

Medical Devices

Making in India - A Leap for Indian Healthcare

March 2016



Contents

1	Foreword
3	Setting the context - the healthcare sector in India
13	Current landscape and key considerations for growth
27	The Market Opportunity for Making in India
39	Realizing the potential of 'Make in India' for medical devices
46	About NATHEALTH
47	About Deloitte
48	Annexure 1 - Key Primary Survey Findings
50	Annexure 2 - List of participants – Primary interactions and survey
51	End Notes
52	Contacts

Foreword

The Indian Healthcare industry is on a high growth trajectory having evolved significantly in the last decade. However, healthcare provision remains inequitable and challenges in access to quality, affordable healthcare persist in large parts of the country.

The medical devices sector has also grown considerably during this period and plays a critical role at each stage of the healthcare continuum. Although it has been instrumental in improving access and affordability of healthcare services, a number of ecosystem constraints have led to a high dependence on imports for addressing domestic demand.

The current demand and supply side dynamics provide a significant opportunity and rationale for manufacturing medical devices in India. The Government of India's 'Make in India' initiative presents a platform for the sector to revisit the operating model, identify key imperatives for growth and explore possibilities for creating a step change in the medical devices sector.

It is in this context that NATHEALTH and Deloitte partnered to undertake a study to map the current landscape and role of the medical devices industry and identify the key constraints and imperatives to leverage the 'Make in India' opportunity.

This report is an outcome of extensive research and several rounds of deliberations with stakeholders across the government and healthcare industry. We hope that it will form the basis for continued discussion and appropriate action to support the growth of the medical devices industry and facilitate the move to a healthier India.

Charu Sehgal

Leader- Life Sciences and
Healthcare
Deloitte Touche
Tohmatsu India LLP

Anjan Bose

Secretary General,
Healthcare Federation
of India
(NATHEALTH)





Setting the context: the healthcare sector in India

The healthcare industry in India registered a growth of 10% over the past few years and is expected to reach USD 145 billion by 2018 and over USD 280 billion by 2025.

Factors such as changing demographics, rising life expectancy, and growing public awareness have contributed to a higher demand for medical care.

The Indian healthcare industry has been growing at double-digit rates and has evolved significantly in the last decade. However, a number of challenges need to be addressed in providing access to quality, affordable healthcare in the country.

However, the Indian healthcare system continues to be impacted by aspects of availability, affordability and quality of health services. Given these, India lags behind averages of BRIC Countries.

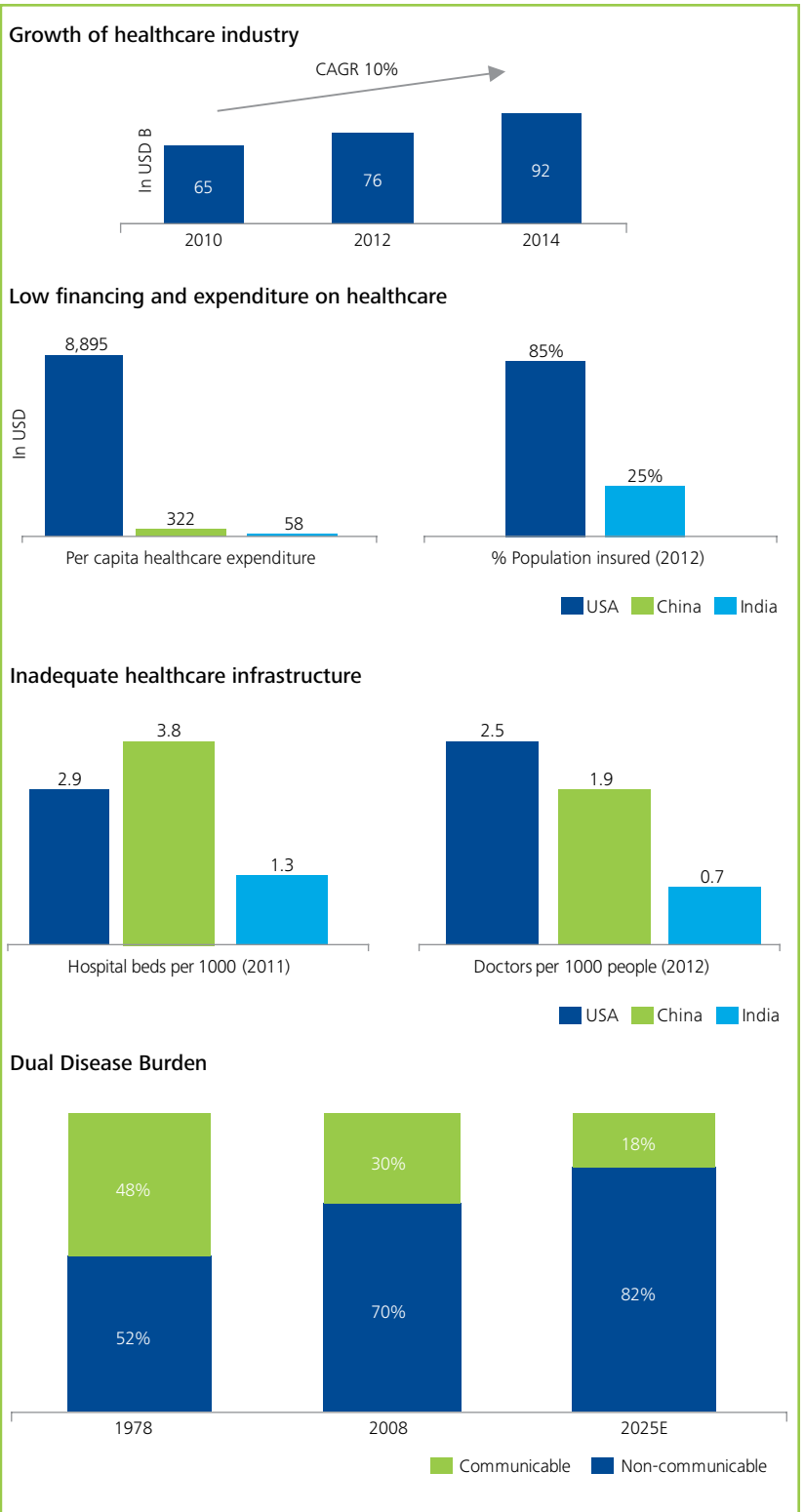
A key area of concern for India is the proportion of non-communicable diseases which is expected to rise in the next decade.

The total healthcare expenditure¹ in India was only 3.9% of GDP, compared to 8.9% for Brazil, 6.2% for Russia and 5.2% for China¹. Out-of-pocket expenditure is as high as 61%², with only 25% of the population being covered by health insurance.

While the government and value chain participants have undertaken several steps to address the issues of healthcare access, quality and affordability, these have been executed in silos. Specifically, while medical device companies have focused largely on extending life expectancy and improving quality of care, there is a need to increase affordability for a widespread impact.

The challenge therefore for companies in India is to produce medical devices that are both cost competitive and effective to increase penetration and use. It is in this context that the Make in India initiative becomes significant for the medical devices industry

Exhibit 1: Health care scenario in India



Medical devices play a role not only in screening, diagnosing and treating patients but also in restoring patients to normal lives and in regularly monitoring health indicators to prevent diseases. With technological advancements, the role of medical devices is now expanding to improve quality of care across each stage of the healthcare continuum:

• **Screening and diagnosis:**

Both accuracy and complexity of screening and diagnosis are increasing. Point-of-care / portable diagnostic devices provide care at home resulting in improved outcomes, patient satisfaction and, increased access to care in under-penetrated and remote regions, while facilitating treatment outside health facilities

• **Treatment/Care:**

Advanced surgical equipment is not only enabling doctors treat highly critical and complex cases but also reducing length of hospital stays. It is increasingly allowing elective but complex surgeries like knee replacement, bariatric, pain management, etc. to be shifted to outpatient / short stay surgery centers

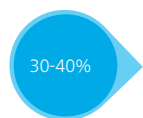
• **Restoration:**

Hospitals and physiotherapy-rehabilitative centers are now enabling patients to restore their health faster and return to normal productive lives through the use of advanced assistive and rehabilitative devices

• **Monitoring:**

Health screening devices are enabling patients to take charge of their health at home and regularly monitor health indicators. Further, devices are being used to monitor patients remotely for early diagnosis thus minimizing hospital visits and reducing pressure on the country's over-burdened medical resources

Medical technology contributes significantly to healthcare delivery costs. An estimated 30-40% of capital costs² of setting up a tertiary care hospital is attributable to medical technology. Additionally, depending on the hospital type, cost of medical devices and diagnostics contribute approximately 20%-25% to the cost of medical services³

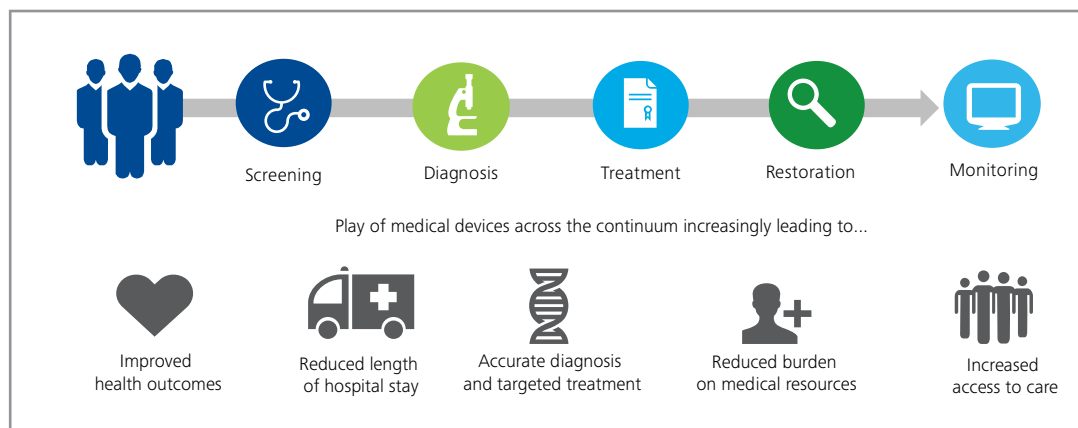


Share of Medical technology cost in setting up a tertiary care hospital



Cost of medical technology/equipment/devices in total healthcare cost for a patient

Exhibit 2: Role of medical devices across the healthcare continuum



The medical devices sector plays a critical role in improving healthcare access. However, the ecosystem is currently not conducive for the sector to drive accessibility and affordability.

In India, the medical devices industry is small, with a disproportionate reliance on imports and a complex regulatory environment

The global medical devices and technology market is expected to grow to USD 520 billion² by 2020 from an estimated USD 3.7 billion in 2014. The Indian market is among the top twenty in the world by market size, and fourth in Asia after Japan, China and South Korea.

However, the per capita spend on medical devices in India is the lowest among BRIC countries at USD 3 (USD 7 in China, USD 21 in Brazil and USD 42 in Russia). It is significantly behind developed economies like the USA (USD 340). This current under – penetration of medical devices in India represents a sizeable growth opportunity.



Existent Regulatory environment Ambiguous, complex and lacking transparency

The policy for the pharmaceutical industry has largely been applicable to medical devices as it so far has been subsumed under the larger pharmaceutical structure. It therefore requires a clear, unambiguous and transparent policy to enable investments and growth.

The opportunity is significant and most recent studies indicate that medical devices expected to be a USD 25-30 billion industry in India by 2025. The Indian market is currently growing at a healthy CAGR of around 15%, significantly higher than global industry growth of 4-6%⁴.

The industry is largely dependent on imports with most local manufacturers producing products in the lower end of the technology value chain



Import dependence Limited availability of technology and funds not enabling indigenous manufacturing

Imports constitute around 75% of the medical devices industry sales in India⁵. A range of factors contribute to this high percentage share of imports

1. An inverted duty structure historically favoring import of finished goods than raw materials /components for medical devices manufacturing
2. Absence of a concrete regulatory framework specific to medical devices constraining investments in the market and, lack of a component manufacturing ecosystem and skills base to support domestic manufacturing of medical devices. In addition, global capacities of multinational firms are also boosting imports

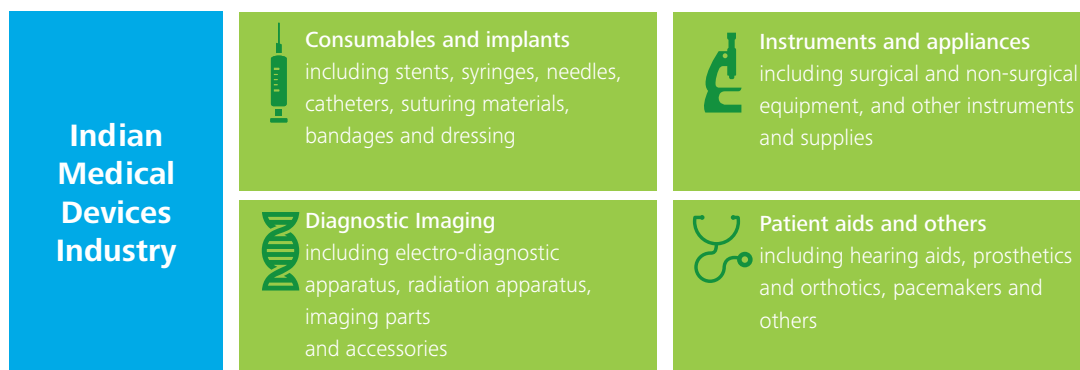
The Indian medical devices industry comprises four segments – consumables and implants, diagnostic imaging, instruments & appliances and patient aids and, others.

In order to bridge the gap existing in medium – high end technology products, an increasing number of multinational companies⁶ are establishing and growing their presence in India. Nearly all of the top 40 global medical devices companies today have a presence

in the country. The share of multinational firms is around 40% – 50% in consumables and instruments and appliances and, as 80% – 90% in all other

sub-segments. Most multinational companies have their production base outside India and import their products for the Indian market.

Exhibit 3: Medical devices industry segments



With changing economic and regulatory environment, the medical devices industry is expected to grow significantly, fueled by a range of factors



Demand side factors

Rising prevalence of chronic diseases resulting in a higher demand for healthcare services:

Non-communicable diseases are expected to comprise more than 75% of India’s disease burden by 2025, compared to 45% in 2010

- India is today referred to as the diabetes capital of the world, with the number of diabetes patients increasing from 38 million in 2010 to 46 million in 2015⁷
- Around 62 million patients suffer from coronary heart disease (the leading cause of death in India), compared to 47 million in 2010⁸
- Similarly, around 23 million patients suffer from Chronic Obstructive Pulmonary Disease (the second leading cause of death in India), compared to 21 million in 2010⁹

Ageing population: The share of aged population (>65 years) is expected to increase to 7% (100 million) of the total population in India by 2020, compared to 5% (60 million) in 2010. This would result in a much higher need for healthcare and thus medical devices, both at health facilities and homes

Increasing income and affordability, resulting in higher demand and utilization of healthcare services: The size of the population earning more than USD 5,000 per annum is estimated to increase to around 450 million (~28% of the total population) in 2025 from the current 145 million (~12% of the total population)¹⁰. This is partly driven by increasing urbanization in India, which is expected to reach 40% by 2030 from the current level of 32%

In addition, health insurance coverage is also expected to increase from the current 300 million people to 655 million by 2020¹¹. As a result, the share of spend on

healthcare as a percentage of total household spend is expected to increase from 7% in 2005 to 13% in 2025¹².

