

Medical Device Industry in India

The Evolving Landscape,
Opportunities and Challenges

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Foreword

The Indian government's 2017 National Health Policy deals with progressive universal healthcare for citizens, envisioning equitable health and well-being for all sections of society. The policy seeks to increase access and adoption, improve quality, and lower healthcare delivery costs in the country. The government has recognized the changing disease patterns in the country, the need to address the significant growing burden of non-communicable diseases, and the emergence of a robust and successful private healthcare industry. The bulk of government spending will be directed towards reviving and strengthening primary healthcare systems, focusing on rural and lower tier urban areas that lag behind in quality and access. The government is likely to take on the role of a payer rather than a provider, resulting in improved outcomes and better utilization of healthcare expenditure in the country.

The global medical device industry is highly innovative and technology driven, changing the face of healthcare worldwide. Globally, it is a rapidly advancing industry impacting and improving aspects such as diagnosis, treatment, and delivery, but in India, it is still very nascent with low levels of penetration and adoption. This presents an exciting opportunity to develop this industry and to play a larger role in the transformation of Indian healthcare. A good understanding of the nature of this industry will help ensure that the country is poised to capitalize on opportunities provided by medical technology to improve national healthcare.

A new national medical device policy is currently being developed and the Indian government is actively engaged in discussions and consultations with various stakeholders. Policymakers working collaboratively with stakeholders in the healthcare eco-system are attempting to lay down a roadmap that provides consistency and predictability. The path to realizing healthcare goals is complex, and various fundamental issues and challenges need to be addressed and solved holistically. Long-term plans need periodic policy and regulatory interventions to ensure fair conduct within the industry while providing the support needed for profitable and sustainable growth. These activities will enable the medical device industry to accelerate rapidly and play a key role in making India healthier and stronger.

AdvaMed has partnered with SKP to publish this paper entitled - *Medical Device Industry in India - The evolving landscape, opportunities and challenges*. The paper also examines various policies and regulations impacting the industry and attempts to make recommendations on the way forward from the perspective of different stakeholders. Extensive research, both primary and secondary with deliberations and discussions with several stakeholders across the healthcare chain have served as inputs for this paper.

AdvaMed and SKP would like to thank everyone for their insights and valuable contributions towards this paper.

We hope that this paves the way for further deliberations and helps in shaping the industry in a positive manner.



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Abbreviations

AIIMS	All India Institute of Medical Sciences	JV	Joint Venture
AIMED	Association of Indian Medical Device Industry	MDC	Medical Disposables and Consumables
AP	Andhra Pradesh	MEA	Ministry of External Affairs
AYUSH	Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy	MDP	Medical Device Park
BMS	Bare Metal Stents	MII	Make in India
BRICS	Brazil, Russia, India, China and South Africa	MSDE	Ministry for Skill Development & Entrepreneurship
CAD	Coronary Artery Disease	MNC	Multinational Company
CAGR	Compounded Annual Growth Rate	MoHFW	Ministry of Health and Family Welfare
CBU	Central Buying Unit	MRI	Magnetic Resonance Imaging
CDSCO	Central Drugs Standard Control Organization	MRP	Maximum Retail Price
CE	Conformité Européene	MTAB	Medical Technology Assessment Board
CLAA	Central or State License Approval Authority	NABCB	National Accreditation Board for Certification Bodies
CPAP	Continuous Positive Airway Pressure	NABH	National Accreditation Board for Hospitals & Healthcare Providers
CRS	Chronic Rhinosinusitis	NCR	National Capital Region (Delhi area)
CT	Computed Tomography	NHP	National Health Policy
CVD	Cardiovascular Disease	NMDP	National Medical Devices Policy
DCA	Drugs and Cosmetics Act 1940	NCD	Non-Communicable Disease
DES	Drug Eluting Stents	NCMD	National Centre for Medical Devices
DCGI	Drug Controller General of India	NIC	National Intervention Council
DoC	Department of Commerce	NICU	Neonatal Intensive Care Unit
DoP	Department of Pharmaceuticals	NITI	National Institution for Transforming India
DRG	Diagnosis Related Groups	NLEM	National List of Essential Medicines
ECB	External Commercial Borrowing	NMD	New Medical Device
eHC	eHealth Center	NPPA	National Pharmaceutical Pricing Authority
EKG	Electrocardiogram	PCI	Percutaneous Coronary Intervention
EOU	Export Oriented Unit	PE	Permanent Establishment
EU	European Union	PED	Product Engineering & Development
FDI	Foreign Direct Investment	PPP	Public Private Partnership
GDP	Gross Domestic Product	PTD	Price to Distributor
GHTF	Global Harmonization Task Force	PTH	Price to Hospital
GMP	Good Manufacturing Practices	QCI	Quality Council of India
HSIDC	Haryana State and Industrial Development Corporation	R&D	Research and Development
HSSC	Healthcare Sector Skill Council	RDS	Respiratory Distress Syndrome
HTA	Healthcare Technology Assessment	SHI	Statutory Health Insurance
ICMED	Indian Certification of Medical Devices	SEZ	Special Economic Zone
IMF	International Monetary Fund	TRIPS	Trade Related Aspects of Intellectual Property
IOA	Indian Orthopedic Association	USD	United States Dollar
INR	Indian Rupee	US FDA	US Food and Drug Administration
IPR	Intellectual Property Rights	VAP	Ventilator Associated Pneumonia
IT	Informational Technology	WHO	World Health Organization
JCI	Joint Commission International	WTO	World Trade Organization

Executive Summary

The healthcare industry in India has made rapid progress in the last decade, but significantly lags behind other nations in availability and quality of equitable medical care and services for citizens. This in turn presents an enormous opportunity given the large population, growing economic prosperity, and the disease burden. Major issues such as availability of adequate infrastructure, trained human resources, geographic spread, rapidly changing disease burden, and high/often catastrophic out of pocket expenditures are challenges that the government is keen to address. The Indian government is committed to raising public expenditure on health to 2.5% of the GDP. Public and private sectors need to play equally important but different roles in bringing rapid change to the healthcare scenario in the coming decade.

The medical devices industry in India is currently valued at approximately USD 6 billion and has expanded at a significant double digit growth rate over the past few years. The industry is still at a nascent stage with sub-optimal penetration and usage of medical devices. Currently, India comprises only 1.7% of the world market, the industry is significantly import dependent, and current demand does not offer scale in various product categories. This will transform as demand significantly escalates to realize potential.

The Make in India initiative is intended to attract both Foreign Direct Investment (FDI) and domestic investment

in this sector. Government initiatives around opening up FDI and infrastructure development are welcome initiatives that will enhance the ecosystem for investment. The Indian medical device industry appreciates government's efforts to remove bureaucratic hurdles and improve the ease of doing business, but believes that additional steps can be taken to strengthen its approach.

Our discussions with the industry leaders indicate that given the lack of scale in many products, the government should prioritize certain products for manufacturing in India. High volume, low-tech, labor intensive manufacturing sectors should be the initial target. Very rapid import substitution may not be practical or desirable. It is also felt that the government should position and promote India as a global manufacturing hub or destination, rather than focus on just the domestic market. Frugal innovation is a significant strength that India can offer the world. Innovation to develop new products for emerging markets should be encouraged, and this will also ensure manufacturing volumes needed for profitable operations. This approach will help India attract the right technology, upgrade manufacturing processes and quality, and build local R&D capability.

The Indian medical device industry believes inclusive policy making by the government, and understanding and addressing legitimate concerns will greatly benefit the healthcare industry as a whole. The recent pricing

control regulation and the new Public Procurement Policy with preferential Market Access do not fully reflect this and has alarmed many industry participants. A clear long term vision and roadmap for the industry and predictability of policy would excite the industry. The government needs to provide policy support for both the supply and demand side of the medical device industry to successfully accelerate growth. Industry and government need to work together to improve awareness, access, adoption, and affordability for medical devices in India. The government has indicated that in the new healthcare policy that they will focus strongly on preventive and primary healthcare and in facilitating build-up of the required medical, paramedical, and allied health human resources in the country. Leaving secondary and tertiary healthcare delivery largely in the hands of the private sector will result in significant improvement in efficiency of spends. The private sector also plays a very significant role in training medical and allied resources in the latest technology, innovations, and procedures and in bringing in global standards in delivery and care. The government has indicated that they will take on an increasing role as a payer, facilitate widening insurance coverage significantly, and use resources to purchase services from the private sector for the underprivileged through cost effective modalities, including public-private partnerships.

Healthcare industry participants including medical device players suffer from poor public perception regarding their conduct and practices. It is crucial for the government and the industry to work together to improve this image and perception. There is a need to assess the information asymmetry that exists, and bring in transparency in areas such as pricing and cost at the product and services/procedures level. While guarding against profiteering, regulators need to ensure that the healthcare industry is profitable and can grow and upgrade to bring in all required technological advancement. Data suggests that healthcare costs in India are among the lowest in the world even when adjusted for purchasing power. Analysis of available financial statements do not indicate profiteering either in the medical device or healthcare delivery sector.

The industry feels that the recently announced price control policy, while intended to improve affordability, needs reconsideration and change before roll-out to other categories. As formulated and implemented today, the policy will have limited impact on patient cost and could also deprive India of new technology in the future, besides stifling sectors like medical tourism. The government needs to consider options that include more tiers in pricing and give new technology the benefit of being spared from price control for a certain number of years. The industry believes that trade margin regulation should be approached by first looking at essential products based on burden of disease and recommends the government review essentiality of devices when

determining devices to price regulate. Issues like high trade margins can be tackled with conversations with all stake holders. Bulk purchasing of specific devices at low prices to support government schemes that serve the underprivileged and using the insurance industry to determine reimbursement prices and co-pay levels could also ensure value in the usage of devices and delivery.

The government has moved in the right direction by separating out medical devices from drugs from a policy/ regulations perspective, but more work is still required. Improved understanding of important differences between the two sub sectors will continue to help shape appropriate policy. Key to this is an appreciation of the industry's technology and innovation lifecycle, and a willingness to reward technology and continuing innovation. The industry believes that a full separation of drugs and devices via a separate medical devices act and regulatory body and expanding the coverage and scope of the medical device rules to cover most if not all devices, will ensure that devices marketed in India meet global standards of quality and safety. This combined with a drive to ensure accreditation by NABH will strengthen the quality of care and improve outcomes. It is important for the government to build the capability to conduct robust Healthcare Technology Assessment (HTA) in the country. Establishing a functioning Medical Technology Assessment Board (MTAB) will help the evaluation of the differentiation and value of various medical devices.

Industry participants also strongly feel that the government should broaden its vision from Make in India to include both *Innovate in India and Heal in India*. With attractive healthcare costs, a well-trained and qualified medical and technical work force, and a vibrant private sector, such a strategy has the potential to be very rewarding for the country. A faster-growing healthcare delivery sector will boost demand for medical devices and also lead to significant employment generation in services. Additionally, this focus will help India innovate, establish global standards in products and services, and improve the balance of trade favorably especially with medical tourism growth. Such a strategy could also help cross-subsidize healthcare for the under privileged segments to a degree, again boosting demand at the lower end.

The healthcare and medical device industries are at a critical threshold where growth can be significantly accelerated to ensure that India embraces the benefits of advancing medical technology to uplift standards of healthcare sharply in the next decade. A vibrant and profitable private sector is critical for success. By proactively listening to and understanding each other better, government and industry can collaborate effectively to realize the vision of the 2017 National Health Policy.

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An overview of Medical Device Industry

- Healthcare Indicators
- Medical Devices in India
- Structure of the Industry
- Segments
- Existing Clusters
- Growth Drivers
- Challenges



Healthcare Indicators

The healthcare industry in India has registered a compound growth rate of 20% over the past few years and is expected to reach USD 175 billion by 2020. Factors such as changing demographics, rising life expectancy, growing incomes and public awareness have contributed to a higher demand for medical care.

However, the Indian healthcare system continues to lag behind both developed and other developing countries in terms of awareness, availability, affordability, and access to quality health services. While the government and value chain participants are undertaking several steps to address these issues, they have been executed in silos.

A more focused approach from the government, with increased public expenditure on health, greater utilization of technology, vibrant private sector participation, and continued innovation can transform the sector and move India closer to its goal of providing quality universal healthcare.

Some of the key issues faced by the Indian healthcare industry are evident in the tables below.

- Medical service providers are not only inadequate but are also unevenly distributed across rural and urban areas. This shortfall occurs despite an increase in the number of medical colleges from 23 in 1947 to 398 in 2014. The quality and availability of healthcare deteriorates as one moves away from large urban centers to lower-tier towns and rural areas.

- India is the only country out of the major world economies where out-of-pocket expenses are increasing, despite a concurrent increase in public spending. This effectively means that more people are availing private healthcare services due to rising incomes, or are forced to spend due to inadequate public expenditure.
- With India's disease burden shifting from acute to chronic diseases, large numbers of the population continue to not have access to basic healthcare services. Public health infrastructure is poorly equipped to deal with this shift toward NCDs. It is essential that healthcare professionals are appropriately trained and adequate in numbers.

Countries	Beds Per 10000 population	Physicians per 10000 Population	Government Expenditure of Total Healthcare Expenditure	Out of Pocket Expenditure	Total Healthcare Expenditure as a % of GDP
Global	27	14	58.80%	49.70%	9.10%
India	7	7	30.00%	62.40%	4.70%
Brazil	23	19	46.00%	25.50%	8.30%
China	38	15	55.80%	32.00%	5.50%
Germany	82	38	77.00%	13.20%	11.30%
Japan	137	23	83.60%	13.90%	10.20%
USA	29	25	48.30%	11.00%	17.10%

Source: SKP Analysis, OECD

(Figures USD per capita)

Country	Healthcare Expenditure (2016)	Medical Devices Expenditure (2015)	Income - 2016/2017	Income 2020
USA	9892	415	52195	54800
China	420	178	6895	8330
France	4600	232	42013	43100
India	75	3	1862	3500
Brazil	1318	28	10826	11730
Germany	5267	313	45552	47200
Japan	4519	221	47608	46200
Global Average	948	47		

Source: World Bank, WHO

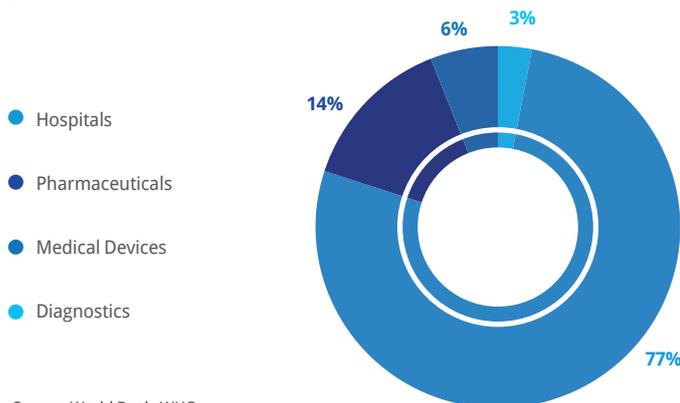
Medical Device Industry in India

The Indian healthcare industry was valued at over USD 100 billion in 2016 and is expected to reach more than USD 175 billion by 2020, resulting in a CAGR of 20%. The medical device industry is valued at USD 6 billion. The medical device industry was accorded the status

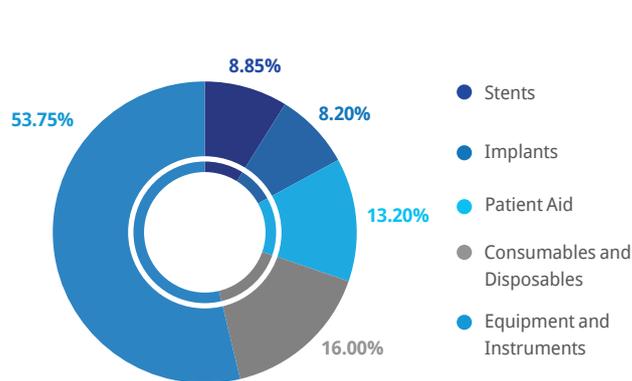
of an independent industry in 2014 when it was included as one of the focus sectors of the 'Make in India' program reflecting of the government's intention to support growth and development in this sector.

The medical device sector today is clearly small and indicates low penetration in the country. However, it has the potential to grow at double-digit rates in the years to come given the growing demand from India's large population.

Indian Healthcare Market



Indian Medical Device Market



Source: World Bank, WHO

Structure of the Industry

The Indian medical device industry is highly fragmented. Currently, this sector is dominated by MNCs with 70–75% of the demand being met through imports. Approximately 30% of the domestically manufactured devices are exported, in which the consumables and disposables segment has the largest share.

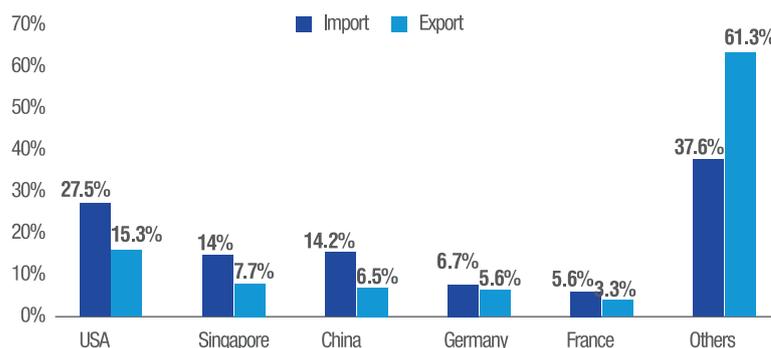
Numerous factors underlie the prevalence of higher imports in the country. Some of these are:

- Lack of favorable policy and regulatory framework.
- Medical devices, unlike pharmaceuticals, are dependent

on a mix of technologies such as engineering, electronics, material sciences and information technology. Innovation, capital and technology drive the industry. However, India has not been able to bridge the gap between investments, skilled resources and innovation to fully capitalize on these opportunities.

- There is no clear comparative cost advantage in comparison to other emerging markets and policy issues like inverted duty structure do not help in creating a positive environment.

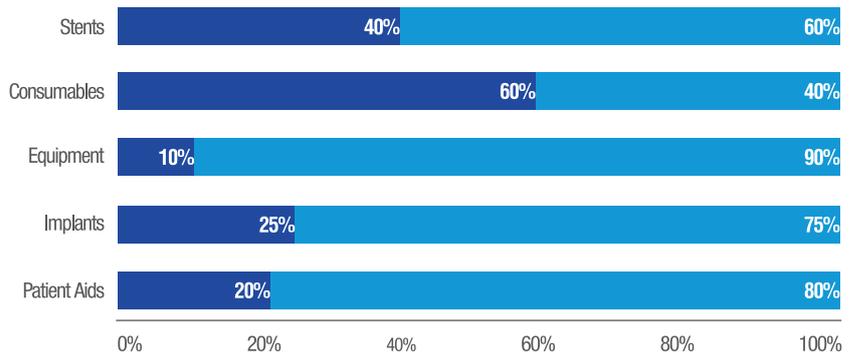
Import and Export of Medical Devices in India from Various Countries



Source: SKP Research and Analysis

International medical device companies looking to explore the Indian market initially acquire/need a distributor to market their products. Whereas, companies that intend to expand their global footprint and export to other neighboring countries may set up/acquire a manufacturing plant in India.

