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Government of India

AMTZ

MAKE IN INDIA

Medical Device

Manufacturing in India - A Sunrise

Medical Device Manufacturing in India - A Sunrise

Disclaimer

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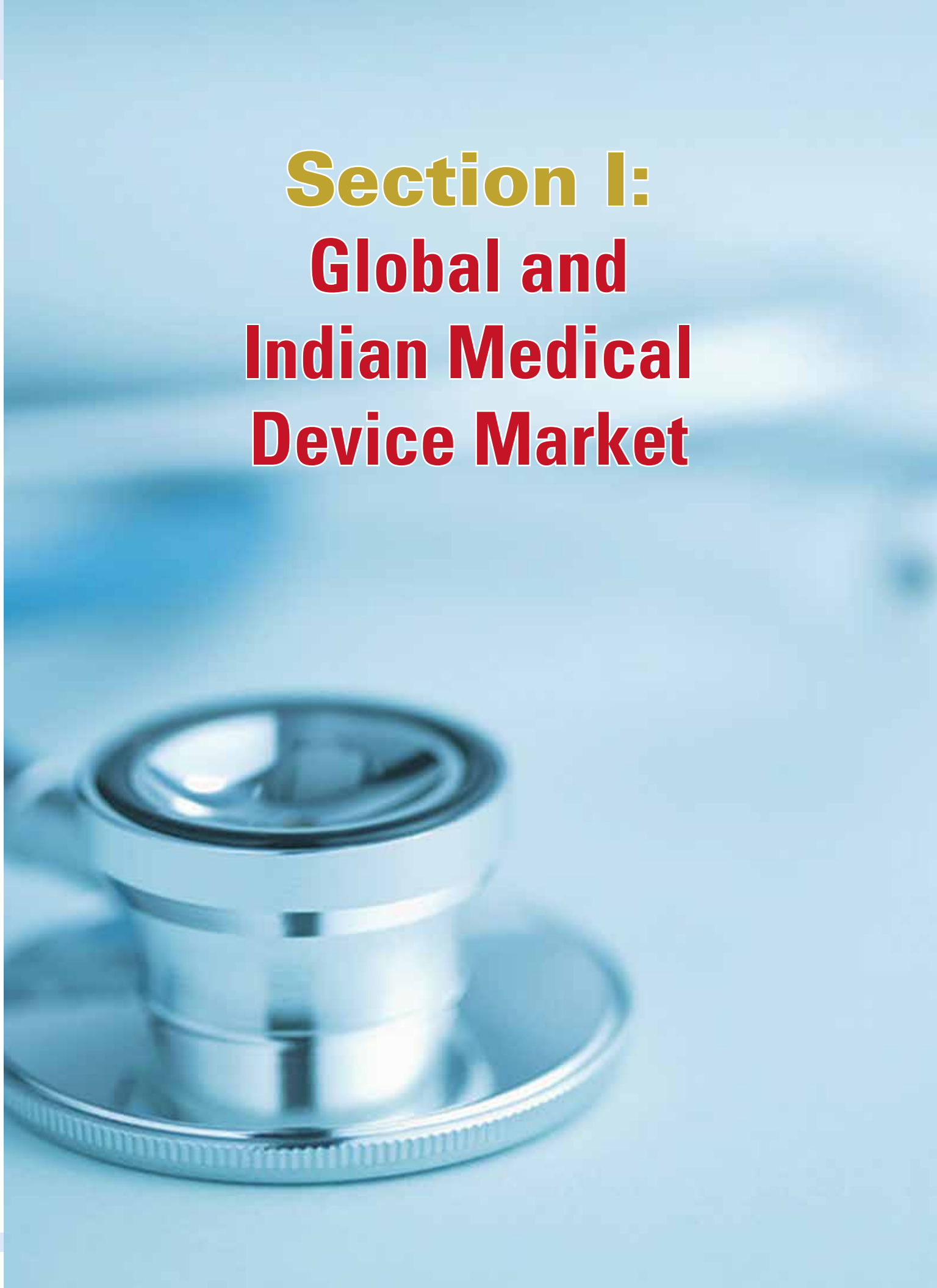
List of Abbreviations

AIMED	Association of Indian Medical Device Industry
AMTZ	Andhra Pradesh MedTech Zone
bn	Billion
CAGR	Compounded Annual Growth Rate
Cardiac/ Cardio	Cardiac Science (Cardiology and Cardiac Surgery)
CDSCO	Central Drugs Standard Control Organization
CSSD	Central sterlized services department
CT	Comuted Tomography
CVD	Countervailing Duties
DoP	Departent of Pharmaceuticals
EEG	Electroencephalography
FDI	Foreign Direct Investment
FY	Financial Year
GMP	Good Manufacturing Practices
GoI	Government of India
Govt.	Government
ICMED	Indian Certification of Medical Devices Scheme
INR	Indian National Rupee
ISO	International Organization of Standardization
IT	Information Technology
IV	Intravenous therapy
JCI	Joint Commission International
M&A	Mergers & Acquisition
mn	Million
MRI	Magnetic Resonance Imaging
MSME	Ministry of Micro, Small and Medium Enterprises
NA	Not Available/ Not Applicable
NABH	National Accreditation Board for Hospitals and Healthcare Providers
NABL	National Accreditation Board For Testing And Calibration Laboratories
NMDA	'National Medical Device Authority
Ortho	Orthopaedic
PCNL	Percutaneous nephrolithotomy
PE	Private Equity
PPP	Public Private Partnership
QCI	Quality Council of India
R&D	Reasearch & Development
SAARC	South Asian Association for Regional Cooperation
SAD	Special Additional Duty
SEZ	Special Economic Zone
USA	United States of America
USD	United States Dollar
USG	Ultrasonograph
WHO	World Health Organization



Section I:
Global and Indian Medical Device Market

1 - Medical Device Market

1.1 Medical Device Market Size – Global

- The global medical device market was estimated at USD 228 bn in 2015 (INR 14.82 lakh crores).
- Industry estimates suggest that the global medical device market will grow at a CAGR of 7.8% from 2010 to 2020.
- The market is expected to reach USD 332 bn (INR 21.58 lakh crores) by 2020[1].

Global Medical Device Market Size

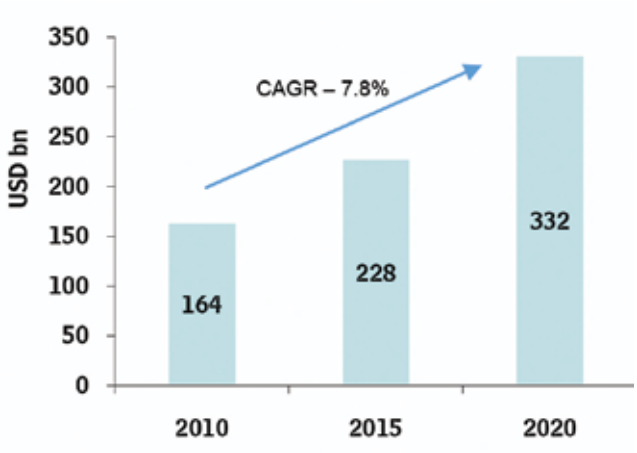


Figure 1: Global Medical Device Market Size

1.2 Global Medical Devices Market

- The global medical device market is categorized mainly into seven segments as listed below. The major equipments included under each of these segments have been detailed in Table.1. High Potential Segments in India.
  - Diagnostic imaging
  - Orthopedic and prosthetic devices
  - Patient aids
  - Consumables
  - Dental products
  - IV diagnostics
  - Others
- Diagnostics imaging is the largest segment constituting 26% of the medical device market, with an annual sales estimate of USD 60 bn (INR 3.85 lakh crores) in 2015.

Segment Wise Medical Device Sale Globally (2015)

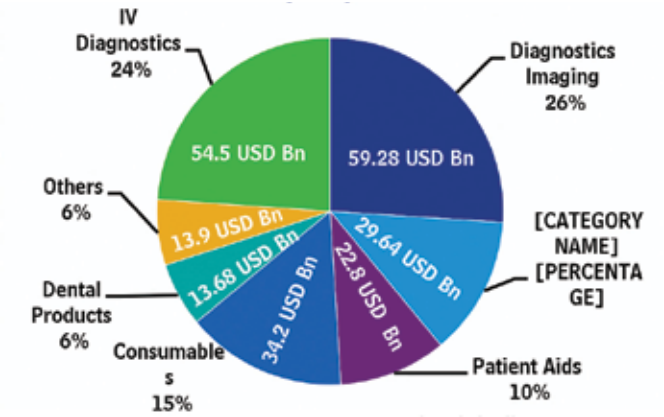


Figure 2: Segment-wise sale globally

1 Analysts: Device market growth will outpace pharma by 2018, http://www.fiercebiotech.com/medical-devices/analysts-device-market-growth-will-outpace-pharma-by-2018, Cunningham, Dolan, et al, Medical Device Sectoral Overview, Whitaker Institute and NUI, Galway, April 2015, http://galwaydashboard.ie/publications/medical-sector.pdf, (accessed on 10th July 2015), Opportunities, Ecosystems & Roadmap to Innovations in the Health Sector, Report of Sector Innovation Council for Health, NHSRC, KPMG Analysis

- IV Diagnostics is the second largest segment with an estimated 24% share at approximately USD 54.5 bn (INR 3.54 lakh crores).
- Dental products including dental implants, dental chairs and equipment account for the smallest share of USD 13.68 bn (INR 88,920 crore)[1].

Table 1: Share of Medical Device Segments Globally

Medical Device Segments	USD bn (2015)	INR crs (2015)
Diagnostics imaging	59.28	3,85,320
IV diagnostics	54.5	3,54,250
Orthopedic and prosthetic devices	29.64	1,92,660
Consumables	34.2	2,22,300
Patient aids	22.8	1,48,200
Others	13.9	90,350
Dental products	13.68	88,920

- Americas (both North and South) is the largest medical device market globally at 45% of the total global medical device sale.
- Western Europe is the second largest market at 27% of the total global medical device sale
- Asia is the third largest market at 21% of the total global medical device sale[1].

Geography Wise Sale of Medical Devices (2015)

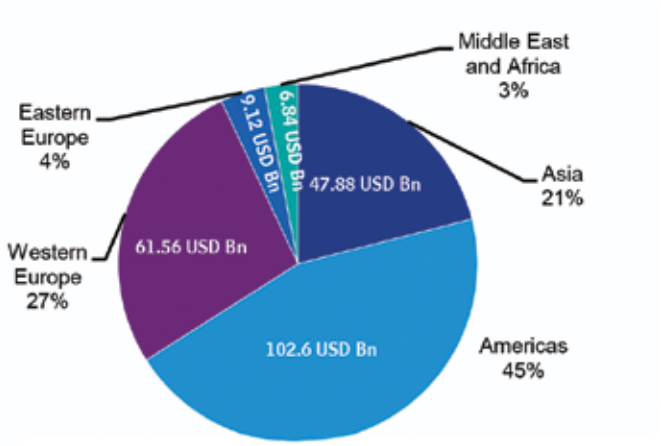


Figure 3: Top Medical Device Markets Globally

Table 2:

Geography	USD Bn (2015)	INR Cr.(2015)
Americas	102.6	6,66,900
Western Europe	61.56	4,00,140
Asia	47.88	3,11,220
Eastern Europe	9.12	59,280
Middle East and Africa	6.84	44,460

Geography-wise medical device market

- It is estimated that 65-70% of the total global medical device market is driven by 20 global medical device companies[2].

2 Cunningham, Dolan, et al, Medical Device Sectoral Overview, Whitaker Institute and NUI, Galway, April 2015 (http://galwaydashboard.ie/publications/medical-sector.pdf, (accessed on 10th July 2015)

1.3 Indian Medical Device Market

- The Indian medical device market has grown from USD 2.02 bn (INR 13,130 Crores) in 2009 to USD 3.9 bn (INR 25,259 Crores) in 2015 at CAGR of 15.8%[3]. This accounts for approximately 1.7% of the global medical device market in 2015[3].
- The Indian Medical Device market contributes to 4% of the Indian healthcare market which is pegged at USD 96.7 bn (INR 6.29 Lakh Crores), in 2015[4].
- The industry estimate suggests that the Indian medical device market will grow to USD 8.16 bn (INR 53,053 crore) in 2020 at CAGR of 16%[4].