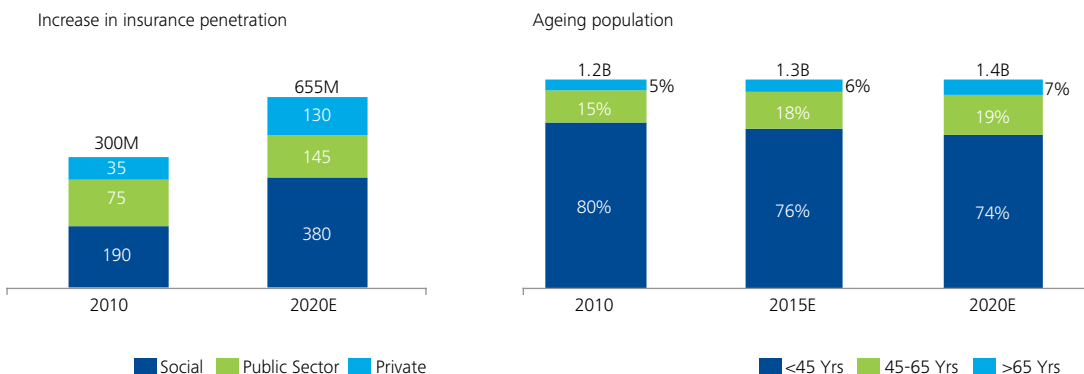
The Government of India has in recent years, implemented several policy measures to address the challenges of medical devices industry. Some of these include:

- Draft Drugs & Cosmetics Amendments Bill (2015)
- 100% FDI in medical devices under automatic route
- ‘Make in India’ initiative for promoting indigenous manufacturing
- The development of a quality standardization framework in India that is based on international standards and certifies the quality, safety and performance of medical devices

Availability of advanced and sophisticated medical technology is creating new markets / applications, increasing the dependence by doctors on advanced medical devices, and is leading to rapid obsolescence of existing medical technology thereby creating demand for replacement/up-gradation of products. The Government of India’s focus on digital and increasing penetration of mobile and internet (eight-fold in the past decade), are other important factors contributing to rising awareness and demand.

The advent of frugal engineering innovations have led to the recent development of low cost products that are at par with existing products on quality.

Exhibit 4: Demand side factors



Funds/Investments and changing business models

The inflow of FDI in medical devices was ~USD 90 million between December 2014 to August 2015, post the government permitting 100% FDI under the automatic route.

Several MNCs have been increasing their manufacturing footprint and locating research centers in India to serve both the Indian and global markets. Increased funding and investments have also reflected in other supply side changes in healthcare delivery in India, such as:

Overall growth in healthcare infrastructure

- There is a significant increase in the number of hospitals and hospital beds in India. Bed strength had increased from 0.8 million in 2002 to 1.6 million in 2012, and is further expected to increase to around 2.9 million by 2025¹³. This increase has been driven primarily by growing presence of corporate hospital chains, international companies and service providers entering tier 2 and tier 3 cities
- There is an increasing presence of diagnostics laboratory chains focusing on imaging and pathology. It is estimated that there are more than 100,000 diagnostic laboratories across the country, with the number expected to grow at a rate of 15% – 20%¹⁴
- The healthcare industry is also witnessing the emergence of new formats like chains of multi-specialty outpatient clinics, mother-and-child hospitals, short stay surgery centers, IVF centers, etc., which are driving demand for medical devices

Increasing focus of healthcare providers on quality and accreditation

There has been a strong focus on upgrading medical technology by hospitals and laboratories to comply with accreditation requirements. Around 285 hospitals in India are NABH accredited with 472 additional proposals submitted for accreditation. Similarly, 347 laboratories in India are NABL accredited with 150 additional proposals submitted¹⁵.

At this critical juncture, the 'Make in India' initiative provides an opportunity to create a 'step change' in Indian healthcare, especially in the medical devices industry

While the potential of the medical devices sector is acknowledged with its inclusion in the 'Make in India' initiative, it is essential to leverage the initiative to kick-start indigenous manufacturing and realize the twin objectives of accessibility and affordability.

Deloitte's effort is aimed at understanding the context, constraints and opportunities for medical device players, healthcare providers and key policy makers; exploring the significance of India vis-à-vis other global manufacturing destinations; and aligning 'Make in India' for medical devices with other key government initiatives.

Deloitte has undertaken a structured exercise to determine the imperatives and develop the recommendations for actualizing 'Make in India' for the medical devices industry. The study has covered key stakeholders across the medical devices ecosystem – manufacturers, providers/consumers/other buyers and regulators. The findings of this research, along with the context and trajectory of India's economic and healthcare landscape, have then been juxtaposed with the key objectives of 'Make in India'.

Focus on manufacturing in India...



New Manufacturing Policy aims to raise manufacturing contribution to GDP from 16% (~USD 0.3 Tn) in 2013 to 25% of GDP (~USD 1 Tn) by 2025

Source: DIPP

The imperatives for the medical devices industry are aligned to the objectives of 'Make in India'



Investments

Capital and technology investments for setting up manufacturing facilities in India



Innovation

India specific innovation to help improve accessibility and affordability of medical devices



Skill

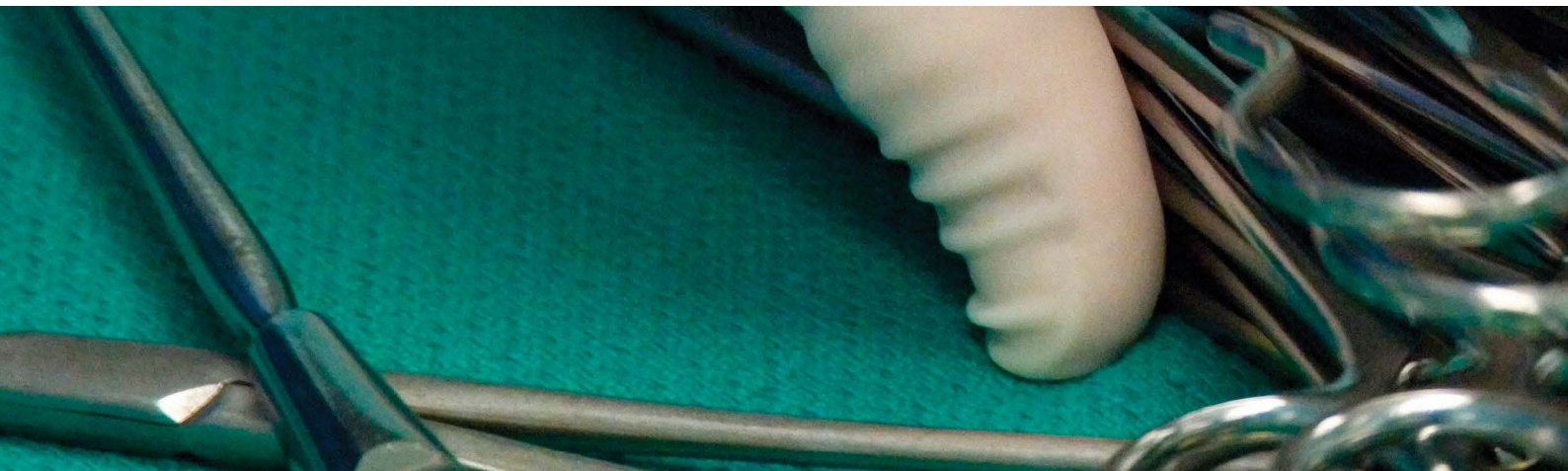
Training and development of human resources for manufacturing, operations and services



Infrastructure

Best-in-class infrastructure in compliance with global standards for supporting high-technology industry

NATHEALTH and Deloitte have partnered to undertake an exercise to synthesize the views and perspectives on 'Make in India' for Medical Devices



Build context

1. Context of 'Make in India' initiative

Establish context of 'Make in India' program – innovation, IP, best-in-class manufacturing, skill development



2. Significance of Medical devices industry

Establish significance of medical devices in overall healthcare continuum and provide market overview of medical devices industry in India covering the sub-segments: instruments and appliances, diagnostic imaging, consumables and patient aids



3. Manufacturing landscape of medical devices in India

Manufacturing landscape of medical devices in India – level and nature of imports/exports, degree of manufacturing; learnings from allied industries and global manufacturing destinations



Obtain stakeholder inputs

4. Personal interactions

Personal interactions with key stakeholders (providers, medical devices, central & state government) to get required inputs



5. Online Questionnaire-based survey

Questionnaire based survey to capture the sentiments of NATHEALTH executives around key themes of the initiative



6. Industry viewpoint along thematic areas

Understand and synthesize the industry viewpoint around ease of doing business, infrastructural support requirement, medical devices ecosystem, viability of manufacturing in India and enablers required for the shift



Develop suggestions

7. Articulation of measures to achieve objectives of 'Make in India'

Initiatives to be taken across multiple areas: policy measures, regulatory framework, development of manufacturing clusters, strengthening of ecosystem for innovation and manufacturing

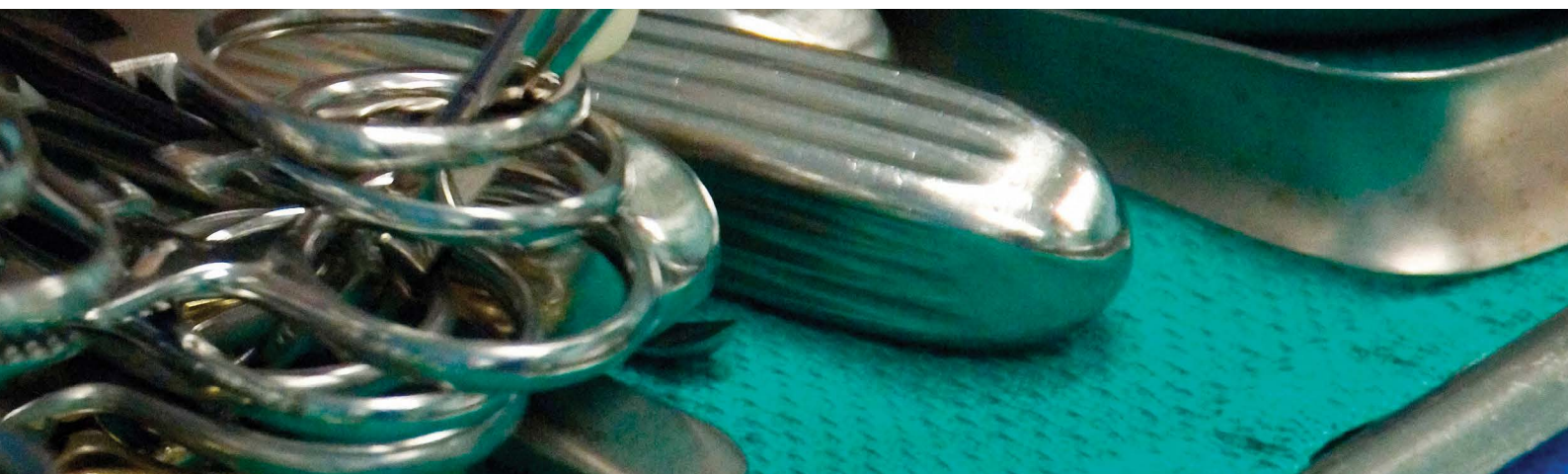


8. Visibility and communication of the study to all stakeholders

Ensuring visibility and communication of the study to all stakeholders



Note: List of participants for primary interactions and survey in the annexure





Current landscape and key considerations for growth

The medical devices market is estimated to grow organically at ~15% to USD 8.6 billion by 2020. Industry estimates indicate a much larger potential to grow at ~28% to USD 50 billion by 2025

The medical devices market grew at a 10% CAGR in the past five years, reaching a value of USD 3.7 billion¹⁶ in 2014. From 2014 levels, if the industry continues on its organic growth trajectory, it is expected to reach USD 8.6 billion in size by 2020, growing at a CAGR of around 15% against the expected global industry growth of 4-6%¹⁷.

In this scenario, the focus on augmenting healthcare infrastructure due to increased demand and improved access is expected to provide the requisite industry growth. Currently, the Indian medical devices industry represents just over 1.3% of the global medical devices

market of USD 335 billion, which is dominated by USA (USD 134 billion in 2014)¹⁸.

With an enabling policy framework and ecosystem support, industry estimates indicate a potential to grow at ~28% to USD 50 billion by 2025¹⁹. This growth is expected to be driven by indigenous manufacturing and exports and, sales from local innovation.

At this rate of growth, India is expected to contribute significantly to the incremental share of the global market. The contribution of Indian medical devices market to the incremental growth of the global market for 2020-2025 is expected to be around 30% (USD 33.6 billion in the overall global contribution of USD 108.6 billion), which is significant for global trade.