Indigenous Sales vs Imports



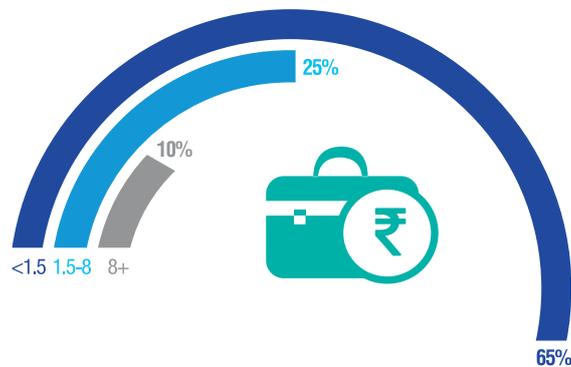
Source: SKP Research

■ Indigenous Sales ■ Imports

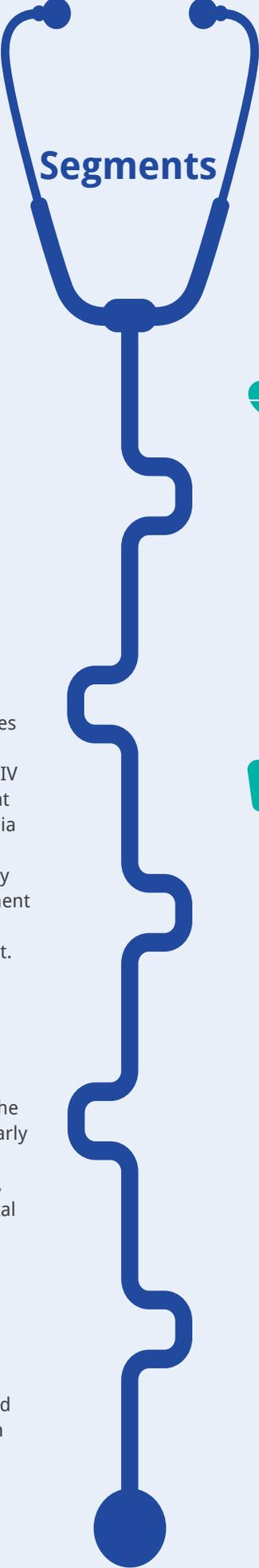
Currently, there are approximately 800 medical device manufacturers in India, 10% of which have a turnover of more than USD 8 million.

The growing focus of the government and better availability of capital has led medical device companies to upgrade their technology, manufacturing facilities and product portfolio customization to compete with the international companies.

Fragmentation of Players (Figures in USD million)



Source: Recommendations of the Task Force on the medical devices sector in India – 2015, DoP, Ministry of Chemicals and Fertilizers



Segments



Consumables and Disposables

The medical disposable and consumables sector consists of products such as disposable plastic syringes, blood bags, IV fluid sets and many others. This segment is dominated by domestic players in India due to its low technology requirements. Needles and syringes constitute majority of the sales. However, wound management products and medical apparels are the fastest growing products in this segment.



Equipment and Instruments

This segment is the largest segment of the medical device industry constituting nearly 54% of the segment and is dependent on imports. MRI machines, CT scanners, ultrasound machines, dental drills, dental chairs, dental x-ray machines. are some of the key products of this segment. It is dominated by MNCs like GE Healthcare, Philips Healthcare, Schiller Healthcare, Danaher Corporation, and Roche Diagnostics.

This segment is growing due to advanced technology being increasingly applied in medical procedures.



Patient Aid

Hearing aids and pacemakers form a major part of the patient aid segment and constitute 70% of the segment collectively. Most of the products are sourced from Ireland, USA, Australia, Singapore, China, and South Korea. Some of the key players in this segment are Abbot Healthcare, Shree Pacetronics, Medisafe International, and Medtronic.



Implants

The Indian implants segment has witnessed an encouraging growth rate of CAGR 25%. With a healthy mix of both domestic companies and MNCs, this segment has witnessed intense competition between players due to strong pricing pressure. The domestic players have realized the market potential which demands customization and differentiated product quality.

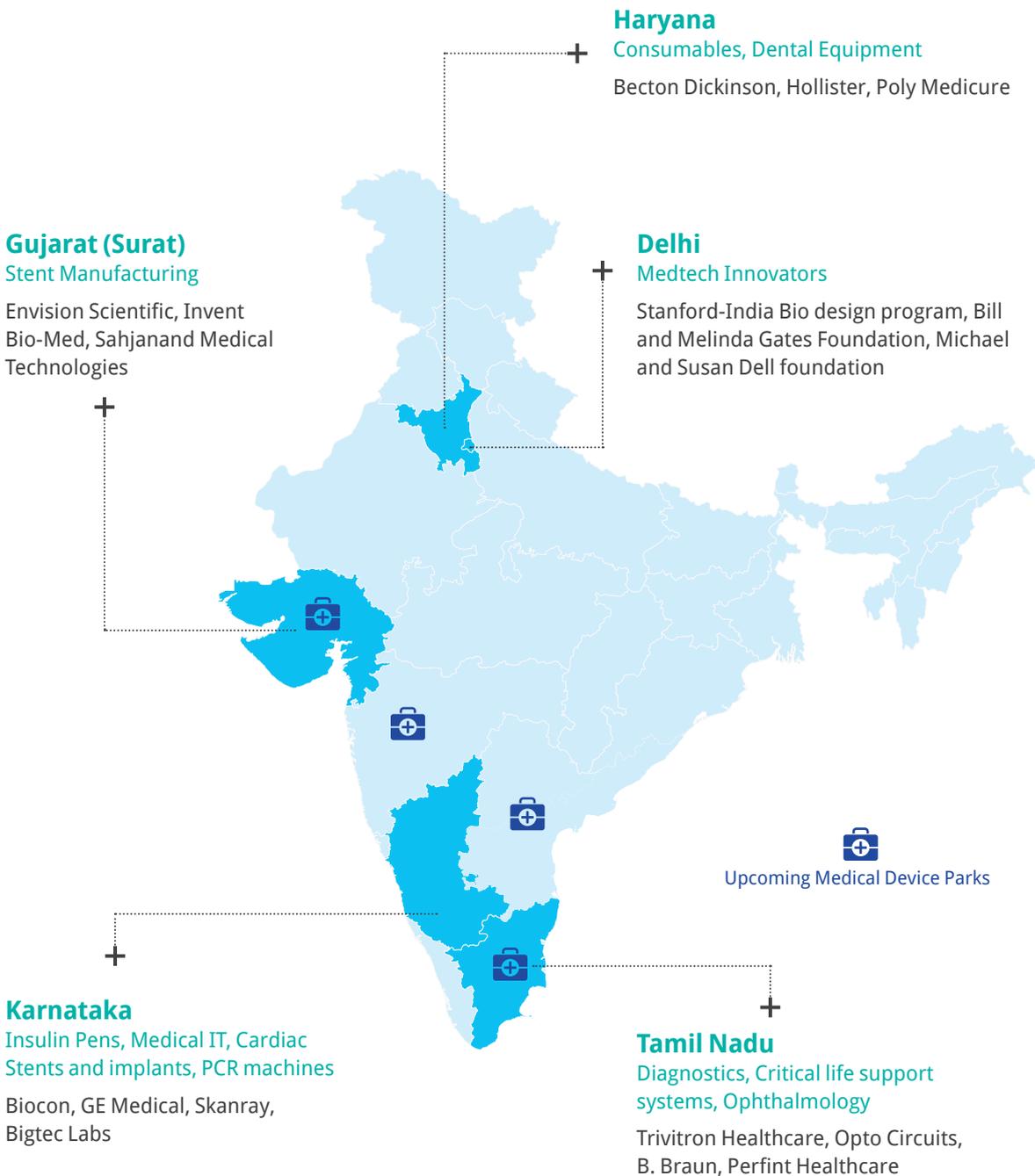


Stents

Drug-eluting stents and bare metal stents form a major part of the stents segment and constitute more than 70% of the segment collectively. Most products are sourced from the USA and Europe. While domestic companies are manufacturing cost competitive products, they still face competition from international players on account of quality. Abbott Vascular, Boston Scientific, Medtronic, Meril Lifesciences Sahajanand and are some of the prominent players in this segment.

Existing Clusters

The Indian medical device manufacturing sector is fragmented, both in its scale and geography. Currently, there are five device manufacturing clusters in the country. These clusters along with the upcoming medical device parks and MedTech parks developing around them, have the potential to create a large ecosystem of manufacturers, suppliers, and developers. It will also create manufacturing capability, encourage R&D, improve quality, and reduce dependence on imports.



Growth Drivers

Key factors that will help drive growth in the Indian medical devices sector are listed below.

- The disease burden has shifted from acute to chronic diseases due to lifestyle changes and ageing. India's population above the age of 60 was estimated at 104 million in the 2011 census, and is expected to increase to 200 million by 2025 and to 300 million by 2050.
- According to the World Bank, per capita income in India is estimated to rise to USD 3,500 by 2020 from USD 1,862 in 2016, thus adding significant numbers to the already expanding middle-income group.
- Awareness levels are increasing with the increased media reach and coverage. There has been an increase in diagnosis and treatment as people are becoming more aware of advancements in medical technology.
- The increase in insurance coverage has led to better affordability and accessibility.
- There is an increase in healthcare spending both by public and private players. Currently, the government's healthcare spend is 1.04% of the GDP and is proposed to be raised to 2.5% of GDP by 2020. These will drive improvements in healthcare infrastructure and access.
- Medical devices were classified as one of the priority sectors in the Make in India campaign.
- There has been an increase in medical tourism due to affordable treatment.
- An increase in adoption because of technological upgradation and more skilled healthcare professionals has taken place.

Challenges

The growth in the healthcare industry has been attractive. However, much more needs to be done. Despite the advent of private players and better government spending, most Indians can only afford and/or have access to basic healthcare. Hence, the path to universal healthcare coverage is challenging. Some of the obstacles faced are listed below.

- Low Penetration - The per capita medical device spending of USD 3, compared to USD 7 in China and USD 42 in Russia is significantly low.
- Lack of Accessibility - The Indian healthcare system is inadequate, inefficient, and unevenly distributed. 69% of the Indian population lives in rural areas, while 73% of qualified consulting doctors reside in urban areas. Eight percent of qualified doctors are in rural areas, and the remaining 19% are in semi-rural areas.
- Inadequate regulatory systems: Non-alignment with global standards and the lack of quality product testing infrastructure are issues that hinder sectoral progress.
- Real estate prices and high capital costs limit the growth of delivery infrastructure.
- Insufficient attention by policymakers and a complex tax regime are also responsible for the sector's underdevelopment.
- The lack of a comprehensive policy and focus to develop the healthcare eco-system.
- The limited attractiveness of India as a destination for medical devices due to uncertain regulations and pricing environment, unavailability of skilled resources, and ease of doing business compared to other comparable destinations in Asia.
- Lack of innovation and customization resulting in fewer options available to the patients.



Regulatory and Business Environment

INSIDE

- Regulatory Regime
- New Medical Device Rules – Key Highlights
- Business Environment
- Proposed Government Initiatives to Help Create a Favorable Environment
- The Shift in the Medical Device Sector Post Regulatory Changes



Regulatory Regime

The existing regulatory framework for medical devices in India is inadequate for a USD 6 billion industry. Medical devices were unregulated in India until recently. At present, 22 medical devices have been notified by the MoHFW and are treated as 'drugs' under the Drugs & Cosmetics Act (DCA), 1940 & Rules.

The MoHFW released the first draft of The Medical Device Rules in July 2016 and after consulting the industry and stakeholders, released the second draft in October 2016. In January 2017, the MoHFW notified the Medical Devices Rules, 2017 and announced that they would be effective from 1 January 2018, thereby giving the industry time to adapt to the new Rules. The Rules clearly separate medical devices as being distinct from drugs, clearing some hurdles for the industry.

However, medical devices still continue to be defined as drugs under the DCA and going forward ideally the government should pursue a full separation of medical devices and drugs with each having distinct and separate regulations.

The Rules generally adhere to the framework laid down by the Global Harmonization Task Force (GHTF) on medical devices and are on similar lines with global standards.

The Rules further address procedural issues such as the need for constant re-approval of manufacturing licenses, while eliminating the need to apply for a registration as well as an import license. The process of tracking applications for licenses is made easier with online systems. While the new Rules attempt to plug various loopholes within the existing framework, it has caused ambiguity amongst medical device companies.

It is anticipated that as the Indian market and manufacturers mature, the perception of devices manufactured in India will also improve and these rules will help quality improvement.

OCT 2014

Formation of Task Force

The DoP constitutes a task force to identify issues relating to the promotion of domestic production of high-end medical devices

APR 2015

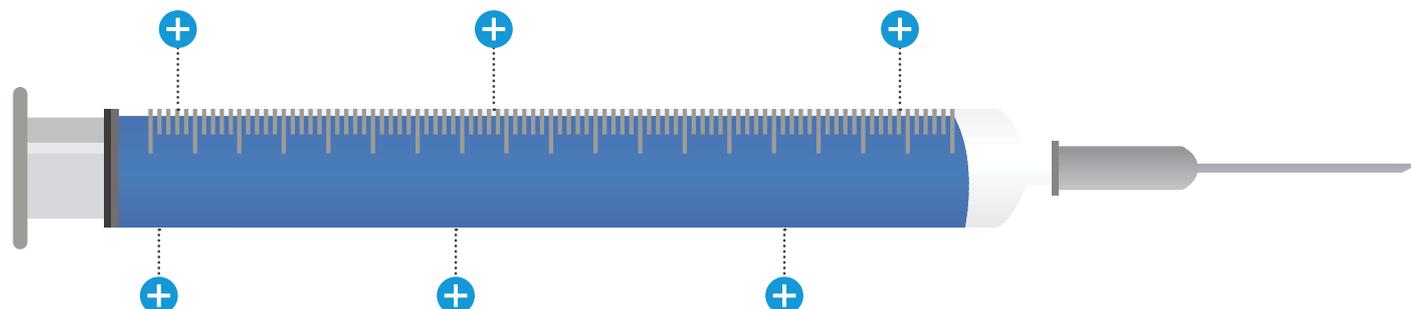
Medical Device Parks

Introduced, in four major states, to create an ecosystem for high-end medical device manufacturing, to reduce imports and eventually export

JAN 2017

Medical Devices Rules

The MoHFW notified the first ever Medical Devices Rules for the country and laid down a risk-based classification of the medical devices.



SEP 2014

Make in India

Prime Minister announced the Make in India campaign with focus on 25 sectors, including medical devices

DEC 2014

100% FDI Allowed

Medical device sector was carved out from pharmaceutical sector thereby allowing 100% FDI under the automatic route, for brownfield as well as greenfield set-ups

JAN 2016

Duty Structure

Recommended increase in import duty and removal of additional customs duty exemptions for certain medical devices to promote domestic manufacturing

New Medical Device Rules – Key Highlights

Increased Number of Notified Medical Devices

- Regulation: Notified in the official gazette by the central government
- Authority: Drug Controller General of India (DCGI)
- Impact: Process for seeking registration and license of device for intended use in India based on regulated/not regulated product

Classification of Medical Devices under Schedule M-III

- Regulation: The new rules classify products based on the risk these devices may pose
- Authority: Drug Controller General of India (DCGI)
- Impact: Device with lowest risk – Class A, devices with moderate risk – Class B, devices with moderate-high risk – Class C, devices with high risk – Class D

Clinical Investigation

- Regulation: Separate provisions for clinical trials of medical devices to assess safety, performance or effectiveness
- Authority: Central Drugs Standard Control Organization (CDSCO)
- Impact: The provisions have eliminated the four-phase stringent trial norms of pharmaceuticals and introduced a two-phase trial

Quality Certification

- Authority: Certifying bodies have to be accredited by the National Accreditation Board for Certification Bodies (NABCB)
- Impact: Third party assessment and certify quality management systems of Class A and B medical device manufacturers

Registration and Licensing

- Regulation: Conformity assessment to ensure compliance to safety and quality standards and grant of sale in the Indian market
- Authority: Central or State License Approval Authority (CLAA)
- The new Rules have eliminated the need for constant re-approval of manufacturing licenses and these licenses have now been made valid unless the license is suspended, terminated or surrendered. The entire process has been made online for easy tracking

Post-Market Surveillance

- Regulation: Process to collect and analyze information, after its launch in the market, on compliance, safety, performance and adaptability of the device
- Authority: CLAA-appointed notified bodies
- Impact: Imported or manufactured devices bearing license may be subject to warnings and recalls

Source: MoHFW, CDSCO, Medical Device Rules 2017, EAC

The Medical Device Rules 2017 are a good step in the right direction. There still exist significant gaps and ambiguity and the industry is hopeful that these will be addressed soon. A full separation of 'drug' and 'device' regulation will facilitate formulation of medical device regulations that are appropriate for this category and also aligned with global best practices. This will also facilitate better focus on standards, quality and compliance bringing up the industry stature.

Business Environment

In past few years, the Indian government has taken several measures to improve the business environment for foreign investors in India. This section describes some of these initiatives as well as some of the continuing challenges that the industry faces.

Foreign Direct Investment (FDI)

FDI up to 100% under the automatic route is permitted for manufacturing medical devices. The sector is also witnessing strong FDI inflows, which reflect the confidence of global players in the Indian market.

According to DIPP estimates, the medical and surgical equipment sector received a total of approximately USD 1,452 million between 2000 and 2016. Out of this, about USD 600 million FDI was received in the last five years.

Intellectual Property Rights (IPR)

To comply with WTO regulations and specifically Trade Related Aspects of Intellectual Property (TRIPS), the government passed new patent laws in 2005. Before being TRIPS-compliant there was a major concern with respect to IPR for foreign medical device manufacturers.

Currently, India has reasonably defined judicial, statutory, and administrative frameworks to protect IPR. Over the years, many international brands such as Whirlpool and Volvo have protected their trademarks despite not being registered in India.

Product Liability

Pharmaceuticals and medical devices are in constant danger of product recalls and the associated liabilities. Product liability law governs the liability of and vendors for injury to a person or property caused by dangerous or defective products.

The legislation, in respect of product liability in India, was earlier construed narrowly. However, recently, the Courts have adopted a pro-consumer approach.

Ease of Doing Business

India is keen on improving its Ease of Doing Business global ranking. The

Government is taking steps to use technology to increase transparency and ease procedural load such as online filings, single point clearances. Clearly while there is a progress, investors continue to find the bureaucratic and procedural hurdles for a new company to be onerous and hard to navigate and more needs to be done. It is important to create a single point of contact with sectoral insights to drive the ease of doing business, growth, and investments in this sector.

Medical Device Taxation

The medical devices sector has been subject to an inverted duty structure for many years (i.e. finished goods are cheaper to import than raw materials for domestic manufacturing). This structure impacted the industry's growth, often making imports more attractive. In the 2017 Budget, the government has tried to correct this by increasing duties on finished goods. While it is important to reduce raw material costs and duties to boost manufacturing in India, increasing finished goods duties may not be the right approach. In an industry where certain technologies will need to be imported it will be important for Government to ensure that finished goods imports are not made difficult.