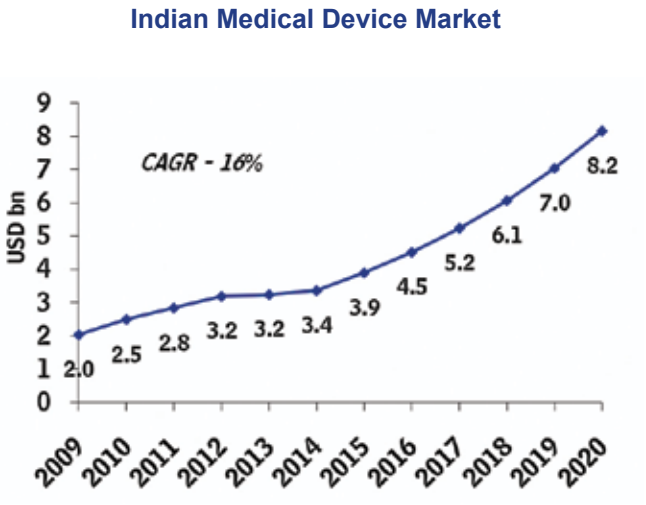


Figure 4: Indian Medical Device Industry Market Size

- India is one of the top 20 global medical device markets and the 4th largest medical device market in Asia[5].

1.4 Medical Device Segments – India

Diagnostic imaging is the largest segment within Indian medical device market in 2015. It constitutes USD 1.18 bn (INR 7,650 crores)[3] in 2015 and will grow to USD 2.47 bn (INR 15,561 Crores)[3] in 2020.

- Others and IV diagnostics[6] comprise largely of electrical and electronic devices. The others category (patient monitors, ECG machine, Defib, etc) is estimated at USD 0.94 Bn (INR 5,922 Crores) in 2015 and will grow to USD 1.98 Bn (12,880 Crores)[3] in 2020. Similarly, the IV diagnostics market constituted of USD 0.39 bn (INR 2,550 crores) in 2015 and will reach USD 0.82 bn (INR 5,356 Crores) in 2020.

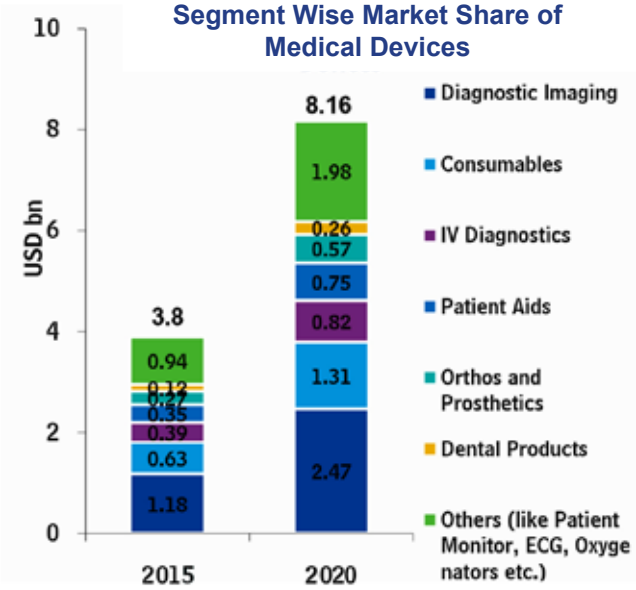


Figure 5: Segment-wise Market Share

3 Espicom, India Medical Devices Report 2016, KPMG Analysis
4 KPMG- AMTZ Analysis
5 Draft National Medical Device Policy, 2015, Department of Pharmaceuticals, GoI
6 IV diagnostics comprises of medical equipment and reagents used for laboratory purposes

- Similarly, Orthopedics & Prosthetics and Consumables will grow from a cumulative USD 0.90 bn (INR 5,850 crores) in 2015 to USD 1.88 bn (INR 12,220 crores)[3] in 2020.
- Dental products and Patient Aids will grow from a cumulative USD 0.47 bn (INR 2,961 Crores)[3] in 2015 to USD 1.1 bn (INR 6,930 Crores) in 2020.

1.5 Growth Factors Driving the Medical Device Demand in India

The various factors are driving the demand of medical device in India as mentioned below.

Growing Population

- India had a population 1,210 mn in 2011 which is growing at a rate of 1.2 per cent per year and will reach ~1360 mn in 2021[7]. The growing population will drive the demand for healthcare services and this in turn will drive the demand for medical devices in India.

Ageing Population

- Out of total population in 2011, the share of aged population (65 years) was 5.3% and is expected to increase to 6% of the total population in India by 2021[7]. The increasing aged population will drive the demand for better healthcare services and medical devices.

Increasing Disease Burden of Chronic Diseases

- Non-communicable diseases like cardio vascular diseases, cancer, diabetes, and other, are expected to comprise more than 75% of India's disease burden by 2025, compared to 45% in 2010[8]. The chronic diseases will drive the demand for healthcare services with basic and advanced medical devices and technology.

Increasing Health Insurance Penetration

- The Indian health insurance penetration has increased in the last one decade. The health insurance market was estimated at USD3.9 bn in FY15 and grew at a phenomenal CAGR of 22 per cent from FY08 to FY15[9]. The Indian health insurance market is expected to reach over USD 8 bn in FY 2020, and close to USD 20 bn in FY 2025. The increasing aged population will drive the demand for healthcare services and medical devices.

Growing Medical Tourism

- India has been increasingly attracting medical tourist from across the globe with SAARC countries contributing to maximum inflow. The medical value travel market in India is expected to grow at a CAGR of ~30 per cent from USD 2.8 bn in 2014 to USD 10.6 bn in 2019[8]. The increasing medical tourist flow will drive the demand for quality healthcare services, medical devices and technology.

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7 Census 2011, KPMG – AMTZ Analysis
8 KPMG Knowledge and Industry Estimates
9 IRDA, KPMG Analysis

Demand for Healthcare Infrastructure

- Currently, the healthcare delivery system has an acute shortage of availability of hospital infrastructure. India has an estimated 1.1 beds per 1,000 people, which is well behind the 3.5 beds per 1000 people recommended by the WHO[10]. The healthcare delivery system will need additional 3.6 mn beds to reach the recommended capacity. The demand for additional beds will drive the demand for medical devices.
- The government has announced a plan in July 2015 to have a medical college in every district. Additionally, five new AIIMS are proposed to be set up in J&K, Punjab, Tamil Nadu, Himachal Pradesh and Assam, and one AIIMS like institute to be set up in Bihar. This is significantly bound to increase the demand for medical devices, considering ~30% of the total project cost is constituted by medical devices.

Emerging Healthcare Service Formats

- In the last two decade the healthcare provider segment in India has witnessed increased number of private players setting up chain of hospitals, diagnostic centres and specialized care facilities. Increasing focus of Indian private healthcare providers on Tier II and Tier III cities will drive the demand for medical devices.
- Emerging new formats in healthcare services like single specialty facilities, home care, dental chain, diagnostic chain, dialysis centers, day care surgical centers, and others. The emergence of new formats in healthcare has provided boost to the medical device sector in India.

Quality and Accreditation of Hospiatals as par with International Standards:

- In India, around 393 hospitals have received the NABH accreditation in the last decade[11]. Apart from the NABH accreditation, India has more than 20 JCI accredited healthcare facilities. The adoption of national and international quality accreditation system has increased focus on medical device maintenance and up-gradation of technology.

10 WHO
11 NABH

1.6 Existing & Proposed Medical Device Clusters in India

Over the years, various medical device clusters have emerged across the country. Some of the key states housing Indian and multinational medical device players are illustrated below[12].

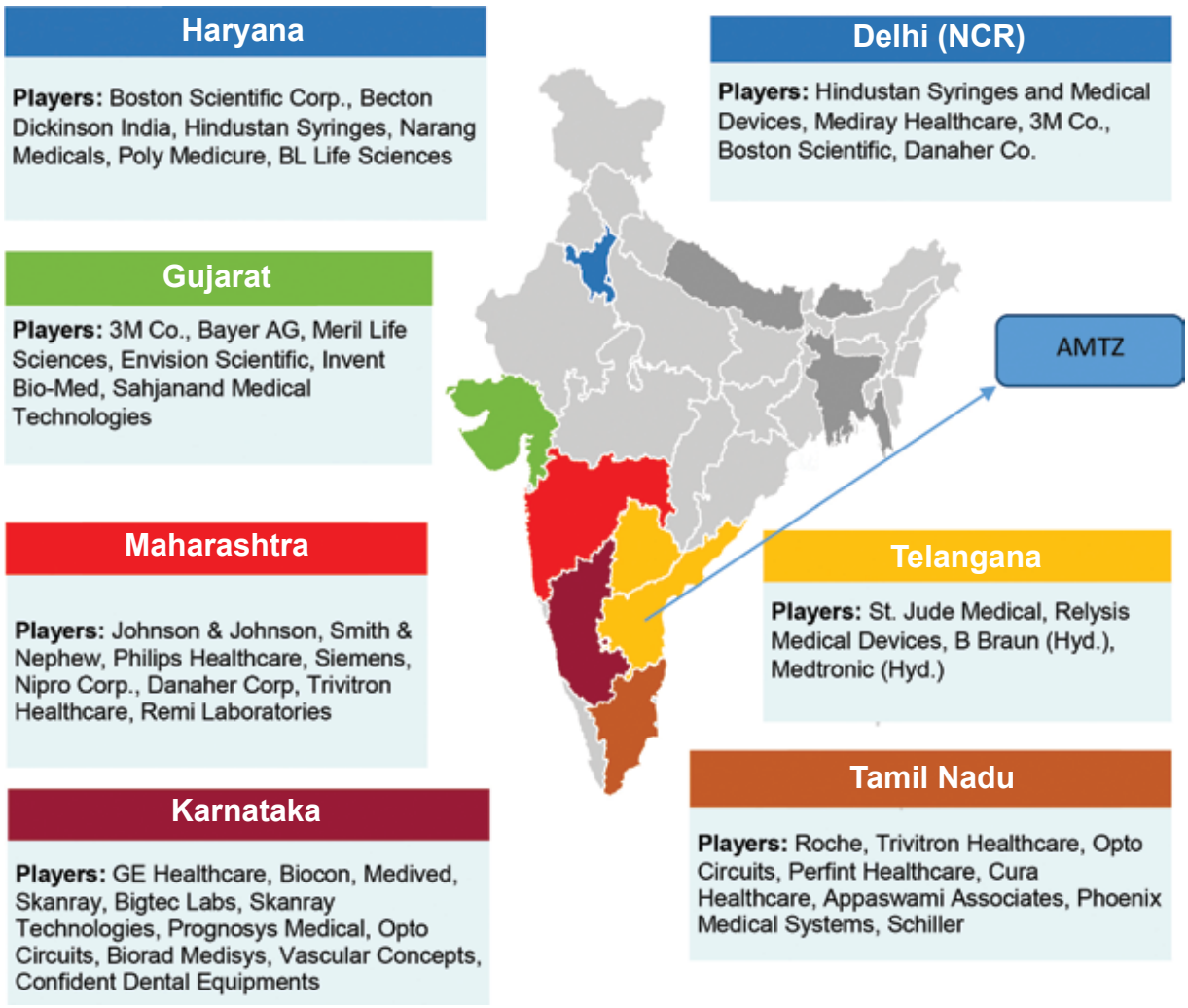

Figure 6: Medical Device Clusters in India

Source: KPMG- AMTZ Analysis

12 FICCI Medical Device Sector Profile

1.7 Import and Export Trend in Indian Medical Device Market

Import and Export Trade in the Last 5 years

- The import of medical devices has grown from USD 2.46 bn (INR 15,990 crores) in FY12 to USD 2.87 bn (INR 18,655 crores) in FY16[13].
- The export of medical devices has grown from USD 0.78 bn (INR 5,070 crores) in FY12 to USD 0.98 bn (INR 6,370 crores) in FY16[13].
- Between FY12 to FY16, the import trade of medical devices has increased by 16.8 per cent, whereas export trade has increased by 25.7 per cent[13].