Exhibit 5: Historical and Expected Performance of Medical devices industry

Scenario 1: Organic growth at 15%

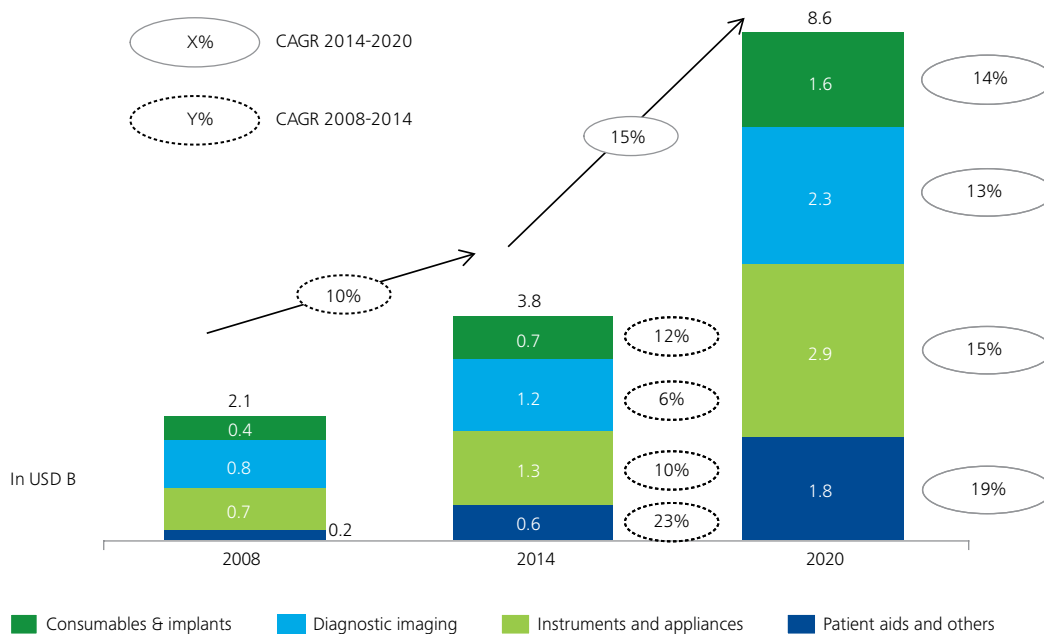
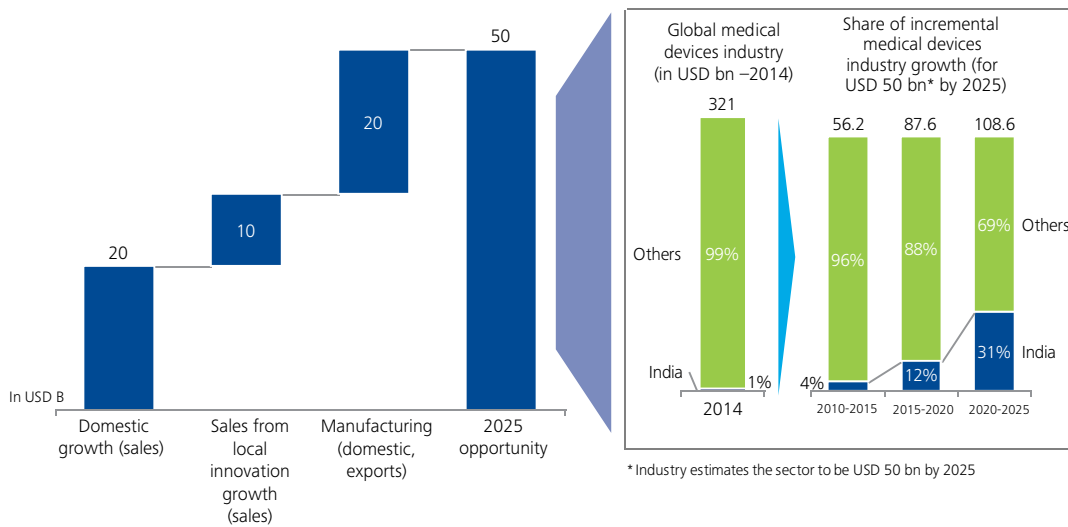


Exhibit 6: Share of incremental medical devices industry growth

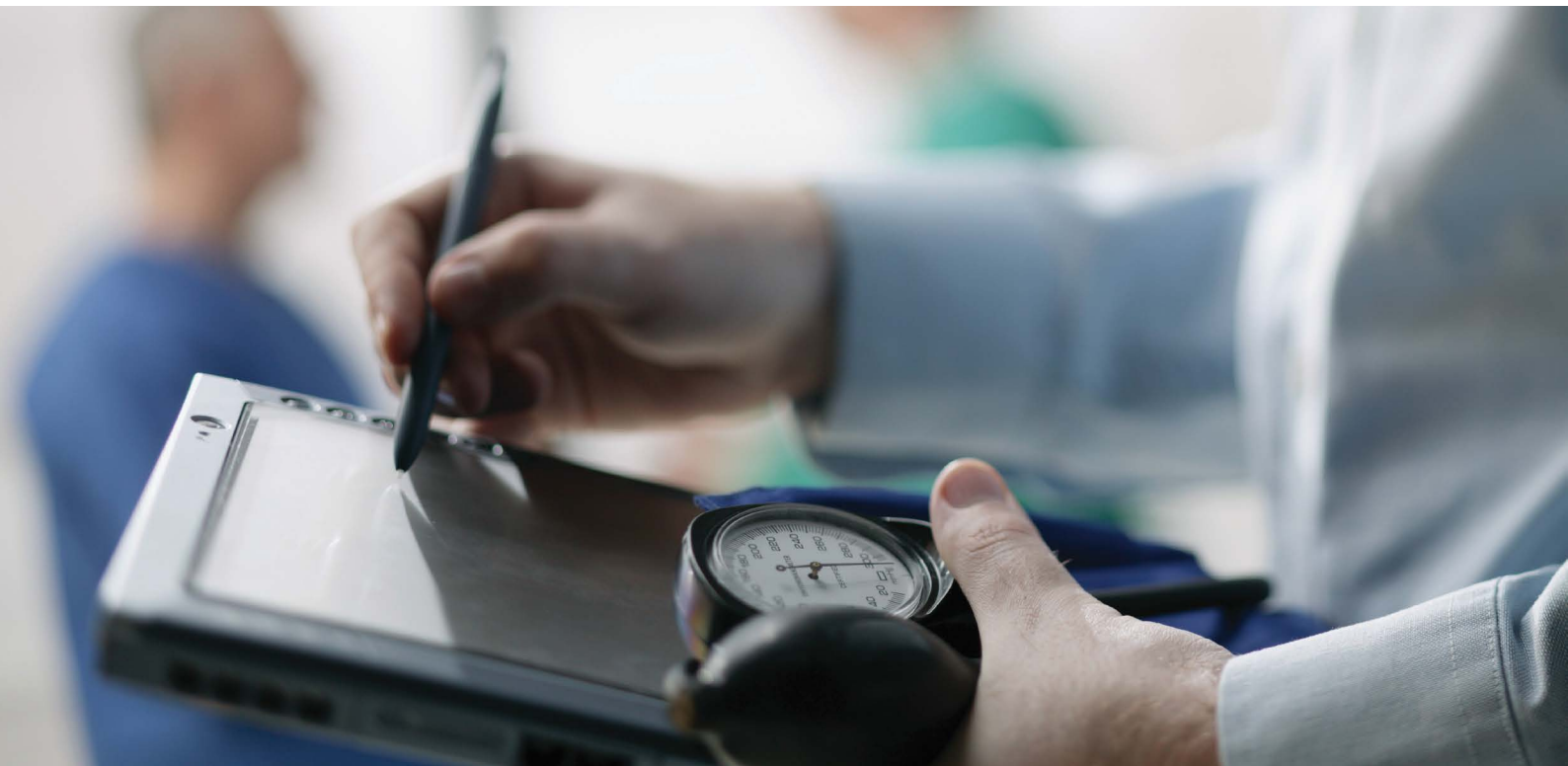
Scenario 2: Industry size as USD 50 B by 2025



The industry comprises four key segments and associated sub-segments with each displaying different characteristics but very similar double digit growth potential

The Indian medical devices industry comprises four industry segments – consumables and implants, diagnostic imaging, instruments & appliances and patient aids and others.

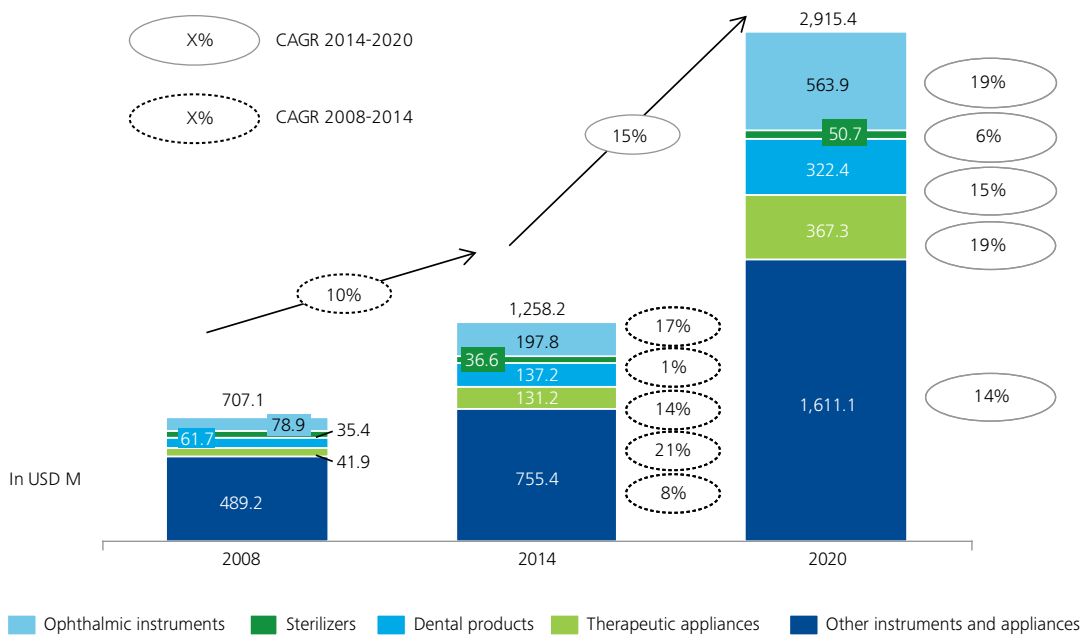
Instruments and appliances represents the largest segment of the medical devices industry in India, constituting 34% (USD 1.26 billion) of the total industry size in 2014. It is expected to grow at a rate of 15% over 2014-2020. Growing at a Compounded Annual Growth Rate of 19%, therapeutic appliances are expected to lead the growth for this segment.

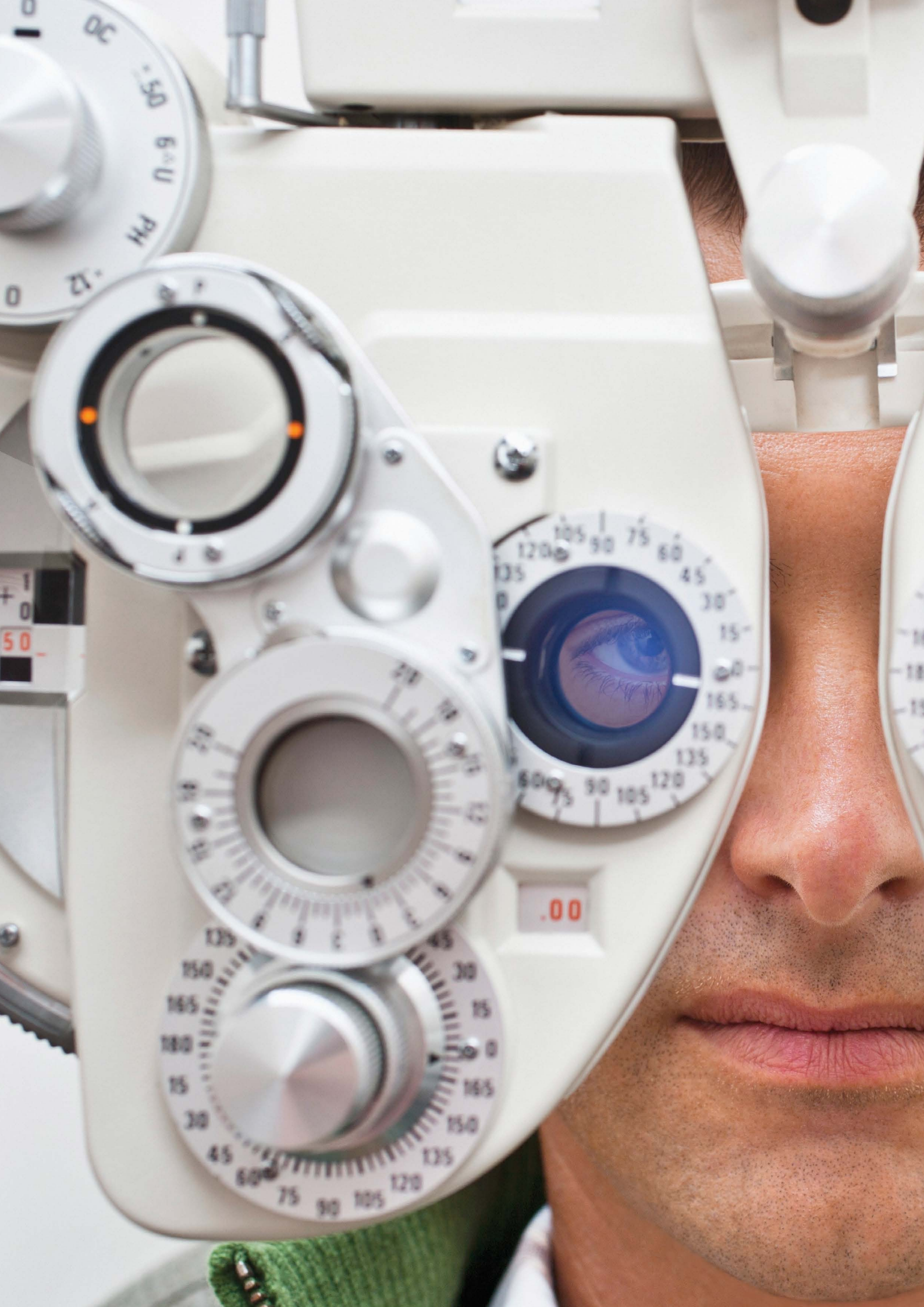


Instruments and appliances: Sub segments and product categories

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

Exhibit 7: Market size and growth rate of instruments and appliances





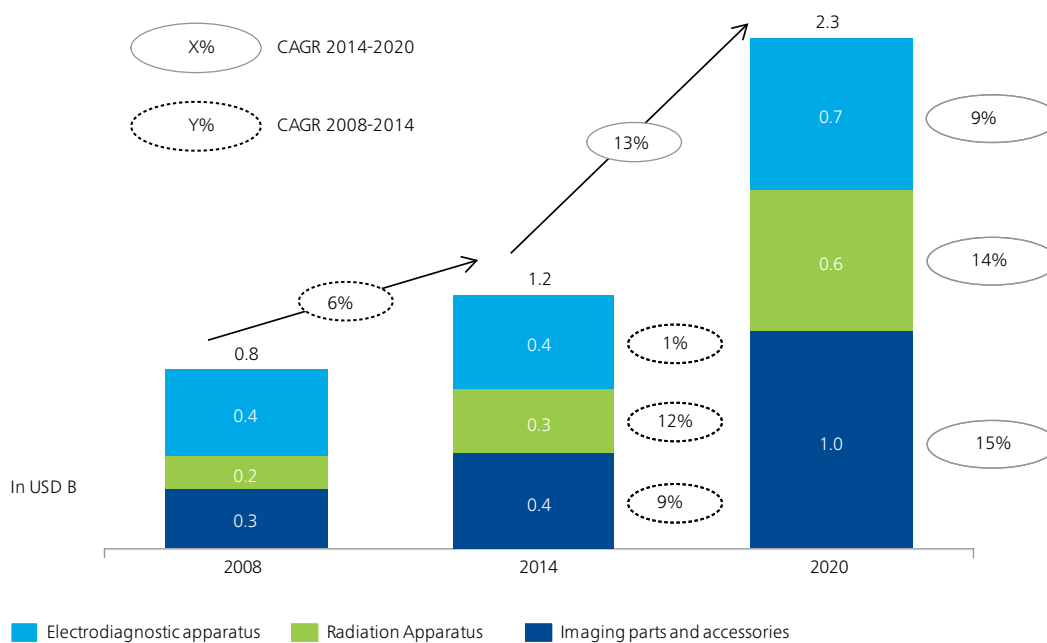
Diagnostic imaging represents the second largest segment of the medical devices industry in India, constituting 31% (USD 1.2 billion) of the total industry size in 2014. It is expected to grow at a rate of 13% over 2014-2020. Building on the existing installed base

of electro-diagnostic and radiation apparatus, imaging parts and accessories are expected to lead this segment, growing at a CAGR of 15% over the next few years.