Innovative Start-ups – Creating a Culture for Frugal Innovation

Over the past few years, the medical device industry has seen rapid innovation to cater to a largely underserved population. This is aided by government encouragement to create a culture for frugal engineering and innovations that

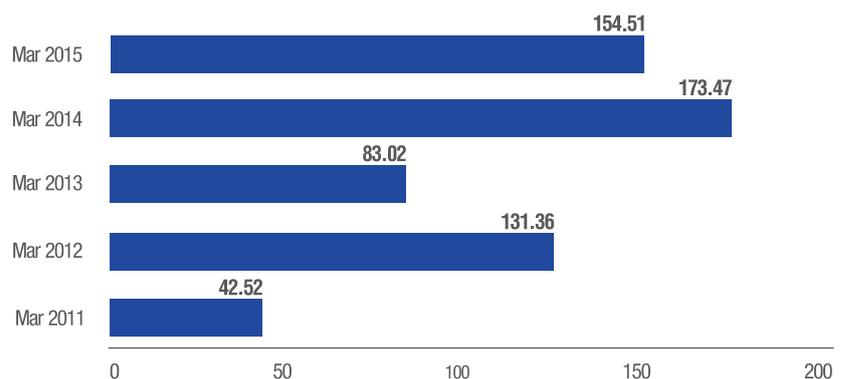
could eventually address affordability and accessibility issues. There are several start-ups such as Innacel's SinuCare, Forus Health and Achira Lab that develop affordable products and cater to the unique needs of India's vast underserved population. The products are inexpensive and do not require skilled resources. In most cases, the products are priced at one-third or one-fourth of their imported competitors. This innovation is not only being pursued by start-ups, but also by established players like Smith & Nephew, who conceptualized, designed and manufactured a product ReSTOR Prosthesis in India which is used worldwide and costs half the price of the competing imported products.

Absence of a Transparent and Predictable Policy Framework

Some of the recent policy initiatives such as the price control in certain devices and preferential procurement of local products have left the industry confused and alarmed. While the need to widen access and support care for underprivileged segments is understood, industry believes that the goals could have been achieved with alternate approaches that would have had less damaging impact on the industry and not impacted investor sentiment.

This could be facilitated through more inclusive policy making, wherein industry concerns are heard and acknowledged in the policy. Additionally a clear long term road map is essential to bridge the healthcare gaps in the country, so that sudden unexpected moves by regulators do not create an alarm.

FDI Inflows (In USD million)



Source: Department of Industrial Policy and Promotion, 2015

Proposed Government Initiatives to Create a Favorable Environment

Upcoming Medical Device Parks

Medical device parks are state-level initiatives wherein states have committed to set-up dedicated industrial parks which will facilitate efficient domestic manufacturing at lower costs. The objective is to create an ecosystem for medical device manufacturing, reduce imports, and eventually export domestically manufactured devices to other countries.

Since these parks will have common facilities for manufacturing and testing, the set-up and manufacturing costs are expected to reduce, thus resulting in better quality and affordable products. Many states including Andhra Pradesh (AP), Maharashtra, and Gujarat have already announced their plan to set up dedicated medical device parks.

Evolving R&D and Infrastructure

With the new indigenous quality certification and dedicated testing labs strategically spread across the country, government intends to improve the quality of medical devices manufactured in India. Based on the recent approval from the Department of Commerce (DoC), two dedicated medical device testing labs will be established at Vadodara in Gujarat and at Noida in Uttar Pradesh. These are few positive first steps, with a few more to soon follow.

While critics have questioned the ability/capacity of two testing labs to manage approximately 14,000 products, it is a positive first step. The government has launched dedicated funds to promote innovation, R&D, and product development within the country in the specified fields of electronics, nano-electronics, and IT.

ICMED Certification

The Indian Certification of Medical Devices (ICMED) is the country's first indigenously developed quality assurance system for medical devices. The certification scheme being launched, has two certification options, ICMED 9000 certification for low-risk medical devices and ICMED 13485 for medium and higher risk devices.

This certification is a joint initiative of the Association of Indian Medical Device Industry (AIMED), Quality Council of India (QCI) and the National Accreditation Board for Certification Bodies (NABCB). NABCB is an accrediting, certifying and inspecting body and its accreditation programs are internationally equivalent, placing it on-par with European and American accreditation bodies. The utility of creating a separate certification body is however, in question, since, if a domestic company has to compete with global companies it is preferable to go for International standards.

Promote Skilled Talent

The Ministry for Skill Development & Entrepreneurship (MSDE) was formed to focus on providing relevant skills to the youth and increasing their employability. Under the MSDE, the Healthcare Sector Skill Council (HSSC) caters to the skill development of health and medical device sub-sectors. The council has identified a large unmet demand for medical equipment/allied health technicians - those involved in operating, servicing and maintenance (allied health).

The council has a mandate to create occupational skill standards and works along with industry partners. They create 'Qualifications Packs' which set validated standards for each skill and performance criteria. These then enter the national qualification register. They are also creating training content and curricula for the Qualification Packs. This training is provided by manufacturers, hospitals and standalone training partners. The council also sets standards for trainers and training infrastructure and then accredits them. Examinations are conducted on behalf of the Skill Council and a certification is provided to students along with placement support.

Many skill development and training programs are being carried out by the government and private sector to design and develop medical devices of international quality and

standards, and to meet the desired regulatory requirements. For e.g. NIPER Ahmedabad will initiate National Centre for Medical Devices (NCMD) for development of skilled manpower for manufacturing in the medical device industry.

Preferential Purchase Policy

Domestic manufacturers have been demanding a preferential purchase policy for a decade. The aim is to encourage domestic manufacturing and give preference to domestically manufactured products in public procurement. Some countries provide preferential pricing for domestically manufactured products in government procurement if all technical parameters are met and the prices are competitive with imported products.

However, Indian Medical Device Industry is still in its nascent stage and it takes time to match the global quality norms. In most of the segments there are hardly one or two players who can match global quality standards. Hence, any Preferential Public procurement policy may lead to a monopolistic escalation of cost with quality compromised. We need to keep in mind the government resources are limited. "Our policy of import substitution under high protection has given rise to a group of small firms none of which are competitive in the world market. In contrast, a focus on the global market can potentially result in output worth hundreds of billions of dollars and hence a large number of well-paid jobs," the Niti Aayog said.

The Shift in the Medical Device Sector Post Regulatory Changes

The Indian Medical Device sector is undergoing significant changes for the better and will continue to do so in the foreseeable future. From both the regulatory and domestic innovations perspective, recent changes in this sector, especially with the government's focus on the Make in India campaign, will cause a shift in the industry's structure, conduct, and performance.

Manufacturing will get more organized and international companies will assess plans to manufacture in India in selected product segments due to harmonized global standards. The increase in testing labs, clinical trials and certifications will increase R&D in India and eventually more customized products for the Indian market will emerge.

Structure	Conduct	Performance
Pre-Regulatory and Policy Framework Changes		
Nascent regulatory framework	International players preferred to import and distribute. Selective participation due to the uncertainty of rules	International players focused on high-end products to achieve reasonable margins
Lack of conducive environment for technological innovations	Domestic companies continued to focus on low-end products and refrained from investment in R&D	Domestic players focused on cost competitive/high volume products resulting in low margins. No efforts to build competency in R&D
Inverted duty structure	Low investments were made in manufacturing and R&D infrastructure	
Post Regulatory and Policy Framework Changes		
Robust regulatory framework	Conducive environment for technological innovations	Companies who demonstrate quality standards together with cost efficiencies to thrive
Focus on manufacturing and research in India	<p>More International companies to manufacture in India and expand their presence across segments</p> <p>International companies will look at domestic innovation opportunities</p> <p>Domestic companies to focus on raising quality standards and technological upgradation</p> <p>International and domestic companies to customize products for Indian needs</p> <p>International and domestic companies to collaborate with each other through joint ventures or associations</p>	<p>Focus on technology and innovation to drive down cost and improve margins with better and differentiated products</p> <p>Patients to benefit from competitive costs and better quality products from both domestic and international companies</p>

Make and Heal in India

- The Make in India Campaign
- Objectives of the Government
- Critical Success Factors for Developing and Making in India
- Heal in India – Bolstering Medical Devices and Healthcare Growth
- Conclusion



The Make in India Campaign

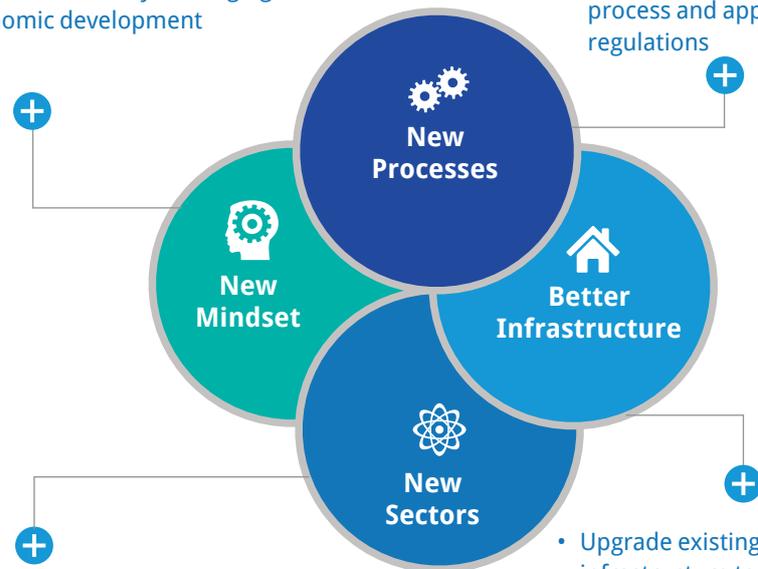
Make in India is one of the flagship campaigns of Prime Minister (PM) Narendra Modi and aims to bring more manufacturing to India. This initiative is intended to bring self-sufficiency through domestic supply and develop India as a global manufacturing hub. With overall costs rising in China and manufacturers contemplating moving to other countries, this might be the right time for India to move in and capture this space. As a manufacturing hub, India aims to create significant employment opportunities for its increasing young population.

The Medical Technology/Device industry is one that has been targeted for this campaign given the current high import intensity. However, the response towards the initiative has been lukewarm for a variety of reasons discussed in this section.

Four pillars of the Make in India Campaign

- Shift in perception of the government from that of a regulator to being a facilitator
- Position government as a partner to industry in bringing economic development

- Boost entrepreneurship through the ease of doing business
- Reduce the complexities of business set up by streamlining the licensing process and appropriate regulations



Several Reasons for Manufacturing in India

- High import intensity, and likely prospects for substituting with domestic production.
- Long-term growth prospects with improving access and adoption given current low penetration levels. Expected significant volume growth through servicing of untapped domestic demand
- Outsourcing of manufacturing and R&D activities to India to take advantage of cost arbitrage.
- Availability of skilled and qualified technical and professional manpower resources.
- Opportunity to design and manufacture India centric products at lower price points for untapped segment volumes.

Objectives of the Government

Manufacturing Cost-competitive Quality Products

'Make in India' is one of the strategies the government is using to address the patient affordability issue and bring down price of healthcare. They believe that local production costs of certain high volume devices may be lower than imported costs.

Reduced dependency on imports and increase exports

Net imports of medical devices are close to USD 2.5 billion and expected to grow at 10-12% CAGR - a significant portion of trade imbalance and a cause of concern for the government that needs to be managed.

Employment Generation

It is estimated that India adds 12 million people every year to its workforce. Manufacturing as a sector has traditionally created significant employment. The government hopes to create a total of 100 million new jobs in 25 sectors by 2022 through the Make in India campaign.

Based on our conversations with several stakeholders, the government's intention to 'Make in India' is warranted. However, regulators need to look at the larger idea representation - Make and Heal in India. A limited approach to making in India may not create the required, sustainable healthcare ecosystem or meet some of the other important objectives.





Critical Success Factors for Innovating and Making in India

While the government is systematically making efforts to address the challenges described above at the macro level, there are various issues which need to be addressed for companies to consider manufacturing in India. Some of the critical success factors for the 'Make in India' campaign are mentioned below.



Developing and manufacturing in India has its own pros and cons, but needs active consideration by the industry. Private players have a big role to play in the modernization and the growth of the market through innovation, localization, increasing awareness and training.

There are several examples of companies successfully manufacturing medical devices in India. Some of which are highlighted below.

Smith & Nephew

The company's ReSTOR Prosthesis was conceptualized, designed, and manufactured in India and is now sold across the world.

GE Healthcare

GE Healthcare introduced an electrocardiogram (EKG) system that is priced 80% lower than a similar imported product available in India. They also introduced a cardiac ultrasound machine that is about 50% cheaper than its imported counterparts. GE conducted R&D for several years before finalizing the design and made sure that a substantial amount of components of the machine could be sourced locally. Hence, it not only created an India specific product but has also assisted in creating an ecosystem around it.

Philips

Philips India launched Mobile Diagnost Opta, a digital X-ray system, and BV Vectra, a mobile C-arm system dedicated to orthopedic surgical procedures in 2015. Both of these products were conceptualized, designed and manufactured in India. Philips also plans to increase localization of these products which varies currently from 10-50% and creates an ecosystem for these products. Nearly 20-25% of the total production at its Chakan plant is exported to 90 countries. India has become an important region, not only for R&D but for manufacturing as well.

Make in India, Make for India or do both?

The Make in India campaign speaks about cost competitive manufacturing in India by leveraging the availability of highly skilled labor and indigenous resources. This is expected to boost exports and strengthen the domestic production base.

Make in India will require a significant jump in technological and professional expertise, which remains a constraint. It also necessitates a dynamic infrastructure and policy environment that needs to be built. Major investments in R&D and infrastructure development are required to achieve these objectives.

Given the attractive future potential and large population size, Make in India could be a game changer for such companies.

While Make in India essentially covers both manufacturing for indigenous and export markets, it's critical for companies to look at Make for India as well. Make for India can help the country achieve equitable growth for its population. Inclusiveness is already a recognized priority and should be adopted through Make for India. Make for India involves R&D and innovation that results in a product designed for India's specific needs at appropriate price points.

Make in India and Make for India feature outcomes that could bode well for the country. Though they differ in their approach, they have a common aim of developing India. These initiatives need an underlying climate that is crucial for success. The creation of a hybrid model is required which satisfies the domestic developmental deficit while giving considerable policy space for dynamically adjusting to the international economic climate.

Heal in India – Bolstering Medical Device and Healthcare Growth

Healthcare in India is at a crossroads and needs various interventions. The success of initiatives such as 'Make in India' is dependent on a number of policy initiatives described earlier.

Industry players believe that a campaign like 'Heal in India' will be synergistic to the Make in India initiative. An attractive Heal in India campaign can result in a significant expansion and upgradation of healthcare infrastructure in the country benefiting Indian residents and providing value addition through medical tourism. India emerged as an important player in the medical tourism space as early as the 1990s, but awareness spread only in this millennium. The country is witnessing a growth of 22-25% CAGR in medical tourism, and healthcare providers expect the industry to double to USD 6 billion by 2018 and grow to USD 8 billion by 2020.

Quality of care, availability of high end technology/facilities and costs are the key drivers. Important medical tourism procedures are tertiary care driven such as cardiac surgery and interventional cardiology, orthopedic surgery, transplant surgery, oncology, bariatric surgery, dentistry, cosmetic surgery and in-vitro fertilization. Patients from Africa and the Middle East access private healthcare in the country due to lack of quality facilities and trained doctors in their respective countries. Medical tourists from - developed countries use India for surgeries that are not covered by insurance, or where waiting periods for non-life threatening procedures is very long in government funded markets.

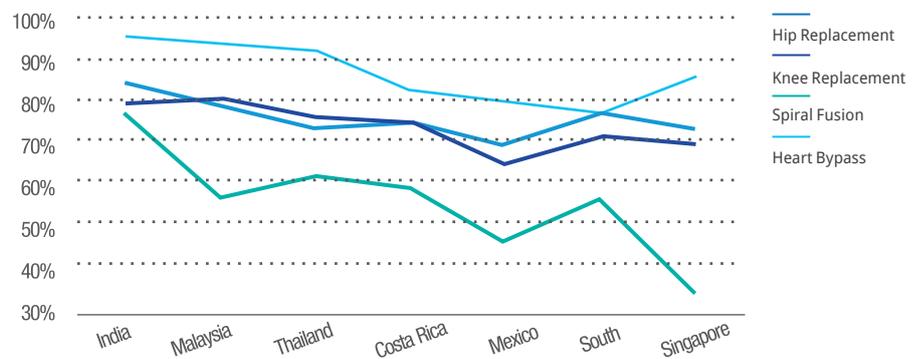
The expanding medical tourism sub-sector should also provide additional impetus to the overall growth of the device industry.

Foreign medical tourists



Source: Ministry of Tourism and IBEF, Healthcare, January 2017

India - Lowest Cost Destination for Treatment



Source: Indraprastha Apollo Hospitals, Annual Report 2015-2016

Treatments in India are 50%- 90% lower than the US, making it one of the most affordable medical tourism destinations.

The expanding medical tourism sub-sector should also provide additional impetus to the overall growth of the device industry.

The Impact of Heal in India

Employment Creation

It is estimated that every hospital bed added to the current capacity, creates direct employment for five people and indirect employment of up to 25 people. In 2015, the Indian healthcare sector became the fifth largest employer, in terms of direct and indirect employment. Advanced medical procedures generally have a huge multiplier effect on employment generation. The healthcare delivery sector will generate high-value service jobs, thus resulting in a more skilled and equipped India.

Compliment and Synergize Make in India

Heal in India will accelerate the development of the overall healthcare ecosystem, directly impacting awareness, adoption and access of medical devices and technology. This will provide an additional impetus to the overall growth of the device industry. This strategy will also ensure upgradation of technology to global standards, and ensure value optimization of the same. All improved demand will also result in scale and cost economics, benefiting price and affordability in the long term. The technology and upgradation benefits of medical tourism will spill over and benefit the local community equally.

Export Earnings and Balance of Trade

A successful medical tourism industry can help boost export earnings significantly. This can also support imports of high technology assets/ devices without hurting the balance of trade.

Continuous Learning and Innovation

A drive to Heal in India will increase international tie-ups and collaboration in both medical devices technology and delivery sectors. These collaborative efforts will open up channels for continuous learning, improved access to technology and its use, and further elevate the quality and availability of healthcare.

Enlarge the Medical Device market in India and Accelerate Growth

This initiative will lead to increased medical procedures and drive up volumes for the medical device industry. Medical Tourism being at the top of the pricing pyramid will also facilitate the adoption of the high-end products and thereby improve margins for the industry. This in turn will also incentivize innovation among both domestic and international players and ensure continuous access to advanced technology.

Stakeholders should collaborate and initiate a campaign to Make, Innovate and Heal in India unlocking India's healthcare potential and addressing awareness, adoption, access and affordability.

Price Control Policy – Impact and Implications

- Price Control – Economic Regulation
- Fundamental Concerns and Anomalies in the New Price Control Regulations for Devices
- Healthcare Industry Economics – Does Profiteering Exist?
- Lessons India can learn from other countries
- Implications of Price Control Policies Introduced for Devices
- Recommendations



Price Control – Economic Regulation

The Government of India has been consistent in communicating its intent to make healthcare more affordable and accessible to all citizens, an objective reiterated in its 2017 National Health Policy. While pharmaceuticals (drugs) have been under price control for many decades, it is only recently that medical devices have fallen under the government's radar for price control.

In a scenario where a market fails to achieve the optimal and reasonable price for a trade, as the Government of India believes has occurred in this instance, regulators intervene and explore economic regulations such as price capping.

