry Growth Rates

Due to natural business needs the majority of the producers are catering to either export promotion (56 per cent) or import substitution (61 per cent). The target for addressing diseases which have wider application (28 per cent) and diseases that cause most deaths (24 per cent) were relatively lower.

[266]This is done on the basis of the 98 respondents.

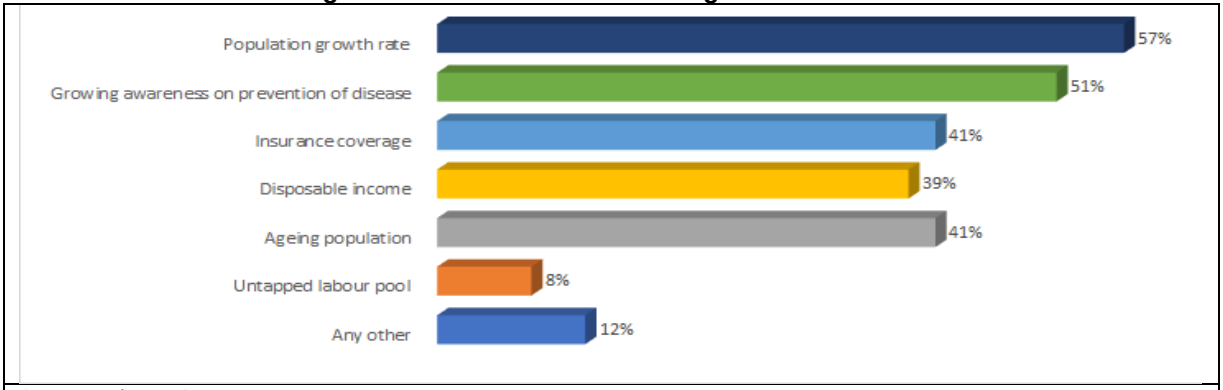
Figure 5.4 Addressing National Need



Source: Primary Survey

While natural growth rate of population is the most important factor (57 per cent) that is pushing the medical device market, growing awareness about prevention of diseases (51 per cent) is the second most important factor followed by degree of insurance coverage (41 per cent). (Figure 5.6) National Health Mission (NHM) was launched by the government of India in 2013 subsuming the National Rural Health Mission and National Urban Health Mission. It was further extended in March 2018, to continue till March 2020. The main programmatic components include Health System Strengthening in rural and urban areas for - Reproductive-Maternal- Neonatal-Child and Adolescent Health (RMNCH+A), and Communicable and Non-Communicable Diseases. The NHM envisages achievement of universal access to equitable, affordable & quality health care services that are accountable and responsive to people's needs. NHM and Government's health assurance scheme PMJAY will play a major role in promoting the devices market.

Figure 5.5 Direct Factor Affecting Market Growth

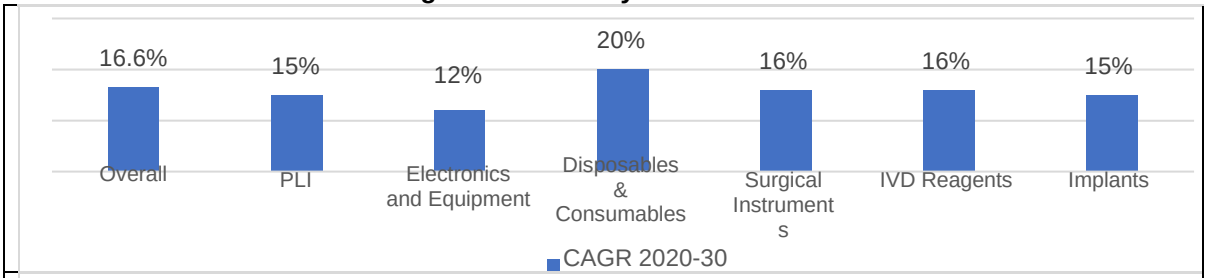


Source: Primary Survey

As per stakeholder views, overall growth rate of the market is estimated at around 16 to 17 per cent. Industry estimated growth rates for PLI identified categories[267] is 15 per cent. Growth rates for the various categories of devices were estimated as follows: implants 15 per cent, consumables/ disposables 20 per cent, electronics, and equipment 12 per cent, surgical instruments 16 per cent and IVD 16 per cent.

[267] Appears as PLI in the rest of this section

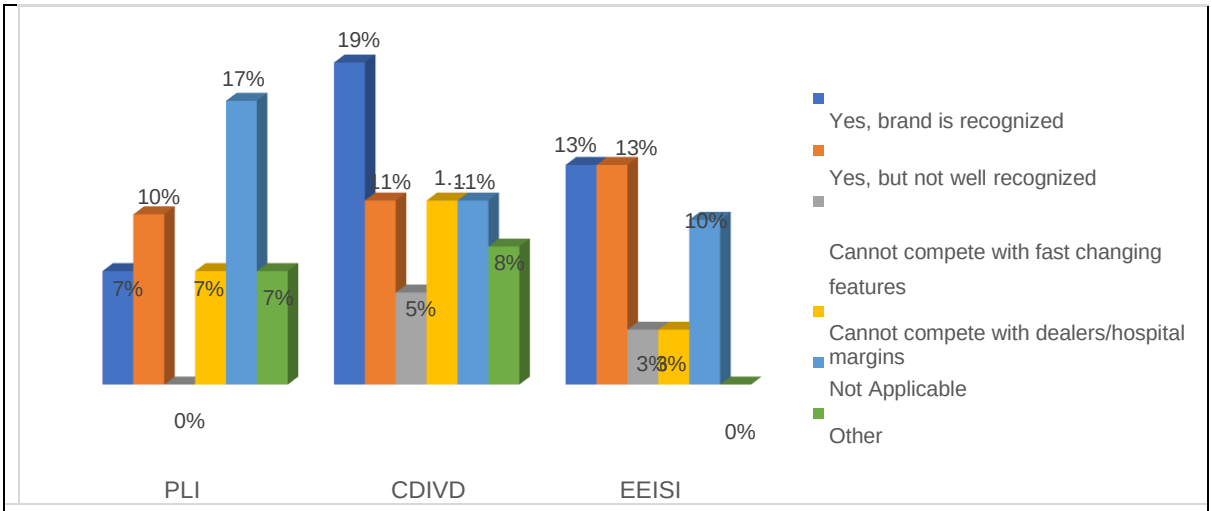
Figure 5.6 Industry Growth Rates



Source: Primary Survey

Only 7 per cent of the PLI groups said that their brand was recognized. The brand recognition was higher for consumables/disposables and IVD (CDIVD) as compared to electronics and equipment/implants /surgical instruments (EEISI), etc.

Figure 5.7 Why Indian Medical Devices are unable to Compete with Imported Products

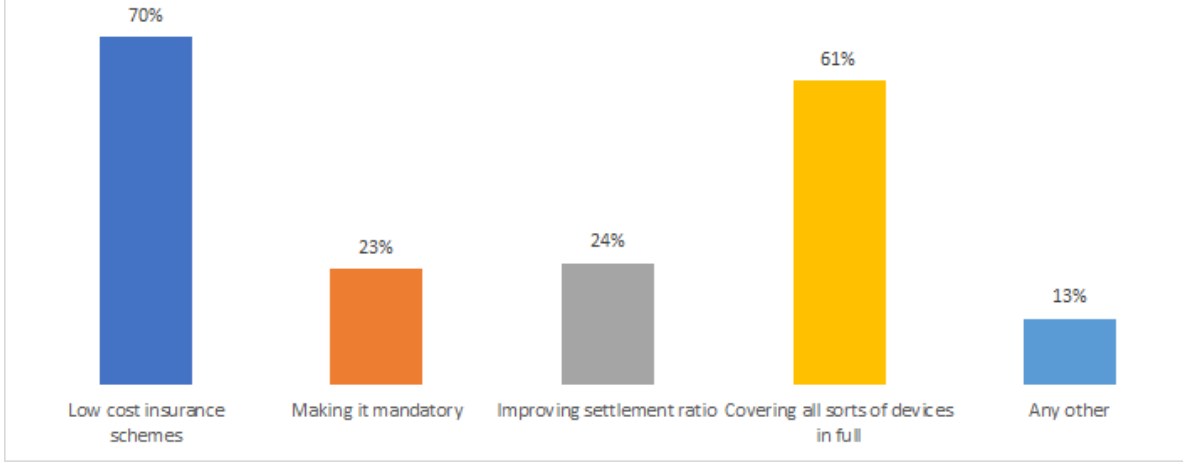


Source: Primary Survey

5.19.3 SWOT Analysis of the Industry

More than two-thirds of the respondents felt that low-cost insurance schemes can help in enhancing market size of the medical devices sector whereas 61 per cent said that covering all sorts of devices in full can contribute towards enhancing market size. 13 per cent of the respondents suggested promotion of preventive care facilities and putting a price cap on diagnostic test facilities will positively impact the medical devices market in India.

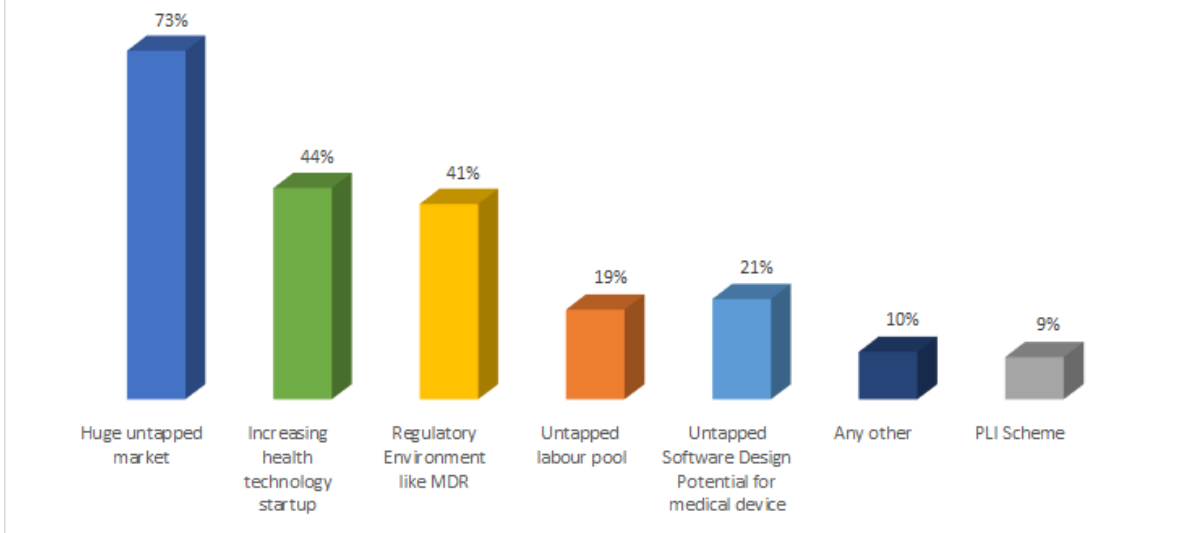
Figure 5.8 Impact of Public Health Insurance on Medical Devices Market in India



Source: Primary Survey

Around three-fourth of the respondents felt that the strength of the Indian medical device industry lies in its untapped market, nearly 44 per cent of respondents suggested the role of health technology start-ups will have a positive impact. 41 per cent of respondents felt that the encouraging regulatory environment will give boost the domestic medical devices industry.

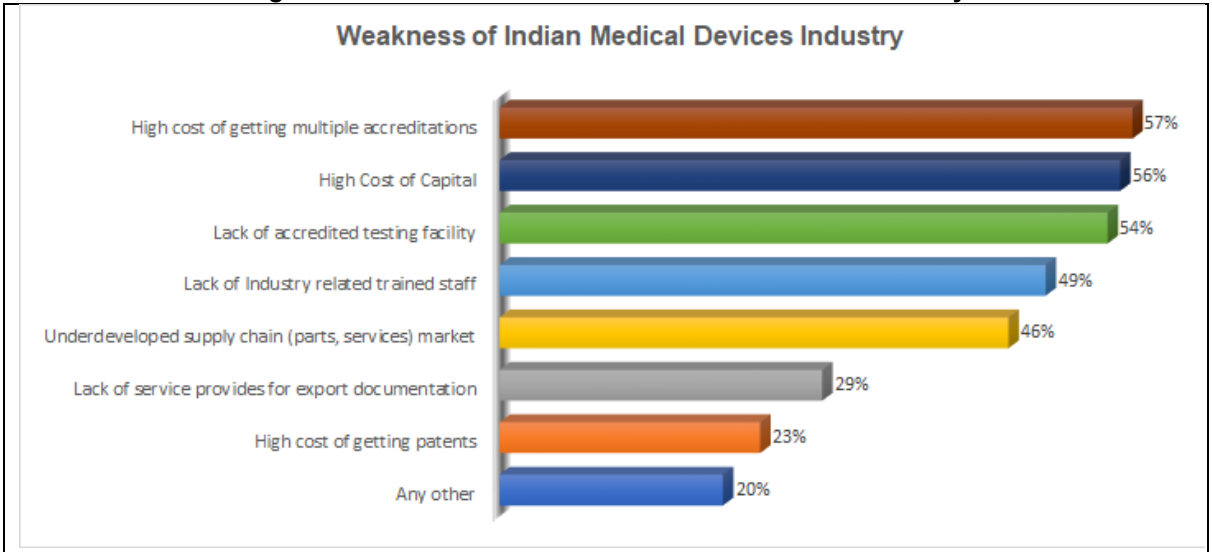
Figure 5.9 Strength of Indian Medical Devices Industry



Source: Primary Survey

Nearly sixty per cent of the entrepreneurs interviewed felt that high cost of multiple accreditations (57 per cent) and high cost of capital (56 per cent) were the biggest impediment for the industry. The other major weakness as perceived by entrepreneurs were lack of accredited testing facilities (54 per cent), trained staff (49 per cent) and lack of dependable raw material and parts provider and service provider (46 per cent). Nearly 80 per cent of the respondents felt that the major threats for continuous growth are lack of R&D and 58 per cent felt that relatively weak industry academia linkages are a major cause. Interestingly, neither limited FDI nor MRP was suggested as a threat factor.