Diagnostic imaging: Sub segments and product categories

1	Electro-diagnostic apparatus	Electro-cardiographs, ultrasound, MRI, scintigraphic apparatus and other electro-diagnostic apparatus
2	Radiation apparatus	CT scanners, X-Ray, and other A, B, C ray apparatus
3	Imaging parts and accessories	Contrast media, medical X-Ray films (flat and rolled), X-Ray tubes and other imaging parts / accessories

Exhibit 8: Market size and growth rate of diagnostic imaging

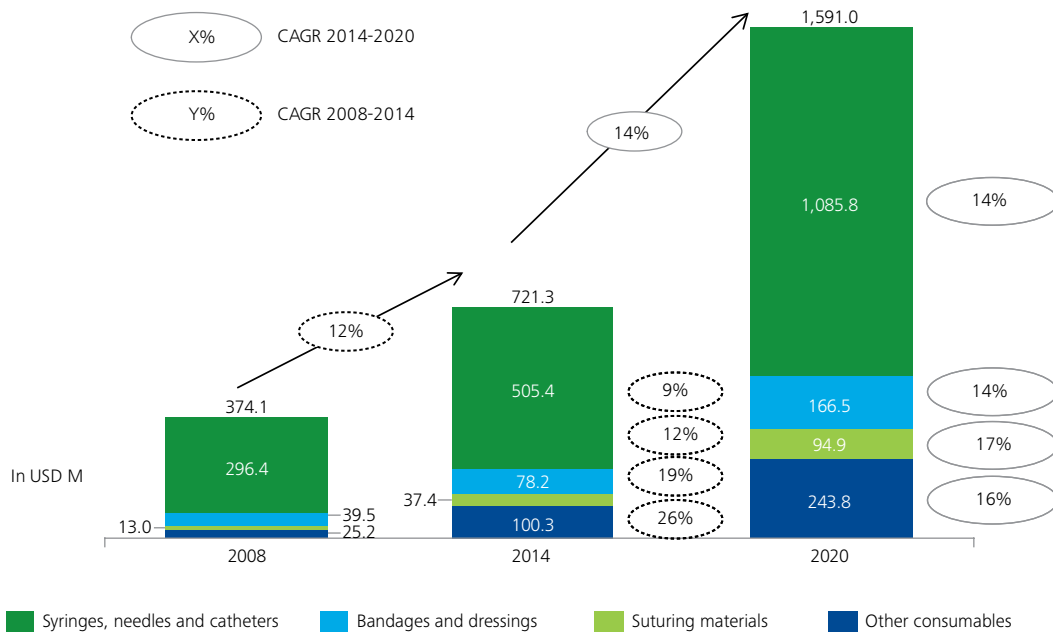


Consumables and implants constituted 19% (USD 0.72 billion) of the total industry size in 2014. It is expected to grow at a rate of 14% over 2014 – 2020.

Consumables and implants: Sub segments and product categories

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

Exhibit 9: Market size and growth rate of consumables and implants

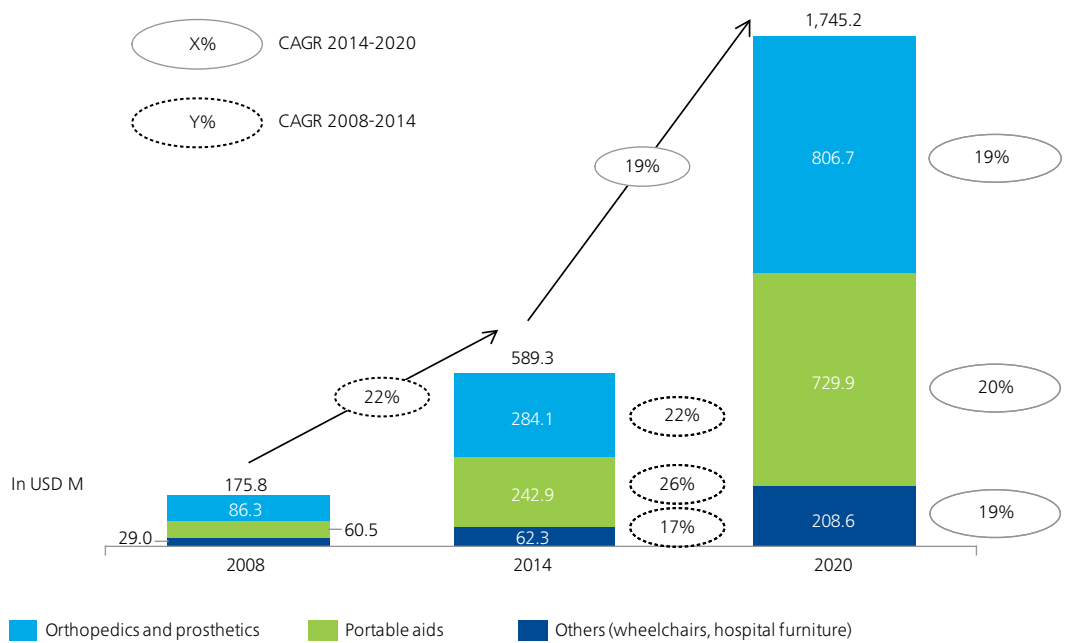


Patient aids and others is the fastest growing segment of the medical devices industry in India and constituted 16% (USD 0.59 billion) of the total industry size in 2014. It is expected to grow at a rate of 19% over 2014-2020.

Patient aids and others: Sub segments and product categories

1	Orthopedics and prosthetics	Fixation devices, artificial joints and other artificial body parts
2	Portable aids	Hearing aids, pacemakers and other portable aids
3	Others	Wheelchairs and hospital furniture

Exhibit 10: Market size and growth rate of patient aids and others

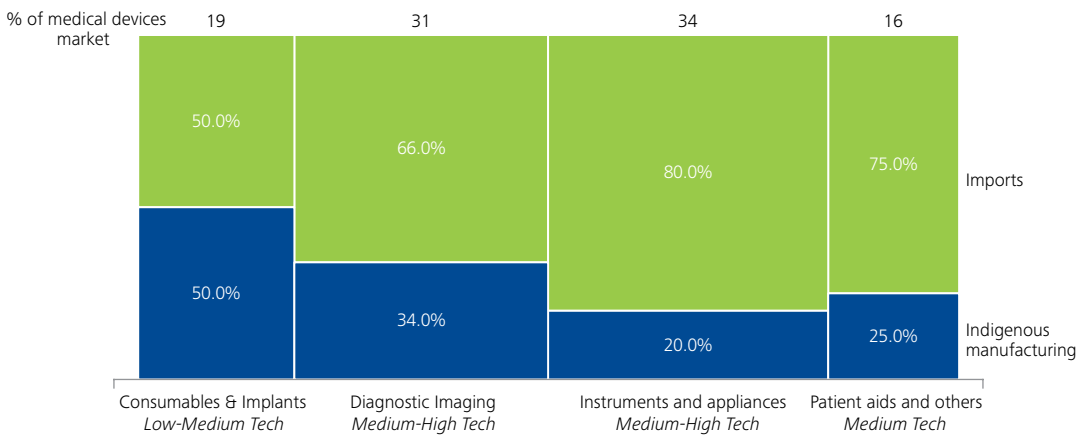


Despite the significant presence of domestic players in the industry, the Indian medical devices market is still largely dependent on imports

The Indian market is largely dependent on imports, which currently comprise 70% of the market and

have increased four-fold in the last ten years. The contribution of the industry to the overall import bill is estimated to be USD 2.58 B in 2014 .The continued dependence on imports is likely to contribute significantly to the import bill as the market continues to expand.

Exhibit 11: Level of imports across segments



Between the four segments, the level of indigenous manufacturing is high for consumables and implants. However, within this segment too, there is still dependence on imports for mid to high-tech products.

Several factors relating to the policy framework and tax structure lead to high dependence on imports these include historical presence of inverted duty structure favoring imports of finished goods over raw materials, limited access to technology, IP protection and, size and scale of indigenous manufacturers.

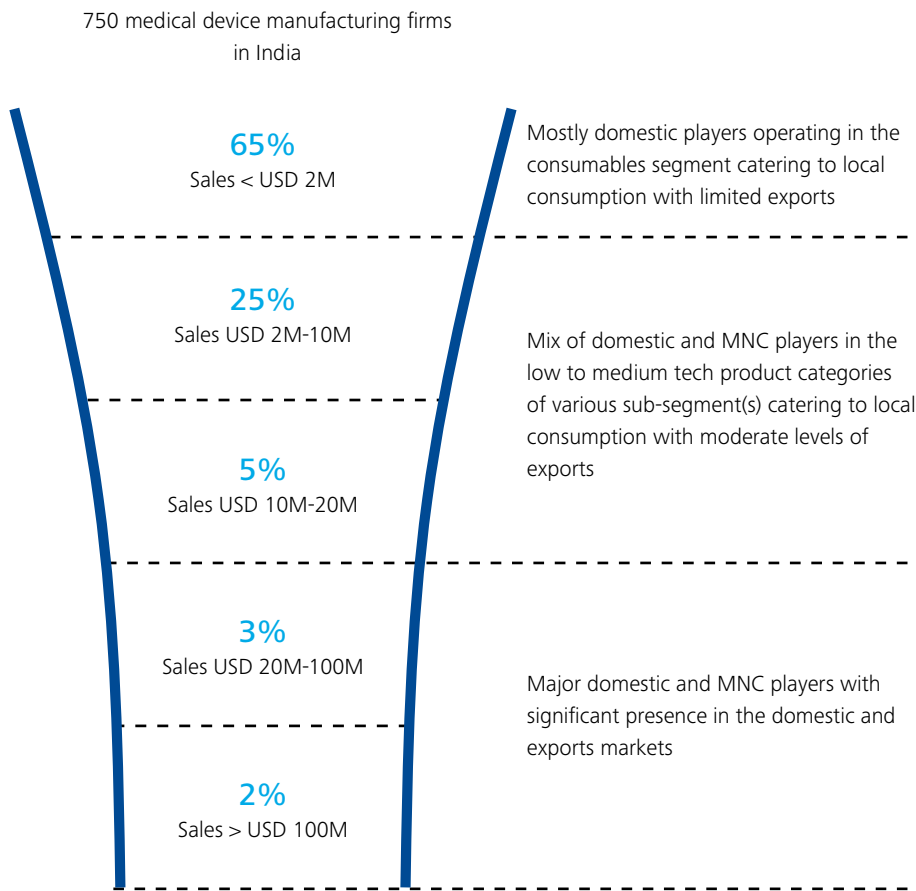
The size of indigenous manufacturing is small and fragmented although characterized by the presence of both domestic and MNC players

In the current state, indigenous manufacturing is limited to products in the lower end of technology value chain, and driven by the consumables and implants segment. Complex medical devices are manufactured in a limited manner by multinational companies present in India or imported. Local manufacturers are primarily focusing their R&D efforts on developing affordable medical devices for the lower and middle income segments of the Indian market and therefore operate predominantly in the low priced, high volume market segments.

Of the 750 medical devices manufacturers present in India, a majority are SMEs and MSMEs (90% have an annual turnover of less than USD 10M) and contribute 30% or (USD 1.1 billion) to the Indian medical devices market²¹.

While indigenous manufacturing is yet to scale up in India, Maharashtra and Tamil Nadu are leading examples of states that have developed a holistic ecosystem to boost the indigenous medical devices industry. With their manufacturing base, cities of Bangalore, Mumbai and Chennai have also developed the presence of R&D centers. Indigenous innovative products are being designed and developed in these R&D centers by MNCs as well as several domestic players. Proximity to R&D facilities and adequate ecosystem support (policy and tax incentives) have led to the organic development of medical devices centers.

Exhibit 12: Medical devices manufacturing industry structure



Source: AIMED

‘Local innovation’ by MNCs as well as domestic players is expected to drive indigenous manufacturing and lead to rapid growth of exports

Export of medical devices have grown at a rate of around 12% over the past five years, reaching a

value of USD 1.2 billion in 2014. This indicates strong performance of the domestic manufacturing industry although limited in size. The Consumables and implants segment accounts for more than 40% of exports from India with USA being the leading destination of export of medical devices.