India has been facing challenges to provide quality healthcare to its 1.4 billion people. NCDs such as heart disease, diabetes and respiratory diseases comprised of 45% of all diseases in 2010, and are expected to reach up to 75% by 2025. Despite a 42% increase in the number of angioplasties performed in 2015, only 2% of the patients needing this type of surgery were treated last year, according to a report by the National Intervention Council (NIC).

While price capping is meant to make healthcare more affordable and accessible to a wider population, it may not benefit the market in the long run. This section investigates the impact and implications of the ongoing government interventions and examines the policy options.

The total number of coronary interventions in 2015 amounted to 375,000 with an average use of 1.3 stents per procedure. Out of all PCIs, 60% were funded by patients and private insurance while 35-40% of coronary stents were provided to the public at the Central Government Healthcare Scheme (CGHS) price.

Source: National Intervention Council (NIC) Data

Price Control Mechanism – Implemented by Regulators

The National Pharmaceutical Pricing Authority (NPPA), an organization of the Government of India under the Ministry of Chemical and Fertilizer's Department of Pharmaceuticals (DoP), was set up through an executive order and is therefore not a statutory body. Its aim is to monitor, fix and/or revise the prices of controlled bulk drugs and formulations and to further enforce prices as well as ensure the availability of these medicines in the country. The NPPA usually fixes the prices of any drug after it is included in the National List of Essential Medicines (NLEM). However, it has emergency powers to act suo motto.

The first device to receive the DoP's attention has been coronary stents. Prior to the pricing control, the average

retail price for a bare metal stent was approximately USD 700, while drug-eluting stents were priced at approximately USD 1900. The industry offers a large number of models priced according to their technology and value. Although the average Price to Distributor (PTD) was significantly lower, MRP prices were high, leading to unreasonable trade margins. In light of these large margins, in February 2017, the NPPA, fixed a ceiling on the price of cardiac stents and slashed their rates by nearly 75%. While it considered various price identification models based on landed costs, production costs and other industry submissions, the NPPA finally chose to classify all stents under two kinds, namely, Bare Metal Stents (BMS) and Drug Eluting Stents (DES). The revised prices are listed in the table below.

Sr. No.	Coronary Stents	Ceiling Price (INR)	Ceiling Price (USD)
1	Bare Metal Stents (BMS)	7,260	114
2	Drug Eluting Stents (DES) including metallic DES and Bioresorbable Vascular Scaffold(BVS)/Biodegradable Stents	29,600	463

The NPPA subsequently issued a notification stating that the ceiling prices were inclusive of the eight percent trade margins for the distributor.

In the larger scheme of things, less than 0.02% of the population opt for coronary intervention procedures. This is far lower than the number of people affected by other healthcare diseases. However, this directive sets a precedent to include price control measures on other medical devices as well. Given the significant slashing of prices, many manufacturers have found it extremely difficult to continue selling some models. Hence, major stent manufacturers such as Abbott Vascular and Medtronic have submitted applications to increase the ceiling prices for their latest generation of products and/or allow them to withdraw the products from the market.

Post the price capping of stents, the NPPA published a list of 19 medical devices that were placed on its monitoring list in May 2017. The devices which were covered under this order included catheters, heart valves, orthopedic implants and internal prosthetic replacements amongst others. It is believed that this step is a precursor to bringing additional devices under the ambit of price control. It is important to note that after the price cap notification is issued, no manufacturer can withdraw the products from the market for a period of 12 months from the date of notification without the prior approval of the NPPA.

After capping prices for coronary stents, the NPPA focused its attention on orthopedic implants. In August 2017, it capped the prices of knee implants used both for primary and revision surgeries and further capped the trade margins for distributors/importers and hospitals. Before capping the prices for knee implants, the NPPA released an analysis of trade margins for the same and revealed that the margins ranged from 135% to 300%.

Type of Knee Implants	Old Price (INR)	New Price (INR)	New Price (USD)
Cobalt Chromium Knee Implant	1,58,300	54,270	848
Titanium Oxidized Zirconium	250,000 - 450,000	76,600	1197
High Flexibility Implant	180,000 - 450,000	56,490	882
Revision Implants	275,000 - 600,000	113,950	1780
Specialized Implant	275,000 to 900,000	113,950	1780

The NPPA carried out extensive deliberations with the committee to reach the conclusion that the margins within the healthcare supply chain indicate a 'failed market system', where asymmetry of information resulted in unethical practices.

Source: SKP analysis

Fundamental Concerns and Anomalies in the New Price Control Regulations for Devices

Devices vs Drugs

In India, medical devices are treated as drugs as they do not have a separate Act that governs them. The government understands the need for separate regulations for devices and has accordingly introduced the Medical Device Rules. However, its recent decision to treat medical devices as drugs under the price control regulations directly contradicts these efforts.

The following table highlights the imperative to use different and distinct regulatory frameworks to govern drugs and devices. A lack of understanding of the dynamics of medical devices will lead to inappropriate sectoral policies.

Differences between Drugs and Devices			
Sr No	Parameters	Drugs	Devices
1	Scope	Based on pharmacology, chemistry, biotechnology and genetic engineering	Based on mechanical, electrical, IT, and systems engineering
2	Outcome	Dependent on patient response	Depends significantly on the surgeon's skills and training
3	Monitoring	Patients can monitor themselves	Patient training and education is required
4	Life Cycle	Very long development cycles with extensive phases of R&D trials	Shorter development cycle with thorough evaluation during the design phase
5	Volume	High volume, standard batch sizes	Low volume, variable batch sizes
6	Costs	Low manufacturing and distribution costs as set processes	Large investments in manufacturing distribution, and training/education
7	Obsolescence	Very slow	Rapid

Source – IMS Health, 2016

For pharma companies, price is a function of the product, whereas for medical devices it is a function of product and delivery. Medical device companies need to straddle both innovation and obsolescence, due to which their products have shorter lifecycles of only a few years and smaller volumes.

In our conversations with medical device manufacturers, we found that most of them agree with the government on the need to make devices more accessible and affordable, as well as to create more transparent and fair trade practices. The industry did make numerous suggestions about potential approaches and models.

However, they feel that such a drastic price capping will significantly distort healthcare economics and most medical device manufacturers question the approach used while appreciating the intent of the policy. In both the cases of Coronary Stents and Knee Implants, it was observed that the trade margins - that is the difference between the Price to the Dealer and the MRP (maximum retail price) was too high. Efforts are required to address the Trade Margin through conversation and proper analysis with various stake holders. But in practice the Price cap was decided based on Landing Cost/Ex-Factory cost reducing margins of the importing company. This will severely constrain the ability of the importing companies to invest in Skill Development or introduce New Technologies in India.

Technology Assessment of Devices and the Evaluation of Clinical Benefits

The subcommittee and the NPPA decided to consider different stents as equivalent except for the difference between bare metal and drug eluting models. Bare-metal stents (BMS) were first introduced in 1986, followed by drug-eluting stents (DES) in the early 2000s, which have since been followed by four other generations of stents (DES). Stents today not only differ in clinical outcomes but also in drug dose/elution kinetics, platform material/design and polymer type/coating, thereby impacting their performance and long-term patient outcomes. Globally, new devices are approved for marketing after conducting efficacy studies against current products.

The Industry believes that pricing should ideally be set by market forces. In some economies payers/governments use Health Technology Assessment (HTA) selectively to determine pricing based on health economic value of the technology. HTA is considered a specialized task that needs to be done by qualified scientific organization. Some industry experts believe that this task be given to the MTAB, a government created body, and that the MTAB be provided adequate resources to accomplish this task, including full HTA on a selective basis.. The MTAB will be better placed to provide recommendations to the regulators on technology differentiation and if necessary value.

NPPA's Stent Assessment Differs from the Cardiologist's Viewpoint

Cardiologists, in general, feel that there are important differences in the various generations of stents from a clinical benefit viewpoint. Patients have differing anatomies, vascular structures and clinical conditions, including disease anatomies, vascular structures and

clinical conditions, including disease stage and complicating co-morbidities, and often display different lesion characteristics in their coronary vessels. Thus, it is important to understand that all coronary artery disease (CAD) patients are not the same and different products may have significant and distinct clinical benefits. The assessing authorities should take into account the current technology for factors such as the ease of procedure, probability of restenosis, improved recovery, shortened lengths of hospital stay and reduced readmission rates. For example, the use of an older generation stent on a diabetic patient may result in restenosis for 70-80% of patients, resulting in higher long term costs to the system.

Willingness to Reward Innovation and Quality

Currently, there is a striking difference in the number of clinical studies among DES products for different manufacturers. Many studies support the products sold across global markets, whereas some products approved only in India for the Indian market are supported by very few, if any, clinical studies.

With extensive regulatory requirements in place for US FDA approvals and CE Mark, the safety of medical devices is ensured. Indian regulations in their current form appear to be inadequate to measure and ensure the safety and performance of medical devices to be used for patients in India.

The greater volume of clinical evidence published for globally marketed DES models, provides greater certainty for medical practitioners, as well as patients, about the safety and performance of those stent models. It is important to recognize this investment in R&D and consider it in pricing if India wants to encourage development and innovation.

Linkage between Device Cost and Total Procedure Cost to Patients

Reduction in device costs alone may not significantly impact procedure costs which is the real parameter that can widen affordability and usage. In most cases, the cost of implants (Ortho and Cardiac) is less than 25% of the overall cost that a patient bears and very rarely exceeds 35-40%.

Medical service providers fee (surgeon, physicians, nurses and other consultant charges) and infrastructure costs such as operation theatre charges, room rent and diagnostics are significant components of the treatment costs. Contrary to popular belief, over the last 4-5 years, the cost of implants as a percentage of total procedure costs has declined. The cost of stents for patients has gone down by more than six percent in the last four years.

According to the WHO, following in the footsteps and practices of the 'access to essential medicines' may not be enough to achieve the overall objective of improving access. The agenda to improve access to medical devices requires, and deserves, its own unique modalities.

Healthcare Industry Economics – Does Profiteering Exist?

Healthcare delivery in India is managed by two participants: the public sector (government) (30%) and the private sector (70%). It is private investment and entrepreneurship that have addressed the accessibility issue to a significant extent, especially in tertiary care, throughout the healthcare ecosystem, from manufacturer to healthcare delivery. Studies have indicated that patients' trust in government hospitals has decreased because of the unavailability of skilled medical service providers, robust infrastructure and medical supplies.

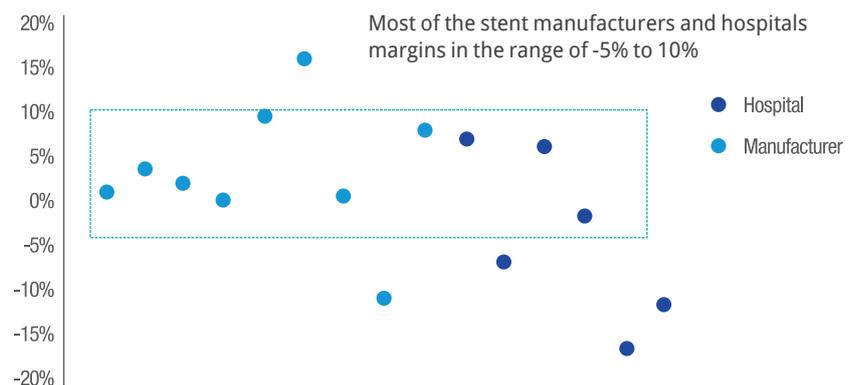
The Indian coronary stent market is dominated by MNCs with approximately 60% of the market share. The leading companies in this segment are Abbott Vascular, Medtronic and Boston Scientific. The Indian entity of these MNCs imports the devices from the U.S. or Europe and sells them in India through distributors after adding their own margin on the landed costs.

Net Margins of Manufacturers and Hospitals

This paper has studied some of the prominent stent manufacturers and hospital chains to obtain an analysis of margins made in the industry.

It is pertinent to note that most of the manufacturers and hospitals in our samples have net margins (profit after tax) in the range of -5% to 10%, negating the notion that manufacturers or hospitals are profiteering and exploiting patients. Manufacturers have also contributed by activities such as providing 30-40% of total stents in the country at a low rate of USD 370 under the CGHS.

Hospitals invest heavily in building infrastructure and the return on capital in this industry is not high. Cost of land and capital equipment in India is higher than most countries and this makes quality healthcare impossible to deliver at very low price points. Manufacturers too spend significant resources on R&D, training of medical service providers and these costs are not always visible to consumers.



While it might be true that the cost to patients is high for stents, it might also be equally true that stakeholders are not profiteering. Hence, the issue requires a deeper understanding of the overall healthcare delivery mechanism in India and the various socio-economic factors at play.

Product Price Caps, Procedure Price Caps or Both?

Recently, the state of West Bengal amended its Clinical Establishment Act, 2010 by introducing the West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act, 2017. It aims to bring greater transparency, to bring an end the harassment of patients and check medical negligence in private hospitals and nursing homes. The act has many patient friendly steps, from requiring healthcare providers to treat accident victims without the advance payment of fees to outlawing the practice of holding a deceased patient's body until their hospital dues are paid.

An important pro-patient step in the act is the capping of package rates for consultations, investigations, bed charges, intensive care, ventilation, implants and other similar procedures. Further, any additional treatments or procedures will not be charged to the patient over and above the fixed package rates, irrespective of whether any additional treatment is provided to the patient or not. The state of Karnataka has also introduced a similar legislation termed the Karnataka Private Medical Establishments (Amendment) Bill, 2017. However, it has been kept in abeyance given the strong protest from the medical community.

The key aim of both these pieces of legislation has been to curb healthcare costs and regulate the private healthcare sector, and they have been careful to exclude government healthcare institutions from their purview. The experience in West Bengal indicates that this legislation may not have been well drafted. For instance, there have been cases of medical service providers refusing difficult or complicated cases due to the significant liability burden on them which includes fines and imprisonment. The package prices have not yet been introduced, but, if done, may lead to an exodus of private investment from the state. Also, patients that are refused treatment will seek treatment elsewhere.

Costs Distributed across the Supply Chain

Limiting prices may impact all stakeholders - medical device manufacturers, distributors, and hospitals, and may, in turn, have an adverse impact on their ability to invest in newer infrastructure. This could lead to limited healthcare access growth for the underserved sections of Indian society.

The costs incurred to make devices accessible are listed below.

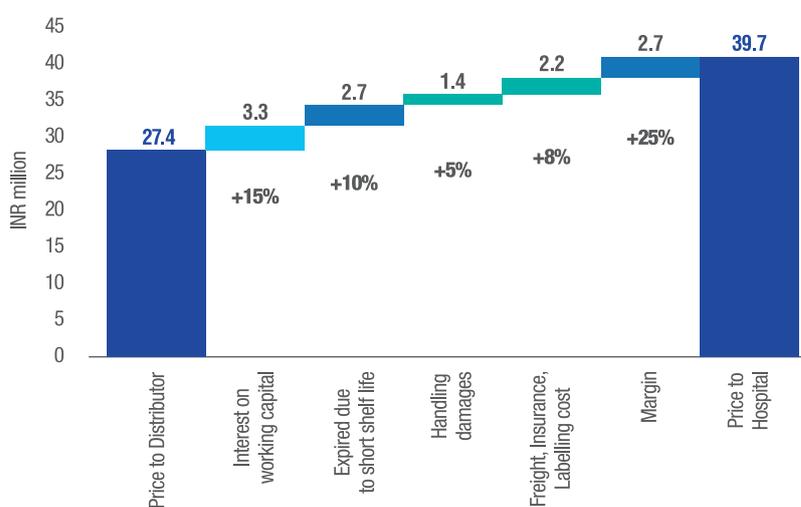
- High Working Capital inventory and a large number of days of sales outstanding in government schemes
- High precision instruments on loaner basis with highly skilled and trained experts to help in the selection and usage of instruments and devices
- Cost of training the surgeons and paramedics staff to ensure high-quality procedures and patient

outcomes. Many of the Indian teaching institutions do not have the infrastructure to train their students on the newer technologies and devices and the industry plays a major role here.

- Rush orders and off-time deliveries result in higher logistics cost
- Huge investments in infrastructure – capital expenditure and interest cost

There are several costs incurred by the distributor in making the devices available within the market. We have considered the example given below of costs incurred for the distribution of stents to hospitals.

Stent Distributor Margin Analysis



Source: SKP Research and Analysis

The price to hospitals derived from the equation given above is closer to the average prices prevailing in the industry. Accordingly, the PTD + 8% margin suggested by the NPPA might fail to make the model commercially attractive for distributors, who would prefer to distribute low-cost stents and other profitable products. Further, various stakeholders feel that the efforts involved in distribution require margins in the range of 20-25%. While

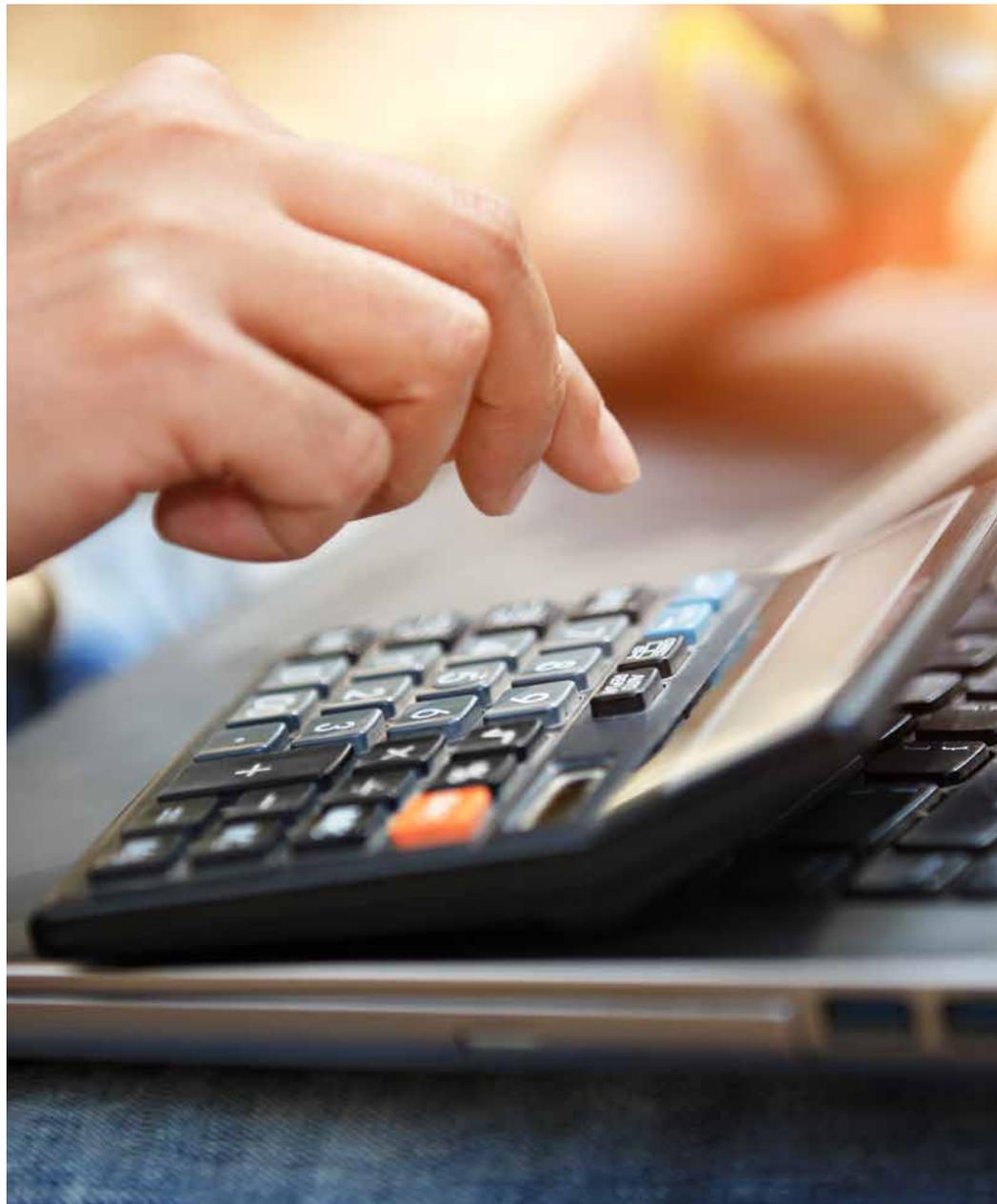
many large hospitals directly negotiate prices with manufacturers, distributors play a critical role in facilitating unorganized healthcare delivery. The role and costs incurred by distributors vary for different devices. Therefore, it will be more reasonable for a regulator to regulate the prices at Price to Hospital (PTH) levels.