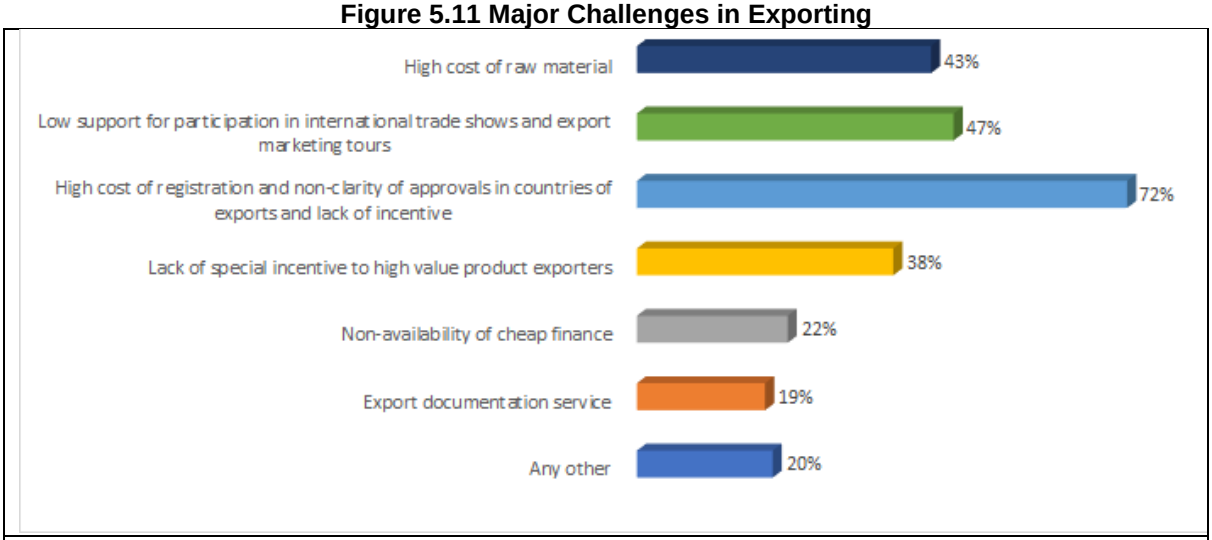
Figure 5.10 Weakness of Indian Medical Devices Industry



Source: Primary Survey

Nearly three fourths of the respondents were exporters. Biggest challenge faced by exporters was high cost of registration and non-clarity[268] of approvals in countries of exports and lack of incentive (72 per cent). The next major areas of concern were limited support for international trade show participation (47 per cent) and the high cost of raw materials (43 per cent). 38 per cent of the respondents spoke for special incentives to exporters.

Figure 5.11 Major Challenges in Exporting



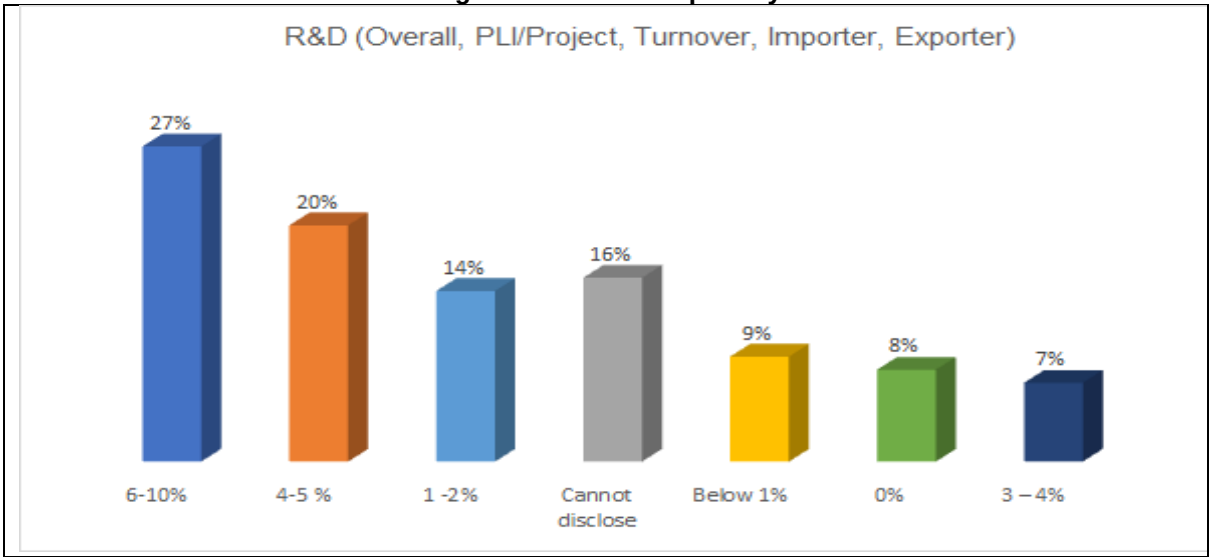
Source: Primary Survey

5.19.4 R&D and Innovation

Among those who disclosed their investment in R&D, 27 per cent touched the global leaders' ratio of 8 percent (average) and 20 per cent did an average of 4.5 per cent. The overall average for the respondents was 4 per cent.

[268] Often due to lack of desired supply of knowledge inputs

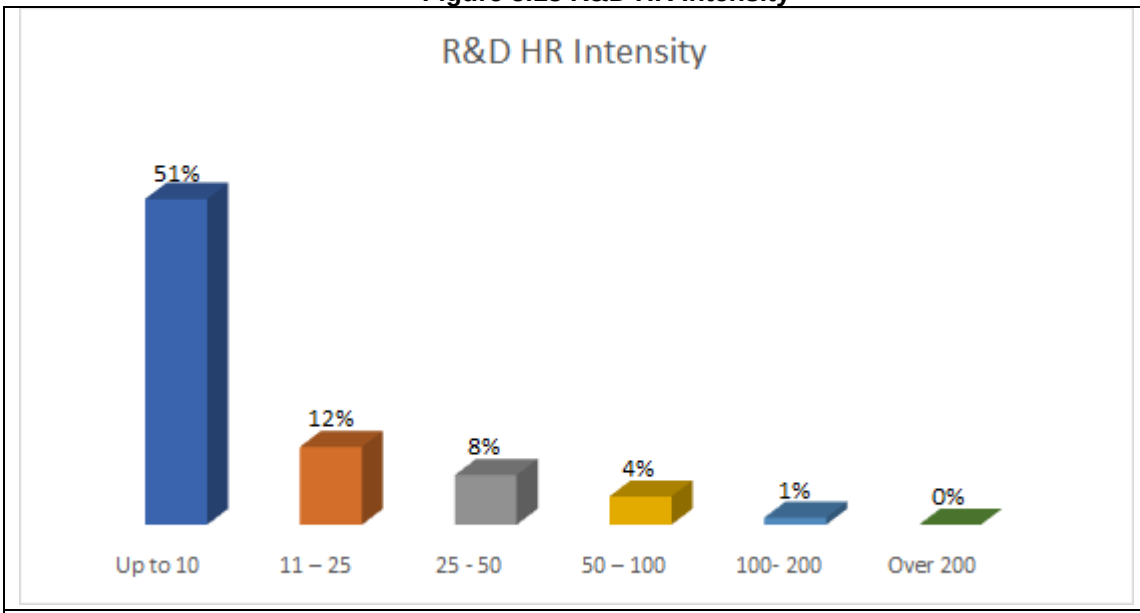
Figure 5.12 R&D Propensity



Source: Primary Survey

Nearly half of the enterprises reporting R&D spending has less than 10 persons in their R&D pursuit.

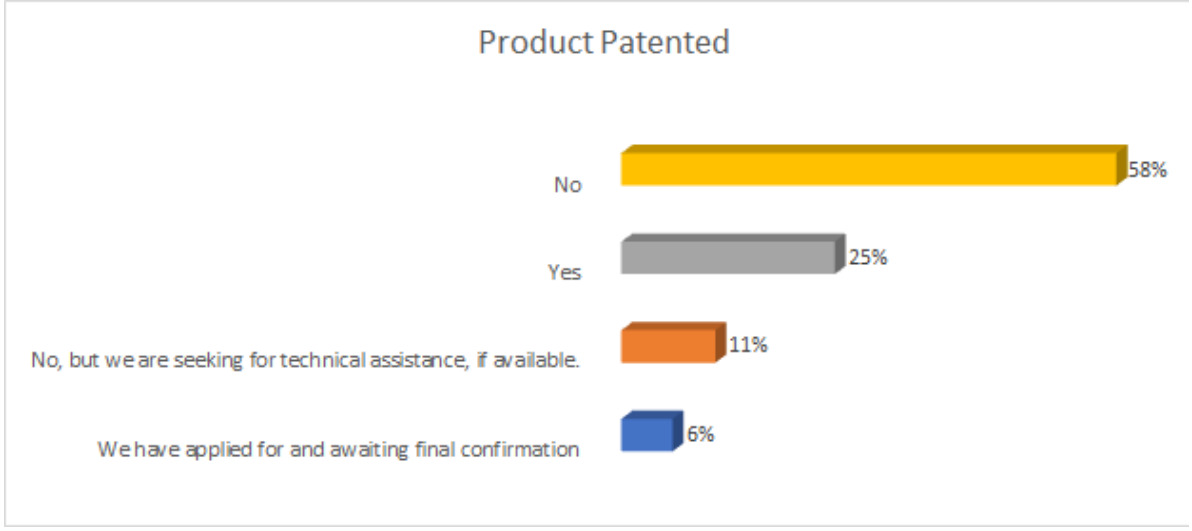
Figure 5.13 R&D HR Intensity



Source: Primary Survey

Two-third of the respondents do not have any patent. 25 per cent of the respondents said that they have patents and another 6 per cent have applied for it and are waiting for final confirmation.

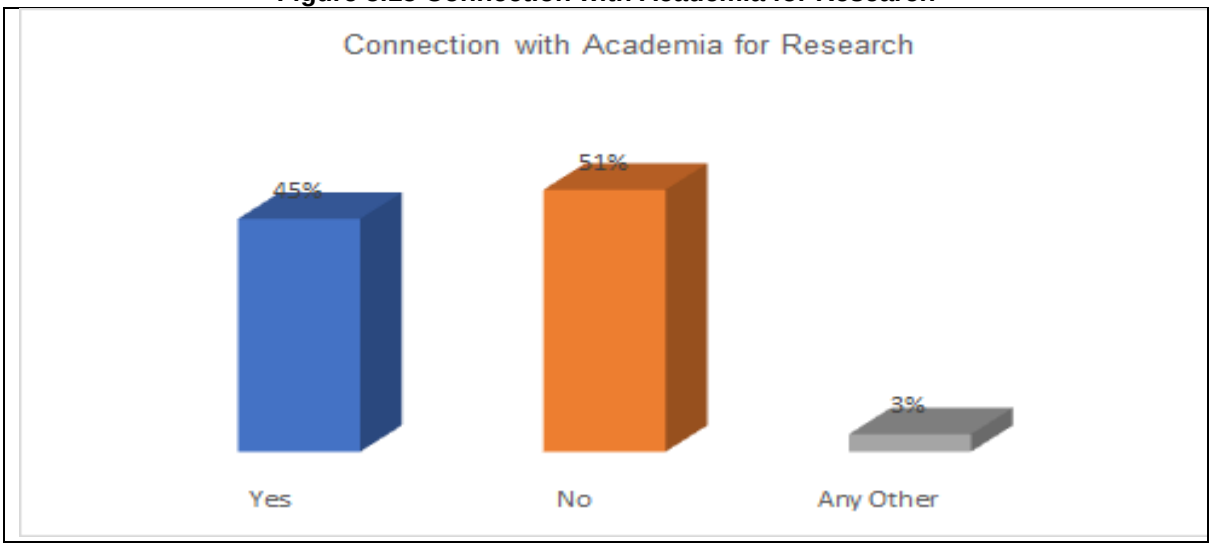
Figure 5.14 Products Patented



Source: Primary Survey

Half of the respondents did not have any contact with academic institutions.