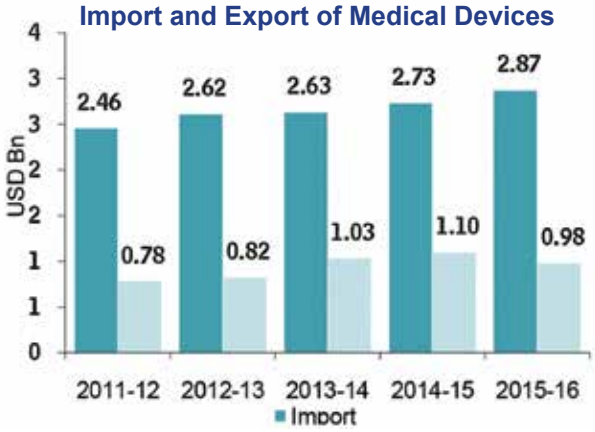

Figure 7: Import & Export of Medical Devices in India

Import Trade of Medical Device

- The total import of medical devices is more than 75 per cent of total medical devices sales in India[13], however it is estimated that import trade will fall with increasing number of international and Indian manufacturer setting up medical device manufacturing set up in India.

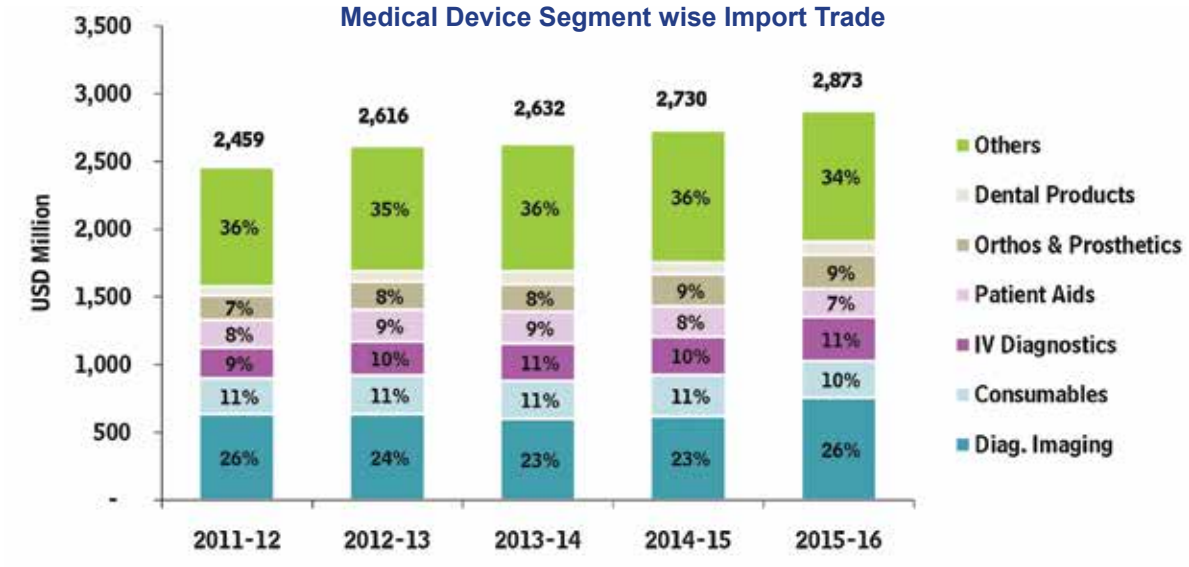

Figure 8: Import Trade of different segments in the medical device market

- Diagnostic imaging (e.g. CT scan, X-Ray, MRI, USG, X ray-tubes etc.), IV Diagnostic (lab equipment and reagents, etc.) and Other Medical Device (ECG, opthal equipment, heart lung machine, etc.) form 70% of total import in India in FY16[13].

13 Directorate General of Foreign Trade

- USA, Germany, China, Japan, and Singapore constitute the five largest exporters of high technology medical equipment to India. In FY 2015 imports alone from these five countries accounted for approximately 65 per cent of total import of high technology medical equipment while USA, remained the largest exporter accounting for 28.1 per cent[13].

Table 3: Share of Medical Device Segments Globally

USD Mn

Segments/Year	2011-12	2012-13	2013-14	2014-15	2015-16
Diagnostic Imaging	636	638	602	620	757
Consumables	266	286	280	306	273
IV Diagnostics	225	250	277	281	322
Patient Aids	203	236	232	227	210
Orthos & Prosthetics	184	204	204	234	249
Dental Products	67	77	97	89	98
Others	878	926	941	974	964
Total	**2,459**	**2,616**	**2,632**	**2,730**	**2,873**

- Diagnostic imaging medical device import trade has grown by 19% from USD 636 mn (INR 4,134 Crores) in FY12 to USD 757 mn (INR 4,921 Crores) in FY 16[13].
- IV Diagnostic medical device import trade has grown by 43.2% from USD 225 mn (INR 1,463 Crores) in FY12 to USD 322 mn (INR 2,093 Crores) in FY 16[13].
- Other Medical Device (e.g. ECG, opthal equipment, heart lung machine, etc.) has grown by 9.6% from USD 878 mn (INR 5,707 Crores) in FY12 to USD 964 mn (INR 6,266 Crores) in FY 16[13].

Export Trade of Medical Device

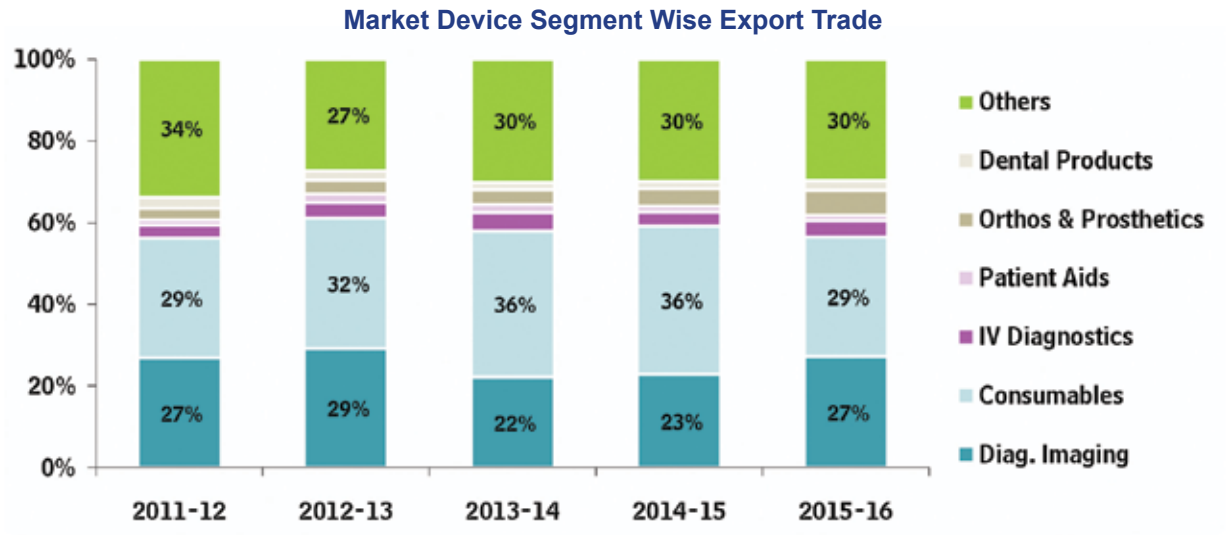

Figure 9: Export Trade of different segments of medical device market

- Diagnostic imaging, consumables and other medical devices form 86 per cent of total export trade in India in FY16[13].
- Amongst the exporters' portfolio, USA was the chief destination for export and contributes close to 15 per cent of the export trade. Singapore, Germany and China were the other leading export destinations with shares of 7.0 per cent, 6.7 per cent and 6.4 per cent respectively. The European Union (incl. Germany) cumulatively constitutes of 21.7 per cent of the total export trade[13].

Table 4: Segment-wise export trade of medical devices

USD mn

Segments	2011-12	2012-13	2013-14	2014-15	2015-16
Diagnostic Imaging	210	241	229	250	267
Consumables	228	263	371	399	288
IV Diagnostics	24	31	45	37	39
Patient Aids	11	17	21	16	13
Ortho. & Prosthetics	22	28	38	48	59
Dental Products	21	19	18	19	23
Others	264	225	312	329	292
Total	**781**	**825**	**1,035**	**1,097**	**983**

- Diagnostic imaging medical device export trade has grown by 27.2 per cent from USD 210 mn (INR 1,365 Crores) in FY12 to USD 267 mn (INR 1,736 Crores) in FY16[13].
- Medical Consumables export trade has grown by 26.1 per cent from USD 228 mn (INR 1,482 Crores) in FY12 to USD 288 mn (INR 1,872 Crores) in FY16[13].
- IV Diagnostic devices export trade has grown by 58.7 per cent from USD 24 mn (INR 156 Crores) in FY12 to USD 39 mn (INR 254 Crores) in FY16[13].
- Ortho and prosthetics export trade has grown by 173.8 per cent from USD 22 mn (INR 143 Crores) in FY12 to USD 59 mn (INR 384 Crores) in FY16[13].
- Patient Aids export trade has grown by 20.9 per cent from USD 11 mn (INR 72 Crores) in FY12 to USD 13 mn (INR 85 Crores) in FY16[13].

1.8 High Potential Manufacturing Segments in India

An Evaluation of factors such as import dependency, existing manufacturing capabilities and share of the segments in the overall medical device market in India was undertaken. Based on this, segments having high potential for investments for medical device manufacturing in India has been identified as below:

Table 5: High Potential Segments in India

Key Segment	Sub-segment	% of Import dependency[14]	Share of the overall Medical Device market	Overall attractiveness for Indian Manufacturers to invest in this segment
Consumables	Cardiac Catheter, Other needle, Syringe, Lab reagent, Suture, Strips & cartridge, Dialysers and Filters, cannula	35%	16%	High
Dental Product	Dental Implant, Artificial teeth, Dental instruments	60%	3%	Medium
Diagnostic Imaging	X-Ray tubes, USG Probe, Radiation beam delivery system, Radiation generator unit, CT Scan, MRI, PET Scan, ALPHA, BTA/GMA Radiation for other use in radiography equipment	52%	30%	Very High
IV Diagnostics	Lab reagent & accessories	67%	10%	High
Orthopaedic & Prosthetics	Artificial joints & joint implants	62%	8%	High
Others	Artificial dialysis apparatus & haemodialyser, defibrillator, Lithotripsy equipment, ECHO, EEG, ECG, anesthesia equipments, Laparoscope, endoscope	83%	24%	Very High
Patient Aids	Pacemaker, Hearing aid, Cochlear implant, Stents	50%	9%	Medium

It was identified that segments for Diagnostic Imaging and Other medical devices have Very High potential, while IV Diagnostics, Orthopaedic & Prosthetics and Consumables have High potential.

14 % of Import dependency is defined as Import of the Segment/Market Share of the Segment

1.9 Foreign Direct Investment and Other Investment in Indian Medical Device Sector

Foreign Direct Investment in the Last 5 years

- FDI in medical devices has grown by 25.4 per cent from USD 131.4 mn in FY12 to USD 164.7 mn in FY16[15].
- In January 2015, Government of India modified the FDI regulations allowing 100 per cent FDI under automatic route in Greenfield and brownfield projects in medical device sector.
- USA, Europe and Japan are the key source countries for FDI in medical devices.
- The equipment and instruments, consumables and implants segments have attracted the most FDI.