Unlike other large economies, India spends a substantially lower amount of its GDP on healthcare. Consequently, while the government's intention of decreasing this burden is understandable, capping device prices might not be the most effective way to do this.

For the healthcare industry in India to operate effectively, it is imperative that legislation and regulation do not put them under undue stress and make it difficult to conduct business as usual. As demonstrated above, there are not enough margins in the entire value chain to have a sustainable industry that attracts fresh investment with price caps at both procedure and product levels.

Thus, the central and state governments need to come together and adopt a holistic and methodical approach to reduce costs and increase affordability. A diligent way to achieve this might be for NITI Aayog first to first prepare a model 'Clinical Establishment's Bill', which can then be introduced in Parliament and later adopted by the majority of states.

Alternatively, the regulator could have looked at only capping the total Trade Margin of specific devices, especially in a market where distributors service most of the hospitals. However this cannot be a fixed margin across all device categories, as the services provided by distributors varies significantly for different devices, resulting in substantial variances in costs and investments at the trade level.



Mapping Learnings from Other Countries with India

Developed countries, such as those mentioned below, have robust public health insurance frameworks that account for a majority of healthcare benefits and fund a large chunk of the

hospital care costs. Inherent to this system is transparency and predictability in the provider pricing of healthcare services – one of the key elements missing in Indian healthcare at present.

Some of the best practices taken from other countries which can be replicated are as follows:

Parameters	USA	France	UK	India
Product based reimbursement/co-payment	Patient shared billing with government and insurers	Case-mix system of reimbursement based on treatment in public or private hospitals	Fixed annual budgets by local clinical commissioning group (CCG's) along with regional Strategic Health Authorities (SHA's)	Mostly out of pocket expenses - Patient shared billing with government and insurers
Bundled/Package Rates	Fixed procedure fee based on diagnosis-related groups (DRG) payment system	Fixed procedure fee based on French DRG payment system	Fixed procedure fee based on DRG payment system, except few cases paid as unbundled rates	Procedure fees deviate based on hospital, quality of device and region
Device Pricing	Covered in package rates	List of reimbursable products and services covers both generic and branded products with incremental value	Manufacturer's free to set prices but have to negotiate with CCG's	Price capping for stents, implants market forces drive the prices for all other products
Price Capping	Capping at healthcare provider fees	Capping at healthcare provider fees and device fee	Capping at healthcare provider fees	Initiated capping at device fee
Value proposition from the country	Incentivize hospitals to shorten surgical time and length of stay	Differentiate between novel brands with incremental value	Controls hospital budgets allowing free competition in product prices	-

India faces three major challenges in implementing similar incentives for hospitals.

- First, India does not fund its hospitals sufficiently to address the costs of many medical products, particularly imported medical device implants. Thus, unlike the countries mentioned above, the entire burden of pricing in India is shared by private and insurance agents.
- Second, the infrastructure and data requirements needed to launch a DRG payment system can be difficult due to the lack of treatment guidelines and patient records.

- Third, the Indian delivery market is largely unorganized and therefore, price capping for healthcare provider fees needs a much more robust information system.

It should be recognized that every stakeholder in the healthcare supply chain — manufacturers, providers, and payers have a responsibility to address variation in cost and quality to patients. When transparency of hospital procedure costs and product-pricing is absent, patients bear the burden, particularly those who self-pay and therefore have no bargaining power on the prices they pay.

Coronary stents and knee implants are the only products currently under price control. However NPPA has published a list of 19 medical devices in May 2017 that as per indications could be subject to price caps.

Other Key Takeaways

- A comprehensive review on the essentiality of procedures is required to determine essentiality for medical devices. Medical devices are just one element of service delivery.
 - It would be encouraging if new innovations are kept out of the 'essentiality purview' until a return on investment is achieved. Tiered pricing could be one of the ways to create differentiation in products.
 - Creating regional databases of overall costs and outlining the appropriate patient-borne costs for each procedure that is funded.
- This database would document the local governmental procedure payment and the 'typical' range of patient charges that accompany that procedure in the local geography where the hospital resides. Bringing in total transparency of both procedure prices and those of services and supplies involved including medical devices.
- Bulk purchase mechanism should be streamlined to ensure that there is an efficient supply chain.
 - Provide patient with Procedure Choices and Hospital Competition: the patient must be provided the regional range of costs for the recommended procedure along with the expected costs at the treating hospital. This new system would require hospitals to publish their own 'to patient' price for the total procedure.

If device pricing as well as total treatment costs are transparent, it will support greater competition among hospitals as well as all-around budgeting, planning and parity. Premium pricing should be based on demonstrated quality, efficiency and efficacy.

Implications of the Price Control Policies Introduced for Devices

In a free market where information symmetry exists, the market price is 'fair' due to the competition between companies as well as buyers. But when information asymmetry exists, external measures may be taken to bring more transparency in the system and ensure that procedure costs are controlled at the provider level. While drafting policy, some regulatory officials might look for the easy short-term win, rather than consider the long-term implications of their decisions. While such regulations seem easier to adopt, they are often difficult to apply and may not bring the desired benefit to the consumers. Some of the immediate effects of the price ceiling could be the emergence of excess demand or a shortage of devices in the market.

Although regulators intend to improve the affordability of these devices for patients, their policies impact stakeholders in the healthcare ecosystem in different ways. Unless certain counter steps are taken to safeguard the interests of each stakeholder, the economics driving the system may fail.

Some of the concerns raised by industry experts on price capping are:

- A manufacturing company who brings in state-of-the-art technology will fail to be justly remunerated for their R&D efforts and would thus end up withdrawing these products from the market. In the past few months, there have been applications by multinational companies such as Abbott and Medtronic to withdraw some of their latest-generation stents from the Indian market as the unit economics do not make them commercially viable. They have also argued that since the NPPA deems them equivalent to low priced products, it should not be an issue for the regulator. This also discourages investment by the manufacturers into R&D and will prevent newer generation products in this dynamic and innovative industry from being introduced in India.
- Given the lack of cutting-edge technology products, older products will be in the market for longer than they should be and the customers who wish to use the latest technology products will be forced to compromise or find newer avenues to access the desired product or adopt different procedures.
- There will be a substantial impact on medical tourism as foreign patients seeking high quality healthcare products will not travel to India for treatments and Indian patients will have to visit neighboring countries to obtain newer generation products. Similarly, high-income Indian customers who provide some cross subsidy to hospitals for low-income patients may opt to obtain treatment overseas, further straining the providers' P&L.
- Restricts private players' contributions in building a robust ecosystem. As quoted by a renowned cardiologist, "MNCs are not conducting training conferences because they can no

longer sell their latest products in India and their margins on other products are not high enough to conduct these conferences or sessions".

- A sudden and severe downturn in profits for manufacturers and healthcare providers might lead to an increase in the prices of products that do not fall under price caps.
- Reduced returns would detrimentally affect capital expenditure on infrastructure such as catheterization labs.

Although manufacturers might not ignore India due to its sizeable market, the undesirable unit economics will weaken the case for introducing new generation of stents and implants. They will continue to sell the generic devices, and as a result, the quality of care will suffer.

This makes it necessary to rethink some of the critical parameters that must be considered while drafting appropriate regulations and in shaping the Indian healthcare ecosystem:

- Is it appropriate to reclassify devices as drugs and apply similar rules?
- Is it right in considering that newer generations of devices have minimal value addition from the previous ones?
- Are regulators focusing on generic devices or quality devices for Indian patients? Or should they focus on both and allow patients to make the choice?
- Are we depriving patients the choice of quality of medical devices and products? Will extreme price capping hamper innovation?
- Are the levels of margins reported real and carefully analyzed?
- Has price capping resulted in a reduction of the overall treatment cost as intended by regulators?

To be 'efficient', the market must maximize consumers' (patients) and producers' (device manufacturer's) surplus

Deadweight loss is the waste of resources and economic inefficiency

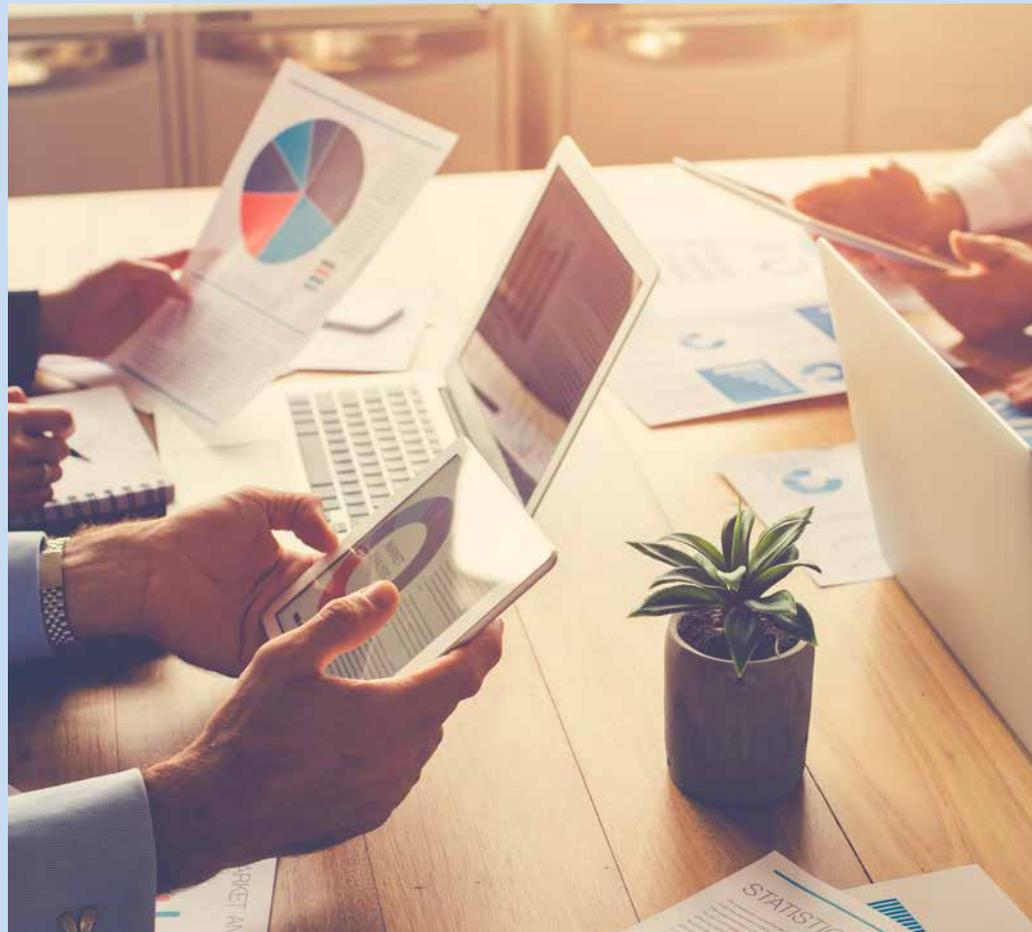
The price ceiling would also increase demand, creating shortages if resources are not available (unmet needs)

If the government wants to address the demand, it can be done through the government directly producing the goods or offering subsidies to encourage production

Price capping may be an easy fix from the regulator's perspective, though this may not have the desired impact on transparency and in creating a better payment system. It has the potential to hamper the building of a robust healthcare ecosystem, depriving every stakeholder the benefit of being part of the supply chain

Recommendations

- Cap Trade Margins and not Price to the dealers, should be capped after detailed evaluation of each Medical Device segment and the role of trade. Trade margins should be fixed differentially for different categories of devices, based on service requirements and role of distributors. Allow the dealers to compete with each other and provide a fair price to the hospitals based on the terms and conditions of services and payments.
- Evaluate the model of tiered pricing as observed in the French healthcare ecosystem, wherein the NPPA cap the generic products and leave the latest generation products with incremental value out of the 'essentiality purview'. The incremental value could be on account of efficacy, material used, ease of delivery and shortened recovery time. Various combinations are possible here such as: an increase in the number of tiers, allowing new introductions to be free of price intervention for a certain number of years.
- There is a need to work towards bundled payment models as used in many other countries to better align incentives for hospitals and their business models.
- Specify certain quantities/proportions of supply of different stents at lower prices to specified government agencies for use with underprivileged sections.
- Empower the Medical Technology Assessment Board (MTAB) to identify priority medical devices and procedures that demonstrates the greatest need stemming from disease burden. MTAB along with other regulators for medical devices should ensure that there are minimum quality parameters—in terms of safety, clinical efficacy, and cost-effectiveness—for medical devices that get used in the public and private health system, such that long-term costs are lowered over a patient's lifespan, with need for fewer hospital readmissions, lowered need for medication, and overall better health outcomes.
- Increase government healthcare spending as a percentage of GDP. India lags behind the other BRICS in this regard.
- Adequate utilization of government infrastructure to reduce the cost to private players – PPP model could be an attractive alternative to explore.



Market 2020

- Five Structural Factors Influencing Demand
- Medical Devices Required at Each Stage of Healthcare
- Expected Growth by 2020
- Conclusion



Five Structural Factors Influencing Demand

When the demand rises, supply will keep pace. Factors driving both demand and supply are:

Rising Chronic Disease

Lifestyle-related diseases, NCDs, are the single largest reason for deaths in India. Diabetes alone has shown 100% growth in the last 15 years in patient numbers leading to India being tagged as the 'Diabetes Capital of the world.' There are at least 45 million patients of coronary heart diseases. One-fifth of the deaths in India are from coronary heart diseases. By the year 2020, it will account for one-third of all deaths.

Ageing Population

It is expected that by 2020, India will have seven percent of the total population above the age of 65 years. The surge in this demographic would lead to a higher demand in healthcare and in-turn, medical devices. The industry believes that the higher life expectancy rates will also spruce up the demand for medical devices.

Increasing income

The rising middle class of India, with its higher discretionary income, can increasingly afford to demand high-quality medical devices.

Increasing Insurance Coverage

The health insurance industry grew at about 16% in 2015, which is more than twice the rate at which India's gross domestic product (GDP) is growing. The industry has seen year-on-year growth of more than 27% in direct premium collections.

Increasing Awareness

The involvement of various stakeholders from manufacturers to delivery providers reaching patients and creating awareness will be key to the increasing demand. This would also require Public Private Partnerships to reach the mass rural population.

Medical Devices Required – at Each Stage of Healthcare

As India grows economically and socially, the shift in the disease burden is becoming more pronounced. The public sector has been unable to keep up with the need to develop capability, skills, and infrastructure for the healthcare market, particularly in the tertiary care sector. The gap is increasingly filled by the private sector providing higher quality healthcare services with better infrastructure and qualified healthcare medical providers.

It is important to note that medical devices are required at each stage of the healthcare continuum. The role of medical devices is not only restricted to diagnosis and treatment, but also required in the constant management and monitoring of on-going health.

Medical device manufacturing is a technologically dynamic industry characterized by continuous innovation. While current unit volumes may be small, it is reasonable to expect significant growth over time.

The 2020 and beyond opportunities for the Indian medical devices industry are very attractive despite hiccups, such as price controls. The industry should comfortably witness a double-digit growth rate.

Expected Growth by 2020

The Indian Medical Device industry is going through a phase of scrutiny and regulatory uncertainty. This might hamper the strong progress that was expected at the start of this decade. Nonetheless, the industry still expects the sector to grow at a respectable pace of 10-11% CAGR, taking its valuation to USD 8.21 billion by the year 2020.

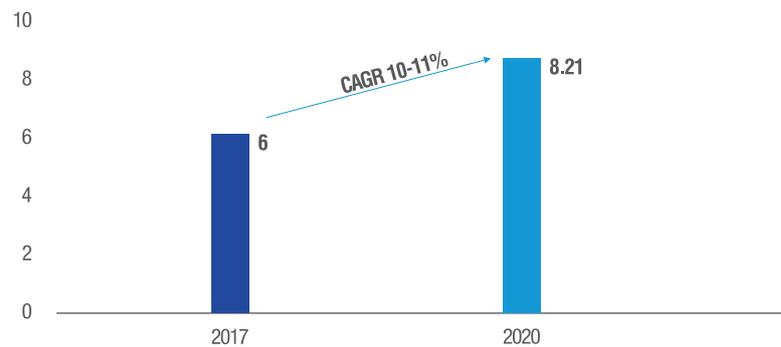
The individual sub-segments within the sector will have varying growth rates depending on segment-specific factors.

The 2020 scenario assumes that there will be a significant focus on improving healthcare infrastructure to enable the government's goal of accessibility and availability. Patient aids will be the fastest growing segment of the industry, clocking an impressive CAGR of 15%. This growth will largely be driven by devices like pacemakers, hearing aids and the likes.

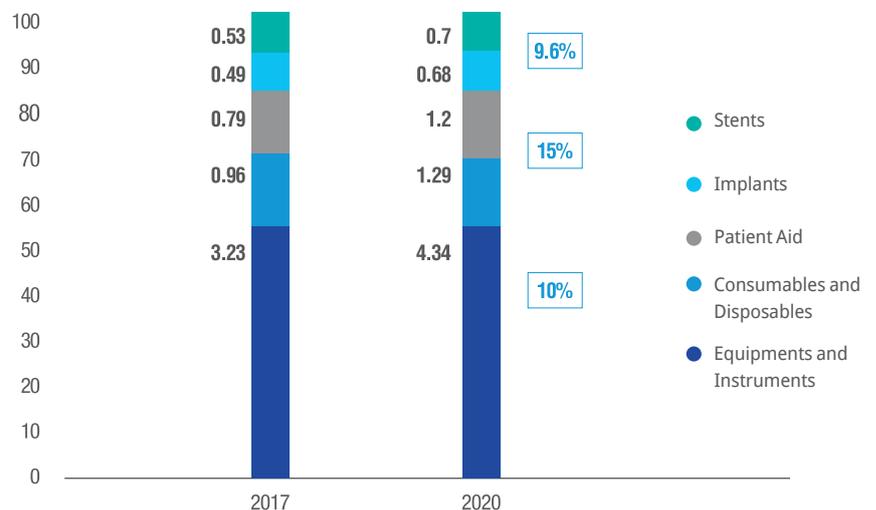
Implants will continue to grow with increasing awareness and the reducing overhang or underhang, in cases where the implant is bigger/smaller than the bone surface, with orthopedic surgeries. Until 2016, implants were one of the top-two fastest growing segments of the sector. However, after the inclusion of these devices under monitoring for price control, their growth rate might be effected.