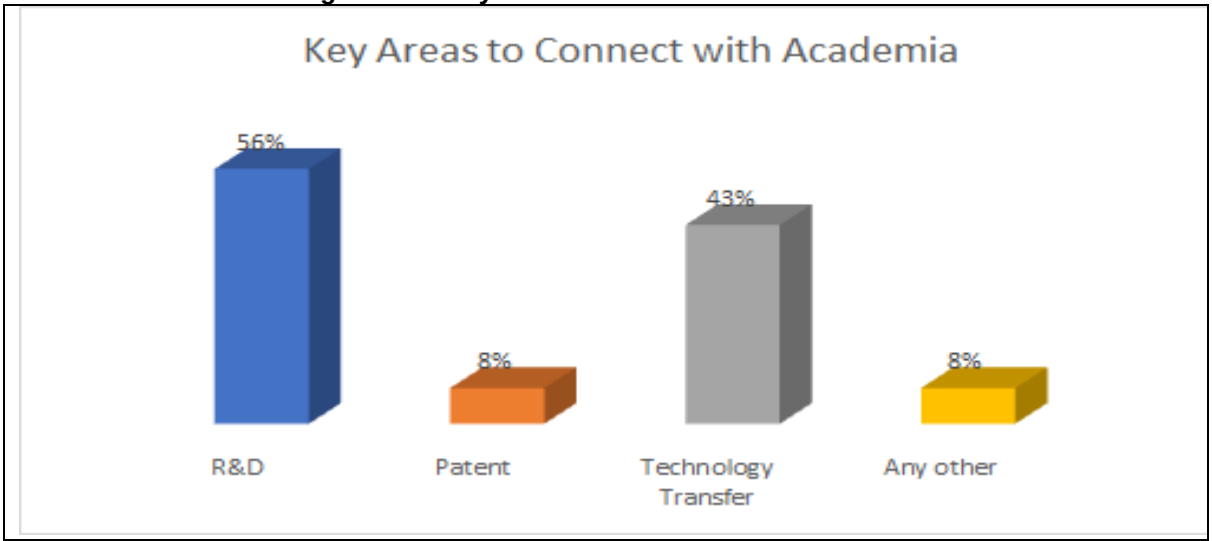
Figure 5.15 Connection with Academia for Research



Source: Primary Survey

Nearly 90 per cent of the respondents said that they would like to get associated with academic institutions for R&D or technology transfer. Others were interested in skill development or clinical trials. The opinion was clearly in favor of working on business related challenges.

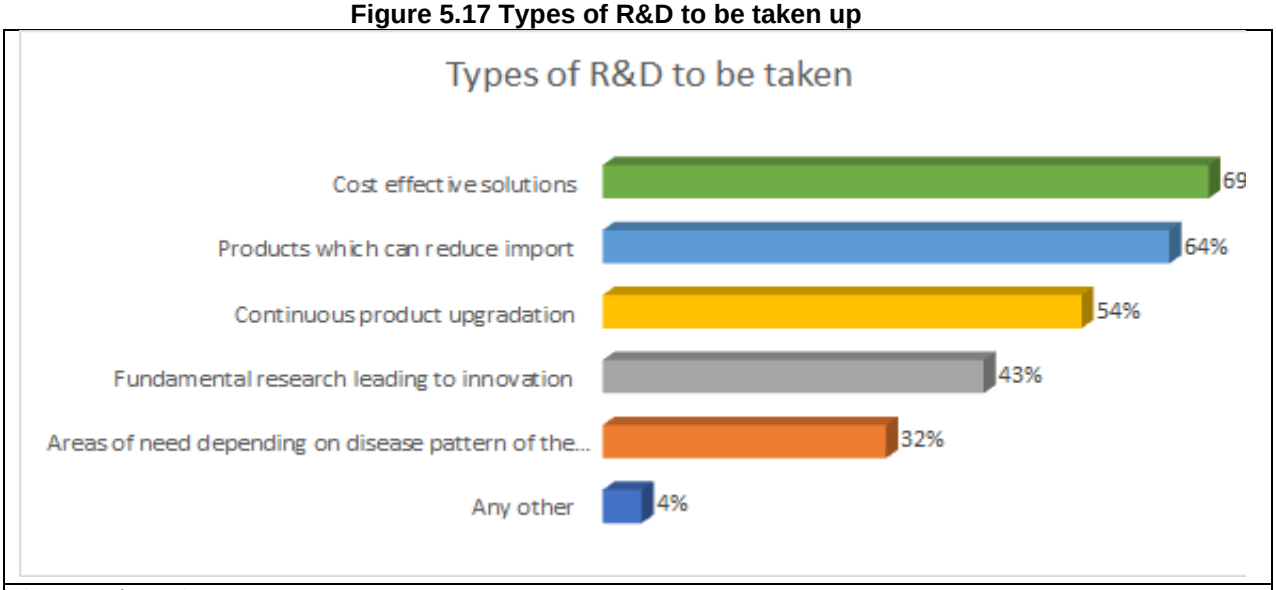
Figure 5.16 Key Areas to Connect with Academia



Source: Primary Survey

69 per cent of the respondents felt that R&D should be undertaken for cost effective solutions whereas 64 per cent felt that it should be for products which can reduce import. 54 per cent opined that it should be for continuous product upgradation. Only 43 per cent said that it should be for fundamental research leading to innovation and 32 per cent said that it should be based on needs arising out of the disease pattern of the country.

Figure 5.17 Types of R&D to be taken up



Source: Primary Survey

5.19.5 Technology Development

Indian companies started specializing, though might not be of desired level. Specialization can be seen in the form of stents, low-cost ventilators, reagents, RTPCR kits etc. Respondents felt that start-ups should play more role in leap frogging technology and degree of support may be linked to the degree of deep-tech-ness of the product. Respondent suggested that often, we get technology from abroad which are useful. However, those industries are also improving upon it on a regular basis as the life cycle of a technology is very short in medical devices. Now, the price of that technology falls over a period of time. However as and when price starts to fall, the manufacturer stops making the product and shifts to a new technology. So, the benefit which less endowed persons could have received, now that the price has fallen, gets lost.

High cost is the biggest problem in doing clinical research per 45 per cent of the respondents. Other challenges include infrastructure (25 per cent) and availability of technical manpower (21 per cent). 49

per cent of the respondents said that faster regulatory approvals can help Indian firms to promote R&D. It can also be promoted by giving tax incentive as per 45 per cent of the respondents. Higher incentive to higher value adding firms and incentive or purchase of patents by start-ups can also contribute significantly towards promotion of R&D. Financial support and acceptability of Indian products are also factors which can contribute towards R&D promotion.

For example, the creation of the Regional Centre of Biotechnology (RCB) in Faridabad has solved their problem to a great extent. "...Regional Centre for Biotechnology (RCB) is an academic institution established by the Department of Biotechnology, Govt. of India with regional and global partnerships synergizing with the programs of UNESCO...." More than 30 start-ups from BIRAC have taken support of this facility to experiment with their findings through in-vitro as well as in-vivo situation for fees as low as Rs 12,000 to Rs 21,000 per month. RCB has 3 sets of each machine required for such purpose. This was created with the support of BIRAC.

Box 5.1 Promoting Start-up in Bio-Engineering - BSC BioNEST Bio-Incubator (BBB) [269]

"...A leading Bio-Incubator located in the National Capital Region on Faridabad-Gurugram Expressway, with a vision to foster innovation, research and entrepreneurial activities in biotechnology related areas. The mission of BBB is to stimulate the establishment and growth of biotechnology-based start-up companies. BBB is funded by BIRAC under the BioNEST (Bio-incubators Nurturing Entrepreneurship for Scaling Technologies) scheme, managed and operated by Regional Centre for Biotechnology (RCB) which is recognized as an institute of national importance by the Parliament of India and is a Category II centre under the auspices of UNESCO.

- BBB provides excellent incubation facilities infrastructure, spread across 35000 sq. ft. covered area which includes Lab Space, Office Space, Professional Business Suites, Culture Facility and Instrumentation Facility.
- Incubator provides globally competitive & superior incubation services to start-ups & innovators, helping them to become successful enterprise. BBB can accommodate about 35 start-ups in the facility.
- We provide shared wet lab benches for young start-ups and independent lab cubicles for innovators who need bigger lab spaces. The facility is available at an affordable cost to support the start-ups entrepreneurial journey.

The facility has spacious, well equipped Meeting Rooms to conduct discussions & business meetings. A separate Video Conference Facility and Classroom / Seminar Facility is also available within the premise. Incubatees have access to Advanced Technology Platform Centre (ATPC), which has cutting-edge technologies and instrumentation facilities to provide deep insight in biological processes and provide the best opportunity to commercialize their discoveries. Facilities available at ATPC are Flow Cytometry, Mass Spectrometry, Optical Microscopy, Electron Microscopy, Mass Spectrometry, Genomics, Molecular Interactions, and Protein Purification etc."

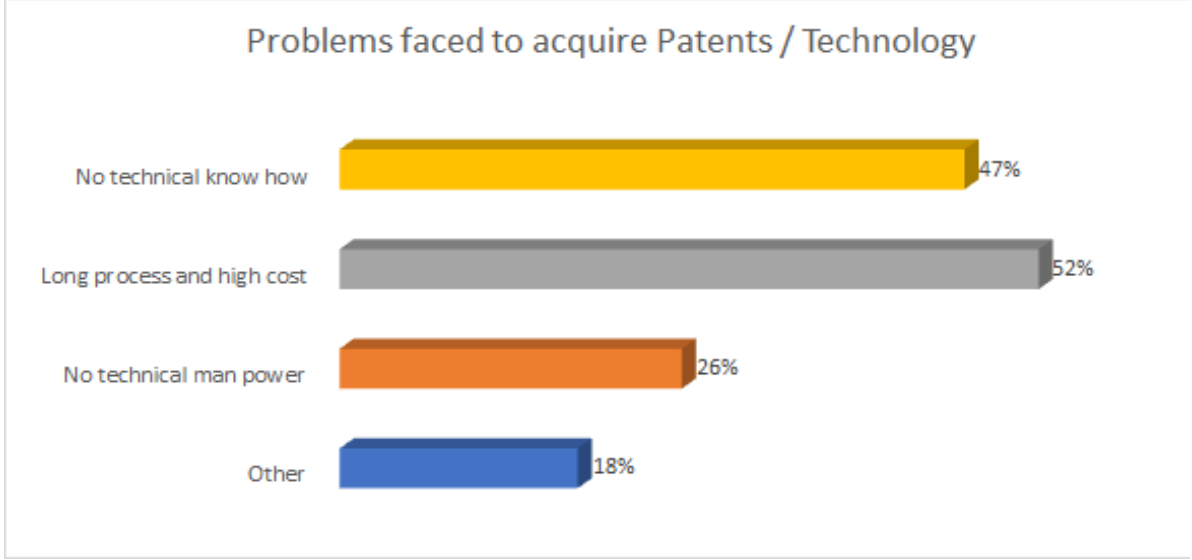
Source RCB Website

5.19.6 Patents and Technology Transfer

For acquiring a patent in the medical device industry 47 per cent said that they faced problems as they had no technical know-how, the process was long drawn and was of high cost. 26 per cent said that they did not have affordable technical manpower. It was suggested that innovators sometimes get engrossed in technology and the concept of innovation gets lost. Target is not patent, but product creation. Indian companies must go for substitutes and at lower cost.

[269] https://bbb.rcb.res.in/

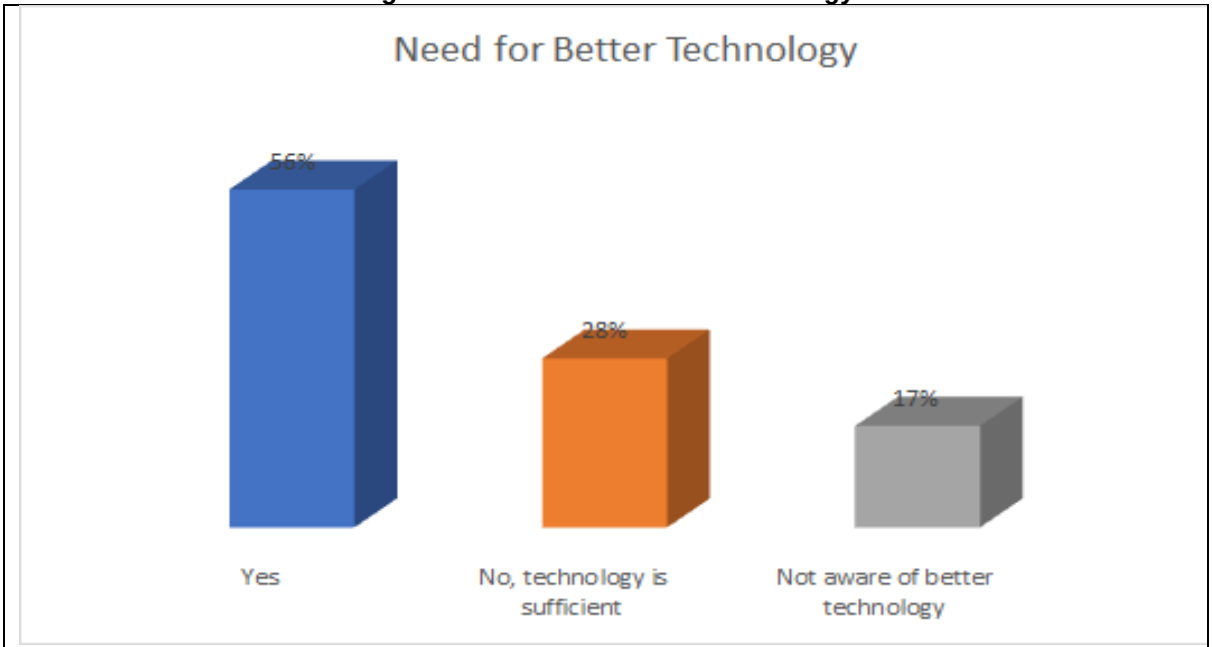
Figure 5.18 Problem Faced to Acquire Patents/Technology



Source: Primary Survey

56 per cent of the respondents said that they need better technology, while 28% said that technology is sufficient. Lack of awareness was identified by 17% of the respondents.