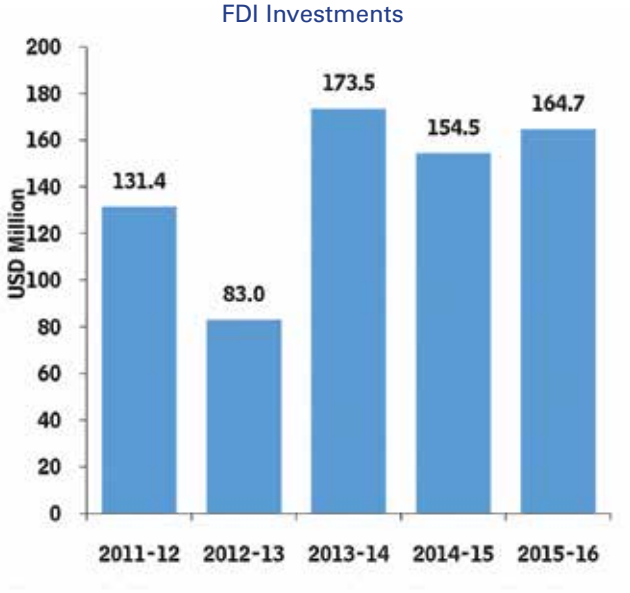

Figure 10: FDI Investments in the Indian Medical Device Sector

Source: Department Of Industrial Policy & Promotion, GoI,

Merger and Acquisition, Venture Capital and Private Equity Investment in Medical Device

Table 6: Deals in medical device sector in India

Year		Merger and Acquisition (USD mn)	PE/ VC/ Angel Funding (USD mn)
2010	No. of deals	7	3
	Value	90.6	14.7
2011	No. of deals	5	2
	Value	0.9	4.5
2012	No. of deals	8	14
	Value	26.6	162.2
2013	No. of deals	4	13
	Value	40.2	125.0
2014	No. of deals	2	9
	Value	4.9	27.9
2015	No. of deals	1	2
	Value	NA	7.5
Total	No. of deals	27	43
	Value	163.2	341.8

15 Department Of Industrial Policy & Promotion, GoI.

- The Indian medical device sector has received an investment of USD 505 mn from 27 M&A transactions and around 43 venture capital/ private equity investment in last five years[16].
- The Equipment and Instruments and Consumables segments attracted the majority of M&A and PE investments.

List of Key Merger and Acquisitions in Indian Medical Device Sector

Table 7: M&A in medical device sector in India

Date	Target	Buyer	Particulars	M&A Type	Deal Value (USD mn)	Country
Mar-10	MNE Technologies Pvt. Ltd.	Ital TBS SpA	Integrated development of technology (in both IT and telematics)	Inbound	8.5	India
Apr-10	NS Remedies Pvt. Ltd.	Opto Circuits India Ltd.	Manufactures invasive and non-invasive peripheral vascular devices	Domestic	1.5	India
May-10	Techtran Polylenses Ltd.	Credence Infrastructure Ltd.		Domestic	1.2	India
Jul-10	Unetixs Vascular Inc.	Opto Circuits India Ltd.	Manufactures invasive and non-invasive peripheral vascular devices	Outbound	9.7	USA
Sep-10	IVAX Diagnostics Inc.	Erba Diagnostics Mannheim GmbH	Laboratory equipmets - Hematology, Immunoassey, Electrolyte analyzer	Outbound	15.0	USA
Oct-10	Cardiac Science Corp.	Opto Circuits India Ltd.	Manufactures invasive and non-invasive peripheral vascular devices	Outbound	54.8	USA
Dec-10	Janak Healthcare Pvt. Ltd.	Midmark Corporation	Procedure chair,Power procedure table, ECG, Holter,	Inbound	NA	India
Jan-11	Diasis Diagnostic Systems Inc.	Erba Diagnostics Mannheim GmbH	Laboratory equipmets - Hematology, Immunoassay, Electrolyte analyzer	Outbound	NA	Turkey
Apr-11	Span Diagnostics Ltd., Hematology Analyser Business	Nihon Kohden India Pvt. Ltd.	Storage of oocytes, embryos and blastocysts, fertilization, culture and transfer,Culture medium, micropipets, ICSI (Intracytoplasmic Sperm Injection)	Domestic	0.9	India
Jun-11	Techtran Ophthalmics Pvt. Ltd.	Credence Infrastructure Ltd.	Hearing aids	Domestic	NA	India
Jul-11	Kiran Medical Systems Ltd.	Trivitron Healthcare Pvt. Ltd.	Biochemical analyzers, hematology analyzers, immunology analyzers, allergy and food intolerance products, antiphospholipid syndrome products, and infection and autoimmune disease products	Domestic	NA	India
Nov-11	John Fowler Ophthalmics Pvt. Ltd.	Barwale Group	Laboratory equipmets	Domestic	NA	India
Mar-12	Trivector Origio Scientific Pvt. Ltd.	Origio A/s	Laboratory equipmets	Inbound	4.4	India
Apr-12	Otic Hearing Solutions Pvt. Ltd.	William Demant Holding A/S	Patient Monitoring Systems, High-frequency X-ray devices, Electro-surgical units, Anaesthesia workstations, ICU Ventilators, Syringe pumps, Dental and Critical care devices	Inbound	NA	India

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Date	Target	Buyer	Particulars	M&A Type	Deal Value (USD mn)	Country
Sep-12	Maxmat S.A.	Erba Lachema S.R.O.	Ultrasound systems, In-Vitro Diagnostic reagents, Molecular Diagnostic products, Hemodialysis systems, Implantable medical devices, New Born screening Kits	M&A	NA	France
Oct-12	Drew Scientific Inc	Transasia Bio-Medicals Ltd.	Ultrasound systems, In-Vitro Diagnostic reagents, Molecular Diagnostic products, Hemodialysis systems, Implantable medical devices, New Born screening Kits	Outbound	NA	USA
Oct-12	JAS Diagnostics Inc.	Transasia Bio-Medicals Ltd.	Conceptualization and designing of a new plant, as well as existing plant, to its construction, and also setting up manufacturing facilities to its commissioning	Outbound	NA	USA
Nov-12	Larsen and Toubro Ltd., Medical Equipment Business	Skanray Healthcare Pvt. Ltd.	Advanced Wound Management, Orthopaedic Reconstruction, Trauma & Extremities implant	Domestic	NA	India
Nov-12	Labsystems Diagnostics OY	Trivitron Healthcare Pvt. Ltd.	Introducer sheaths, Coronary catheters, ,Guiding sheaths , Guidewires, Guide wires, Microcatheters, Embolics	Outbound	22.2	Finland
Dec-12	Star Trivitron	Trivitron Healthcare Pvt. Ltd.	Patient Monitoring Systems, High-frequency X-ray devices, Electro-surgical units, Anaesthesia workstations, ICU Ventilators, Syringe pumps, Dental and Critical care devices	Outbound	NA	U.A.E
Mar-13	Raaj Medisafe India Ltd.	Sushen Remedies Pvt. Ltd.	Latex Gloves	Domestic	0.0	India
May-13	Adler Mediequip Pvt. Ltd.	Smith and Nephew Plc	Ultrasound systems, In-Vitro Diagnostic reagents, Molecular Diagnostic products, Hemodialysis systems, Implantable medical devices, New Born screening Kits	Inbound	23.2	India
Jul-13	Terumo Penpol Ltd.	Terumo Corporation	Procedure chair, Power procedure table, ECG, Holter,	Inbound	17.0	India
Nov-13	Pricol Engineering Industries Ltd., Healthcare Business	Skanray Technologies Pvt. Ltd.		Domestic	NA	India
Oct-14	Kiran Medical Systems Ltd.	Trivitron Healthcare Pvt. Ltd.	Digital radiography systems, mobile computed radiography systems, HF X-ray systems, X-ray tables and accessories. Patient monitoring systems, defibrillators, ECG, Stress Test systems and pulse oximeters.	Domestic	NA	India
Dec-14	Janak Healthcare Pvt. Ltd.	Midmark Corporation	Integrated development of technology (in both IT and telematics)	Inbound	NA	India
Jul-15	Tuscano Equipments Pvt. Ltd.	Cura Healthcare Pvt. Ltd.	Manufactures invasive and non-invasive peripheral vascular devices	Domestic	NA	India

Source: VCCedge, 2016

- Indian medical device sector has witnessed around 7 inbound, 8 outbound and 13 domestic merger and acquisition tractions in the last five years[16].
- Opto Circuits India Private Ltd., Transasia Bio-Medicals Ltd., Trivitron Healthcare Private Ltd. and Skanray Healthcare Pvt. Ltd. are the leading players with more than one merger and acquisitions deal in the last five years.

List of Private Equity Funding in Indian Medical Device Sector

Table 8: Private Equity Funding in medical device sector in India

Date	Target	Buyer / Lender	PE Type	Deal Value (USD mn)	Particulars
Oct-12	Trivitron Healthcare Pvt. Ltd.	Fidelity Growth Partners India	PE	74.11	The company was founded in 1997 and is based in Chennai, Tamil Nadu. Manufactures diagnostic imaging, IV diagnostics, molecular diagnostic products, hemodialysis machines, new born equipment, implant, etc.
Sep-12	Sutures India Pvt. Ltd.	CX Partners Fund I	PE	38.42	The company was founded in 1997 and is based in Chennai, Tamil Nadu. Manufactures diagnostic imaging, IV diagnostics, molecular diagnostic products, hemodialysis machines, new born equipment, implant, etc.
Nov-13	Trivitron Healthcare Pvt. Ltd.	India Value Fund IV	PE	24.62	The company was founded in 1997 and is based in Chennai, Tamil Nadu. Manufactures diagnostic imaging, IV diagnostics, molecular diagnostic products, hemodialysis machines, new born equipment, implant, etc.
Sep-13	Lotus Surgical Specialties Pvt. Ltd.	Samara Capital Partners Fund II Ltd.	PE	24.21	Manufacturing and supplying medical consumables. The company was founded in 2005 and is based in Mumbai, Maharashtra.
Mar-13	Sutures India Pvt. Ltd.	TPG Capital Inc.	PE	22.53	Manufacturing of suture products and consumables. The company was founded in 1992 and is based in Bengaluru, Karnataka.
May-13	BPL Medical Technologies Pvt. Ltd. (subsidiary of BPL Ltd.)	Goldman Sachs PE Group	PE	21.56	Manufacturing of medical equipment. Its products include electrocardiographs, patient monitors, defibrillators, central nursing stations, stress test systems, oxygenators, ultrasound scanners, colposcopes, foetal monitors, foetal Doppler and X-Rays. The company was founded in 2012 and is based in Bengaluru, Karnataka.
Aug-13	Skanray Technologies Pvt. Ltd.	Ascent India Fund III	PE	11.4	Manufacturing medical equipment like high frequency x-ray imaging systems, critical care device, etc. The company was founded in 2007 and is based in Mysore, Karnataka.
Dec-12	Perfint Healthcare Pvt. Ltd.	Norwest Venture Partners X LP	VC	11.04	Manufacturing medical devices CT guided robotic positioning system (ROBIO ex) and automated device for planning, execution and confirmation of targeted tumor ablation therapy ((MAXIO). The company was founded in 2005 and is based in Chennai, Tamil Nadu.
Dec-14	Total Prosthetics and Orthotics India Pvt. Ltd.	India Life Sciences Fund II LLC	VC	10	Product line include orthotic, prosthetic and orthopedic rehabilitation, lower limb prosthetics, upper limb prosthetics, fracture bracing, foot care products and central fabrication. The company was founded in 2005 and is based in Gurgaon, Haryana.