Equipment and instruments remain the largest segment of the industry with a growth rate of CAGR 10%. The size of the segment has increased from USD 3.2 billion to USD 4.34 billion, lead by ophthalmic instruments, imaging, and radiology equipment. A positive approach towards the sector in policy making should augment well for the industry.

Medical Device Industry in India



Medical Device Industry in India 2020



Conclusion

Healthcare in India is at a crossroads and needs intervention in many ways. The success of initiatives such as Make in India is dependent on a number of policy initiatives as described earlier.

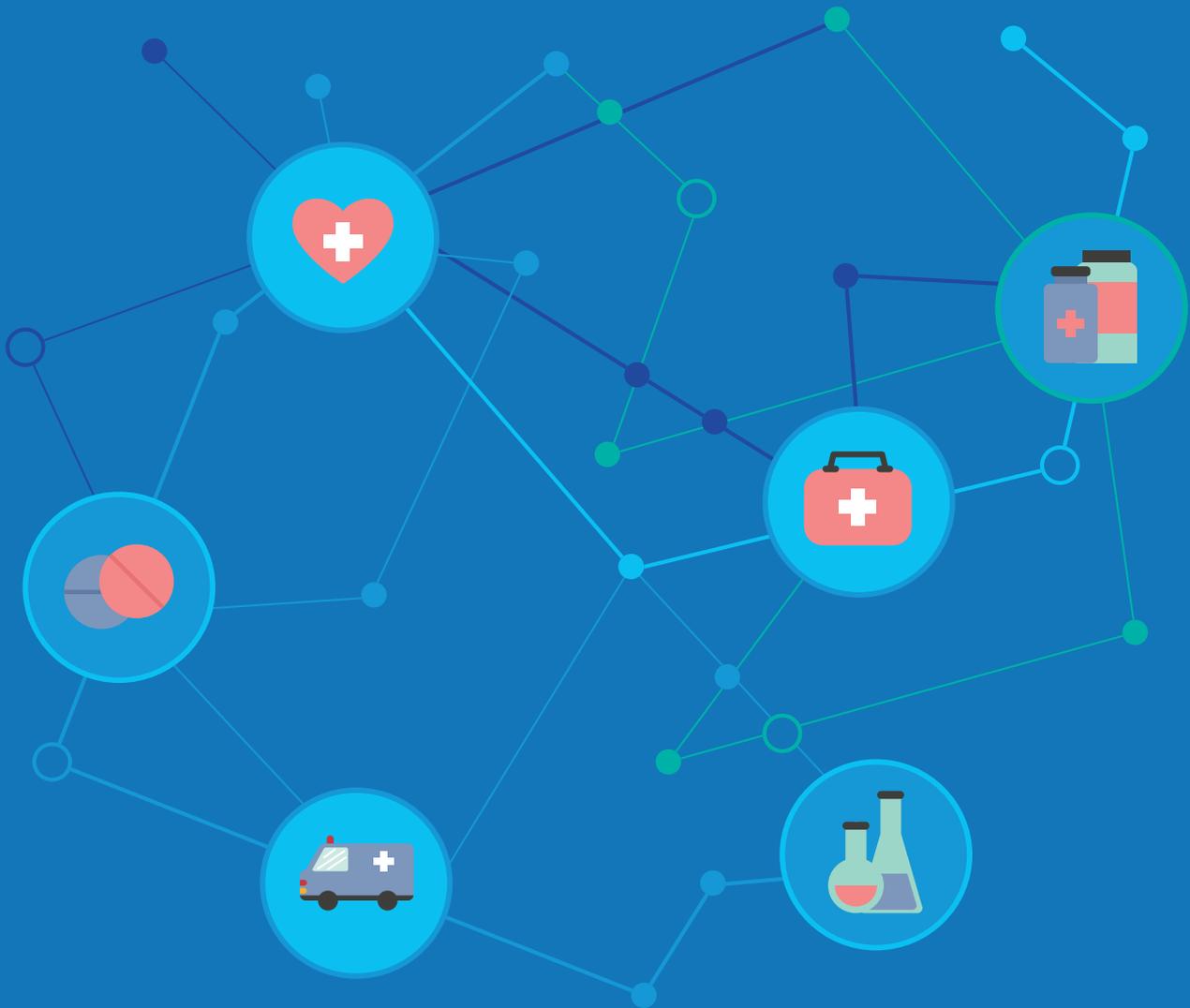
While Make in India is a laudable initiative, it would be very worthwhile for the government to combine it with as many experts are starting to call for a Heal in India campaign. This would have a multiplier benefit on the entire healthcare sector and significantly increase investments in healthcare through increased participation from private players.

Indian companies, across sectors, are immensely dependent on foreign technology transfer. The medical devices industry is no different, the majority of these 800 manufacturers produce products which are less technology dependent. The industry would require new investments and policies to support its development.

The manufacturing curve for India in medical devices is likely follow the growth rate of the middle class.

With the Make in India campaign, the government intends to manufacture cost-competitive quality products in India, reducing import dependency and creating employment. However, all of these objectives may not be achieved by a single-focus agenda. Stakeholders should collaborate to initiate a campaign titled Make and Heal in India, unlocking India's healthcare potential and addressing accessibility, affordability, awareness and adoptability.

Survey Findings



To understand the larger industry view on the relevant aspects of the industry, a survey was conducted among broader industry players. The responses are summarized in this section.

Growth Drivers and Challenges

The industry believes that insurance penetration and government spending will be major growth drivers while healthcare infrastructure and inadequate regulations are major challenges to the industry.

Affordability and Accessibility

Insurance penetration and engaging the industry through a PPP model to increase healthcare spending are the measures that the industry believes will increase accessibility and affordability.

Price Caps

The industry is of the view that Trade margins should be capped. Proper differentiation between different generations of technologies needs to be done. Financial returns and the introduction of new products are the immediate impacts of price capping on devices.

Make in India

Commercial attractiveness of India in comparison to other emerging markets and adequate demand are factors which will influence a decision on 'Make in India'.

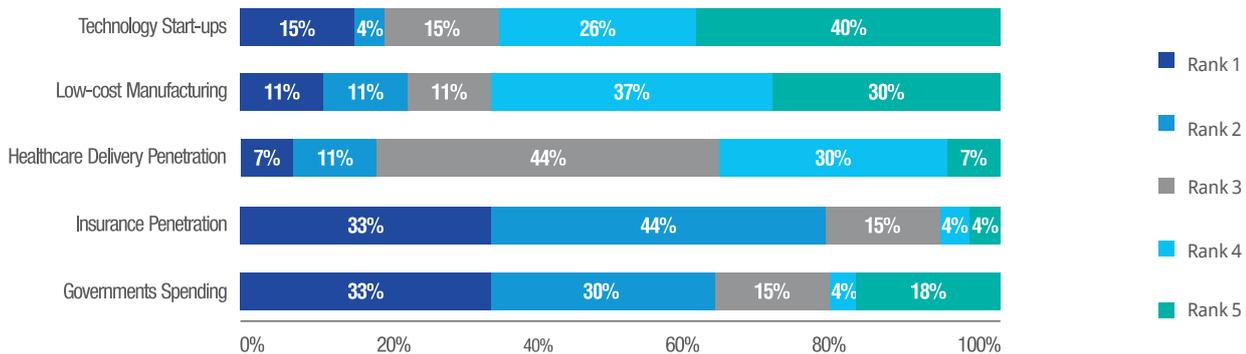
Regulatory Environment

The draft of the regulatory changes is a step in right direction. However, more is required to have a substantial impact. For example, addressing the inverted duty structure is a good step,

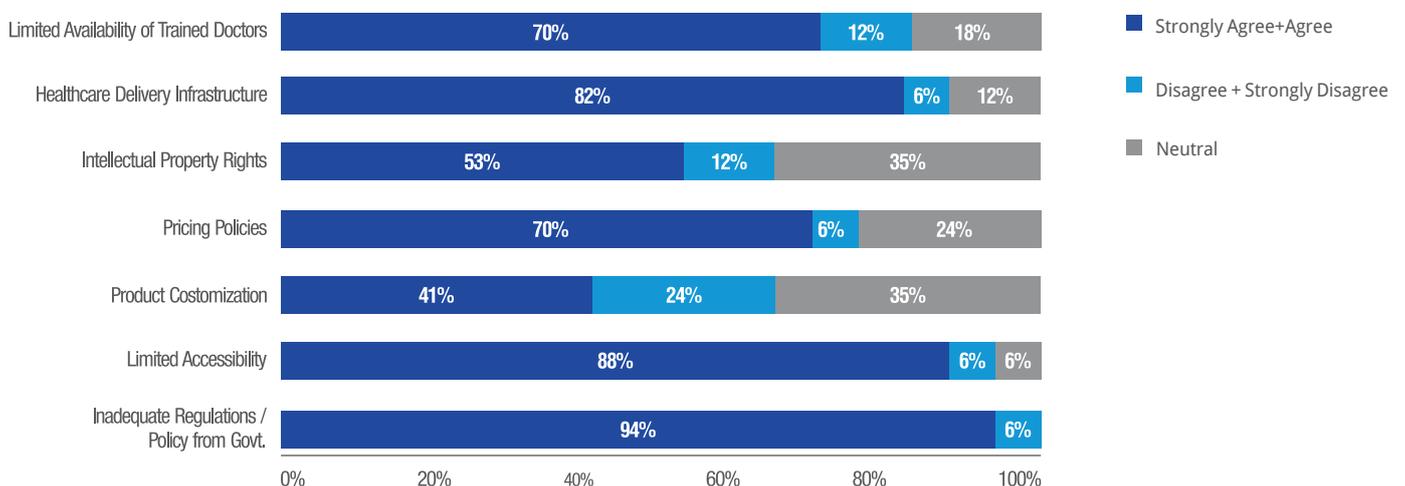
but it is not sufficient to kick-start domestic manufacturing. Also, in the age of global harmonization, creating a separate standards like ICMED and make the local companies less competitive in the global market. The domestic companies should instead be advised to adapt to tested Global norms.

Sectoral Outlook: Even though the industry remains positive on the sector's outlook, issues like ease of doing business in India need to be addressed more significantly as they remain a major hurdle while considering any new investment in the country.

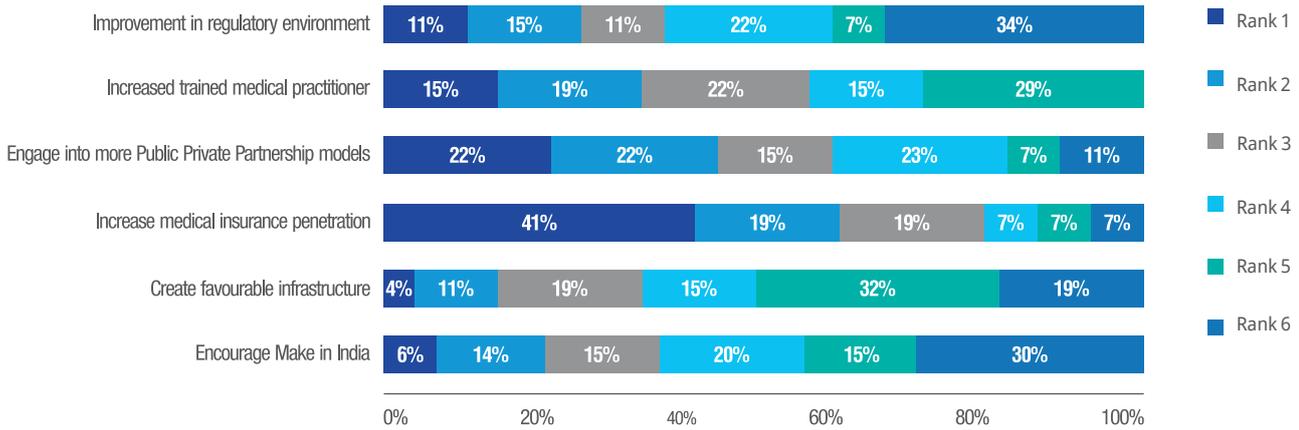
Indian Medical Device Industries Growth Drivers



Challenges in Indian Medical Device Industry

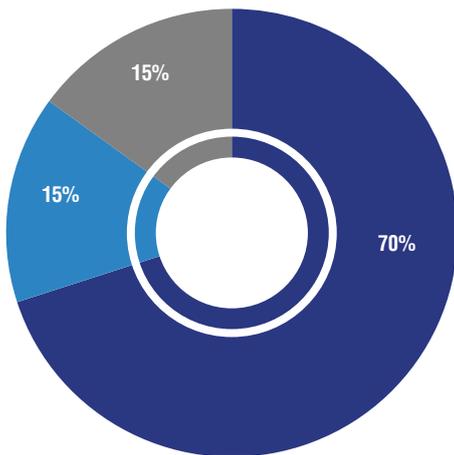


Measures to Improve Affordability

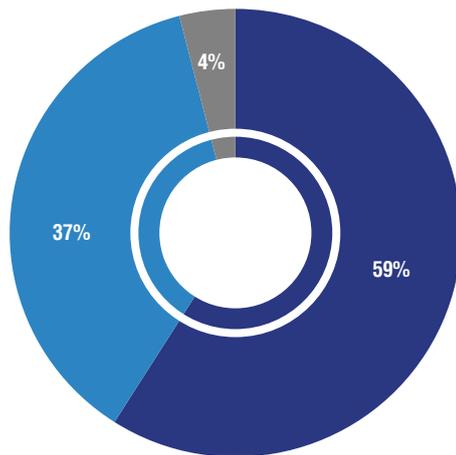


Immediate Impact of the Price Caps on the Medical Device Manufacturers

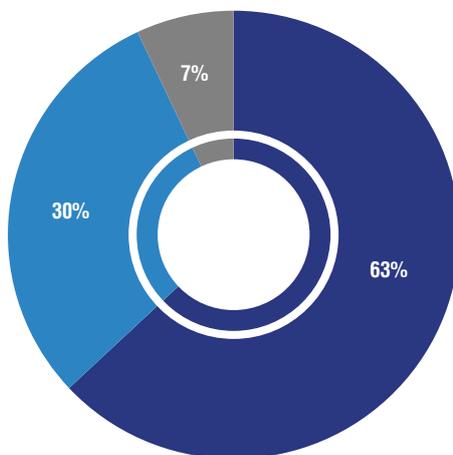
Financial Impact - Lower Returns



Challenges to introduce new products

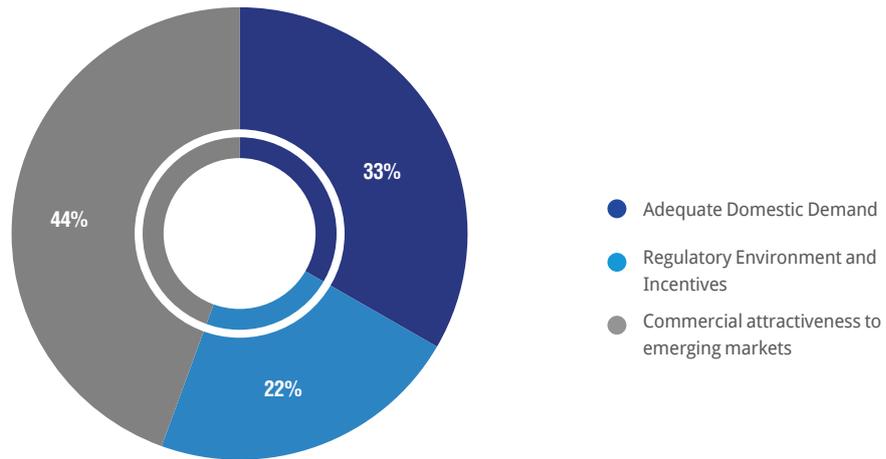


Lower or no new investment

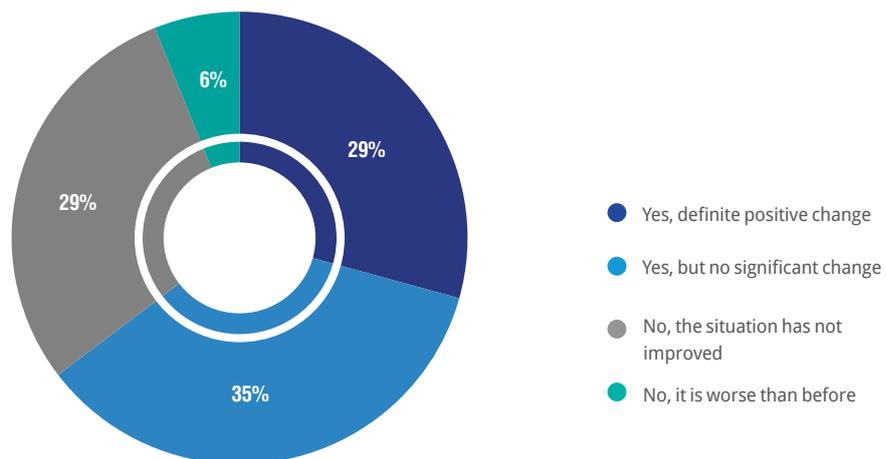


- Strongly Agree + Agree
- Disagree + Strongly Disagree
- Neutral

Factors to be considered under Make in India Projects



Change in ease of doing business in India



Section 7

Case Studies

Abbott

Empowering Stakeholders and Creating Opportunities

GE Healthcare

Focus on Make in India

Global US Headquartered Medical Device Manufacturer

A Greenfield Set-up (Circa 2006-2009)

InnAccel

Driving Affordable Innovations for Emerging Markets

Narayana Health

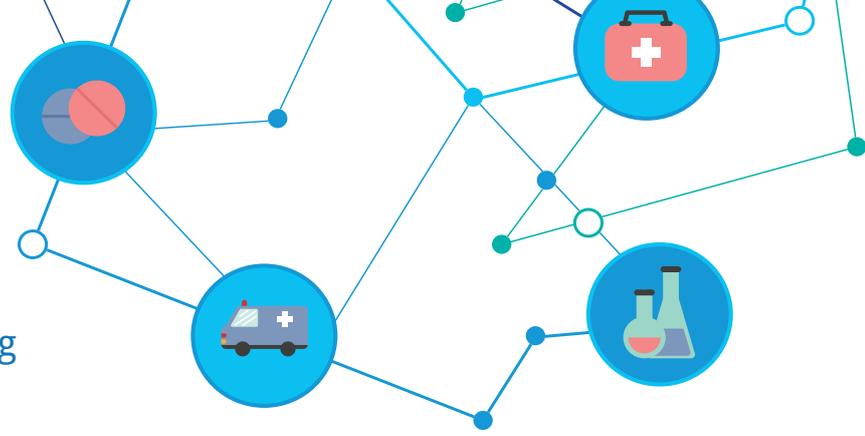
Revolutionizing Healthcare Delivery in India



Case Study

Abbott

Empowering Stakeholders and Creating Opportunities



This case study details how Abbott selected the Cardio Vascular devices as an underdeveloped market and played a critical role in developing the market and empowering various stakeholders, thus creating accessibility and awareness.