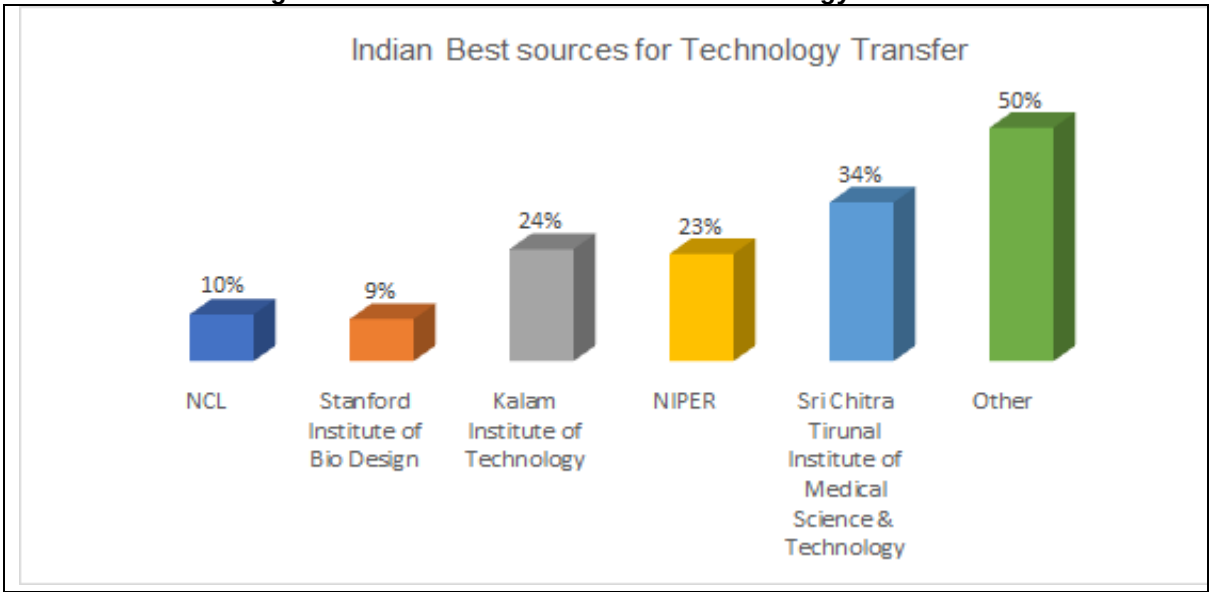
Figure 5.19 Need for Better Technology



Source: Primary Survey

34 per cent of the respondents recognized Sri Chitra Tirunal Institute of Medical Science and Technology as a good source for technology transfer from Indian Institution, 23 per cent identified NIPER and 24 per cent opined for Kalam Institute of Technology, 9 per cent identified Stanford Institute of Bio Design and 10 per cent identified NCL.

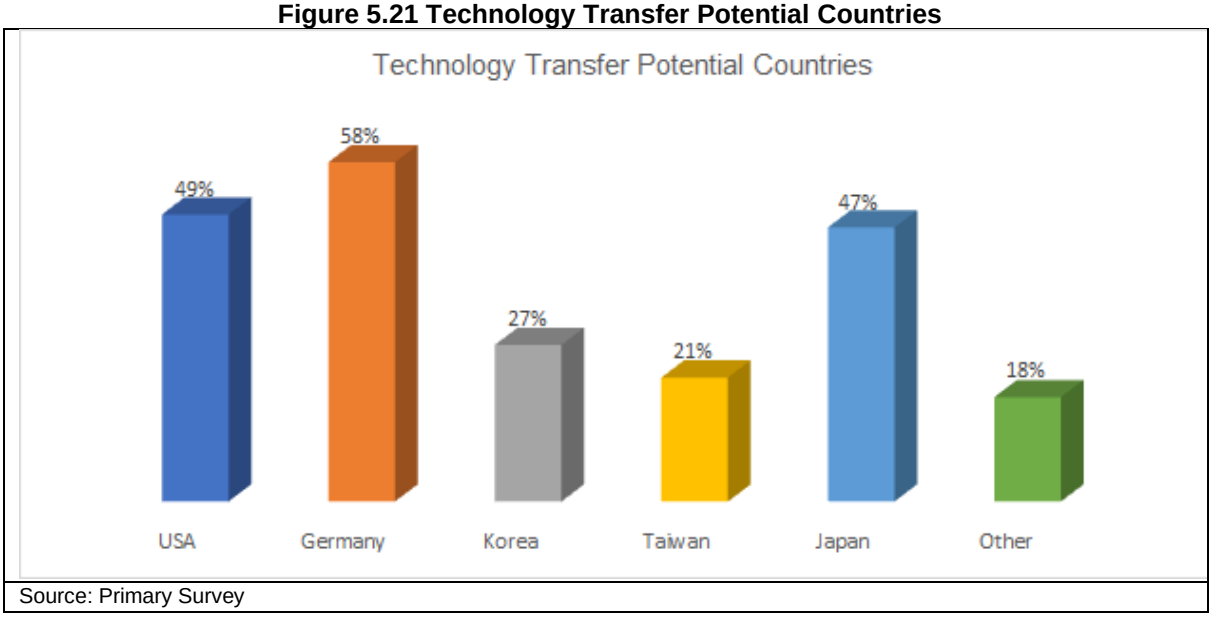
Figure 5.20 Best Indian Sources for Technology Transfer



Source: Primary Survey

Germany is the most potential country for technology transfer according to 58 per cent of the respondents. This is followed by USA as per 49 per cent of the respondents and closely followed by Japan according to 47 per cent of the respondents. 27 and 21 per cent of the respondents also felt that Korea and Taiwan are the other potential respondents. According to 18 per cent of the respondents there are other countries as well like China, Finland, France, etc. who can be potential sources of technology transfer.

Figure 5.21 Technology Transfer Potential Countries

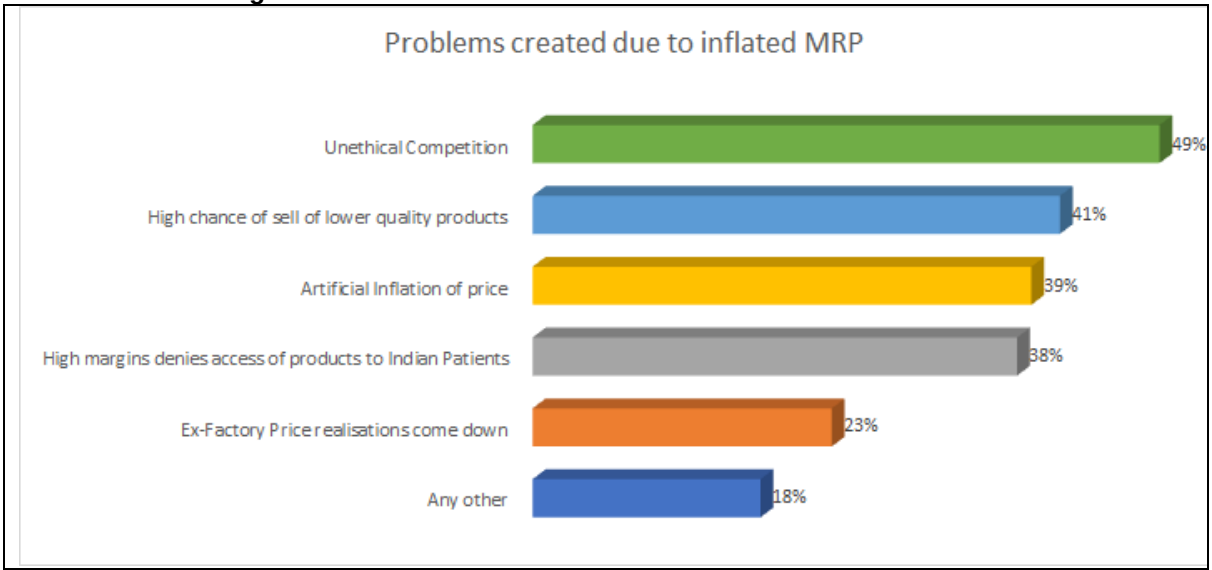


Source: Primary Survey

5.19.7 Maximum Retail Price (MRP)

Around half the respondents felt that without a limit on MRP it can lead to unethical competition. About 41 per cent respondents said inflated MRP can lead to a high chance of selling lower quality products, 39 per cent felt that artificial inflation of price is a problem and nearly 38 per cent feel high margin denies access of products to Indian patients.

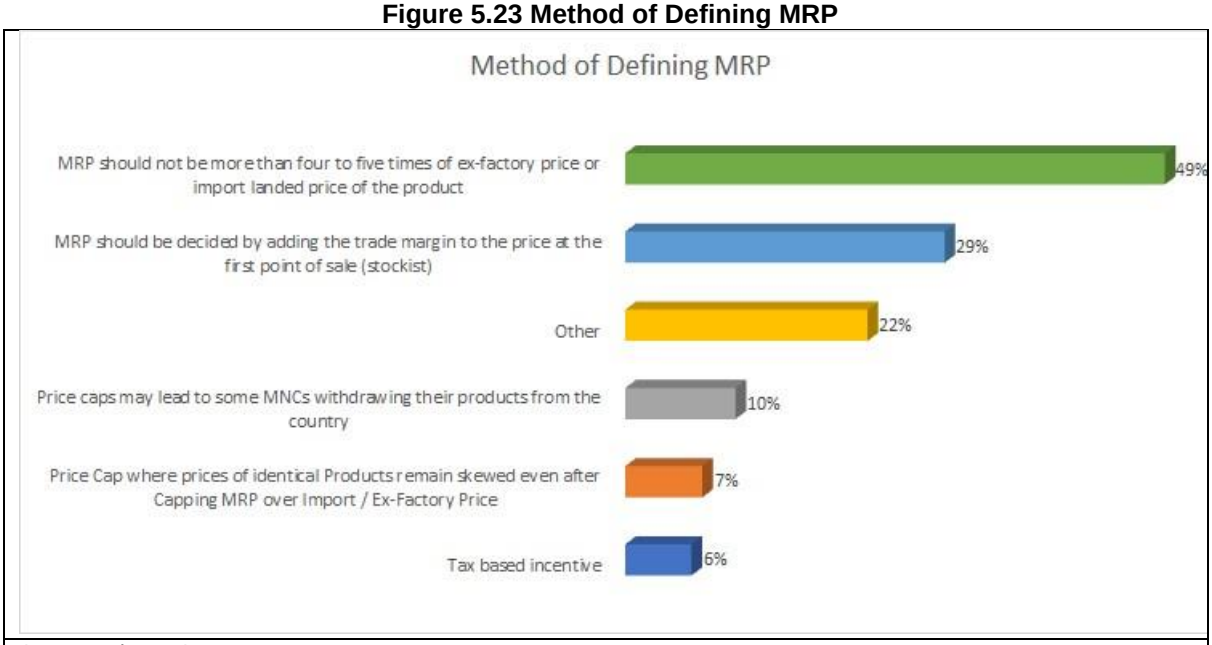
Figure 5.22 Problems Created due to Excessive/Inflated MRP



Source: Primary Survey

Nearly half of the respondents felt that MRP should not be more than four to five times ex-factory price or imported landed price of the product. Nearly one-third of the respondents felt that MRP should be decided by adding the trade margin to the price at the first point of sale (stockist). However, 22 per cent opined that there are other reasons as well to define MRP. In view of the difference in opinion, it was suggested that there can be an exclusive committee to define MRP with due representation from medical device industry.

Figure 5.23 Method of Defining MRP



Source: Primary Survey

Two-third of the respondents felt that medical device industry should have a separate code for marketing practices from that of pharmaceuticals. Only 4 per cent opined that the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) with changes appropriate for medical device sector may work out well.