Date	Target	Buyer / Lender	PE Type	Deal Value (USD mn)	Particulars
Jan-12	Cura Healthcare Pvt. Ltd.	Peepul Capital III LLC	VC	8.86	Manufacturing and supplying of medical equipment include digital radiography, computerized radiography and mammography systems. The company was founded in 2001 and is based in Chennai, Tamil Nadu.
Dec-13	Forus Health Pvt. Ltd.	IDG Ventures India Fund, Accel India III LP, Asian Healthcare Fund	VC	8.04	Developing, designing and service deployment of healthcare equipment. Its products include 3nethra classic and 3nethra royal. The company was founded in 2010 and is based in Bengaluru, Karnataka.
Apr-12	Insightra Medical Inc.	Aarin Capital Fund I	PE	8	Develops medical devices in the areas of cardiology, surgery, endoscopy, and urology. It offers tissue retractors; catheters, CoCr stents, and rapid exchange coronary dilatation balloons, as well as products for the repair of inguinal hernia. The company is based in California, United States of America.
Jun-10	Perfint Healthcare Pvt. Ltd.	Accel India Venture Fund, IDG Ventures India Fund, Norwest Venture Partners X LP	VC	7.23	Manufacturing medical devices CT guided robotic positioning system (ROBIO ex) and automated device for planning, execution and confirmation of targeted tumor ablation therapy ((MAXIO). The company was founded in 2005 and is based in Chennai, Tamil Nadu.
Mar-10	Mardil Medical Devices Pvt. Ltd.	Biotechnology Venture Fund, VenturEast Life Fund III LLC	VC	6.4	Manufacturing of heart valves etc. The company was founded in 2001 and is based in Hyderabad, Telangana.
Feb-12	Perfint Healthcare Pvt. Ltd.	Accel India Venture Fund, IDG Ventures India Fund, Norwest Venture Partners X LP	VC	6	Manufacturing medical devices CT guided robotic positioning system (ROBIO ex) and automated device for planning, execution and confirmation of targeted tumor ablation therapy (MAXIO). The company was founded in 2005 and is based in Chennai, Tamil Nadu.
Jun-14	Cura Healthcare Pvt. Ltd.	Peepul Capital LLC	PE	6	Manufacturing and supplying of medical equipment include digital radiography, computerized radiography and mammography systems. The company was founded in 2001 and is based in Chennai, Tamil Nadu.

Source: VCCedge, 2016

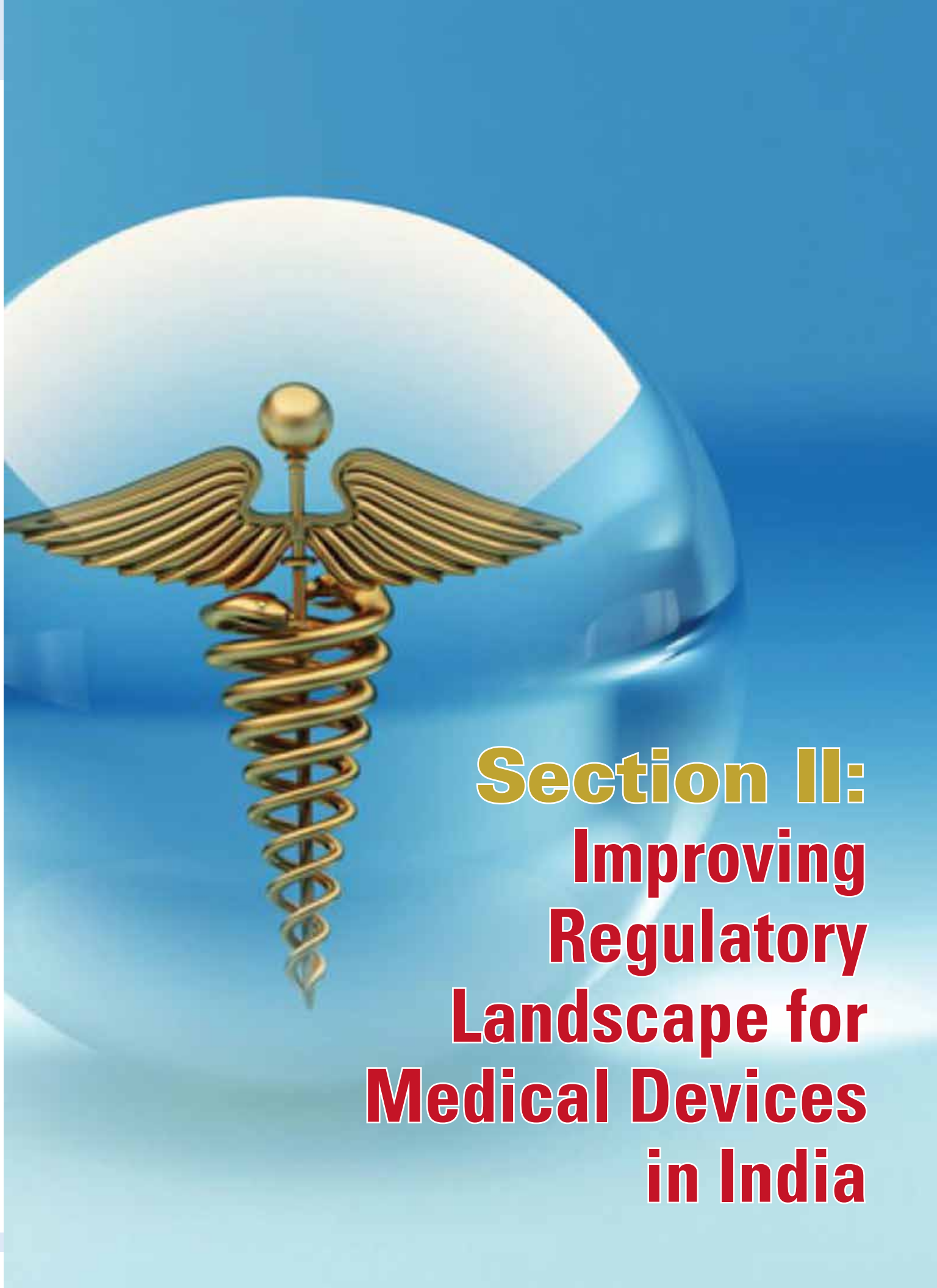
List of Angel / Seed Funding in Indian Medical Device Sector

Table 9: Angel/ Seed Funding in medical device sector in India

Date	Target	Buyer / Lender	Deal Value (USD mn)	Business Description
Mar-12	Biosense Technologies Pvt. Ltd.	Global Super Angels Forum and others private investors	0.15	Manufacturing of diagnostics equipment. It offers ToucHB product which is a noninvasive diagnostic tool for Anemia with patented needle-free haemoglobin measurement system. The company was founded in 2008 and is based in Thane, Maharashtra.
Mar-12	2mpower Health Management Services Pvt. Ltd.	NA	0.06	2mpower Health Management Services Pvt. Ltd. is engaged in developing wearable devices. The company was founded in 2009 and based in Bangalore, Karnataka.
Aug-12	Skanray Technologies Pvt. Ltd.	Arun Kumar	3.00	Manufacturing medical equipment like high frequency x-ray imaging systems, critical care device, primary healthcare and telemedicine compatible devices. The firm also offers primary healthcare, original equipment manufacturing (OEM) and contract manufacturing services. The company was founded in 2007 and is based in Mysore, Karnataka.
May-13	Windmill Health Technologies Pvt. Ltd.	Villgro Innovation Marketing Pvt. Ltd.	NA	Medical equipment like resuscitation device, etc. The company was founded in 2011 and is based in New Delhi, Delhi.
Aug-13	Embrace Innovations Inc	Khosla Impact, Ranjan Ramdas Pai, Steven Lurie	NA	Manufacturing medical devices like infant warmers, etc. The company was founded in 2011 and is based in Bangalore, Karnataka.
Oct-13	OneBreath India Pvt. Ltd.	Villgro, Incubation Center	0.04	Manufacturing medical devices like mechanical ventilator, etc. The company was founded in 2010 and is based in Bangalore, Karnataka.
Jan-14	OneBreath India Pvt. Ltd.	Ventureast Fund Advisors India Ltd., Bodanapu Venkat Ramamohan Reddy, Pierre Omidyar, Rajiv Kuchhal	3.00	Manufacturing medical devices like mechanical ventilator, etc. The company was founded in 2010 and is based in Bangalore, Karnataka.
May-14	2mpower Health Management Services Pvt. Ltd.	Mohandas Pai Tellicheery Venkataraman, Sharad Hegde	NA	2mpower Health Management Services Pvt. Ltd. is engaged in developing wearable devices. The company was founded in 2009 and based in Bangalore, Karnataka.
Jul-15	Wrig Nanosystems Pvt. Ltd.	Binny Bansal, Malvinder Mohan Singh, Sachin Bansal, Shivinder Mohan Singh	2.34	Manufacturing and supplying of medical devices, hemoglobin meter and bio-senser. The firm manufactures minituarising medical devices. The firm offers its product hemometer under the brand name TrueHb. The startup developed a mobile phone-sized device to measure haemoglobin in a few minutes called TrueHb Hemometer. The company was incorporated in 2009 and is based in New Delhi, India.

Source: VCCedge, 2016

- In the last five years around 9 angel/ seed funding deals was witnessed in medical device companies. The most of these funding was received from individual investors[17].
- Medical device players like Onebreath India Pvt. Ltd. and Skanray Technologies Pvt. Ltd. received more than USD 3 mn funding[17].
- Initiatives like 'Start-up India', 'Make in India' and increase in traction of investors in the healthcare and medical device sector will drive the growth of seed/ angel funding in this sector in the coming years.



Section II: Improving Regulatory Landscape for Medical Devices in India

Regulatory Landscape for Medical Devices in India

The Government of India (GoI) has taken various steps to ensure that medical device sector gets its due recognition. While the Indian medical devices sector offers an unrivalled investment and business opportunity, there are certain regulations and policies that play a significant role for the industry in general.

The government formed a task force on medical devices and initiated the process of implementing its various recommendations such as separating medical devices from the definition of 'drugs', and allowing 100 per cent FDI for brownfield and greenfield investments in the sector. Some of the latest initiaves like Make in India and setting up of medical device parks by the GoI will further boost the Indian medical device sector.