Exhibit 13: Manufacturing Landscape in India

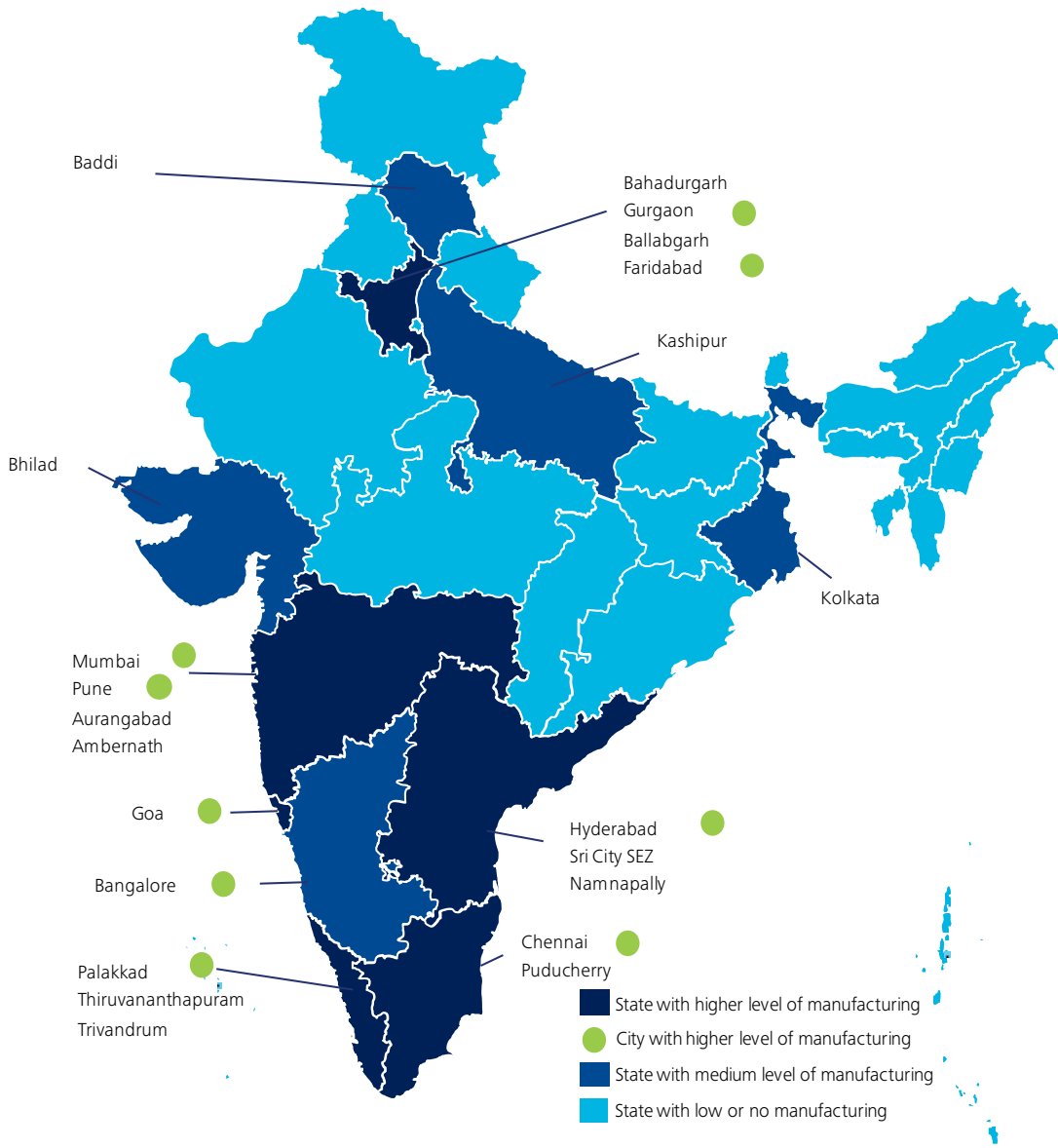


Exhibit 14: Growth trajectory of exports of Medical Devices from India

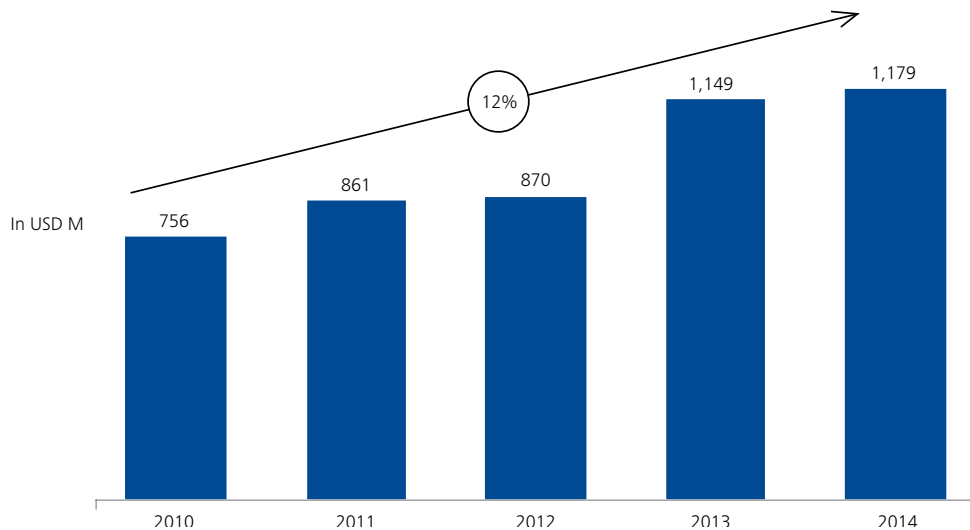
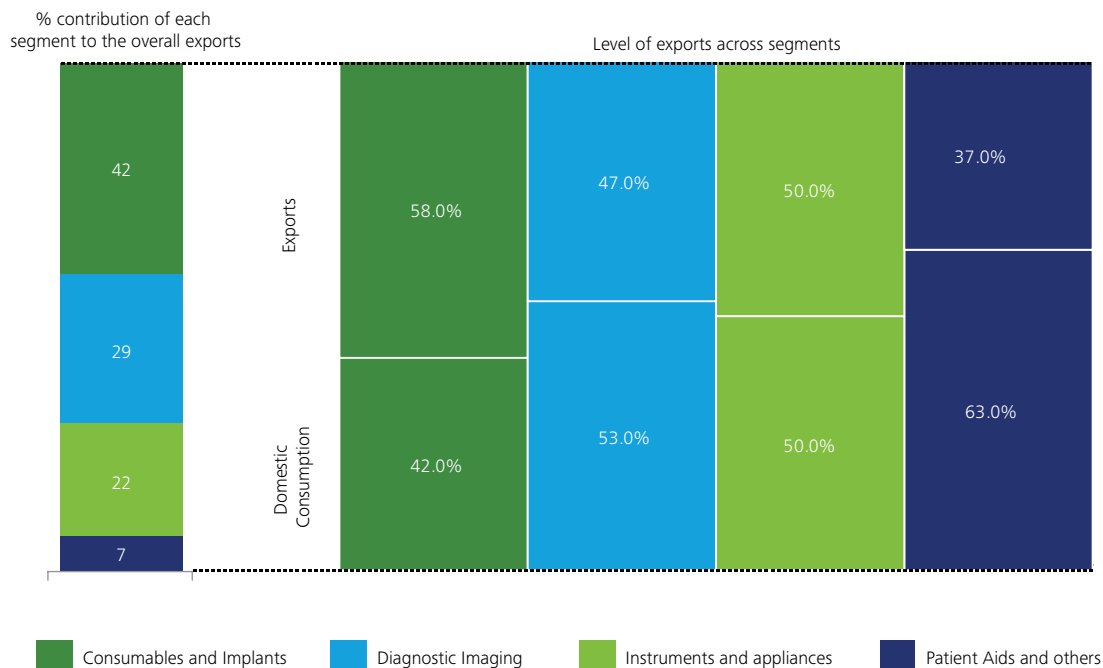


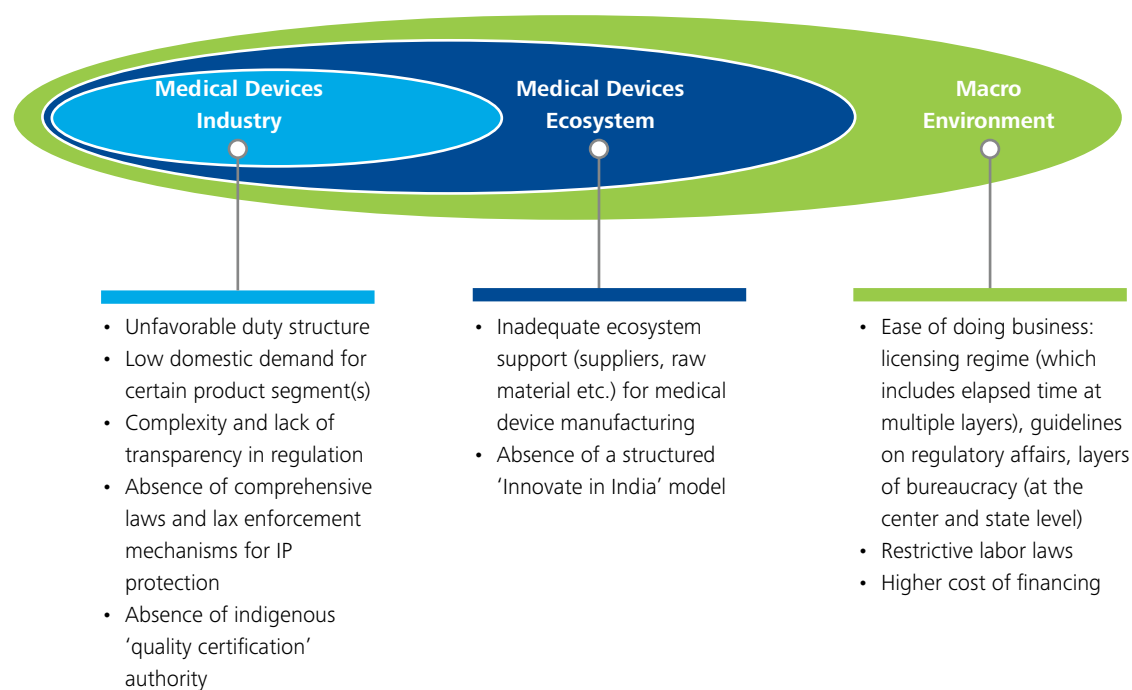
Exhibit 15: Percentage contribution of each segment and level of exports across segments



In the recent years, MNCs and domestic players have designed and developed India specific medical devices in their R&D centers located in India. These products have been designed to suit the needs of the developed

market – in terms of product specifications and pricing. Interestingly, these products have also created demand in other developing markets outside India.

Challenges across multiple dimensions that were disablers to the growth of indigenous medical devices manufacturing in India need to be addressed. These include aspects around the macro economic environment, the medical devices ecosystem and, those specific to the medical devices industry



Medical Devices Industry

- **Unfavourable duty structure:** An unfavourable duty structure in many segments/sub-segments make imports cheaper than manufacturing in India. This further limits the scope for local value addition, especially in segments conducive for manufacturing at present
- **Inadequate domestic demand for certain segments/product categories:** Small markets for most segments/sub-segments of the medical devices industry limit investments, as any investment would require scale for viability. Limited demand coupled with inverted duty structure weakens the case for indigenous manufacturing.
- **Lack of comprehensive laws and lax enforcement mechanisms for IP protection:** IP protection for novel technology is critical for the success of global medical devices players investing outside their home market. In the absence of enforceable IP laws, global players would lack confidence to invest in manufacturing assets, thus limiting India manufacturing.
- **Absence of indigenous 'quality certification' authority:** Absence of a licensing authority reduces export opportunities as many countries require a certificate / license from the country of origin. Currently, indigenous manufacturers are required to get an FDA/CE certification to cater to a section of market in India and other parts of the world. The approval process can take a considerable amount of time, thereby impacting the time to market.

Medical Devices Ecosystem

- **Inadequate ecosystem support:** The setting up of a manufacturing facility goes beyond set up, requiring an effective component supply chain to be in place. Currently, a major challenge for players in most segments/sub-segments is that a large part of the component supply chain is imported.
- **Limited focus on 'Innovate in India':** As the market has been majorly dependent upon imports, the scope for 'local innovation' has been limited. Barring a few players, most have looked at India as one of many export markets, with a primary focus on extensive sales and distribution.

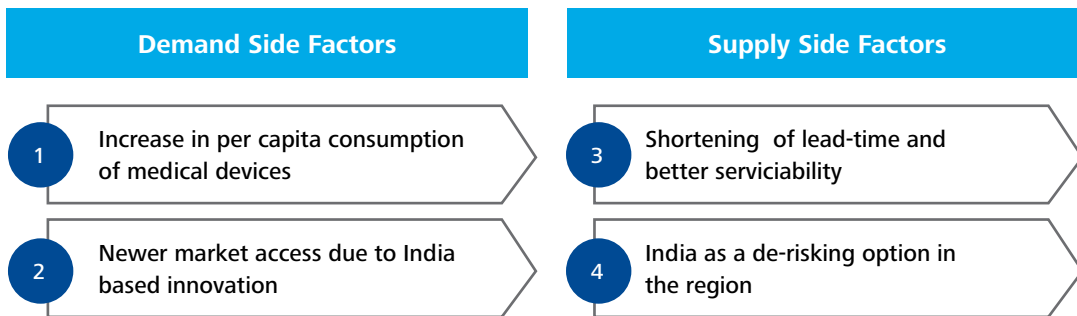
Macro Environment

- **Ease of doing business:** India still lags behind most countries in terms of ease of doing business. Due to complex regulatory requirements, products currently require multiple agency approvals. This leads to time delays at multiple layers, at both the national and state levels.
- **Limited availability of skilled workforce and restrictive labor laws:** Despite sufficient human capital, there are unfavourable labor laws and limited trained workforce in India to install operate, repair and service equipment.
- **High cost of financing:** The industry is capital intensive. Currently, the cost of financing is in the range of 14-18%, thereby increasing the financial burden for players planning to set up manufacturing facilities in India.



Market Opportunity for Making in India

Demand and supply-side dynamics provide an unprecedented opportunity for manufacture of medical devices in India



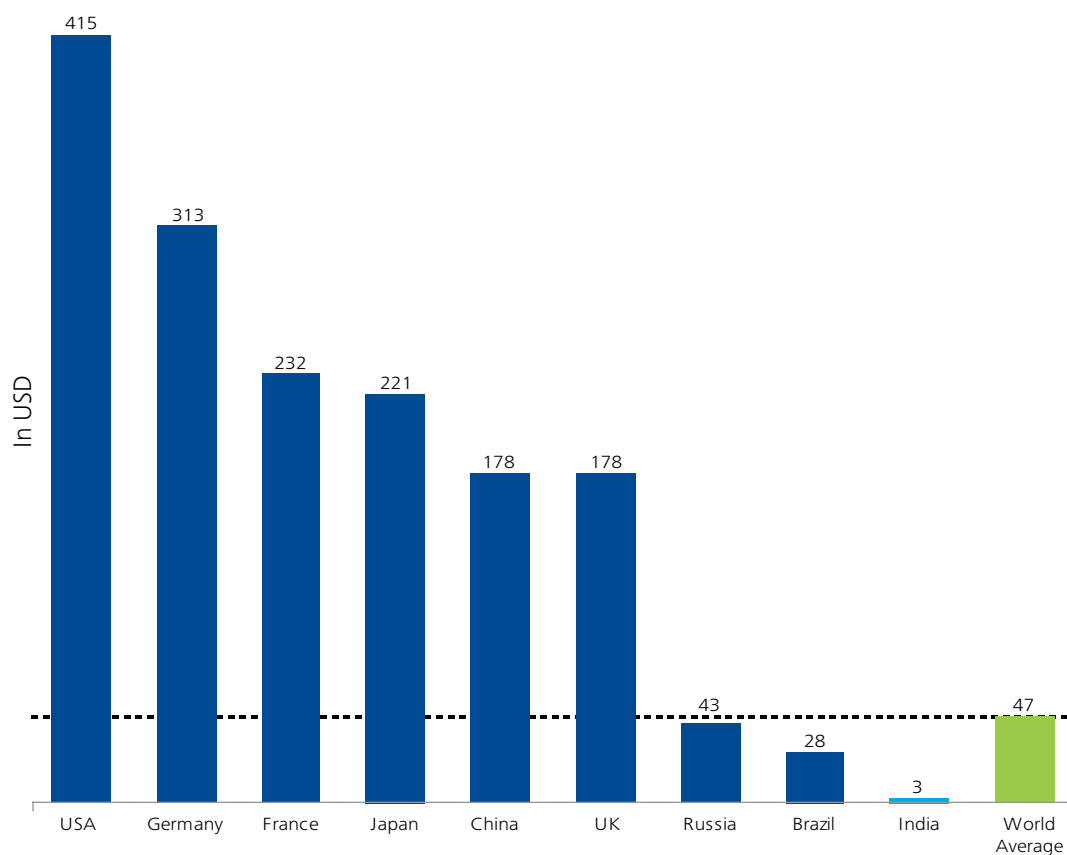
Demand Side Factors

Increase in per capita consumption of medical devices

Indian medical devices market is expected to grow at a rapid rate of 15% in the next decade, fueled by government plans to achieve universal health insurance cover, initiatives like Make in India, and expansion by private healthcare firms. Despite a double digit growth rate of the medical devices market at 10% in the past decade, the Indian per capita consumption of medical devices remains significantly low at ~USD 3.0 . It is much lower than the global average per capita consumption of USD 47 as well as the per capita consumption of developed nations like USA and Germany (USD 415 and USD 313 respectively, in 2015).