5.19.8 Product Costing

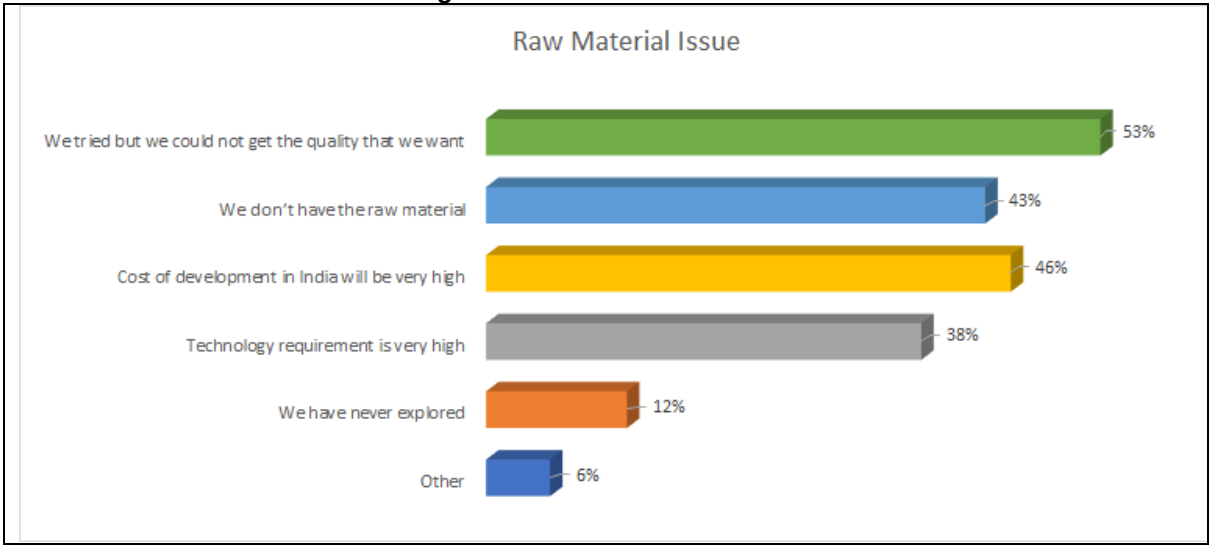
Raw material is the highest contributor to product costing followed by labour, logistics, after sales and IPR. The situation is not very different for high tech products.

Table 5.35 Price Build up: Opinion of Percentage of Respondents

Costing	Up to 10%	10-20%	20-30%	Above 30%
Raw Material	5%	9%	23%	52%
Labour	13%	37%	20%	15%
IPR	33%	15%	5%	3%
Logistics	70%	11%	1%	1%
Promotion	41%	21%	14%	6%
After Sales	54%	18%	4%	3%

53 per cent of the respondents felt that the major issue of sourcing raw material from India is the lack of quality. 43 per cent were of the opinion that India does not have the raw materials and 46 per cent said that cost of development in India will be very high. 38 per cent felt that technology requirement is very high as compared to availability of raw materials whereas 13 per cent never explored the option of sourcing the raw materials from India itself.

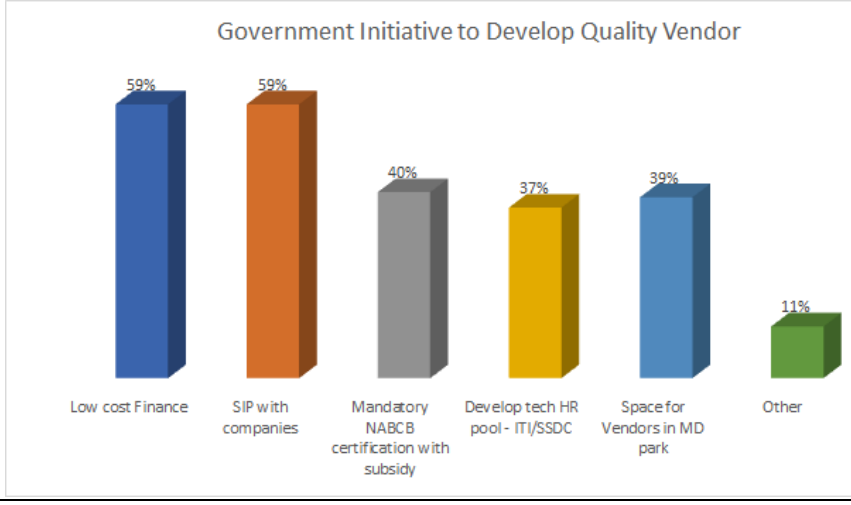
Figure 5.24 Raw Material Issue



Source: Primary Survey

Supplier Integration Program with medical device companies and low-cost finance are the most wanted initiatives that the government must take to develop quality vendors for medical devices for around 60 per cent of the respondents. Space for vendors in the medical device park is an option expressed by 39 per cent of the respondents whereas 40 per cent of the respondents were of the opinion that Mandatory NABCB certification with subsidy and 37 per cent feel developing tech HR pool are major initiatives to be taken by the government to develop quality vendors. Special emphasis needs to be given to the promotion of ancillarisation for key components.

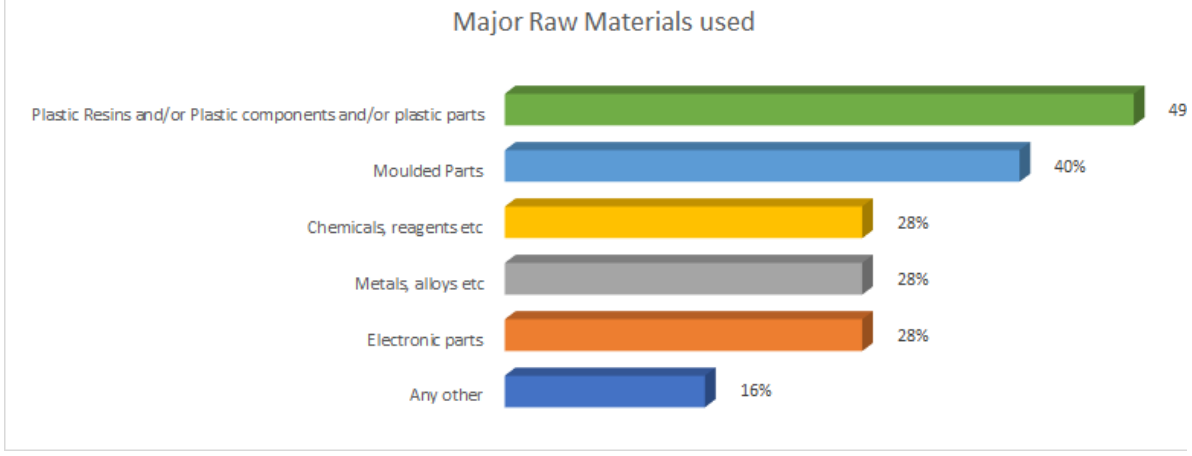
Figure 5.25 Government Initiative to Develop Quality Vendor



Source: Primary Survey

Almost three-fourths of the respondents are exporters. According to 43 per cent of the respondents, the high cost of raw material is a major challenge to export in the medical device industry. While nearly half of the respondents import plastic resin parts, 40 per cent import molded parts and 28 per cent import reagents, alloys, and electronic parts.

Figure 5.26 Major Raw Material Used



Source: Primary Survey

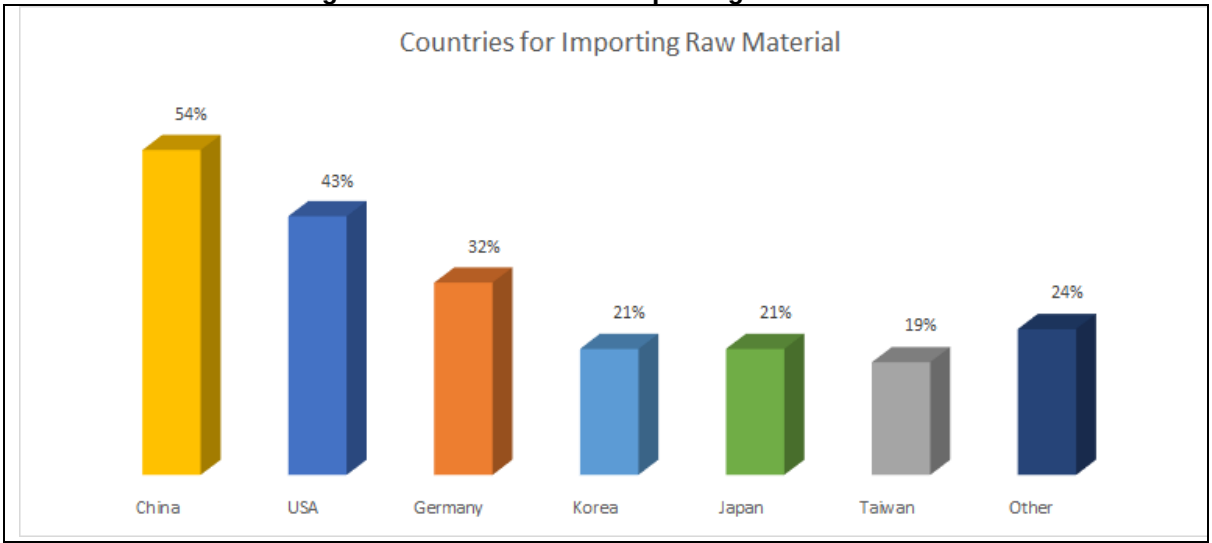
The major imported raw materials are.

Table 5.36 Major Imported Raw Materials

Nature	Name
Electronic Components	Sensors, X-Ray Tubes, IC chips, motor
Metal compounds	SS wire, SS cannula, platinum tungsten alloy, nitinol (Nickel-Titanium) wire, copper, etc.
Plastics	Tubing (plastic, TPU, PTFE, catheter), PP, PVC, synthetic resin, plastic wares, Packaging film, ET, TT
IVD related	Antigen, antibodies, reagents, enzymes, especially DNA polymerase, bile salts, MISPA, ELISA, microbiology grade agar, chromogenic substrates, oligonucleotides
Semi-finished	Hemodialysis catheters, dialyzer, special interface connector, flow regulator

Half of the respondents import raw material from China whereas 43 per cent import from the USA. A major portion of 32, 21 and 21 per cent of the respondents each import from Germany, Japan, and Korea respectively. 24 per cent of the respondents also import from Italy/Malaysia/Spain/Finland/Sweden/ UK.

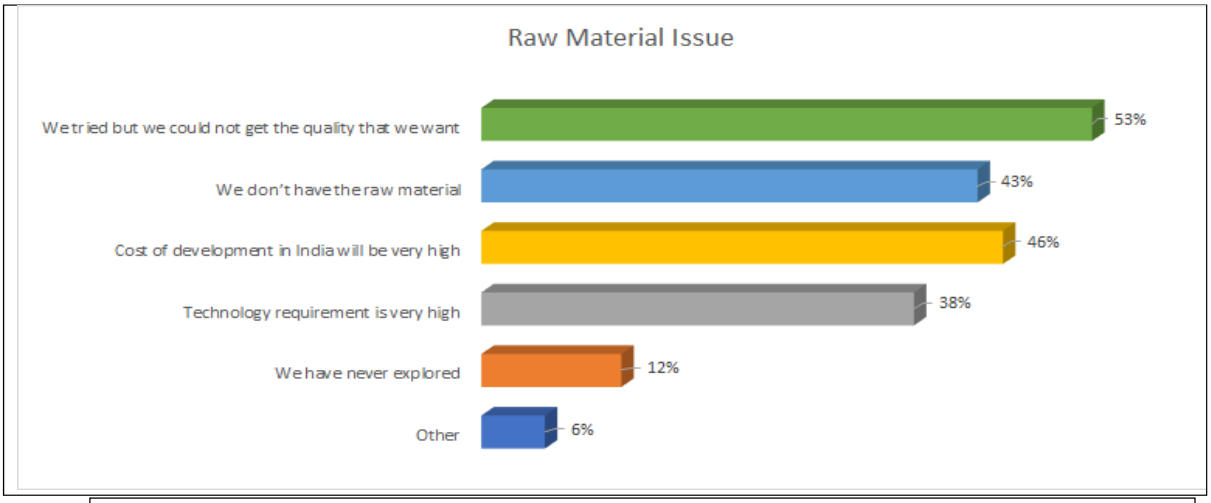
Figure 5.27 Countries for Importing Raw Material



Source: Primary Survey

Getting the appropriate quality of raw materials from India is a major issue for over half of the respondents. 43 per cent were of the opinion that India does not have the raw materials and 46 per cent said that cost of development in India will be very high. 38 per cent felt technology requirement is very high as compared to availability of raw materials whereas 12 per cent never explored the option of sourcing the raw materials from India itself.

Figure 5.28 Raw Material Issue



Source: Primary Survey

Cash flow challenges from delayed payments needs to be addressed. Unlike exports that are paid on time by institutional buyer by L/C, local procurement should not hold back due to delays of, e.g., installation sites not being ready etc. Going by the successful quick clearance drive by the Government during the COVID period, the industry is upbeat that this is a possibility.