Cardio Vascular Market in India: Challenge in Skilled Talent/Resources Availability

Cardiovascular diseases (CVDs), especially coronary heart disease (CHD), have grown to significant proportions worldwide wherein declaring them as an epidemic will not be a stretch. Globally, CVD led to 17.5 million deaths in 2012 where 75% of the deaths occurred in developing countries. The mortality rate from CVD in developing countries is rapidly increasing while the same is declining in developed countries. This increase is driven by industrialization, urbanization, and lifestyle changes and has led to an epidemiological transition. CHD in India has already reached epidemic levels. The Registrar General of India reported that CHD led to 17% of the total deaths and 26% of adult deaths in 2001-2003, which increased to 23% of the total and 32% of adult deaths in 2010-2013. With the disease prevalence high, India is highly ill-equipped to provide care to all these patients.

With critical shortages of trained professionals in modern diagnosis and treatment protocols besides inadequate facilities and healthcare services, much of India lacks the required healthcare infrastructure. In addition, healthcare practitioners in developing nations, like India, often lack access to the latest information on chronic diseases such as diabetes, cancer and heart disease, all of which are increasingly prevalent.

Despite such challenges, Abbott is successfully boosting access to a wide range of healthcare services and products by working in partnership with numerous government agencies, healthcare professional societies, non-governmental organizations and other key stakeholders.

Market Development Strategy

Catapulting to a Leadership Position in the Cardiovascular Device Market

Abbott was founded with the purpose of improving health worldwide. This commitment has remained a critical component of the company's citizenship approach and is integral to its core business strategy in India as well. Through a combination of targeted programs, shared value initiatives, and responsible business practices, the company has successfully expanded access and the use of its products and services among the industry.

Abbott entered the Indian market in the early 2000's and the coronary artery disease treatment was in its infancy stage in India at the time. The numbers of PCI procedures carried out were in a few thousands which have increased to over 300,000 procedures a year. The numbers of catheterization labs were also few and hence, trained physicians were also a scarce commodity. Abbott understood the ecosystem and formed a holistic strategy where it focused first and foremost on training medical service providers around procedures. Abbott also ran several awareness programs

across different stakeholders like physicians, nurses and patients.

These initiatives gave an overwhelming result whereby 2000+ interventional cardiologists were trained across 1000 healthcare delivery centers across the country.

Abbott created an awareness program at all levels and initiated several steps which led to an increased understanding of the procedures, technology and the remedies available for increasing research and development. To put things in perspective, an interventional procedure requires a physician to be an expert on several aspects such as technical, clinical and imaging skills. However, in medical colleges across India at that time, no formal training was provided in this regard and the physicians had to self-train. The industry played a crucial role and trained these fresh medical graduates in these lifesaving procedures. Abbott being a market leader in cardiac interventional products has also taken the lead working on this capability building in the manner described.

- Abbott has run awareness programs across the country for both doctors and patients through various training seminars and education programs.
- The first step in treating a disease is to correctly identify the symptoms. Abbott made sure that the referral communities were aware of the symptoms and able to diagnose it on time.

- Abbott not only provided training to surgeons but also provided them the opportunity to learn from the best interventional cardiologists in the world. This training was not limited to the basics and also included complex procedures with multiple patient issues.
- Abbott also created learning platforms like the Cross Roads Academy. These platforms provided both physical and virtual settings for the young fellows and junior physicians to learn, discuss and deliberate on complex cases, procedural steps and protocols.
- Abbott ensured that its sales personnel were highly trained in the science and technology behind the products and procedures, thereby leading to greater understanding of problems that can occur during the procedures and how to tackle them with devices or otherwise. This leads to more productive and proactive engagement between sales personnel and medical service providers as there was sharing of knowledge and building of trust, thus eventually leading to better clinical outcomes. This helped Abbott to improve the current perception of people about 'unwanted sales visits' to more 'knowledgeable and engaging sessions.'

With these initiatives, Abbott has been consistently able to train more than 500+ cardiologists on an ongoing basis. These trainings have a multiplier effect, thereby leading to greater doctor awareness and skills.

Benefits to Abbott by Engaging with Practitioners and Building their Brand Effectively

Driving Innovation: By being close to their consumer and referrer, Abbott has been able to understand shortcomings of various products better and can deploy resources in the right areas for driving innovation further. Abbott's understanding of the market and human anatomy helped them bring products which were more effective, reduce complications, and improved clinical outcomes.

Increased Adaptability: Due to constant sharing of information between the physicians and the company there is a greater comfort with new technology and a better understanding of the use case of these products. In complex surgeries and cases, it is imperative to have an absolute belief in the technology to do the job.

Market Growth: Abbott has been able to create awareness about diseases, procedures, and technologies, that has led it to develop better products than its competition. Due to extensive outreach programs, Abbott has been able to expand the overall market for its cardiology products and also increase its market share in parallel.

Strong Branding: Due to a strong understanding of the issues at the procedural and disease level, during the product development stage Abbott addresses those issues and backs the results with extensive and exhaustive clinical trials. The results of the trials and subsequent approvals from device regulators like USFDA help in establishing strong credentials, hence resulting in enhanced brand position and recall.

Continuing with similar initiatives to other under developed market segments

To empower communities and consumers with educational programs on the prevention, diagnosis, and treatment of many diseases and health conditions, Abbott launched:

- Thyroid awareness campaign in areas with high prevalence but limited access to diagnosis. The company has placed 100 points of care devices with on-site testing for clinical diagnosis and consultation. Such camps saw participation of 130,000 patients in 2015-2016.
- Collaboration program with the Indian Orthopedic Association (IOA-OEP) disseminates education by IOA panel doctors to 500 orthopedics across the country.

- Under a special program, Abbott representatives meet 8,000 medical service providers and 10,000 retailers every month in four states - Maharashtra, Uttar Pradesh, Madhya Pradesh and Bihar. Such programs have helped the company's products reach 0.7 million people in 381 villages.
- The company has also, at several stages, engaged in educating governments and policymakers about healthcare challenges.

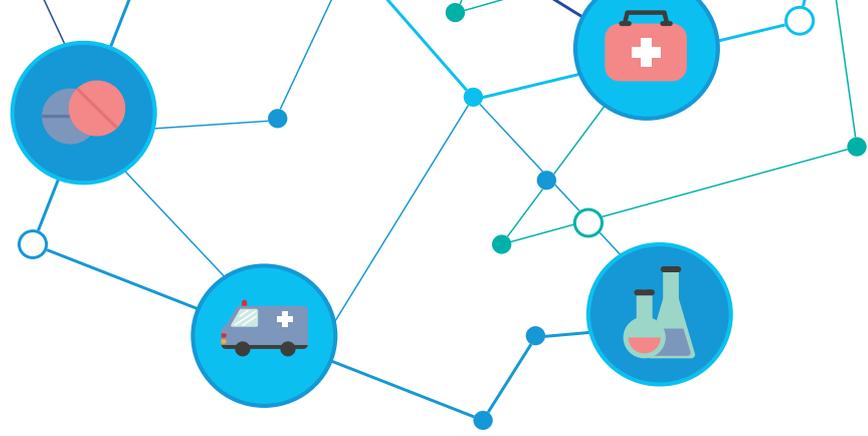
Conclusion

Abbott's approach to India's medical devices industry has been quite unique and equally rewarding. Abbott not only created awareness about the diseases, procedures and new technology but also worked with all stakeholders in the ecosystem to expand the market, and build a sustainable growth.

Case Study

GE Healthcare

Focus on Make in India



This case study details the company's focus on strategies for an organic growth in emerging markets through the development of customized healthcare solutions and improving awareness and access to healthcare.

Strategize the Approach by Understanding Local Market Needs

With large populations in emerging markets having minimal or no access to decent healthcare facilities, there is a grave need to fill the gap in the healthcare ecosystem. The lack of affordability, awareness, and accessibility are the three primary reasons for this dismal state of affairs. Only 25% of the Indian population is covered with health insurance, leaving 900 million people largely incapable of affording most healthcare services. Even if affordability were to be solved, only 24% of the rural areas with 800 million people have healthcare facilities. As India moves towards bridging these gaps, the market potential available for medical device companies can become tremendous. Developing economies are constantly seeking sustainable and effective healthcare solutions for the masses. The low-cost equipment market is expected to continue to grow significantly with increasing awareness among patients and physicians.

Understanding the need of these developing markets, GE Healthcare aims to make affordable healthcare available through its Sustainable Healthcare Solutions (SHS) business in India, South Asia, and Africa. With an investment plan of over USD 300 million, the company's focus lies on expanding its operations in these economies through the development of disruptive low cost, high-value technologies, and healthcare delivery solutions.

As discussed in the earlier part of the paper with the Indian government's focus on the Make in India campaign, GE also initiated discussions with the government on making further investments in the country to improve its infrastructure in healthcare, among other sectors.

The company's strategy is to develop and capture the Indian market in a three-fold approach by:

- Domestic research and development on healthcare technologies and introduction of new products for Indian and other relevant global markets,
- Manufacturing of products in India with resources increasingly sourced locally, and
- Penetration in smaller towns and cities largely lacking necessary healthcare solutions.

GE Healthcare's strategy is already well under way with the development of its affordable care portfolio. The company has designed and developed over 28 products in India that can effectively cater to the needs of the local population keeping in mind the attached constraints. It has set up various research centers through its joint ventures and other alliances to augment GE Healthcare's worldwide operations. Majority of the demand for these GE Healthcare products are intended to be met through manufacturing operations in India.

Customized Products for Indian Patients Needs Rigorous Investment in R&D

Among various products in categories such as ultrasound imaging, X-ray systems, baby warmers and ECGs, a classic and recent example of GE Healthcare's indigenously developed products is the Revolution ACT scanner. The ratio of CT scanners per million population in India is as low as 3. There is a dire need for equipment that is affordable and operable with the limited resources at hand. The Revolution ACT scanner was developed over a period of four years at the company's Bengaluru facility to fill this huge gap and penetrate the unattended rural health centers and clinics. Specially tailored to address the prevailing constraints, the scanner's size was reduced by half and power consumption was brought down by 47%. The machine was also customized with a user interface simplified to counter the lack of trained personnel outside large cities and withstand extreme Indian conditions of heat, dust, and humidity. 30% cheaper than its imported counterparts, 500 units of the ACT scanner have been sold since its launch in 2015, and about 60 have been exported to other emerging economies in Asia and Africa. Majority of the sales are to first time users in locations other than metro and tier I city locations. The company has also partnered with various state governments to increase the reach of the machines to each of the 631 districts in India.

Partnering with Local Companies for Research and Manufacturing

Undertaking a predominantly organic route, GE Healthcare’s execution of its strategy in India is mainly attributed to its strategic collaborations for research and manufacturing with local stakeholders.

The company has partnered with two established domestic companies in majority owned joint ventures, leveraging their local know-how and expertise for innovation and the advancement of solutions specifically tailored for the target markets.

Wipro GE Medical Systems	
GE Healthcare	Wipro Corporation
51%	49%
Product: Diagnostic imaging and patient monitoring equipment JV Partner Expertise: Information Technology solutions and engineering	

GE BE	
GE Healthcare	Bharat Electronics
74%	26%
Product: X-ray tubes, high voltage tanks and detector modules for R&F and CT systems JV Partner Expertise: Electronic equipment for Defence and Communication sectors	

The joint venture companies are responsible for the design and manufacture of numerous products for the global as well as domestic markets. The companies also provide software services and technological solutions for GE Healthcare’s global manufacturing activities. Products developed and manufactured include ultrasound and CT scanners, cardiology products, fetal monitors, X-ray tubes, high voltage tanks, detector modules for CT systems, and more. Facilities of the companies are in compliance with global safety and regulatory standards.

Displaying a strong commitment to R&D, GE’s Global Technology Operations at Bangalore comprises of 650 employees working with GE’s teams worldwide on software development, tables and power components for medical systems.

In addition to developing healthcare solutions and manufacturing its products in India, GE Healthcare is also focused on improving the distribution and service of its equipment across the country through its subsidiary GenWorks Health. The company has entered several Public Private Partnerships with state governments to cater to their lesser developed regions and extend the reach of its equipment to the remotely located health centers.

Increasing Awareness and Accessibility of Healthcare Solutions

With an aim to improve the health of the general populace worldwide, GE Healthcare’s initiatives emphasize its three main objectives:

- Continuous advancement of healthcare technologies and solutions
- Availability of affordable care for the masses
- Competent staff enabling efficient delivery of healthcare solutions.

The process would also help GE Healthcare to directly stay in touch with healthcare professionals and patients, thereby gaining valuable insights from the market and increasing demand for its products.

Cancer research and affordable cancer care - With over 1.2 million new cancer cases each year, the mortality rate owing to cancer in India is very high. Creating awareness and enabling timely detection as well as affordable access to cancer care are crucial to fight the battle against cancer in the country. Availability of skilled and well-trained healthcare professionals, makes the delivery of cancer care solutions challenging. GE Healthcare aims to improve access to cancer care through its various partnerships with governments, clinicians, private operators and NGOs in areas including radiology, cardiology, critical care, fetal medicine and leadership training.

As part of its USD 1 billion commitment for the advancement of oncology solutions, GE Healthcare has

collaborated with Max Healthcare in India to conduct research on cancer care and technology solutions. The collaboration also intends to advance oncology clinical skills by setting up an oncology training institute. Directly catering to the needs of the patients, GE Healthcare has also entered a strategic partnership with Cancer Treatment Services International for the diagnosis and treatment of cancer at 25 well-equipped centers to be set up over a period of five years.

Other Initiatives

While the Integrated Development Centre helps the company to stay close to the patients and understand their needs, the Skill India Initiative keeps the company connected to healthcare professionals. First set up in Bangalore, the IDC intends to conduct more than 1,000 scans annually as a part of clinical trials, using GE’s diagnostic imaging technologies. While the IDC is presently focused on isosmolar contrast agent launched by GE in 1996, its scope will be widened to cover GE’s entire diagnostic imaging portfolio.

The Skill India Initiative, GE Healthcare’s biggest healthcare education program, aspires to train more than 100,000 healthcare professionals over a period of five years through institutes in every state in the country.

Case Study

Global US Headquartered Medical Device Manufacturer

A Greenfield Set-up (Circa 2006-2009)

This case study discusses the Company's strategy to expand and optimize its global manufacturing footprint through high-quality products manufacturing in India

Understanding the manufacturer globally

This firm is an independent, global employee-owned US company that develops, manufactures and markets healthcare products and services worldwide. The company's healthcare portfolio includes consumables, Ostomy Care, Contenance Care, Wound Care and Critical Care products. Growing from its humble beginnings in the mid-west region of USA, the company now has a presence across the Americas, Europe, Middle East and Asia Pacific, with multiple manufacturing and distribution facilities located across the globe, including India. Presently, the company has direct operations in about 40 countries and sells its products in over 100 countries.

Firm's Objectives

1. Achieve World Class status in manufacturing and supply chain with a competitive advantage in the continence care products space.
2. To further the strategic direction of the focused factories.
3. Add capabilities for supporting other business processes closer to the intended markets.

The firm's decision to set up its new manufacturing plant in an emerging economy was preceded by a thorough evaluation of all the pros and cons of entering an unfamiliar territory. This evaluation included the utilization of local professional consultants for validation of various studies. The company's strategy was to set-up a world class facility for a specific range of global products, complimenting their other

focused factory initiatives. This strategy was core to its overall objective of delivering high quality, reliable and cost-competitive products to its customers.

The firm investigated various options worldwide. A detailed study was conducted for several manufacturing regions of the world including Latin and Central America, Eastern Europe (now EU countries), Pacific-Rim and South East Asia. Some of the factors that formed part of their exhaustive evaluation included the availability of skilled labor, quality of management, ease of communication, safeguarding of technologies and copyrights, export regulations, and much more. The company also undertook inflation analysis over a long term period between developed US / Europe and India.

Eventually, the company narrowed down on Asia-Pacific, and within those region countries like India, China, Thailand, and Malaysia. These were countries where the firm's markets were growing at more than twice the rate as other markets, margins were lower and had no manufacturing base. All previous locations of the company were in the USA and Europe.

Finalizing the Location - Making in India for the World

Based on its detailed study, India was chosen to be the location for the firm's next global manufacturing plant. The primary reasons for its selection were:

1. Availability of talent pool

- Large skilled population with an average age of 29 years

- Availability of highly trained and knowledgeable professional human resources at competitive costs
- Universities and colleges producing over 400,000 engineering graduates every year
- A rapidly growing product engineering capability and a world class information technology industry

2. Existing Eco-system for Manufacturing

- The tooling and machinery industry which produced equipment locally at significantly reduced costs
- The construction cost was significantly less than in many other parts of the world
- Increasing availability of raw material suppliers
- Capability to build a facility that meets both GMP and RA requirements of the US. India had at the time the largest number of US FDA approved facilities outside of the US anywhere in the region. Contractors were available for building Class 100K to 1K clean rooms.

3. Conducive environment

- Incentives for manufacturers to set-up in India
- Higher labor productivity was comparable to many regions of the world
- English is the primary business language
- Intellectual Property Rights laws that conform to WTO norms
- Better cultural fit, a stable democratic political system

The State of Haryana, in North India was finalized for location because of the presence of a medical devices cluster of consumables, dental equipment and pharma companies. The establishment of a strong relationship with the State government during the investigative process further promoted the company's decision. Since the firm's investment, this cluster has further enhanced and counts domestic and international companies such as Becton Dickinson, Baxter, Abbott Labs, Ranbaxy, Hindustan Syringes, Narang Medicals, Poly Medicure, BL Lifesciences and others within its boundaries.

Thorough Planning, Effective Execution

The company was allotted land at an attractive price by the State government in the vicinity of the NCR region (Delhi area) which is easily accessible from a major airport under the Special Economic Zone (SEZ) / Export Oriented Unit (EOU) schemes with zoning requirements that allowed for at least 200,000 plus square feet of manufacturing facility including future modular expansions. Primarily set up as an export unit, the products manufactured at the Haryana facility complement and support the company's global operations. In the eight years since it commenced manufacturing in India, the company has produced and exported well over hundred million units of urinary catheters and other continence care products.

This plant has expanded considerably over the years and today has approximately 500 employees on direct payroll and generates several hundreds of indirect jobs, not including many more

in US and Europe to support the global demand. The facility meets the safety and regulatory standards specified by US FDA, CE, CDSCO India and several other local and international regulatory bodies, and it is accredited with the latest ISO certifications. Set up with strong support from the Haryana State and Industrial Development Corporation (HSIDC), the plant boasts of advanced manufacturing technology and equipment and is the greenest facility amongst the company's several facilities.

In comparison with the firm's global operations, the firm could bring down net manufacturing costs significantly. In its formative years of operation in India, the firm kept the same raw material suppliers to reduce the variables. However, over time the company was able to qualify local and regional suppliers for majority of its requirements including sterilization, improve manufacturing process flow, reduce freight costs and bring few of its high quality products closer to the market place.

Critical Success Factors

The firm's success in India lies in unlocking benefits from each variable in a systematic and well-planned manner. Servicing global demand at competitive costs without any compromise on quality, often exceeding and pushed the product margins to an acceptable level for the company as a whole.

To ensure success, the firm implemented a systematic step by step plan that enabled learning and minimized mistakes and mitigated major risks, as envisioned in the business plan. Some of its critical success factors are listed below:

1. They entered the new locale and gradually unlocked other variables such as the sourcing of materials and services. This phased approach was a major contributor to the company's successful track record in India as it minimized RA and FDA-QSR qualifications all at one time, and gave them time to leverage each of the other variables.