One of the primary causes for low per capita consumption is challenges of affordability for high-end technology devices among large portions of the Indian population. Consequently, and like many other segments of the Indian manufacturing industry, medical devices manufacturing is primarily focusing on frugal engineering to develop India-specific low cost products, aimed at lower and middle income segments. The potential of this segment is expected to be unlocked as the demand increases and per capita consumption of medical devices improves.

Exhibit 16: Per capita consumption of medical devices



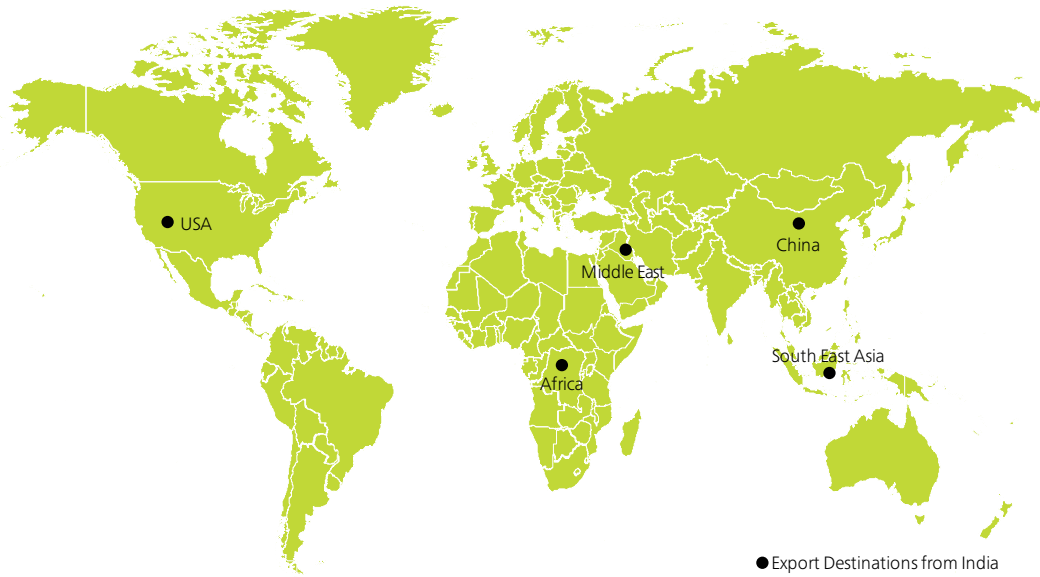
Newer Market access due to India based innovation

Even though manufacturing remains limited to producing low technology products, a few domestic companies and MNCs with manufacturing facilities in India have successfully developed low cost products that are on par in terms of quality with existing products that require complex technical know-how to manufacture. Consequently, these products have developed a niche market in many regions globally. A few such successful products and markets include:

With such success stories, it is not surprising that medical devices exports have recorded strong growth over the past decade. The Consumables and Implants segment has contributed significantly to exports from India, at USD 1.17 billion (2014)²⁵. The top three export destinations from India in terms of value are USA (USD 171 million)²⁶, Singapore (USD 81 million)²⁷ and China (USD 72 million)²⁸.

Indigenous Product	Newly developed exports markets
Heart Valve	Thailand, Kenya, Myanmar
Low cost ACT Scanner	South East Asia
Ultrasound and Color Doppler	Japan
Intraocular Lens	African countries
Low cost tech. products and services	Middle East, SE Asia, and Africa

Exhibit 17: Export Markets for Indian Medical Devices



Supply Side Factors


Shortening of lead-time and better serviceability

With a potential for strong domestic demand and other supporting factors, India is set to emerge as an ideal destination for setting up manufacturing facilities, especially for global companies looking to align their global manufacturing footprint with shifting consumption patterns. A shorter lead-time as well as the opportunity to significantly enhance service levels augurs well for increasing healthcare penetration in India.

India as a de-risking option in the region

For MNC players, India presents a good opportunity to simultaneously de-risk their business from regional/global risks and the growing domestic market. India is set to become a major consumption location, with high potential to become an export oriented country. While China is an example of a location that provides huge domestic demand as well as low cost manufacturing, countries like Ireland, Singapore and Puerto Rico are successful examples of markets that have become major export hubs (where exports are significantly higher than domestic sales).

Indigenous manufacturing would substantially improve serviceability; Hence, healthcare service providers need not build in redundancy. This, in turn, reduces set up cost for the provider



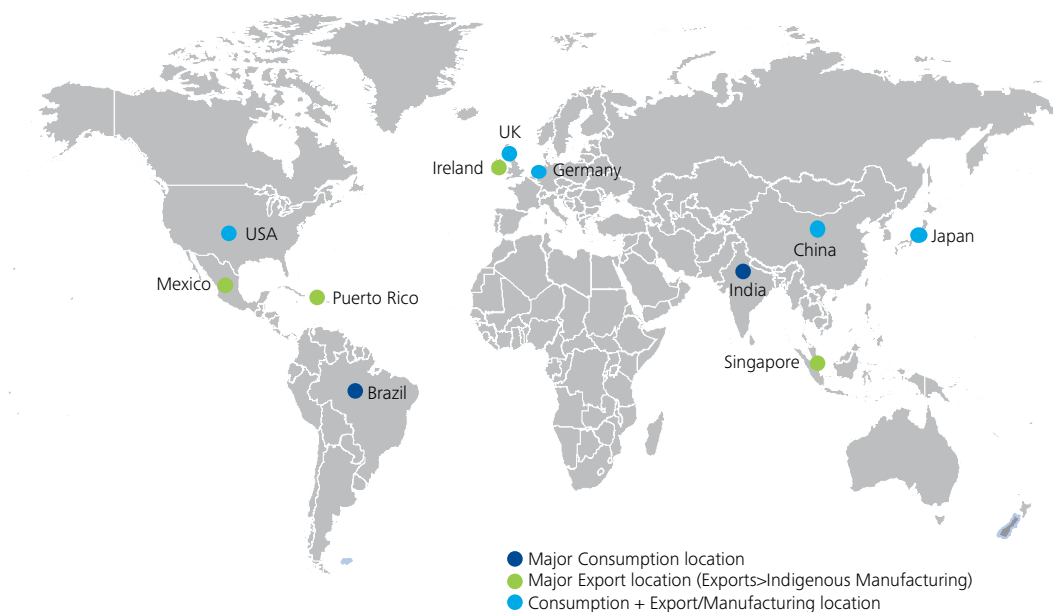
Easy availability of medical devices would help reduce time to set up new healthcare centers and improve the operational efficiency of existing ones



Domestic manufacturing would enable deeper penetration of healthcare services into rural India, hence increasing access of medical devices



Exhibit 18: India as a de-risking option in the region



Capitalizing on these factors, India can move up the technology ladder and focus on manufacturing of low and mid-tech products in the near term

As India continues to innovate and develop new technologies, global demand and potential in the near and medium term provide India with an opportunity to become a major participant in the global supply chain of medical devices. With success stories from domestic manufacturers, India is steadily developing capabilities in manufacturing medical devices. Indian players have developed expertise in manufacturing products in consumables and implants segment. In the near term, the focus needs to be on manufacturing of low and mid-tech products, with a gradual shift towards developing capabilities for design and manufacturing of high-tech products.

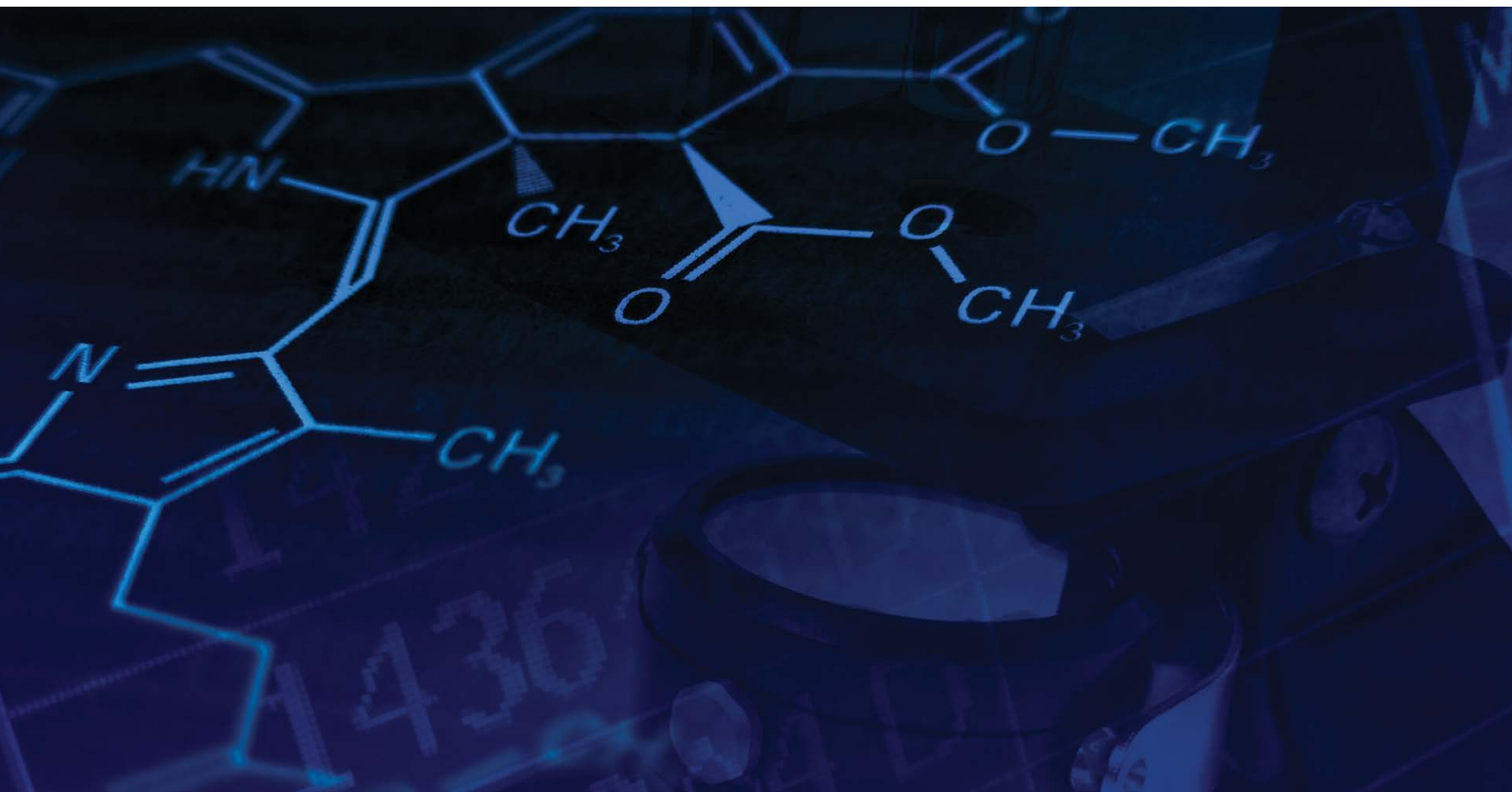
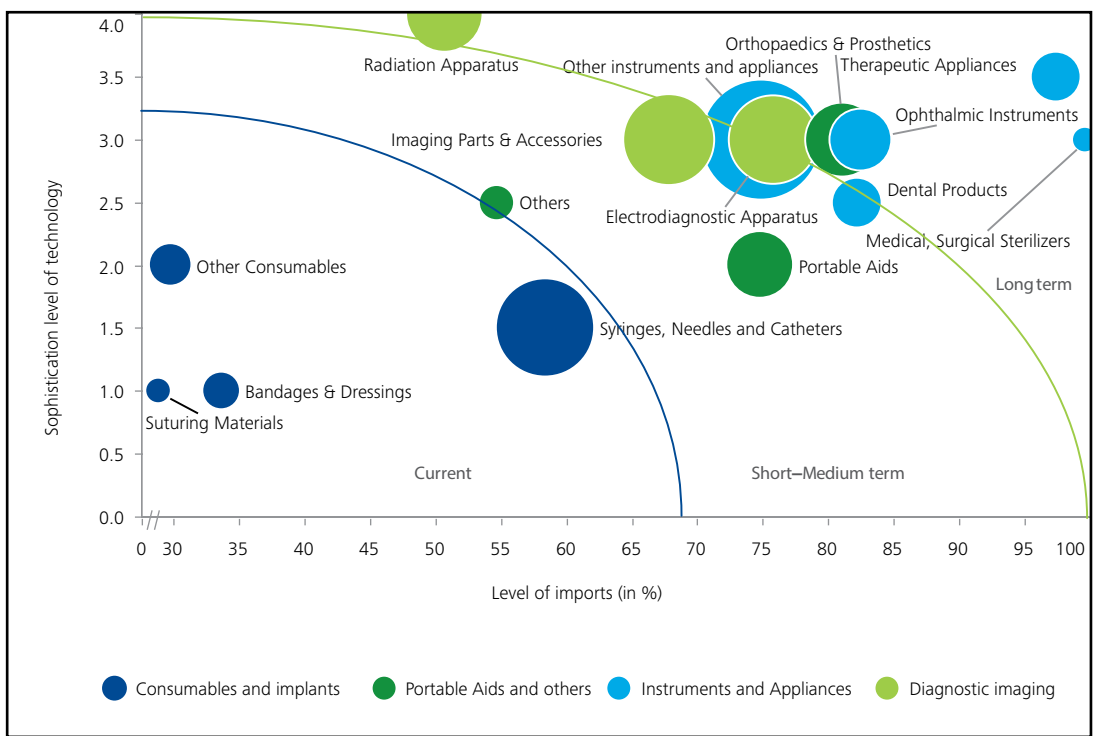
A key concern for the medical device industry today is that irrespective of the sophistication of technology, all segments/sub-segments of medical devices are

being treated uniformly by regulators and other stakeholders in the ecosystem. However, going ahead, as the industry moves towards indigenization, a differential treatment for each segment/sub-segment is necessitated. For instance, most products in medium-high technology segments have a long lead time for development and require large investments. Being low volume products with longer return on investment cycles, such products need to be treated differently, possibly with additional incentives for development and manufacturing.

A phased approach needs to be adopted for indigenization, based on how well the manufacturing ecosystem develops for each segment/sub-segment. Only when the ecosystem matures to enable indigenous manufacturing of comparable global quality standards, tariffs and barriers need to be used to protect indigenous manufacturing. This would ensure orientation of the industry towards quality, thereby making indigenous manufacturing globally competitive.



Exhibit 19: Sophistication level of technology vs level of imports by medical device type



What can India learn from steps taken by other countries to boost their indigenous manufacturing and exports of medical devices?

For India to establish a firm footing in the global market, a robust policy and regulatory framework is required. China (as a consumption and manufacturing hub) and Ireland (as a major exports hub) provide ideal examples on how to develop a sound policy and regulatory environment for the medical devices industry.