5.19.9 Regulatory Issues

A number of regulatory approvals are to be taken by the firms. However, in the majority of the cases, the approval does not take more than six months. The following issues were also suggested

- State Governments should create single point of contact to handle grievances at state levels. Interpretations regarding regulations vary from officer to officer and from time to time. Single point of contact has been fixed. Person with desired qualification may guide and reasonable prescribed fee may be charged for it.

- Need for restriction for next 5 years on import of pre-owned second-hand medical equipment till India has robust regulations to ensure calibration and patient safety
- It was opined that there is need to decriminalize minor offenses such as treating rusting of Needles from poor storage as adulteration by manufacturer or typographical error in Batch No or size in labelling for example any defect generated due to improper storage (part sale) or sample failure due to incorrect test method used by Govt. Labs - in Drugs Act. This will encourage investors.
- It was also opined that Medical Devices Regulatory Framework needed for all Devices to ensure quality, credibility, assured patient safety and fair competition.

5.19.10 Quality Standard

84 per cent of the respondents have ISO 13485 and over 50 per cent have ISO 9001 and MDR 2017 (CDSCO India). Also, in view of the export intensiveness of the respondents, 37 per cent have EU MDR, 11 per cent have US FDA, and 6 per cent have MDSAP. Around 16 per cent have other certifications like WHO GMP, ANVISA (Brazil) and KFDA (Korea), ISO 15917, etc.

Table 5.37 Country Wise Certifications & Registrations Required

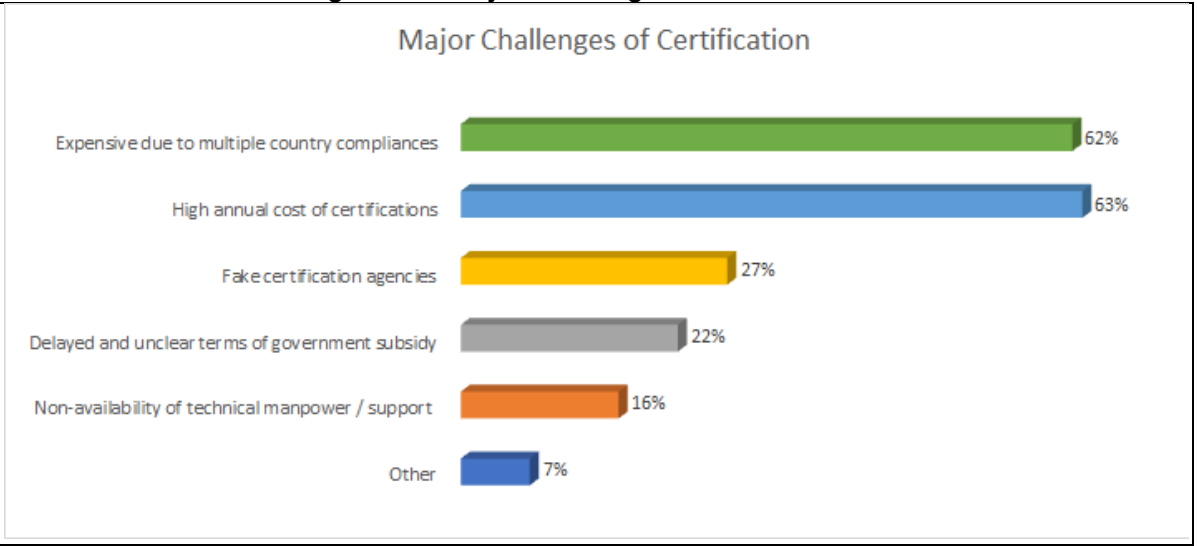
Country	Class	Regulatory Authority	Certifications Required	Registrations Required	Other Requirement
USA	**USFDA (Centre for Devices and Radiological Health (CDRH))**				
USA	Class I	USFDA (Centre for Devices and Radiological Health (CDRH))	ISO 13485 (Optional)	Most Class I devices are exempt from Premarket Notification 510(k):	The Quality System regulation (Title 21 Code of Federal Regulations Part 820)
USA	Class II	USFDA (Centre for Devices and Radiological Health (CDRH))	ISO 13485 (Optional)	Most Class II devices require Premarket Notification 510(k)	The Quality System regulation (Title 21 Code of Federal Regulations Part 820)
USA	Class III	USFDA (Centre for Devices and Radiological Health (CDRH))	ISO 13485 (Optional)	Most Class III devices require Premarket Approval.	The Quality System regulation (Title 21 Code of Federal Regulations Part 820)
Germany	**Federal Institute for Drugs and Medical Devices**				
Germany	Class I/IIa/IIb/III	Federal Institute for Drugs and Medical Devices	ISO 13485 certification, which is valid for three years	CE Marking	Germany does not require additional requirements outside of CE mark
Brazil	**ANVISA (Agência Nacional de Vigilância Sanitária)**				
Country	Class	Regulatory Authority	Certifications Required	Registrations Required	Other Requirement
Brazil	Class I/II/III	ANVISA	Certificate of (GMP) by ANVISA certificate of National Institute of Metrology, Standardization and Industrial Quality (INMETRO) for electro-medical devices		
China	**China National Medical Products Administration (Department of Medical Device Registration)**				
China	Class I	China National Medical Products Administration	ISO 13485	Simple product filing to NMPA	An overseas device company must submit product

Country	Class	Regulatory Authority	Certifications Required	Registrations Required	Other Requirement
China	Class II/III	China National Medical Products Administration	ISO 13485	Manufacturing company must meet all the requirements in the latest regulation, guidelines, and standards	samples to test with the NMPA. In addition, all included product information, packaging, and labels, etc. need to be translated into simplified Chinese.
India	**CDSCO (Central Drugs Standard Control Organization)**				
Country	Class	Regulatory Authority	Certifications Required	Registrations Required	Other Requirement
India	Class A/B/C/D	CDSCO	ISO 13485	Form 28 (for existing units) or Test License under MDR 2017 Rules	Compliance to applicable state level rules laid down from time to time

Source: Various Secondary Sources

Nearly two third respondents said that the major challenges are high cost of annual certifications and expensive nature of certifications due to multiple country compliances. 27 per cent said fake certification agencies and 22 percent said that delays and lack of clarity of terms of subsidy are major challenges.

Figure 5.29 Major Challenges for Certification

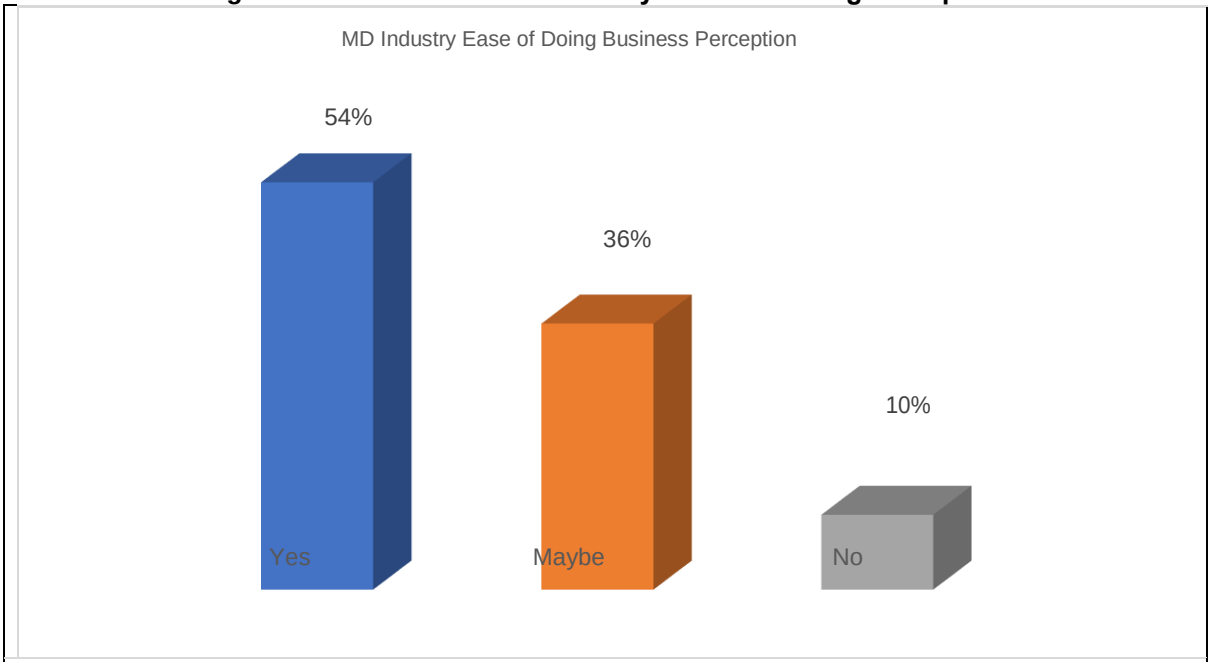


Source: Primary Survey

5.19.11 Entrepreneurship

Entrepreneurs are high on the prospects of the industry, given its growth rate and thus most of the respondents suggested that they will/most probably will suggest budding entrepreneurs to take up this business. Around 90 per cent of the respondents said that they will/may suggest new entrepreneurs to set up business in medical device industry whereas 10% will not do the same.

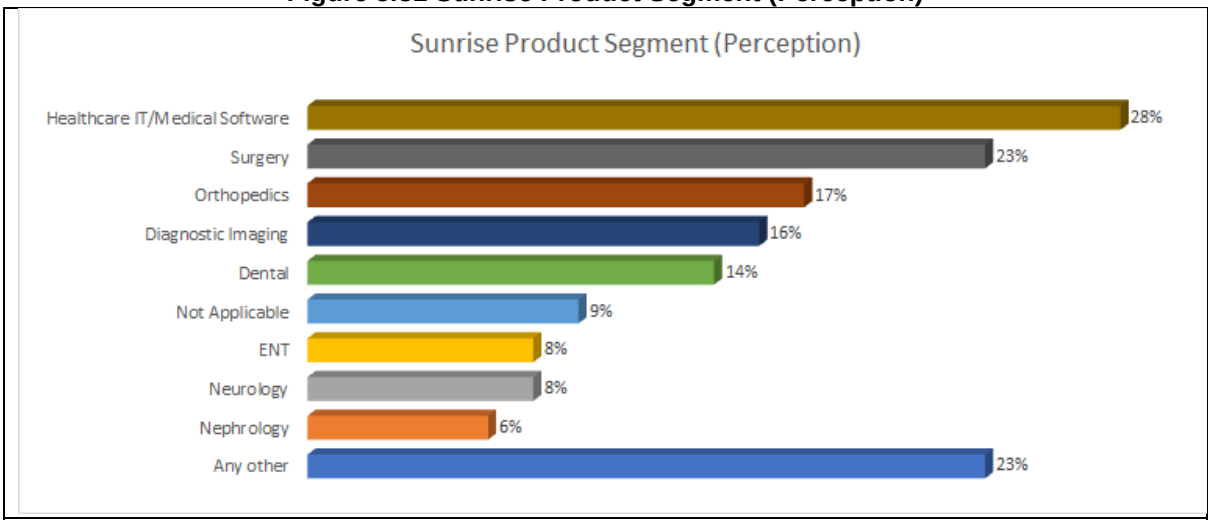
Figure 5.30 Medical Device Industry's Ease of Doing Perception



Source: Primary Survey

Out of the respondents who would suggest setting up business in medical devices, 28% said that business should be set up in healthcare IT, whereas 23% said that surgery is the right segment for new business. Out of the 23% respondents who chose any other as option most have given IVD as the segment to start business in medical devices industry.

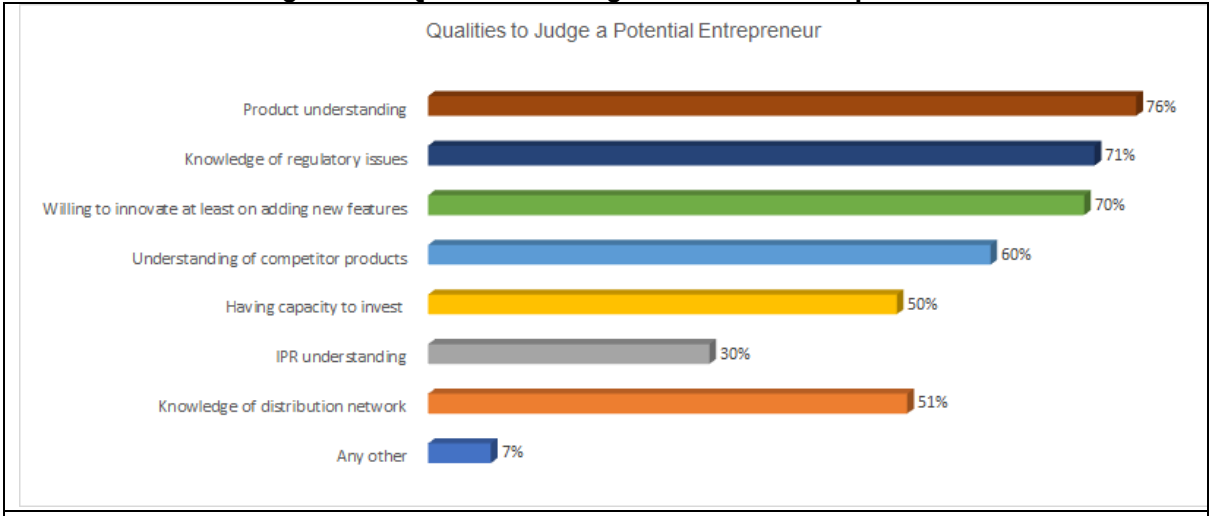
Figure 5.31 Sunrise Product Segment (Perception)



Source: Primary Survey

Product understanding and knowledge of regulatory issues are the two major qualities of a potential entrepreneur in the medical devices industry as responded by 76 per cent and 71 per cent of the respondents respectively closely followed by willing to innovate at least on adding new features as said by 70 per cent of the respondents. According to 60 per cent of the respondents understanding competitor products is a major quality for a potential entrepreneur. Other issues like investment capacity, knowledge of distribution networks, IPR understanding were considered as less important.