Figure 11: Government Support and Initiatives for Medical Device Sector

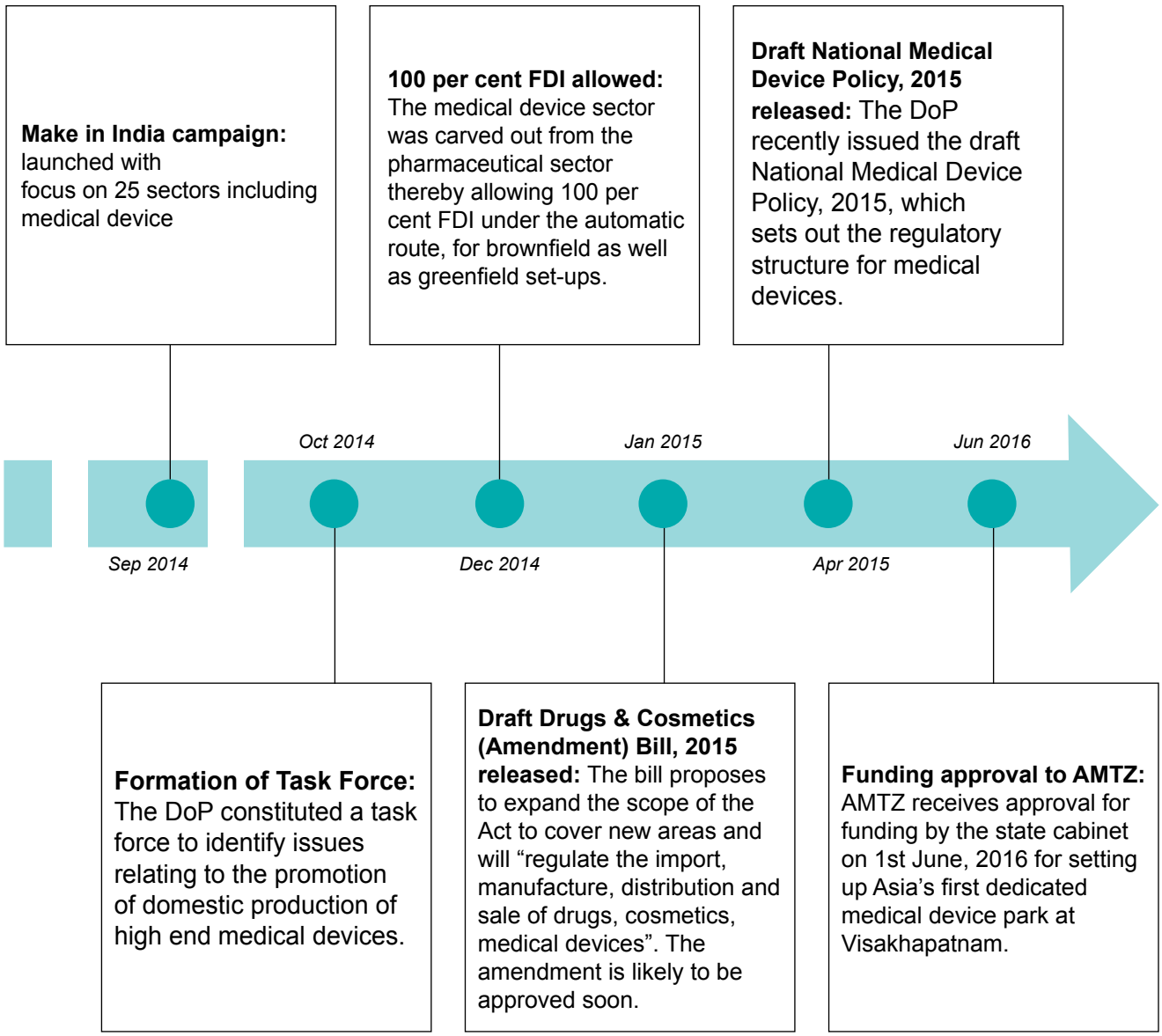


Figure 12: Timeline for Key Government Initiatives Impacting the Medical Device Sector

Materiovigilance Programme of India: The Drug Controller General of India launched the Materiovigilance Programme of India (MvPI) on 6th July 2015 to monitor the safety of medical devices in the country. The scheme is backed by a USD16Mn (INR1.0Bn) budget allocation made by India's central government in 2013 to support four medical surveillance programmes in the country: materiovigilance, pharmacovigilance, biovigilance, and haemovigilance. While the Indian Pharmacopoeia Commission (IPC) will function as the national coordination centre for MvPI, the biotechnology wing of Sree Chitra Tirunal Institute of Medical Sciences & Technology (SCTIMST) will act as National Collaborating Centre for the same. At the same time, the National Health Systems Resource Centre (NHSRC) under the Ministry of Health & Family Welfare will collaborate and work as technical support and resource centre[17]. To begin with, MvPI cells are to be established in 10 medical colleges across the country. The programme will run along the lines of the existing pharmacovigilance and haemovigilance programmes.

The programme aims to monitor medical device-associated adverse events (MDAEs), create awareness among healthcare professionals about the importance of MDAE reporting in India, and monitor the benefit-risk profile of devices. It also intends to generate independent, evidence-based recommendations on the safety of medical devices and to communicate the findings to all key stakeholders. With this view, the adverse events reporting form for medical devices was released in April 2016 after a series of scientific consultations, stakeholder meetings with industry and inputs from scientists and technologists across the country. This programme will help enhance the safety of medical devices and provide evidence-based feedback to the manufacturers on the efficacy of medical devices.

Schedule M-III: In December 2015, the Health Ministry delinked Schedule M-III of the Drugs and Cosmetics Rules (DCR), 1945, which deals with medical devices, from Schedule M, which deals with drugs and pharmaceuticals. This will provide relief to the existing medical device manufacturers who had been arbitrarily inspected so far according to the Schedule M for pharmaceuticals. Moreover, Schedule M-III is aligned to the ISO/IS 13485 standard, an international norm that covers medical devices.[18]

Schedule M-III of the Rules prescribes Good Manufacturing Practices (GMP) and a Quality Management System (QMS), for manufacturing of Notified Medical Devices and In-vitro Diagnostics in India. Every company manufacturing any of the 14 Notified Medical Devices in India has to comply with the QMS provisions of Schedule M-III as a condition of its manufacturing license, else it may lead to cancellation or suspension of the manufacturing license.[19]

In addition the this change, a much broader revision of the existing Drugs and Cosmetics Rules is being worked out by the government, which is further expected to minimise the difficulties faced by medical device industry due to the regulatory linkages the sector has with pharmaceuticals. A system of third-party auditing and certification for medical devices manufactured in India are proposed as a part of this revision.

Significant Experience for Manufacturing Supervisor[18]: The Health Ministry has made it mandatory for the manufacturers of medical devices listed in Schedule C and C1 of the D&C Rules, namely sterilized surgical ligature, sterilized surgical suture, sterile disposable devices for single use only and in-vitro diagnostic devices for HIV, HbsAg and HCV, and those notified by Ministry of Health and Family Welfare, to employ only those whole-time manufacturing supervisors who have considerable experience. Under the old rule, there was no minimum experience prescribed. The table below provides the new minimum experience requirements. This is expected to improve overall quality of manufactoring processes and compliance to good practices.

17 Daily News Monitor, Organisation of Pharmaceutical Producers of India (OPPI), July 10, 2015
18 The Indian Medical Device Industry – Regulatory, Legal and Tax Overview, Nishith Desai Associates, April 2016
19 Draft Schedule M-III – QMS, DoP

Table 10: New minimum experience requirements for Manufacturing Supervisor

Qualification	Minimum experience requirement
Graduate in Pharmacy or Engineering (in appropriate branch)	At least eighteen months practical experience after graduation in manufacturing or testing of devices to which this license applies
Graduate in science, with Physics or Chemistry or Microbiology as one of the subject	At least three years practical experience after graduation in manufacturing or testing of devices to which this license applies
Diploma in Pharmacy or Engineering (in appropriate branch)	At least four years practical experience after graduation in the manufacturing or testing of devices to which this license applies

Drugs and Cosmetic (Amendment) Bill, 2015: Some of the notable amendments/ provisions of this Bill are listed below:

a. The government in the amendment Bill has adopted the Global Harmonization Task Force's (GHTF) definition of medical devices[20].

b. Establishment of regulatory bodies associated with CDSCO such as Ethics Committee, Medical Devices Technical Advisory Board (MDTAB), and a Consultative Committee to advise the Central Government and State Governments on technical matters pertaining to medical devices, and to ensure responsible overseeing of the trials to be formed.

c. Rules pertaining to conducting clinincal trials of medical devices have been developed to safeguard the rights, safety and well-being of all trial participants.

d. Strict legal action/ punishment and penalties have also been introduced for conducting clinical trials without permission or following protocol and manufacturing or sale of spurious/ adulterated/ misbranded medical devices.

Draft National Medical Device Policy, 2015: Some of the prominent provisions/ recommendations of the National Medical Device Policy, 2015 are as under[21]:

a. Creation of an autonomous body 'National Medical Device Authority' (NMDA) to provide a single window mechanism and a supportive framework for the local medical devices industry

b. Incentives for both Greenfield and Brownfield units like interest subsidy, concessional power, favourable tax/ duty structure, minimum duty on import of raw materials/ parts etc.

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20 A **medical device** is defined as any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
   a. diagnosis, prevention, monitoring, treatment or alleviation of disease; or
   b. diagnosis, monitoring, treatment, alleviation of or compensation for an injury; or
   c. investigation, replacement, modification, or support of the anatomy or of a physiological process; or
   d. supporting or sustaining life; or
   e. control of conception; or
   f. disinfection of medical devices; or
   g. providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;
and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means.

21 Draft National Medical Policy-2015, Dept. of Pharmaceuticals, Ministry of Chemicals & Fertilizers

c. Institutional frameworks such as common testing centres, Made in India marking (BIS) for medical devices, and a Skill Development Committee under NMDA

d. Establishment of 'Centres of Excellence' (CoE) for supporting product development and validation/certification

e. Price controls for devices including surgical instruments, implants and diagnostic equipment by notifying a separate Medical Devices Prices Control Order (MDPCO)

Make in India: In September 2014, the Indian government launched the "Make in India" campaign, with the objective of making India a global manufacturing hub; thus, bringing foreign technology and capital into the country. Medical device is one of the 25 focused sectors identified by the Indian government as a part of this campaign[22]. Accordingly, a Task Force was formed under the Chairmanship of Secretary, Department of Pharmaceuticals (DoP), to address issues relating to the promotion of domestic production of high end medical device in the country. The Task Force in its report released on 8th April 2015 had made a set of recommendations for the promotion of medical device industry in the country[23].

Medical Device Parks: Under the Make in India programme for the medical device sector, the government announced to set up three industrial parks dedicated to manufacturing of medical devices. The first such park is to come up in Andhra Pradesh. Andhra Pradesh MedTech Zone (AMTZ), a company established under Government of Andhra Pradesh. AMTZ has already received funding approval by the state cabinet on 1st June, 2016 for setting up Asia's first dedicated medical device park at Visakhapatnam in Andhra Pradesh[24]. The park will span across 270 acres and is proposed to provide modern state-of-the-art common facilities such as specialised laboratories, warehousing, testing centre apart 150 independent manufacturing units. Other parks are being planned in Gujarat and Maharashtra (Nagpur)[25]. Such type of Medical Technology Parks are expected to bolster the capabilities of Indian manufacturers and also improve conditions for global manufacturers to open manufactoring facilities in India.

Establishement of Medical Device Testing Labs[26]: In order to ensure safety and efficacy of medical devices marketed in the country, the Union government plans to set up two dedicated medical device testing laboratories in the country at Vadodara in Gujarat and Noida in UP, based on a survey conducted by NHSRC. The medical device testing lab in Gujarat would be the first and the only dedicated biomaterials and implants testing lab in the country. The lab at Noida will be set up primarily to test electrical and electronic medical devices in the country. Such type of testing labs will allow manufacturers to overcome deficiencies in their products and enhance product value in the market which is a neglected aspect until now.

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22 The Medical Device Industry in India, SKP Business Consulting LLP, 2016

23 Draft National Medical Policy-2015, Dept. of Pharmaceuticals, Ministry of Chemicals & Fertilizers

24 AMTZ gets Capital, Land for Asia's first dedicated medical device park at Vishakhapatnam , Pharmabiz, June 13th 2016 (accessed on 10th July 2016)

25 Making it a walk in park for medical device-makers, The Hindu BusinessLine, March 18th 2016 (accessed on 10th July 2016)

26 Govt. to set up two dedicated medical device testing labs for first time in India, Pharmabiz, February 17th, 2016 (accessed on 10th July 2016)

27 Guidelines For the Implementation of Scheme for Technology and Quality Upgradation Support to MSMEs Under National Manufacturing Competitiveness Programme, Ministry of Micro, Small and Medium Enterprises

Subsidies/ Exemptions:

a. Under the Technology and Quality Upgradation Support provided to MSME, 25% of the project cost is provided as subsidy by Government of India, balance amount is to be funded through loan from SIDBI/ banks/ financial institutions.

b. 75% subsidy is provided to MSME manufacturing units towards licensing of product to National/ International standards. The maximum GoI assistance allowed per MSME is INR 1.5 lakh for obtaining product licensing/ marking to National Standards and INR 2 lakh for international standards.[27]

c. The Department of Electronics and Information Technology introduced M-SIPS in July 2012 which is available for both new projects and expansion projects. The scheme provides capital subsidy of 20% in SEZ (25% in non-SEZ) for units engaged in electronics manufacturing. It also provides for reimbursements of countervailing duties/ excise for capital equipment for the non-SEZ units.[28]

d. Other provisions/ initiatives under the National Electronics Policy, 2012 like Reimbursement of excise duties for capital equiments in non-SEZ units, Exemption from central taxes and duties for 10 years in high tech facilities, and Fund allocation of USD2bn to promote R&D, product commercialization and nano-electronincs.