China
(Domestic Consumption + Manufacturing Hub)

Ease of Business

- China FDA allows fast track approval of domestically produced innovative medical devices; New order reduces registration timeframe by half
- Waiver of clinical trials for class I and selected class II and class III products

Financial Benefits

- Reduced corporate tax for the medical device industry from 25% to 15% as it is an "encouraged" industry
- Extension of tax benefit by three years if investment made in provinces recognized for development of medical devices

Industry Association

- Dedicated associations CAMDI and CMDI for medical devices sector

Proximity to market

- Huge domestic population/market
- Japan and US significant export markets

Driven by domestic consumption, timely intervention by the government to promote manufacturing – reduced corporate tax rate, focus on R&D ecosystem, incentivization for indigenous manufacturing



Ireland
(Major Exports Hub)

Ease of business

- Science Foundation recognizes Medical Devices industry as priority
- Well established medical devices industry in Galway which provides a ready pool of vendors and workers for new manufacturers entering Ireland

Financial Benefits

- Lowest corporate tax rate in Europe of 12.5%

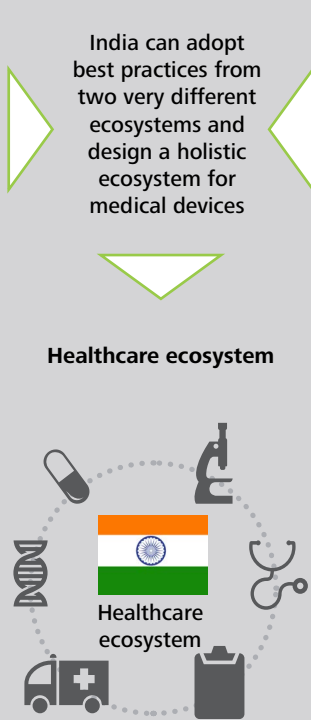
Proximity to market

- Proximity to EU; US companies gateway to Europe

Regulation and IP Protection reforms

- Regulations less stringent for product approvals;
- EU regulations are less stringent than those in US for product approval

Proximity to EU market has been the key driver for the growth of manufacturing set up, ably aided by government interventions including reduced corporate tax rate, easy product approvals, reduced input costs

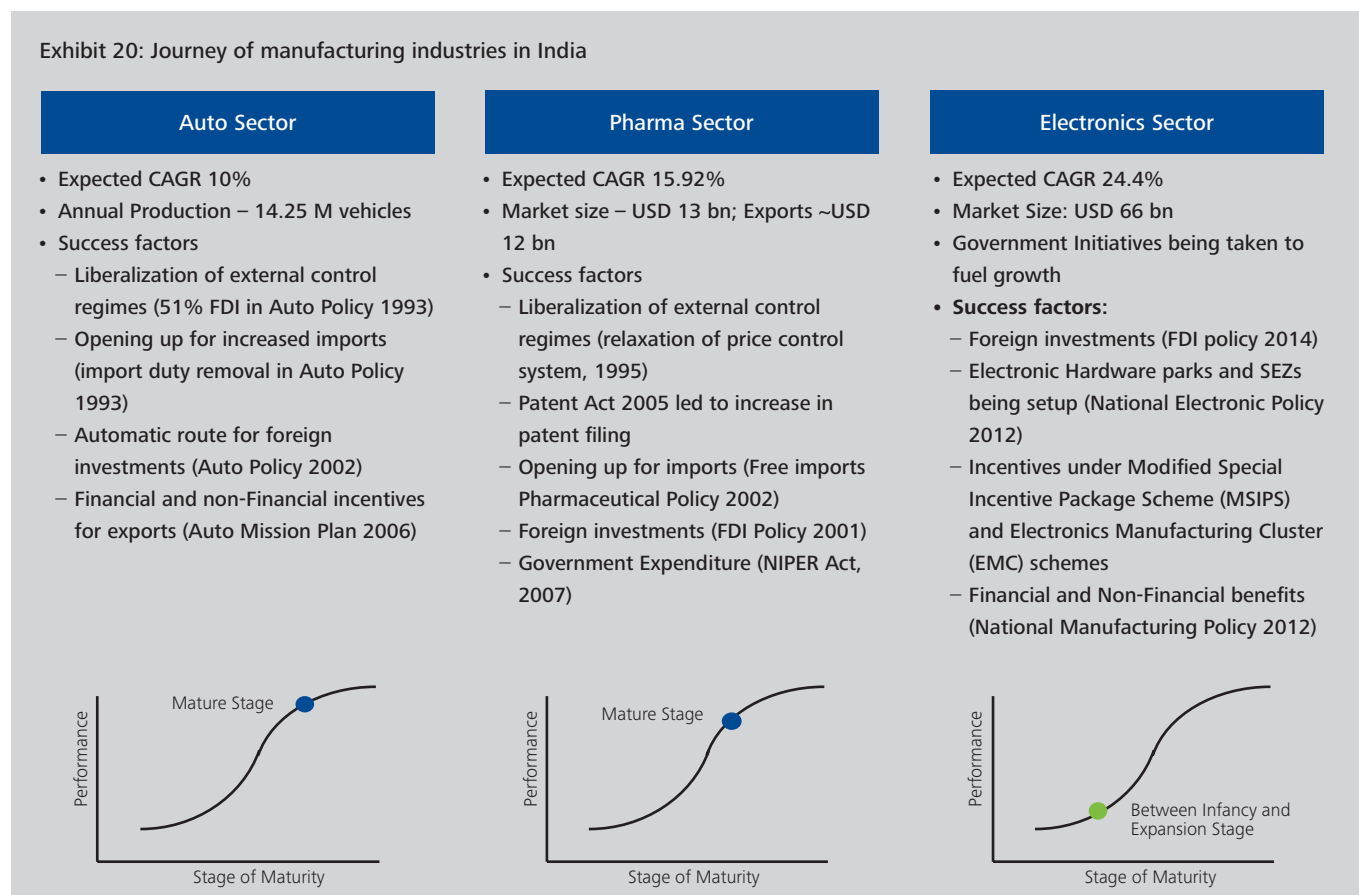


In addition, as the road map for medical devices manufacturing is charted, learnings that created growth trajectories of other industries can be adopted

With automotive and pharmaceutical sectors now reaching manufacturing maturity, other emerging sectors like electronics and allied manufacturing are expected to drive the next phase of growth in manufacturing. Success factors that have led to the growth of automotive and pharmaceutical in the past decade can be applied to the development of other allied manufacturing industries. A few such critical success factors are:

- Liberalization and opening up of markets
- Policy reforms (ease of doing business)
- Financial and non-financial incentives (in terms of import duty, export duty, SEZs)
- Designing comprehensive laws and a robust regulatory environment for high IP industries
- Government expenditure to initiate ecosystem development

Exhibit 20: Journey of manufacturing industries in India

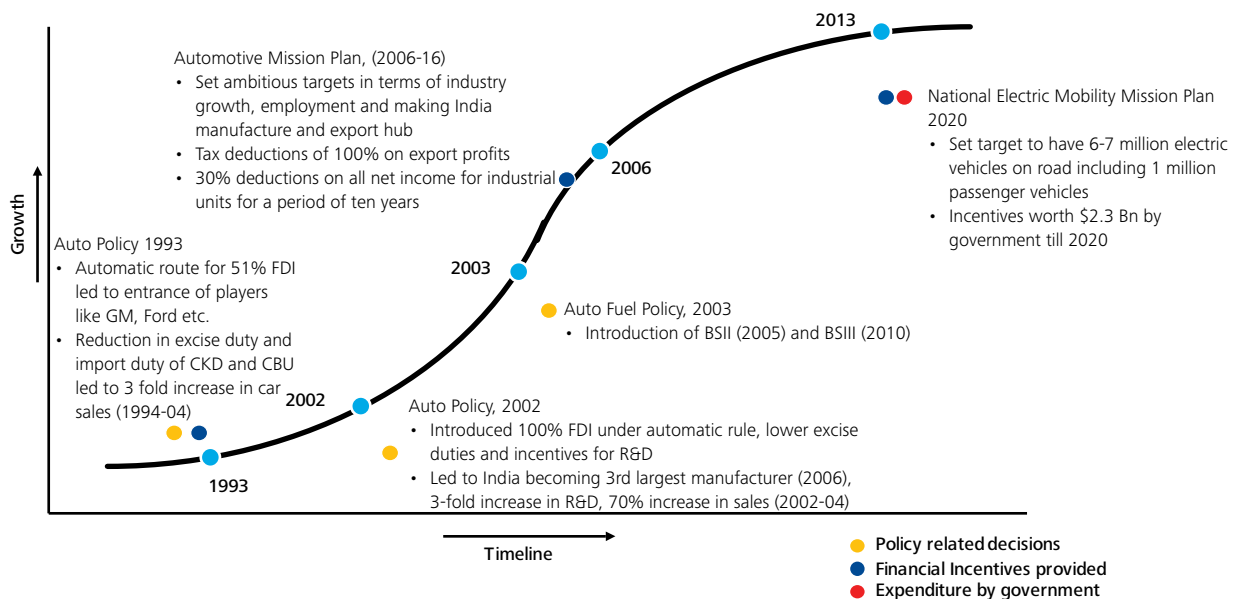


Indian Automotive industry

The Indian Auto industry is now mature with a strong manufacturing model following the strong growth it witnessed after market liberalization in 1991. Key policy initiatives that enabled growth include:

- Auto Policy, 1993: 51% FDI led to entrance of players like GM, Ford etc.
- Auto Policy, 2002: 100% FDI under automatic route, lower excise duty and R&D incentives
- Automotive Mission Plan, 2006: Tax deductions of 100% on export profits
- National Electric Mobility Mission Plan, 2013: Incentives for manufacturing eco-friendly products

Exhibit 21: Journey of Auto Industry in India

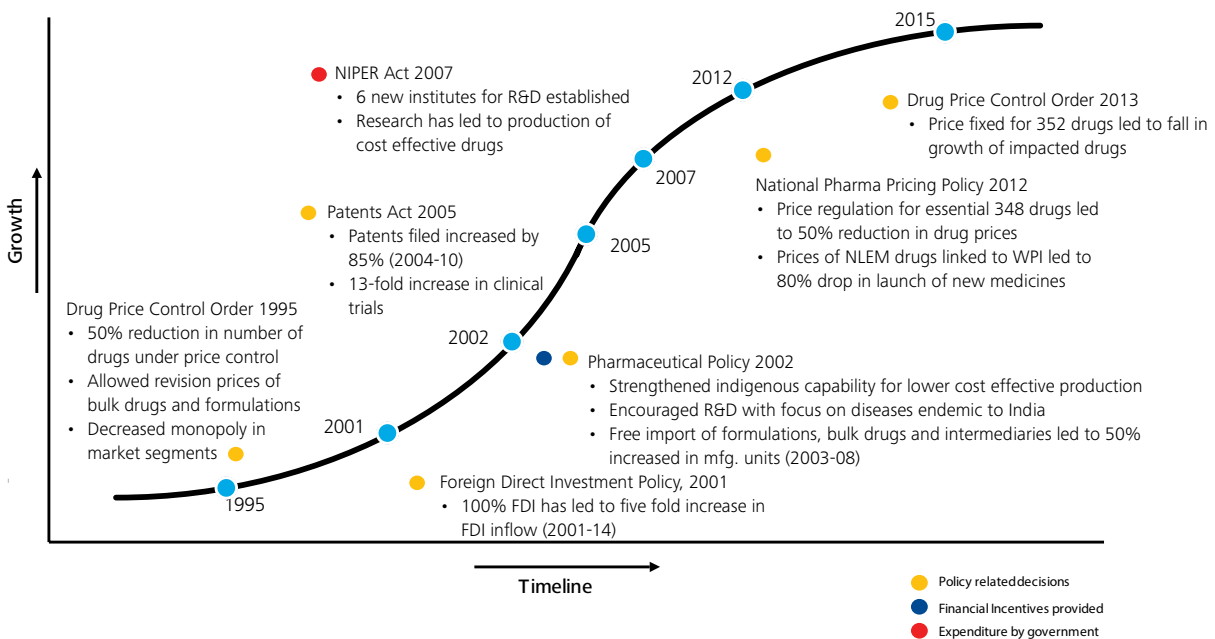


Indian Pharmaceutical industry

India Pharma industry has performed well in the past decade and has reached a mature stage. A few critical steps that led to this growth include:

- Drug Price Control Order, 1995: 50% reduction in number of drugs under price control
- FDI policy, 2001: 100% FDI led to fivefold increase in FDI inflow
- Pharmaceutical Policy, 2002: Import duty incentives for formulation, bulk drugs and intermediaries led to 50% increase in manufacturing units
- Patents Act, 2005: Comprehensive laws led to 85% increase in patent filing
- NIPER Act, 2007: 6 new institutes for R&D were established

Exhibit 22: Journey of the Pharma Industry in India

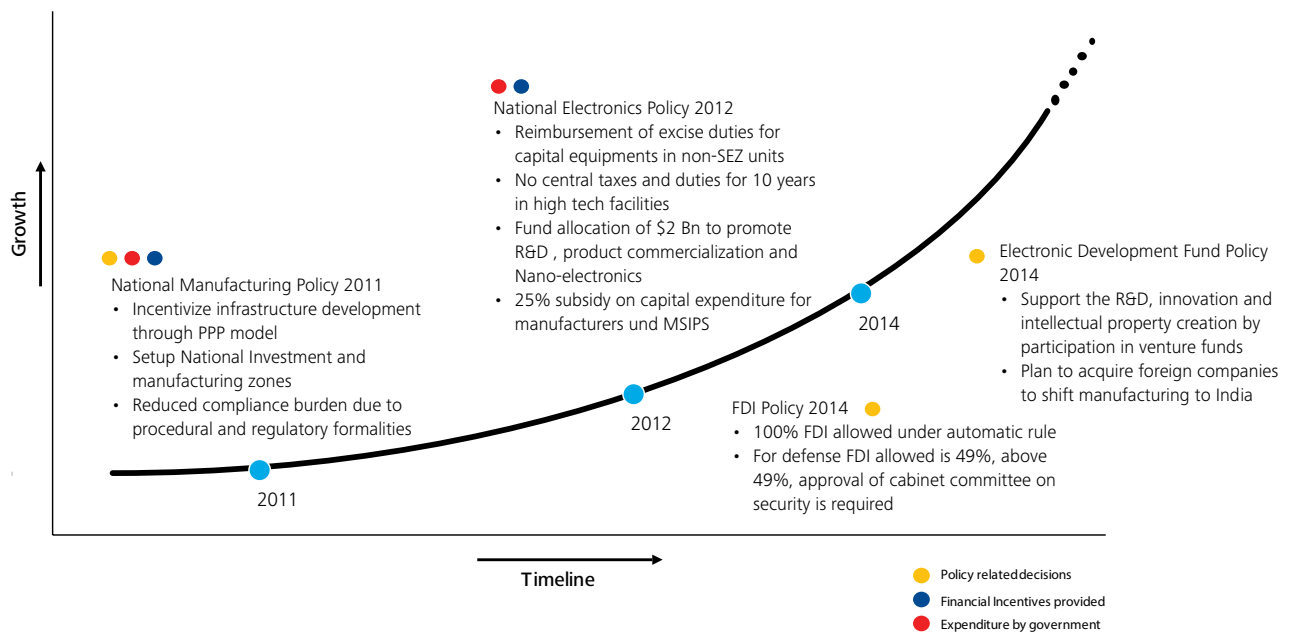


Indian Electronics industry

The electronics industry is still in a nascent stage with the government working on developing a holistic ecosystem for the industry. A few critical steps taken to develop the Electronics industry include:

- National Manufacturing Policy, 2011: Setup of National Investment and manufacturing zones
- National Electronic Policy, 2012: Financial incentives (Reimbursement of excise duties and exemption of central taxes and duties)
- FDI Policy, 2014: 100% FDI allowed under automatic rule
- Electronic Development Fund Policy, 2014: Support to R&D, innovation and IP creation

Exhibit 23: Electronics Industry in India



Possible Impact of 'Make in India' for medical devices

As the 'Make in India' initiative for medical devices gains momentum, import dependence would reduce. This creates the possibility of reducing the import bill, which, if unchecked, can become substantial by 2025. With 70% of the demand for medical devices being met through imports, the import bill will be significant for

both growth trajectories - organic and inorganic growth of the medical devices industry in India.