Figure 5.32 Qualities to Judge a Potential Entrepreneur



Source: Primary Survey

5.19.12 Environment

59 per cent respondents said that NoC from state pollution control board is required, 29 per cent said that Biomedical Waste Management Rules 2016 is required, 21 per cent said that Plastic Waste Management rules are required and 27 per cent said they do not require anything from the mentioned regulations.

Figure 5.33 Regulations Applicable as per Stakeholder Understanding

Source: Primary Survey

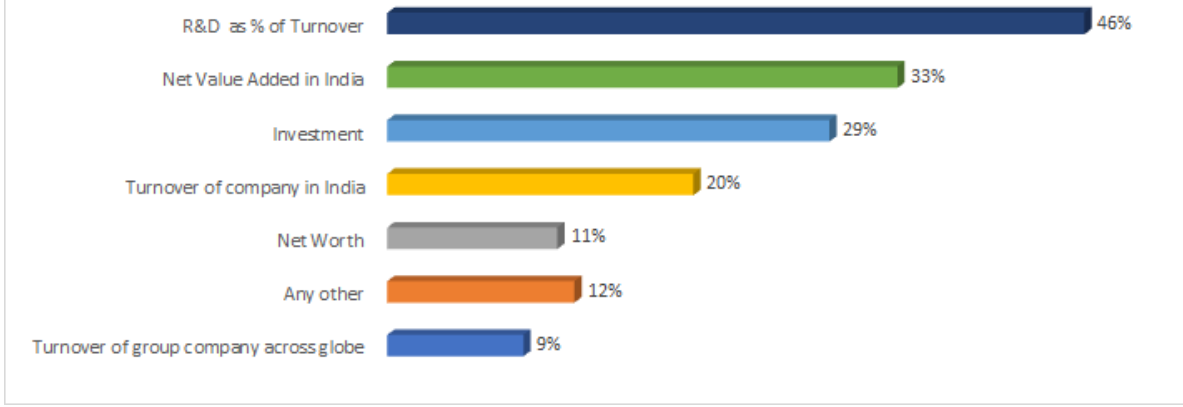
56 per cent said there is no requirement of an EPR, 34 per cent could not comment and 10 per cent said that they require an EPR.

5.19.13 Government Support

Export incentives in the medical device industry is a major need according to close to 80 per cent of the respondents. While 69 per cent were of the opinion that easy availability of capital is essential. The presence of a large talent pool was also stressed by 41 per cent of the respondents.

The industry also felt that R&D as percentage of turnover (46 per cent), net value added in India (33 per cent) and investment (29 per cent) should be the topmost categories for providing support to units.

Figure 5.34 Support to Medical Devices Sector



Source: Primary Survey

Besides, the following were also suggested for Government support:

- Subsidize clinical trial costs which are needed for registrations and introduction of long-acting products and for post marketing clinical feedback.
- Support M&A of technology intensive units abroad.
- Small manufacturers and young entrants may not be able to bear the regulatory cost. This needs to be considered.
- Create a brand image of Medical Devices “Made in India”.
- 64 per cent of the respondents said that they are not aware of any scheme, 28 per cent said they have not applied for any scheme but are aware. Only 8 per cent of the respondents said that they have utilized any scheme. Hence schemes need to be further popularized.

6. Medical Device Parks in India

6.1. Backdrop

According to the United Nations definition, “Industrial Parks (IPs) are the small and middle size organizations that have integrated business and production, benefiting from the common infrastructure services that have allocated in standard fabric buildings”.

As the concept got developed, IPs have been established for the development of industrialization, focusing overall increasing industrial productivity, utility, quality of goods and services, which got recognized as a method of cost alleviation process in the industrialization process.

For the developing countries, IPs are rather more important and beneficial than the developed nations. As the clusters in IPs are small and middle-sized institutions, the importance and productivity of these businesses are comparatively more efficient than in the developed world. IPs promote sizeable incentives for the small and middle business enterprises to invest and enlarge their productivity and profits.

Eventually, IPs lead to significant regional development in all locations where they have come up; besides it has also been noticed that in the long run, IPs have revived the stagnation in the regions by accumulating and providing more employment and promoting balanced economic growth.

At the backdrop of these developments, it all began with the concepts towards developing industrial Parks specific to a gamut of industrial segments like Life Science Industry including Pharmaceutical, Medical Devices, Biotechnology products and their Ancillary and Service Providers, which has come a long way to be identified as a separate industrial segment in it.

The Medical Device industry is highly capital intensive with a long gestation period and requires development and induction of new technologies. It also requires continuous training of health providers to adapt to new technologies. Most of the hi-tech innovative products originate from a well-developed eco-system and innovation cycle which is yet to be fully developed in India.

Since the creation of testing and laboratory facilities requires huge investment, a Scheme “Promotion of Medical Device Parks" has been approved by the Government of India on 20th March 2020. The parks will provide common testing and laboratory facilities center at one place reducing the manufacturing cost significantly and create a robust ecosystem for medical device manufacturing in the country.

Easy access to standard testing and infrastructure facilities through creation of world class Common Infrastructure Facilities for increased competitiveness will result into significant reduction of the cost of production of medical devices leading to better availability and affordability of medical devices in the domestic market. The objective for the Medical Device Parks is also to exploit the benefits arising due to optimization of resources and economies of scale.

6.2. Medical Devices Parks in India

Currently, Andhra Pradesh Med Tech Zone (AMTZ), Andhra Pradesh, is the only fully functional medical devices park. The Park has been partially financed by the various Central Government departments i.e. Department of Pharmaceuticals, DPIIT, Department of Biotechnology and the State Government of Andhra Pradesh. It has various facilities including Centre for 3D Printing, prototyping and rapid tooling facility, Gamma irradiation facility, Electromagnetic compatibility (EMC) and electromagnetic interference (EMI) Electrical Safety Training (EST), Biomaterial testing facility, X-ray, and CT Scan tube manufacturing, etc. It has also set up Kalam Institute of Health Technology (KIHT) for R&D, technology transfer, market intelligence and innovation and market access, Medi Valley Atal Incubation Centre, ECRI Institute, Bio Valley Incubation Council, etc. It plans to have additional facilities like molding, sterilization and toxicity testing, radiation, etc. It has a warehouse facility and plans to have other facilities import – export promotion body, regulatory office, exhibition etc. Land is provided on lease for 33 years, with option to buy land after 10 years of operations.

In the scheme of “Promotion of Medical Device Parks”, Department of Pharmaceuticals received Sixteen States/UTs proposals i.e., Himachal Pradesh, Jammu and Kashmir, Maharashtra, Haryana, Madhya Pradesh, Gujarat, Tamil Nadu, Rajasthan, Uttar Pradesh, Punjab, Telangana, Karnataka,

Kerala, Uttarakhand, Chhattisgarh, and Goa which were evaluated by Project Management Agency of the Scheme. Four states viz. Himachal Pradesh, Tamil Nadu, Madhya Pradesh, and Uttar Pradesh received final approval in 2021-22.

The upcoming medical device park in Himachal Pradesh spans over 265 acres in Solan District, with an estimated project cost of Rs 349.83 crores. The park will comprise of CFCs equipped with design and testing facilities including ESDM, EMC, EMI and sensor testing, gamma irradiation lab, data analytics lab including Internet of Medical Technology (IoMT) Lab, skilling center, common warehouse, and waste management. The park will focus on manufacturing medical electronic devices like ultrasound, c-arm, X-ray machines, and automated lab analyzers, home-based devices like glucometer, thermometer, and oximeters, OT and ICU equipment, and intraocular and orthopedic implants. When fully functional, the park will employ approximately 8000 people. Commercial operations are scheduled to commence from mid-2024.

The upcoming park at Gautam Buddha Nagar in Uttar Pradesh will focus on manufacturing cancer and renal care devices, nuclear imaging devices, and implantable electronics. The park will be built on 350 acres, with an estimated project cost of Rs 435.94 crores. The CFC will have gamma irradiation and mechatronics zone, together with other common facilities including design and testing, waste treatment, etc. The park is expected to be functional from early 2024, employing over 15000 workers.

Madhya Pradesh's upcoming medical device park is set to employ 10,000 workers when it commences operations in early 2024. The CFC in the park will be equipped with 3D printing and prototyping facility, safety and performance testing facility, bio-medical and bio-compatible lab, tool room, ethylene oxide sterilization facility, PC board manufacturing and testing, and skilling center. It will be focused on producing a range of medical devices including stents, implants, and diagnostic devices. The park spans over 360 acres of land at Ujjain in Madhya Pradesh. The estimated project cost is 223 crores.

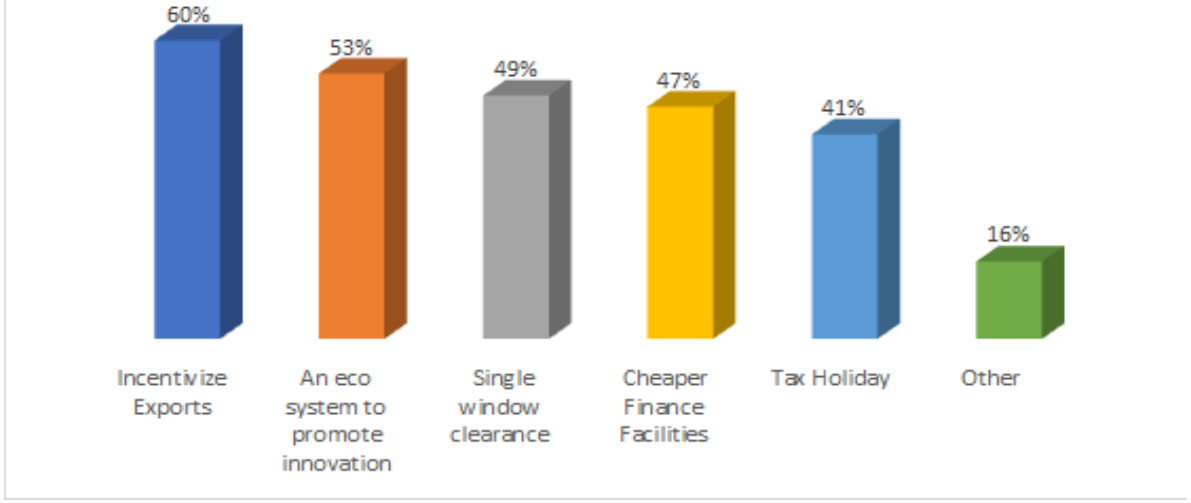
Tamil Nadu's upcoming medical device park spans over 350 acres at Kancheepuram, with an estimated project cost of 212.40 crores. The companies in the park are set to manufacture devices for preventive, diagnostic and therapeutic procedures, also including technical and application software, IVD and reagents, and artificial bio-devices. When fully operational in mid-2024, the park will employ approximately 3000 workers.

TIFAC has also proposed creation of about 5-6 medical devices manufacturing park, in the lines of Andhra Pradesh Medtech Zone Ltd (AMTZ). It has also suggested creation of two specialized parks in IVDs.

6.2.1 Medical Devices Park

According to 60 per cent of the respondents, medical devices parks will help in incentivizing exports. 53 per cent felt that it will create an ecosystem to promote innovation and 49 per cent felt that it will help create a single window clearance. While 47 per cent of respondents felt that such facilities should provide additional support in form of tax holiday and around 41 per cent of the respondents feel medical devices parks should also make cheaper finance available to units who set up units there.