2. The company factored in the effects of inflation, production of incremental units, and other such aspects. In its projections to be as close as to practically achievable. Although the inflation rate in India was higher than developed countries, however, considering the low cost base in India, the analysis showed that the new location would remain competitive for the period of evaluation and longer.
3. The company also outsourced most of its non-core operations including payroll, taxation, security, janitorial, cafeteria services and transportation, to focus completely on its core manufacturing objectives.
4. The funding of the project was internally financed through a combination of equity and External Commercial Borrowing (ECB), which lowered the cost of capital and aided in breaking-even faster.
5. The firm also devised a robust HR Strategy very early on to attract, develop, and retain human resources aligning with the company's global culture, coupled with effective internal communications worldwide. This was very critical for the company to manage its operations successfully in a foreign territory. Its attrition rate remains the lowest in that geographical region.

Make no mistake, the project of this magnitude had its share of challenges. However, overall it was a huge success and validated over time. At the macro level, the company's business case was sound. The company could realize all the gains and more with a significant amount of control owing to its thorough preparedness and effective execution of its strategy. It also provided a new platform for the firm's growth in an earlier unchartered territory.

Case Study

InnAccel

Driving Affordable Innovations for Emerging Markets



Emerging Markets Challenges

Medical Devices are a key component in any healthcare system and play a central role in meeting the needs of patients and providers in delivering quality outcomes. Most of today's medical devices are designed and developed for the advanced developed markets and hence, are suited to those levels of infrastructure and economics. Emerging markets like India and numerous other countries in Africa and Asia have significant challenges in terms of available infrastructure, access, and affordability in the overall healthcare ecosystem. Emerging markets are skill and resource constrained, self-paying, and extremely price sensitive. Adoption of the current portfolio of medical devices and equipment's are therefore often limited in emerging markets because of these issues. This has resulted in a large unmet need for millions of consumers in developing countries like India. To have an affordable and effective healthcare system, it would be beneficial to have medical devices and equipment tailor made for these ecosystems. Hence, affordability and appropriateness have to be the focal points for innovation in medical technology for these markets. It is estimated that expenditure on medical technology is likely to reach USD 42 billion in India and USD 200 billion in BRICS by 2025.

InnAccel is India's leading platform to drive MedTech innovation in India and global emerging markets. InnAccel identifies critical and unmet healthcare needs by using the Stanford Biodesign process and initiates research programs on selected clinical needs with large global markets. The selected needs are taken forward to develop a regulatory-certified, world-

class, product by deploying InnAccel's proprietary Product Engineering & Development (PED) platform in 2 - 3 years. InnAccel aims to capitalize on the aforementioned opportunity by creating a product portfolio which, while addressing emerging market needs, may also have markets in developed economies. InnAccel aims to launch 20 transformational medical products and impact 25 million lives by 2025.

Products

InnAccel's (and associated companies') current portfolio comprises five novel products addressing a global market opportunity of over USD 2 billion annually and treats conditions that lead to almost a million deaths each year in India alone. Some of which are listed below :-

SinuCare

This is a novel and affordable balloon sinuplasty system for in-office treatment of Chronic Rhinosinusitis (CRS) patients in India and EMs. The market opportunity is promising for SinuCare as one in every eight people (150 million in total) suffer from CRS in India. 30 million (20-25%) of all CRS treatments fail within six months of medical therapy, hence requiring surgery to be performed. The Indian market opportunity is worth about USD 150 million and the global market opportunity is over USD 1 billion. The products will have a strong demand in other countries like Europe, Asia and South American markets as most of the similar products are unaffordable or unavailable.

VapCare

It is an intelligent, automated, closed loop, secretion management system for patients who are on long term ventilation systems in ICUs. The device is designed and aims to reduce the incidence of Ventilator Associated Pneumonia (VAP) which is one of the leading causes of deaths in hospitals globally. There are about six million ICU admissions per year, and about 0.5 million patients develop VAP. About 0.2 million deaths are attributed to VAP. This product has an annual market opportunity of USD 50 million in India and a global market opportunity of USD 500 million annually. The company has been granted a patent protecting this invention in the US and has also filed the same patent globally.

Fetal Lite

It is a non-invasive, automated, portable, battery powered and f-ECG-based fetal monitor. Specifically developed for emerging markets, the product requires minimal skill in usage and is aligned to low-resource settings due to the use of advanced sensors and algorithms. The current technology is variable, highly skill dependent, bulky and, not to mention, very expensive. Hence, Fetal Lite is the need of the hour considering, over 300,000 perinatal deaths occur annually in India alone.

Fetal Lite

It is a mechanical device which is used to safely and effectively remove impacted Nasal Foreign Bodies in children and requires limited training and skill. Foreign Bodies being found stuffed in children's noses is soon emerging as a global problem and is frequently reported when children are left unattended. Currently, there is no exclusive device to remove these bodies from the nasal tract. NoXeno is a simple mechanical device that can be handled by paramedics, nurses and general practitioners in clinics in semi-urban and rural areas without any supervision. The company aims to make the device available in all primary healthcare centers in India. It is estimated that the global addressable market stands at USD 200 million.

Saans

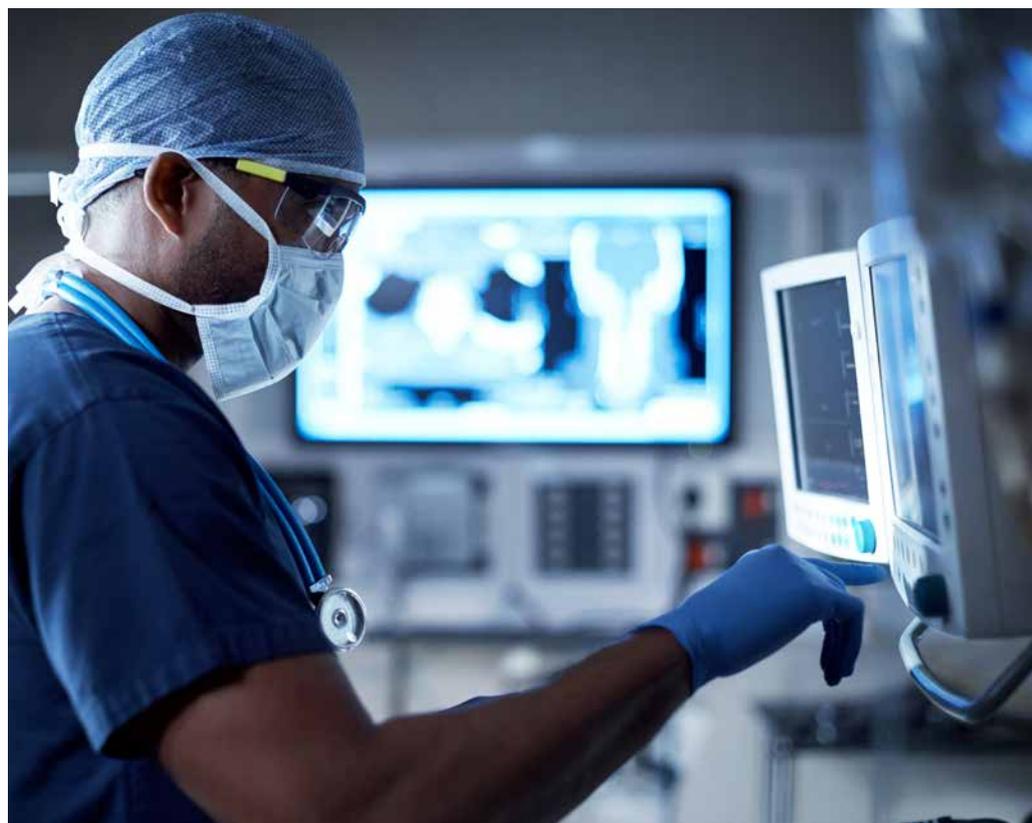
Saans is the first purely mechanical, low skill and continuous positive airway pressure (CPAP) solution to transport neonates with Respiratory Distress Syndrome (RDS) to a NICU. Its performance is equal to a non-portable, electronic CPAP device and can be powered in multiple ways which include a manual setting and requires minimum skill. RDS alone claims more than 400,000 deaths in India and its global addressable market stands at USD 200 million.

Partners

InnAccel has formed strong partnerships and relationships with a number of national and global entities. Partnerships with medical colleges and hospitals in Bangalore enable teams to gain clinical input, conduct fieldwork and carry out early testing of products. The company has built relationships with leading teaching hospitals in India namely AIIMS, St.John's, JIPMER, and CMC, as well as academic institutes like IIT Bombay and Madras, for strong engineering and technical expertise. In addition, they also have forged global partnerships with CAMTech, PATH and few others. thus enhancing the flow of ideas, funds, and entrepreneurs to the medical technology startup ecosystem in India.

Future Plans

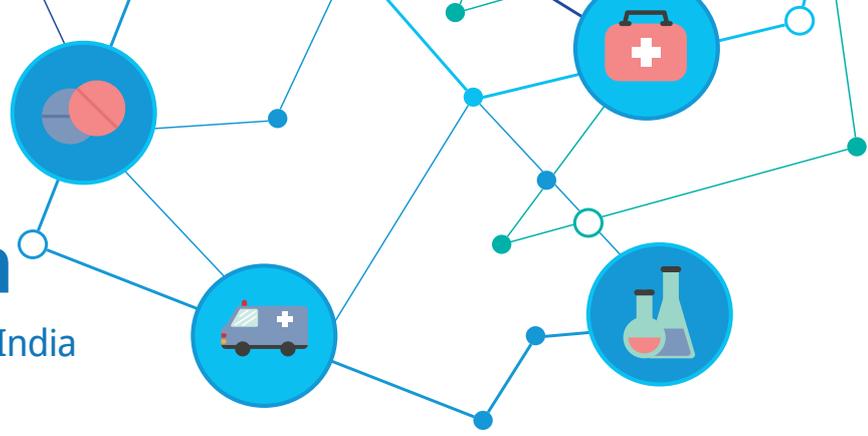
InnAccel has created development platforms and teams in three core clinical areas. These teams will continue to develop products for needs identified through the Biodesign process in these areas and aim to create a portfolio of products in ENT, critical care, and maternal/child care respectively. InnAccel is also setting up two additional teams to create two new development platforms and initiate projects in 2018. InnAccel aims to launch 20 novel products by 2025, positively impacting 25 million lives and transforming healthcare in global emerging markets.



Case Study

Narayana Health

Revolutionizing Healthcare Delivery in India



Process Innovation: A Model that tied Quality with Affordability in Indian Healthcare

India boasts 750,000 doctors and 1.1 million nurses, but practitioner density is about one-fourth of what it is in the U.S. and less than half that of China. Hospital beds are in short supply and many medical facilities are dated, cramped, and often unhygienic. In a country where the nominal per capita income is around USD 1,500 a year, patients typically have to pay 60% of their healthcare expenses from their own pockets. While discussed earlier, these statistics provide a perspective on the unmet needs of Indian patients for good medical treatment.

Dr. Devi Shetty founded Narayana Hrudayalaya (later renamed Narayana Health or NH) in 2001 in Bangalore. His mission was to successfully tie affordable healthcare delivery with quality. NH, which started with humble beginnings with a 280-bed hospital has transformed into an organization with 24-hospitals, seven heart centers and a center in the Cayman Islands. Today, NH has a network of 5,600 operational beds that offer care in 30 specialties.

Heart Surgeries: Craft to Increase the Number of Procedures

Dr. Devi Shetty believes that hands that service is more sacred than lips that pray. Dr. Shetty is sometimes described as the Henry Ford of heart surgeries because his hospitals have managed to achieve economies of scale due to the sheer number of procedures they undertake in a day. NH's average cost of a

bypass surgery is USD1,500 (INR 90,000) compared to USD 144,000 in the US, USD 27,000 in Mexico and USD 14,800 in Colombia. Interestingly, NH's cost of cardiac surgery is significantly lower than what it was in India 13 years ago. Larger volumes of open-heart surgeries and catheterization procedures every day allowed the medical team to decrease the cost of each surgery. At NH, each surgeon performs anything from 400 to 600 procedures a year, compared with 100 to 200 by surgeons in the U.S. Doctors go from one operating table to the next with an assembly line precision that is rare in the Indian healthcare system. Given the numbers, one would assume that the entire process would be chaotic. However, NH has ensured a high-quality systematic process while scaling up the capacity. It has ensured focus on the following to enable quality healthcare to be provided in an affordable manner.

Commitment to Purpose

Commitment to purpose is the most crucial success factor in achieving exemplary execution. A lot of organizations state their vision and mission but rarely follow them stringently. NH is steadfast in pursuing its vision and encourages employees to work towards its purpose to do collective good. Due to this single-minded focus and commitment to execution, NH attracts the best medical service providers who are inclined to provide the best care possible, irrespective of their means.

Uncompromising Quality

The lower costs have not come at the expense of quality. NH's mortality rate (1.27 %) and infection rate (one percent) for a coronary artery bypass

graft procedure are as good as that of US hospitals. The incidence of bedsores after a cardiac surgery globally lies anywhere between 8% and 40%. At NH, it has been close to zero for many years.

Economies of Scale

The model conceptualized by Dr. Shetty leverages economies of scale by building mega hospitals and attracting huge volumes of patients. The aim was to target well-off patients so that the quality of care is not compromised. But at the same time, they aspire to serve every patient irrespective of their economic status, thus enabling a low-cost model. This model works because high volumes ensure that the enterprise is profitable, although the unit economics might be otherwise. As a result, NH has never been dependent on government subsidies, insurances or reimbursements. NH has also institutionalized a number of aspects of healthcare delivery, some of which are as follows:

- Facility use was increased through a shift system wherein the operation theatres are occupied for long hours providing higher utilization of expensive hospital capital equipment.
- The large numbers of patients that come for treatments enable doctors to focus on specific types of medical problems. As volumes increase, relatively rare conditions are treated so often that doctors become world-class experts in those areas. This explains how NH has become a global leader in pediatric open-heart surgery, attracting patients from across Asia and Africa

- From the beginning, NH has focused on upskilling its staff. It encourages general physicians to become specialists and specialists to become super-specialists. It trains nurses to advance to the higher-skilled position of nurse intensivist, akin to a nurse practitioner in the US.
- NH encourages its doctors to be prudent in providing healthcare. It shares P&L information on a daily basis with doctors to make them understand the costs, and suggests cost cutting measures to reduce overall cost incidence to patients.

Task Shifting

Private healthcare institutions like NH in India have taken task-shifting a notch higher by creating new layers of healthcare workers that are relatively inexpensive. NH has teams consisting of a specialist, junior doctors, trainees, nurses, and paramedical staff. It restricts specialists to conducting the critical part of the surgery and expects the junior doctor to carry out the rest of the procedure, thereby freeing up the specialist to conduct more surgeries in a day. The high volume of procedures allows NH to reduce the costs of individual procedures, thereby attracting more patients.

Supply Chain Efficiency

High volumes of patients and procedures have enabled NH to have a stronger purchasing power for their medical supplies. An interesting aspect of its purchasing practice was to:

- Eliminate long term contracts and negotiate at a higher frequency and in many cases, even weekly. More frequent supplies result in lower inventory carrying costs.
- With the cost of consumables being its largest expenditure, it bought this in bulk on a weekly basis through its Central Buying Unit (CBU). Through this move, NH has brought down its prices by almost 35% since it started procurement.
- Instead of buying expensive medical equipment outright, NH pays the supplier a fixed monthly rent in addition to the cost of the reagents that are necessary to run the tests on the machines.

Expansion Through Other Models

NH has looked at all kinds of collaborations, associations, and tie-ups to achieve the kind of scale it is looking to build:

Management Contracts

The company is taking over poorly run hospitals. For example, NH manages the MMI Hospital in Chhattisgarh. Since it took it over, it has increased the number of beds and upgraded the radiology, emergency and trauma centers. It further manages the cardiac centers attached to medical college hospitals such as SS Medical College, Davangere and SDM Medical College, Dharwad, to name a few.

Selective and Joint Investments

Working with organizations interested in partnering with them, who are willing to build hospitals in locations that are underserved. While the organizations/ individuals make the investment in land and building, NH invests in the medical assets.

Speciality Tie-ups with Other Private Hospitals

Through the setting up of embedded heart centers in other hospitals such as Chinmaya Mission, MS Ramiah Mission and St. Marthas on a revenue sharing model, where the civil infrastructure is already present and the hospital infrastructure specific to heart and specific specializations need to be set up.

eHealth Center Program

NH is the healthcare partner to implement, operate, and manage eHealth Centers (eHCs). The company has helped establish 10 eHCs across the country which have witnessed a footfall of 21,765 patients from December 2015 to March 2017.

Telemedicine

NH collaborated with CISCO to integrate and set up advanced telemedicine solutions across three centers in India. This digital solution will help connect patients with specialists conveniently, efficiently, and regardless of distance.

Cross Border Expansion

Recently, the Directorate General of Medical Services of the Bangladesh Armed Forces entered into a MoU with NH to cooperate on patient care, medical education, research and training in exchange for healthcare professionals. NH is also already running a tertiary care hospital in a JV with Ascension Health in the Cayman Islands.

Conclusion

NH is revolutionizing in its own way healthcare in India by bringing together quality, affordability, and profitability with success. They have demonstrated that the healthcare delivery sector can use process innovation to improve quality and dramatically lower costs for patients, process improvements, better manpower and capital productivity, thereby significantly improving patient affordability and access. These benefits are further multiplied through scale.

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SKP's Healthcare Practice

At SKP, we partner with healthcare companies to enable them to drive their strategy. We help in designing business strategies, facilitating entry to new markets, enabling a compliance culture, embedding internal control in business and bringing efficiency through outsourcing. Our regional operations across the country, decades of experiences with healthcare multinationals, trained professionals and our client objective-driven approach help us deliver better value every time.

Thought Leadership

Over the last few years, the Medical Device Industry in India has gone through a phase of transformation. The sector is witnessing change at a policy and regulatory level from the government pushing industry players to bring structural and operational transformation in the industry. These changes are expected to usher the industry into a new era of strong sustainable growth.

With more investments, modern technology and growing medical reach, industry is expected to evolve on (1) Affordability to cover broader market (2) Innovation to cater to demographic need and (3) Reputation of compliance and high ethical standards.

Our thought leadership initiatives are a mode to observe and reflect on the industry modulations including policy efforts by government, market actions (mergers and acquisitions) and business evolution as it happens.

Our Healthcare Credentials

Helped set up a leading American medical device company in record time. SKP worked as an implementation partner and helped strategize the entry into the Indian market and also provided tax (including transfer pricing) and regulatory advisory services.

Provided project management services for post-acquisition integration across seven geographies for a leading American healthcare company in the Fortune 500 list.

Streamlined the finance and accounting processes of an Indian Subsidiary of a US-based healthcare company which resulted in timely vendor payments, reduced risk of noncompliance and easily available management information to take strategic decision.

Helped reduce the contract cycle time of a US-based healthcare multinational by 25%.

Helped highlight internal control weaknesses including potential overpayments and deviations from processes along with recommendations for enhancing controls as a part of our internal audit for a leading pharmaceutical company.

Helped set up a shared service for a Permanent Establishment (PE) backed medical devices firm for its Asian operations covering international compliances as well as finance and accounting.



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