Corrections in the Inverted Duty Structure:

a. The customs department has raised import duty on 67 ITC Categories of Medical Devices from the current 5 per cent to 7.5 per cent to help companies manufacture these products in India itself.[29]

b. Simultaneously, the exemption from special additional duty (SAD) on these medical devices has also been withdrawn, and they now attract 4 per cent SAD.

c. Further, to give fillip to domestic manufacturing, basic customs duty is being reduced from 7.5 per cent to 2.5 per cent along with full exemption from SAD on raw materials, parts and accessories for manufacture of medical devices falling under headings 9018 to 9022[30].

These changes will aid in removing the existing hurdles in domestic manufacturing of medical devices and encourage companies to produce these devices in India, rather than importing them.

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28 Website of Department of Electronics & Information Technology, Ministry of Communications and Information Technology, GoI

29 AIMED: Correction of Inverted Duty Structure & Quality Assurance – Talisman to Boost Confidence in Local Manufacturers, ehealth, June 2016

30 Govt raises import duty on certain medical devices, Livemint, January 20th 2016 (accessed on 10th July 2016)

Table 11: Corrections in the Inverted Duty Structure for Medical Devices

	Customs Duty upto 18 Jan 2016	Customs Duty on or after 19 Jan 2016
Medical devices	• **Basic Customs duty (BCD):** All goods required for medical, surgical, dental or veterinary use (of chapter 90) – 5% • **Additional Customs duty (ACD):** All aforesaid goods – Nil	• **BCD:** All goods required for medical, surgical, dental or veterinary use (of chapter 90) – 7.5% • Specified equipment and devices – 5% • ACD – 4% • Specified equipment and devices – Nil
Raw material, parts and accessories	• **BCD:** Parts required for manufacture of goods for medical, surgical, dental or veterinary use and accessories – 5% • **ACD:** All aforesaid goods – Nil	• **BCD:** Raw material, parts and accessories for use in manufacture of gods for medical, surgical, dental or veterinary use – 2.5% (provided goods are used in manufacture of main equipment) • In case, parts etc. are not for use in manufacture, then BCD of 7.5% applicable • All aforesaid goods – Nil (benefit extended to raw material) • **ACD:** Aforesaid goods – Nil

Union Budget Initiatives: The provisions and initiatives declared as a part of the recent union budgets have reinforced the government's commitment to boost medical device industry and manufacturing in the country.

Table 12: Budget Initiatives for the Medical Device Industry

	Budget 2015	Budget 2016
Government Investment	• A new scheme for providing physical aids and assisted living devices for senior citizens, living below the poverty line • Rationalised the conditions for 100% FDI in the medical device sector through the automatic route	• A National Dialysis Services Programme has been launched under the National Health Mission to provide dialysis services in district hospitals via PPP model
Taxation	• Exemption from basic customs duty and countervailing duties (CVD) on an artificial heart (left ventricular assist device)	• Exemption of dialysis equipment from customs duty and CVD and special additional duty (SAD)

Voluntary Scheme for Certification of Medical Devices: Launched in March 2016, the Indian Certification of Medical Devices Scheme (ICMED) – the first home developed international class certification scheme for the Indian manufactured medical devices – is an initiative of Association of Indian Medical Device Industry (AIMED) in collaboration with the Quality Council of India (QCI) and the National Accreditation Board for Certification Bodies (NABCB)[31]. This Scheme will achieve the following objectives:

a. Enhancing patient safety to provide enhanced consumer protection
b. Provide much needed product credentials to manufacturers for instilling confidence among buyers and users

31 India's first medical device quality assurance system ICMED launched in Delhi, Pharmabiz, March 18 2016 (accessed on 10th July 2016)

32 Indian Certification For Medical Devices (ICMED) Certification Scheme, Certification Process, QCI

33 Intertek approved as India's first Certification Body for the ICMED scheme (Indian Certification for Medical Devices), July 6th 2016 (accessed on 10th July 2016)

c. Significantly eliminate trading of sub-standard products or devices of doubtful origins (spurious)
d. Eliminate the malpractices of sub-standard or fraudulent certification or quality audits
e. Bring down the substantial time and cost-run to obtain globally accepted quality certification for Indian companies

ICMED can be adopted by the companies on a voluntary basis. It provides 3 voluntary certification criteria that are based on related ISO standards:

i. ICMED 9000 certification which is ISO 9001 plus additional requirements
ii. ICMED 13485 which is ISO 13485 plus additional requirements
iii. ICMED 13485 Plus (Product specification as per MoHFW's Technical specifications)[32]

The manufacturers are required to approach any one of the certification bodies approved by QCI under the Scheme for obtaining certification. The certification bodies shall be under the oversight of NABCB, which as the national accreditation body, would accredit these certifying bodies as per applicable international standards. Intertek, a leading Total Quality Assurance provider to industries worldwide, was recently approved as India's first certification body for the ICMED scheme[33].

With the recent initiatives and policies of the Government related to medical devices and equipment like creation of a robust regulatory framework, price regulations, development of manufacturing eco- system and fiscal incentives and subsidies will give a significant boost to indigenous manufacturing and reduce the dependency on imports.

WHO Global Model Regulatory Framework for Medical Devices including IVDs, July 2016

WHO initiated the development of the WHO Global Model Regulatory Framework for Medical Devices including IVDs (the Model) to support its Member States in ensuring the quality and safety of medical devices. Based on Resolution WHA67.20 'Regulatory Systems Strengthening for Medical Products' adopted by the World Health Assembly in 2014, WHO has undertaken a series of activities to scale up and strengthen regulatory capacities worldwide.

The development of the Model represents such an activity for medical devices. The Model presents a two-step approach to regulate the quality and safety of medical devices. The first is a basic level including the establishment of a regulatory framework and controls to gain market oversight and a system for reporting serious adverse events. Building on the basic level controls, expanded level controls are intended to address other stages in the medical device life cycle and to exert more comprehensive controls. In adopting expanded level regulation, the regulatory authority may choose to implement regulatory controls according to national priorities.

(http://www.who.int/medicines/areas/quality_safety/quality_assurance/ModelregulatoryFramework-MedDev-QAS16-664.pdf)

Draft Medical Devices Rules 2016 (under the Drugs & Cosmetics Act) by the Union Ministry of Health & Family Welfare, Government of India

The Union Ministry of Health & Family Welfare has issued the draft Medical Devices Rules which will be applicable in respect of substances covered under sub-clause (i) of clause (b) of section 3 used for in vitro diagnosis; substances that are in the nature of mechanical devices covered under sub-clause (ii) of clause (b) of section 3; and devices specified from time to time by the Central Government by notification in the Official Gazette under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940).

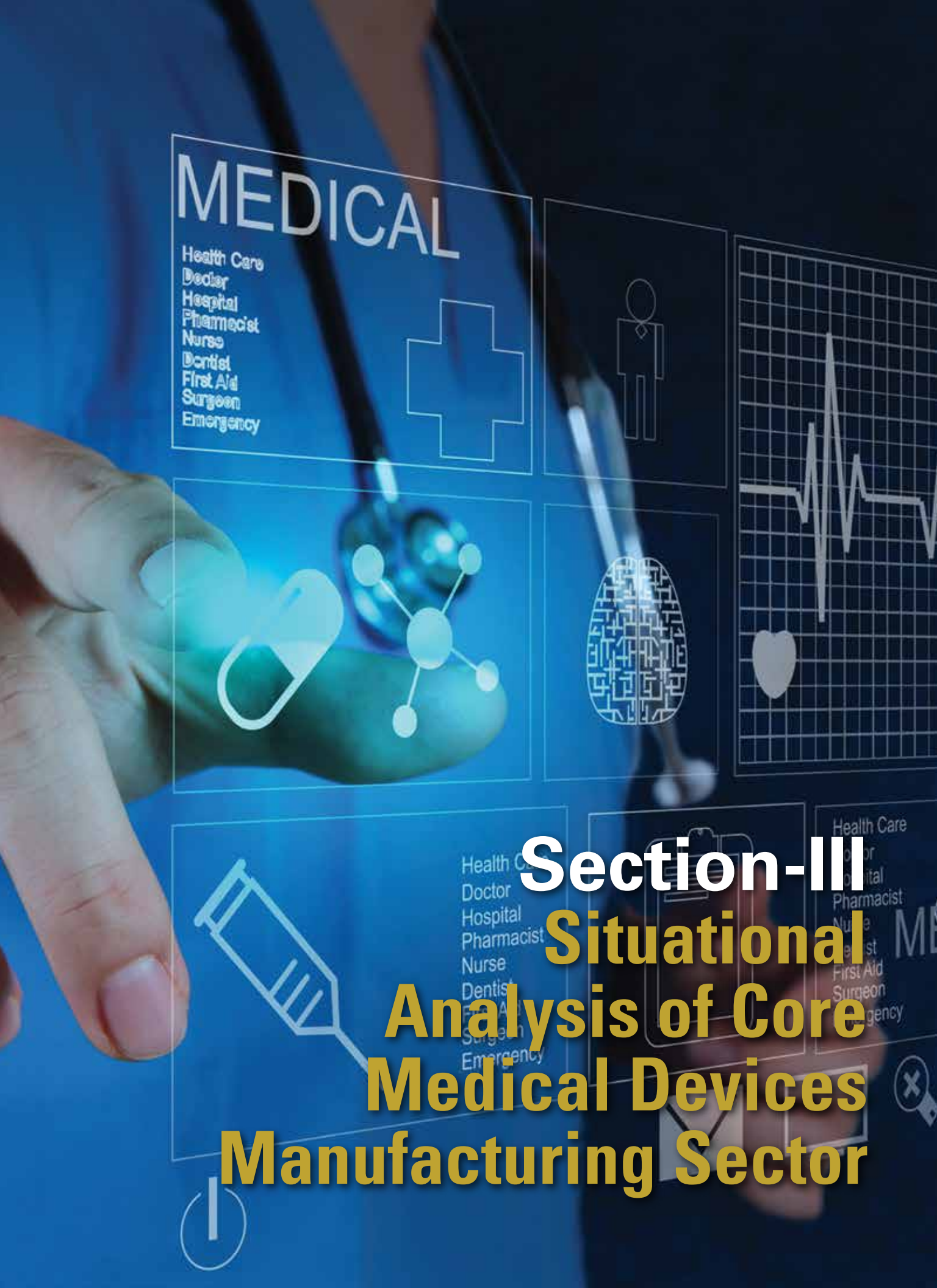
Medical device already marketed in India prior to the commencement of these rules shall continue to be marketed as hitherto before subject to the condition that the manufacturer shall provide evidence of previous sale in India and apply for license within a period of ninety days from the date the device is notified under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940). The Central Government shall, by notification, specify the date from which medical device referred in clause (2) shall be regulated in accordance with these rules.

Under these draft rules, medical devices other than in vitro diagnostic devices shall be classified as low risk (Class A); low moderate risk (Class B); moderate high risk (Class C); and high risk (Class D).

The Drugs Controller General of India shall be the Central Licensing Authority and shall be the competent authority for enforcement of these rules in matters relating to import, manufacture of Class C and Class D medical devices, clinical investigation and clinical performance evaluation of medical devices and other related functions, provided that where any manufacturer intends to manufacture Class C or Class D medical device along with Class A or Class B medical device, the Central Licensing Authority shall be the competent for enforcement of these rules and no separate licence from the State Licensing Authorities shall be required in respect of devices of Class A or Class B.