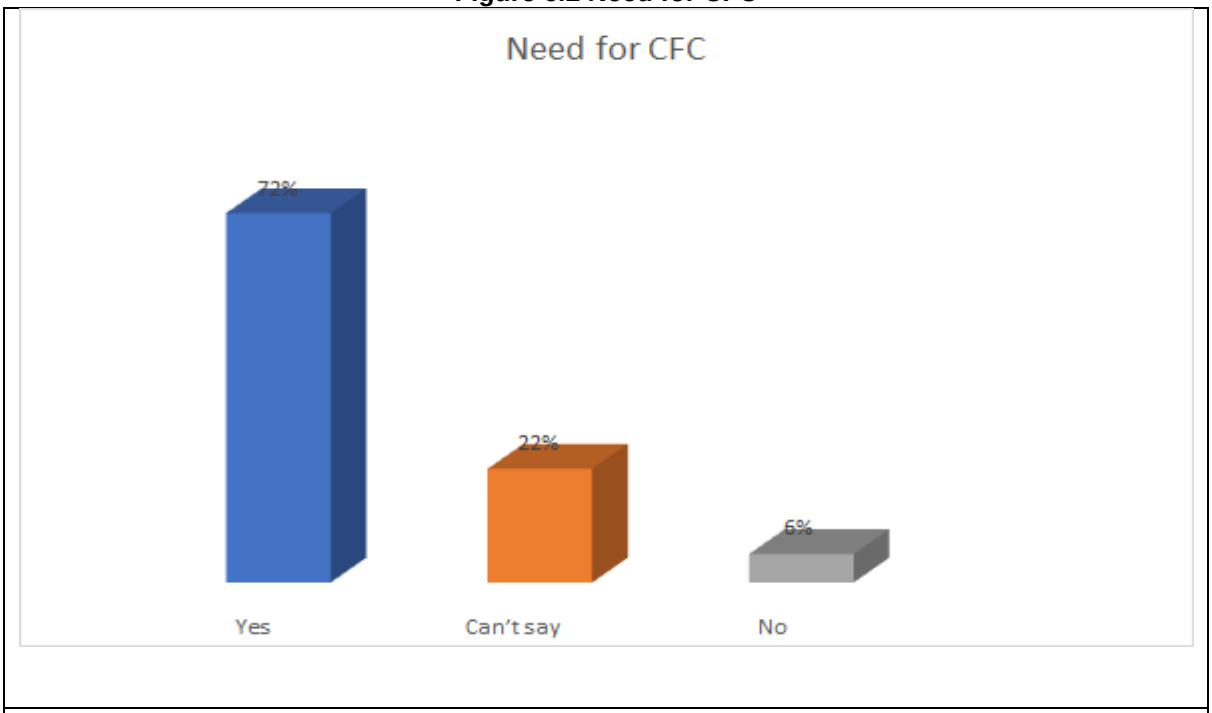
Figure 6.1 Benefits of Medical Device Park



Source: Primary Survey

It was also suggested that land should be available on a long lease rental basis and additional facilities for shifting an existing industry to a park may provide benefits like fast-track regulatory clearance, easy availability of trained persons, import duty waivers, subsidized power tariff, etc. Overall, 72 per cent of the respondents felt the need for common facility centers (CFC).

Figure 6.2 Need for CFC



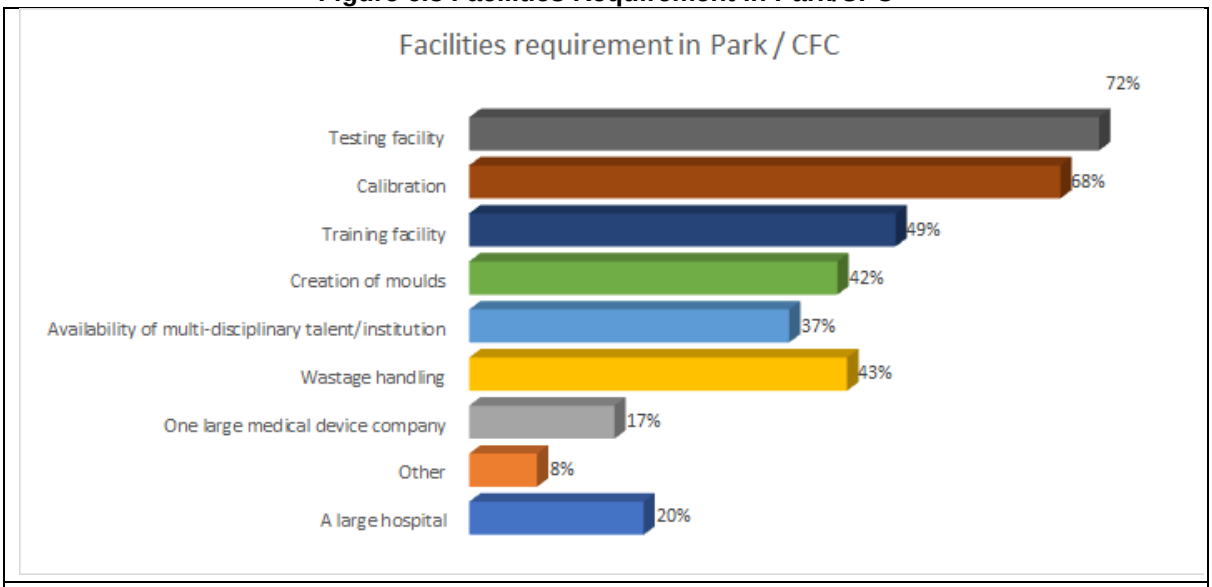
Source: Primary Survey

The park should have facilities and managed services in the areas of common testing, calibration, mould making, bonded warehouse, waste handling clinical trial, technology transfer, vendor development, pilot production and even facility to support small batch production till the product gathers enough momentum in the market. There is missing link between R&D Group and Production Group. While scientists often do not understand the challenges of up-scaling, the shop floor persons do not want to go deep in the clinical requirements. Scaling up requires process standardization, vendor development, product validation, etc. Here a critical role is played by bio-medical engineers - a missing link between clinicians and engineers, especially in technology transfer (from lab to commercialization), vendor development, etc. Such HR may be made available too with ease. Promotion of start-ups was also

highlighted. Ecosystem support in the form of linkage with hospitals availability of quality raw material providers was also emphasized.

Hence such parks should not come up in green field areas. They should ideally come up in areas where there is a natural advantage of availability of talents and history in some areas of specialization, be it plastics, metals, textiles, biochemistry, software, precision engineering (e.g., automobiles/defense[270]), etc. Hence specialized parks may also be considered in areas with specialized competitive advantage, e.g., plastics-based products in Ahmedabad–Vadodara. While many nations are moving towards parks that promotes innovation, the need for parks promoting manufacturing was highlighted as the need of India.

Figure 6.3 Facilities Requirement in Park/CFC



Source: Primary Survey

6.3. Factors For Selecting A Medical Devices Park

Based on the discussion with experts and literature review it was found that the following factors will play a major role towards the success of a park

6.3.1 Basic Commercials

- Distance from port/airport
- Road conditions
- Scope for extension
- Availability of long lease on rentals
- Allowance for sub-lease
- Presence of skilled labour
- Subsidized power tariff
- Pre-commitment of members
- Previous knowledge of proposed management personnel in managing SPV/Park
- Standard project viability

6.3.2 National Needs

- Expected turnover
- Expected employment
- Expected R&D investment
- Commitment for import substitution

[270]Rich history of watch making in Switzerland helped them to move toward medical devices

- Commitment for export promotion
- Commitment for local sourcing of raw materials and components
- Degree of production of high-tech devices
- Degree of solutions expected in national health issues
- Degree of commitment to address point of care services
- Degree of commitment for national and global patent registration
- Degree of commitment for sale of devices innovated in the park
- Degree of commitment for innovative start-up promotion

6.3.3 Strength of Eco System

- Degree of specialization
- Degree of local natural comparative advantage in supply of raw materials and components
- Presence of specialty hospitals in similar areas
- Agreement of collaboration of hospitals with manufacturers
- Previous experience in technology transfer of member firms
- Pre-commitment of global leaders in medical device, particularly in areas of specialization
- Presence of bio-medical engineering colleges in the locality
- Patent held by pre-committed members
- Patents held by hospitals/doctors in those hospitals who have committed for collaborative research
- Patents held by pre-committed collaborative R&D institutes, Colleges
- Pre-commitment of national Centers of Excellence in R&D
- Pre-commitment of global Centers of Excellence in R&D
- Pre-commitment of service providers

6.4. Common Infrastructure Facilities, Testing Facilities & Other Common Facilities Suggested for The Medical Device Parks

The Common facilities with capacity commensurate with the expected number and type of medical device manufacturing units in the park as well as in the region where the Medical Device Park is located. Since the required facilities/centers are constantly evolving, the above-mentioned notification has given an indicative list of such facilities.

Considering the guidelines, facilities as available in some of the established Medical Device Parks in India like AMTZ as well as inputs provided by Industry leaders as well as the feedback received through medical device industry field survey, following broad lists of Common Infrastructure & Other facilities and Common Testing Facilities are shortlisted.

- **Essential Common Infrastructure**
  - Electra-magnetic interference & Electra-magnetic compatibility center
  - Medical grade molding/milling/injection molding/machining/tooling center
  - 3D Design, Prototyping and Rapid Tooling (Prototyping) Facility
  - Engineering services including surface treatments / coating / electrical – mechanical maintenance
  - Common production facilities
  - Sterilization/ETO/Gamma Centre
  - Radiology Tube/Flat Panel Detectors/MRI Magnets/ Piezo electrical crystals/power electronics facility
  - Solid waste management/ETP/STP/Electronic Waste management unit
  - Clinical trial facility
  - Clean room validation/qualification services
  - Calibration and validation of manufacturing equipment
  - Common warehouse
  - Weighbridges

- Centre of Excellence/Technology incubator/ ITI/Training Centers

- **Other Common Infrastructure**
  - Exhibition / Seminar Halls/Auditorium
  - Food Courts
  - Canteens
  - Clinic
  - Bank
  - Necessity Shops

- **Special Common Infrastructure**
  - Green belt
  - Housing for workers and management
  - School
  - Recreation facilities - golf course

- **Common Testing Facilities**
  - Component Testing Centre/ESDM/PCB/Sensor's facility
  - Biomaterial / Biocompatibility /Accelerated Aging testing center
  - Product Stability / Ageing / Life cycle Testing
  - Animal Lab and Toxicity testing center
  - Radiation testing center, etc.
  - Testing facility for raw material
  - Testing facility for components
  - Material Characterization Testing
  - Electronics Products Testing
  - Software validation & testing

- **Essential Services**
  - Internet facilities
  - Skill development activity center regulatory / quality certification / clinical evaluation services providers
  - emergency response center/safety/hazardous operations audit center
  - Business support / market development/
  - Technology transfer / patent registration services
  - Export development / product registration services
  - Logistics (clearing and forwarding, insurance, transportation. customs, etc.)
  - Library and data processing / secretarial services
  - Translation services
  - Routine support by electrician, carpenter, plumber, guard, etc.
  - Online product promotion facility

7. Conclusions

7.1. SWOT Analysis of Indian Medical Devices Industry

7.1.1 Strengths

- Medical device industry is recognized as one of the sunrise sectors.
- A positive policy environment especially in terms of FDI (100% FDI allowed) has helped.
- Presence of global lead firms. Andhra Pradesh MedTech Zone (APMTZ) has shown the way in MD Park.
- Huge untapped market and Scope for import substitution.
- Increasing number of health technology start-ups and Presence of MD clusters.

7.1.2 Weakness

- Low investment in R&D
- Import dependency
- Lack of affordable and trained staff in various fields
- Lack of dependable raw material and parts provider
- Lack of enough affordable service provider for export documentation
- Challenges in exporting – limited knowledge of approvals in countries of export, lack of incentive for exports, limited support for participation in international trade shows and export marketing tours; as suggested by some firms
- Lack of branding in R&D and targeted products

7.1.3 Opportunities

- PLI, MD Park, PMP, Purchase Policy, FDI Policy and various other schemes of the Union and States
- With the advent and continued implementation of Ayushman Bharat, increase in medical facilities as well as people under insurance coverage will lead to increase in market demand.
- Plenty pf scope for start-ups as established manufacturers willing to outsource as per specialization of start-ups.
- Government very keen to support and promote the Indian medical device manufacturing and demonstrating policy flexibility and willingness to adapt the policies as per the requirement.

7.1.4 Threats

- Aggressive investments in R&D by competing nations
- Lack of global presence

7.2. Way Forward

7.2.1 Vision

Vision@2047 is to ensure that India has a strong, fair, competitive, and green industry that derives its strength from digital transformation of healthcare, well functional integrated supply chains, and an approach that caters to the entire lifecycle Medical Devices products, right from production to distribution, consumption, and disposal, in a responsible manner.

The strategy is to derive maximal dividend from our Medical Devices sectors by bridging the gaps and facing the challenges for becoming a recognized centre for high value production and quality research. The Vision@2047 has been divided into three tenures viz. Near term (FY 2022 – 2027), Medium term vision (FY 2027 – FY 2037), Long term (FY 2037 – FY 2047).

7.2.2 Objectives

The objectives are:

- Establish 50 Medical Devices Clusters/Parks
- Focus on with AI & ML in Pharma & MD
- Do 10-12 innovation every year
- Introduce innovative pricing framework
- Increase spending by Government to enhance opportunities in research projects

- Enable recruitment of international faculty and international collaboration for strengthening expertise in
- Funding of research projects of high-risk nature through development of dedicated institutes for high priority areas like NCDs
- Position India as originator of tech such as Robotics, 4D, Organ Bioprinting, Laser Physics, etc.

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