The State Drugs Controller, by whatever name called, shall be the State Licensing Authority and shall be the competent authority for enforcement of these rules in matters relating to manufacture of Class A or Class B medical devices, sale, stock, exhibit or offer for sale of medical devices and other related functions: Provided that where any person intends to manufacture predicate medical device, prior approval from the Central Licensing Authority shall be necessary before applying to the State Licensing Authority.

(http://cdsco.nic.in/writereaddata/Draft_Medical%20Devices%20Rules_2016.pdf)



Section-III
Situational Analysis of Core Medical Devices Manufacturing Sector

While technological advancement and expertise that the global market leaders offered has proved to be an advantage, India's medical device sector is dominated by multi-national companies, which is evident from the fact that about 78% of the sales are generated by imported medical devices. The domestic players, on the other hand, adapting to the circumstances, focus on low cost devices. It remains a matter of surprise that the domestic players in India specializing in low cost- high volume medical devices particularly dealing in disposals and consumables segment export more than 60 percent of their output. Over the years, many multi-nationals have set up operations in India. However, the nature of majority of the operations is to only distribute imported devices and provide support function, although islands of R & D excellence and manufacturing can certainly be seen in the case of few multi-nationals with operations in India.

While the above remains key enablers, a situational analysis of medical devices core manufacturing sector (non-import) would serve as valuable base line for policy formulation, eco-system strengthening and course-correction, if any required. Given that no such baseline survey has ever been done for medical devices manufacturing sector in India, a toolkit for such a primary survey was designed and the survey conducted with support from Association of Medical Device Industry (AIMED); PHD Chambers of Commerce & Industry; and World Association of Small & Medium Scale Enterprises (WASME).

Survey toolkit was designed considering vital components necessary for a comprehensive manufacturing eco-system such as- Financial bandwidth, core capacities, skilled human resource pools, knowledge dimensions such as Patents and IPR, number of products, product quality and sustainability factors. Detailed survey tool is attached as appendix. The survey included mapping of essential information from a sample representative of medical device manufacturers in India. The tool kit was sent through the manufacturing industry associations to their respective members. However, in order to harness the knowledge across wide spread industry, visits were made to key manufacturing clusters particularly those located in the vicinity of industrial cities such as Mumbai, Ambala, Biwani, Ludhiana, Chennai. While it is estimated that there exist about 600 core medical devices manufacturers in India, data collected by means of this survey is from 62 manufacturing companies which comprises approximately 10% of the core medical devices manufacturing population. While in absolute numbers, it could be a small fraction of the med tech industry, capturing key information from over 10% of the entire core manufacturing segment in medical devices is a unique – never done before-exercise. While the findings of the survey could give a situational analysis of the sector, it has in its womb, a great potential for course correction, policy formulation and strength recognition.

INDIAN MEDICAL DEVICE MANUFACTURERS SURVEY ANALYSIS

S.No.	Thematic Areas	Segment Characteristics	Measure
1	Organizational Data	MSME/NSIC Registration %	69.35%
2		Import Export Code Available %	93.54%
3		Component Manufacturing %	66.12%
4		ISO Certification	85.48%
5		R & D Dept. %	66.12%
6	Mode of Investment	Self %	61.29%
		Financed %	19.35%
		Self + Financed %	12.90%
7	Financial Data	Average Investment	17-20 Crore
8		Average Turnover	45-50 Crore
9		Average Export Turnover	17-18 Crore
10		Average Import Turnover	7-8 Crore
11	Human Resources	% Skilled	52.22%
		% Unskilled	47.77%
12	Range of Products Manufactured per company	1 to 10	49 (79.03%)
		10 to 20	6 (9.67%)
		20 & Above	7 (11.29%)
13	Certifications	EU- CE %	85.16%
		US- FDA %	6.88%
		Others %	7.96%
14	Special Certifications (where applicable)	AERB % (For Those to require AERB)	100%
		WHO PQS % (For Those to require PQS)	100%
15	Intellectual Property	% of Companies Filed Patents	17.74%
		% of companies who filled patents in India	100%
		Average patents per company	6.40

Discussion: 1

Registration & Certifications:

Medium and small scale enterprises (MSME) is the segment representing and fostering the promotion and growth of micro, small & medium Enterprises in the country. MSME broadly represents a very unique and progressive segment of manufacturing sector with great potential towards economic enrichment and product development. Certifications are trademarks of quality processes and thereby quality products. Among various certifications, the most popular in largest number of consumer markets is US-FDA and European Union CE. However emerging systems, and even some voluntary certifications by industry such as IC-MED in India are forming grounds among the manufacturer market. As a broader industry practice the ISO 13485 medical device specific standard is also widely used. While International Standards

bring technological, economic and societal benefits, they also help to harmonize technical processes thereby making industry more efficient and breaking down barriers to international trade. Conformity to International Standards helps reassure consumers that products are safe, efficient and good for the environment.

While it is generally assumed, that Indian medical devices manufacturing segment does not get itself standardized comparable to international standards, the detailed survey showed results otherwise, and a summary is tabulated below:

Situational Analysis Findings	Work in Progress
1. According to the survey around 69.35% of Indian Medical Device Manufacturers have MSME/NSIC registration 2. 85.48% of the manufacturers are ISO certified. ISO being a critical step to CE certifications, it also shows the ability of medical devices core manufacturing segment to leap up to internationally benchmarked standards. 3. 85.16% of manufacturers have CE certification for one or more products and 6.88 % have achieved US-FDA approval for one or more products. 4. 93.54% of the companies have import export code 5. Out of those that manufacture radiology products- 100% of them have achieved AERB certification; those that deal with cold chain equipment, 100% of them are WHO-PQS requirement. **Inference:** Despite having MSMEs as major part of manufacturing segment, the manufacturers capabilities are robust in terms of internationally benchmarked quality standards; voluntary certification system; and special quality benchmarks required as in case of special products such as radiology equipment.	• Schedule M-III has been notified; Drugs & Cosmetics Act (Amendment) Bill - 2015 with separate chapter on medical devices is under formulation. • Classification of occupational standards under Health Sector Skill Council have been prepared • AIMED in collaboration with Quality Council of India has launched the IC-MED program as a voluntary certification system for medical device manufacturers • Standardization of specifications for the medical devices for public procurement has been achieved to a large extent by the Healthcare Technology Division at NHSRC, under the Ministry of Health & Family Welfare, Govt. of India

2) R&D and Intellectual Property:

With networks of universities, it is generally considered that small and medium scale enterprises do not have the required technological bandwidth or ecosystem for self R&D. The results however, show otherwise.

Intellectual property rights are the key to securing exclusivity and the key to intellectual property lies in Research and Development. While it is usually assumed that R&D takes place in high-level research institutions like national institutes of health or in the academic sector,

Situational Analysis Findings	Work in Progress
1. R & D setup provides great support in bringing innovations to the commercialized market. Findings of the survey reveal that around 66.12% of manufacturers have an R & D portfolio. 2. 17.74% of the companies have filed patents and filing in Indian Patent Office is a common phenomenon observed even if the company files for patent in any other country 3. Average number of patents per company (out of those which filed patents) is 0.44 and the general range being 1-6 patents across firms. This however does not take into account single company which has 370 patents. **Inference:** With only 1/5th of manufacturing organizations filing patents and an average of 0.44 patents per such company, there is deeper penetration required. This could be achieved if the incubation centers particularly based out of academic institutions are suggested to reach out to med tech manufacturing clusters and provide for an on ground support.	• Launch of National Health Innovation Portal for pooling innovations and facilitating their entry into the public health system (reference: www.nhinp.org) • Government's decision to have more IITs for speeding research along with support from BIRAC, Technology Development Board (TDB) • Ongoing increase in the number of patent examiners at Indian Patent Office • Support offered by Dept. of Commerce for participating in global Med Tech Expos

3) Investments & Turnover:

While financial systems remain the bedrock of enterprise deveopment, the adequancy and avaibility of funding channels are symbolic of overall growth factors. Funding from angel investors, venture capitalists provdie for actue investment needs, however, the traditional manufacturing segment relies on low interest capital available through Banks and key financial institutions that focus on MSMEs such as SIDBI.

Situational Analysis Findings	Work in Progress
1. Survey depicts self-financing as the major mode of investment to the extent of 61.29%. Only 19.35% of representative firms obtained finances through financial institutions and 12.90% followed a mixed model for financing (self-financing + institutional financing). 2. The average investment per manufacturer was found to be around 17-20 crores and an average turnover of around 44-50 cores. 3. Survey depicted an average export turnover of Rs.17-18 Crores and import turnover of Rs.7-8 crores. **Inference:** The urgent need for providing better implementation, penetration and uptake of government schemes as well as low interest financial market remains key to success.	• The Union cabinet approved 100% foreign direct investment (FDI) in companies manufacturing medical devices. • Inverted duty structure correction was achieved which would make manufacturing in India, most cost competitive • Several schemes such as 25% capital subsidy for MSMEs exists and remain in implementation with more rigor and measures are need to make them more attractive and approachable.

4) Human Resources and Skills:

While the movement of "Skill India" picks up the pace, it is heartening to know that medical devices manufacturing sector depends greatly on un-skilled human resources. While the Skill India movement is both timely and much needed, the ability of eco-system to provide for skilled human resources would be critical to success of med tech manufacturing in India

Situational Analysis Findings	Work in Progress
1. Approximately 52.22% of the employees in surveyed organizations could be categorized as skilled human resource whereas 47.77% were from the unskilled sector. 2. Programs of skill building, engagement of existing work force in – on the job- trainings, and carrier development remains the goal **Inference:** Urgent need to provide for cost –effective skilled work force is the need of hour. The extent of skilling and dimensions on which skilling is to be provided could be explored in consultation with the industry.	• Working with stakeholders such as HSSC for promotion of occupational and vocations standards for training of engineering workforce for medical devices industry. • Facilitating and promoting adoption of such standards by the industry. • Undertaking operational research for identification of skill gaps and encouraging satellite training camps in manufacturing hubs in partnership with medical device industry associations as part of their CSR activities.

5) Product range

The Medical Equipment industry is quite wide with more than 14,000 different products. The products range from wound closure pads to stents and IVD machines to MRIs. However, not all manufacturers can make every product. Since product segments are diversified based on nature of science – such as radiation, laser, electronics, electrical, and so on, manufacturers need to specialize on technology segment that capture similar product portfolios.

Situational Analysis Findings	Work in Progress
1. 79.03% of the surveyed firms have product range between 1 to 10. 2. 9.67% had more than 10 but less than 20 products, while 11.29% of the firms had more than 20 products in their manufacturing portfolio **Inference:** The range of products depicts the technological and financial bandwidth of manufacturing firms. There are no schemes that support product diversification exclusively. A need for product diversification mechanism is a long pending requirement for Indian med tech markets to expand.	• Setting up of Medical Technology Industrial Parks, linked with Industrial Corridors are in the making, with lead being taken by Andhra Pradesh Med Tech Zone, a newly formed Public Sector Unit under government of Andhra Pradesh.

ANNEXURE-1

Medical Device Industry Tool Kit

Name of Firm: .....

Year of Inception: .....

Type of Industry (MSME/Large Scale): .....

Serial Number: .....

Part I: Basic Information

S.No.	Elements	Yes	No
1	Registered with MSME or NSIC		
2	Manufacturing License Available		
3	Import Export Code Available		
4	Component Manufacturing		
5	ISO Certification (1) ISO:13485 (2) ISO:9001		
6	R&D Department		

Part II: Financials

Mode of Investment (Self/Financed/FDI): .....

S.No.	Elements	Amount (INR)
1	Total Investment	
2	Total Turnover	
3	Export Turnover	
4	Import Turnover of components and spares	
5	Domestically procured Raw materials	
6	Total Employees: (1) Skilled: (2) Unskilled	

Part III: Product Information

Mode of Investment (Self/Financed/FDI): .....

S.No.	Product Name	Annual Capacity	Quality Certification (WHO PQS/CE/US FDA/ AERB type Approval)

Patents Filed: _____

Pollution Board categorization: _____ (Red/Orange/Green)

Thank You!