Apart from reducing the import bill, 'Make in India' has the potential to attract investments, generate revenue for the exchequer, earn foreign exchange earnings through increased exports and generate direct and indirect employment.

Exhibit 24: Potential reduction in the import bill of medical devices

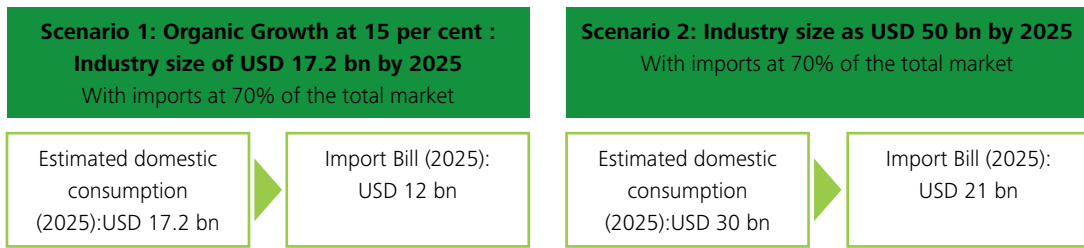
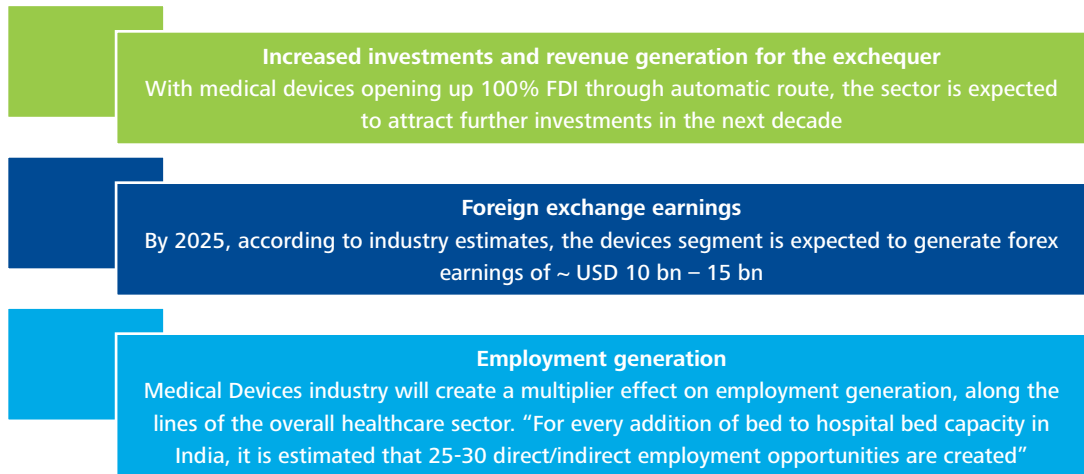
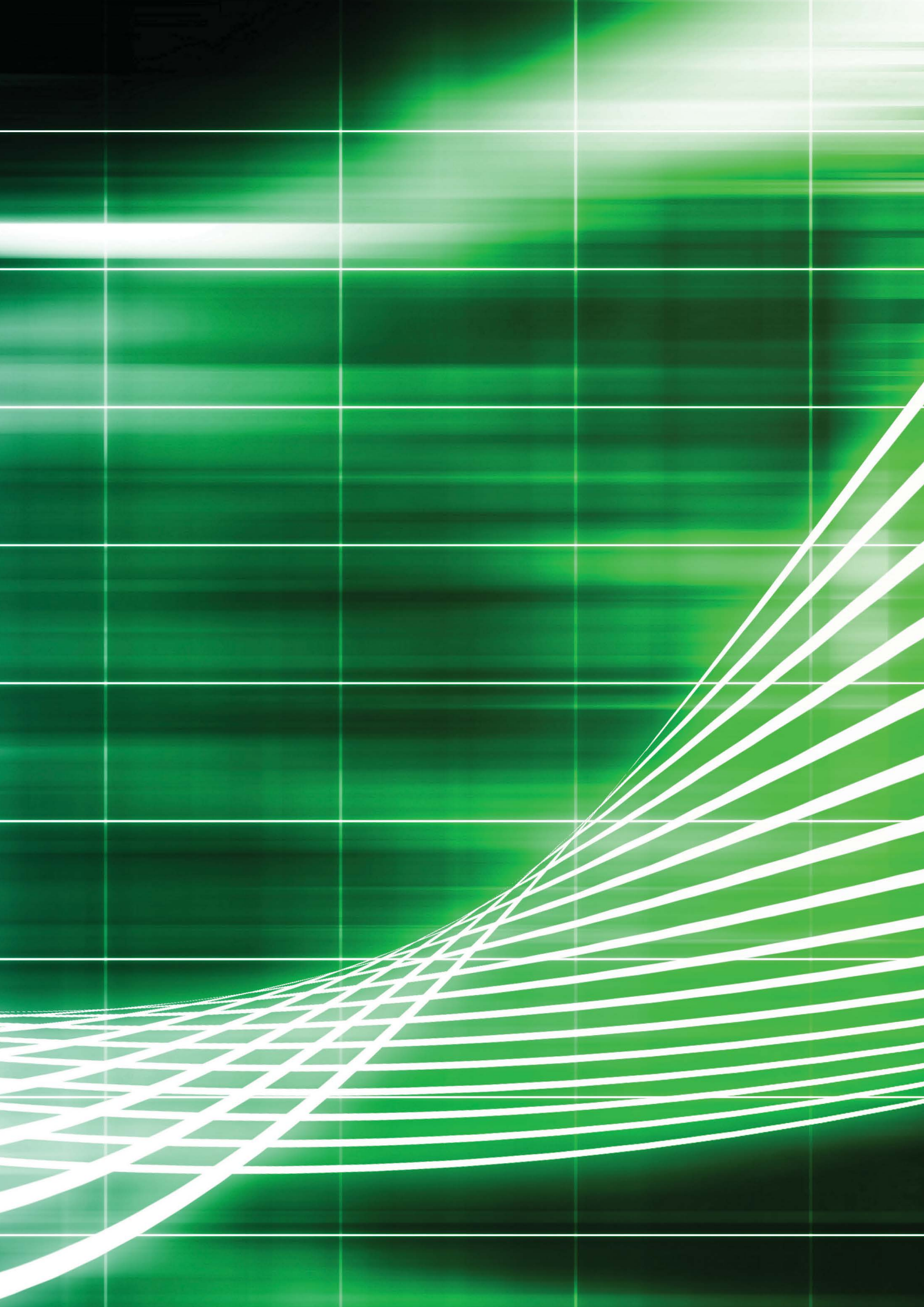


Exhibit 25: 'Potential impact' of Make in India for medical devices





Realizing potential of 'Make in India' for medical devices

For 'Make in India' to realize its vision and objective in the healthcare sector, there is an immediate need for the Government, Industry (Medical devices players, healthcare providers & health insurers) and other stakeholders (academia, research institutes and funding agencies) to step up and, make coordinated and concerted efforts to promote indigenous manufacturing.

The Government of India is the key contributor in developing a conducive policy and regulatory environment and, laying out an implementation framework for the growth of indigenous manufacturing of medical devices. In parallel, industry need to work with the Government to encourage innovation and indigenization among its members, thereby improving access to affordable and quality healthcare.

Role of the government

The government plays multiple roles in the sector that include being a policymaker/regulator for medical devices and the larger healthcare sector development agency/authority for conducive growth of the industry and also a buyer/user of medical devices in its health facilities. Given this, policy interventions are required from the Government for the medical devices industry, the wider medical devices ecosystem from suppliers to customers, and the macro environment to create a conducive business ecosystem.

Government as a policy maker for the medical devices industry

Policy and regulatory measures for the medical devices industry have the potential to create an enabling environment that would set the direction for large scale indigenous manufacturing of various types of medical devices. These actions are pre-requisites to communicate to the medical devices industry and the wider healthcare community on the Government's intent and actions to develop India as an emerging hub for medical technology.

Some of the key policies and strategies that the government could implement include

- Independent regulations for medical devices: While the Government has articulated that the industry is different from pharmaceuticals, the Drugs and Cosmetics (Amendment) Bill 2015 is pending in the Parliament of India. The bill needs to be prioritised to support the industry in having a distinct identity as it

would then enable the industry have specific set of regulations

- Incentivizing medical devices manufacturing: Financial measures need to be undertaken to incentivize manufacturing in this emerging sector and specifically in the early stages of creating the manufacturing ecosystem. Some of these could include:
 - Providing CENVAT/Duty credit on raw material: Parity of duty on raw materials with finished goods should be maintained to enable the industry move from the inverted duty structure. Duty credits on import of raw materials need to be provided
 - Enabling concession duty/VAT parity with imported equipment: In line with the above, concession duty and VAT parity with imported equipment/ devices to be enabled.
- Ensuring quality with FDA or FDA equivalent certifications: Quality certifications that are globally recognised are critical for indigenously manufactured medical devices to compete with products from other countries. This requires domestic manufacturers to align their product quality and processes to global standards. The Government can play a role in enabling medical devices manufacturers with faster access to FDA or FDA equivalent certifications in a cost effective manner. A possible option is to set-up a fast track FDA desk in India, with the Government of India subsidizing certification expenses.
- Segment specific incentives: Product segments ranging from low to medium technology and with a precedence of manufacturing in India can be focused on in the short term. These include disposables, consumables, certain imaging equipment, implants, stents, some categories of laboratory diagnostics equipment, innovative mHealth based solutions etc., which can be incentivized for indigenous manufacturing
- State specific incentives: As with some of the peers like China, states which plan to develop a medical devices manufacturing base can provide specific incentives including cheaper access to land, training subsidies etc

Government as a policy maker and development agency for medical devices value chain

The Government plays a critical role in developing the

ecosystem (suppliers, buyers, distribution etc.) of the medical devices industry. The Government is also a large purchaser of medical devices with its network of medical colleges, secondary care hospitals and primary healthcare through PHCs and sub centres. Various other Government programs also require consumption of medical diagnostics and device

Given this context, there are a number of initiatives that the government needs to consider for implementation. Key initiatives could include:

- Preference for indigenously manufactured devices in Government procurement: To encourage indigenous manufacturing, the Government could provide a price preference or incentives for domestically manufactured products as in the case with the electronic products. Given the size of Government purchase, this would be a significant pull for a number of medical devices companies to manufacture in India
- Standardization in purchase requirements: The specifications for purchase provide certain conditions that are difficult for indigenously manufactured products to meet. These anomalies can be standardized to create a level playing field
- Higher reimbursement for locally manufactured products: As healthcare is increasingly being financed by public and private insurance any preference in reimbursement for indigenously manufactured products would be a key demand-side driver for manufacturing in India
- Expanding skill initiatives to high technology manufacturing: The initiatives taken under skill India can be expanded to high technology segments within medical devices. Human resource availability for both manufacturing and research, development and usage of medical devices should be improved
- Access to cheaper/subsidized funding: Medical

devices manufacturing is capital intensive. Availability of capital at cheaper rates would encourage industry specifically Indian organizations to undertake manufacturing initiatives. The Government can support the process by creating a fund that provides capital at a cheaper rate in the initial years of ecosystem creation

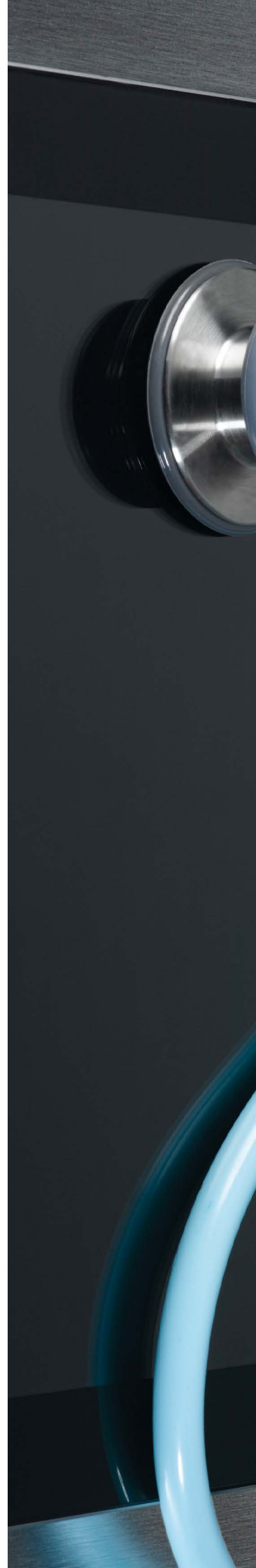
- Promote research, innovation and India specific products: Innovation and manufacturing need to be aligned to generate domestic demand. Products innovated and designed for the Indian market is best manufactured in India. Creating an ecosystem with research institutions, technology parks, incubators etc. along with funding sources would drive innovation and manufacturing in India

Government as a policy maker for macro-economic environment for Make in India Initiative

The Government's role as a policymaker for the macro-economic environment supporting the Make in India initiative would have a significant impact on the initiative for the medical devices industry. While there are dimensions specific to the medical devices/healthcare industry the broader aspects relating to manufacturing in India are industry agnostic and need to be addressed uniformly.

Some of them could include

- Improving ease of doing business: Aspects relating to bureaucracy, license regime, multiple layers of approvals etc. need to be addressed as to encourage both multinational companies and, Indian organizations and entrepreneurs to manufacture in India. Single window clearance for setting up manufacturing plants would be welcome.
- Creating a positive image for brand India: As the Government drives the Make in India initiative across sectors, it needs to focus on creating a positive brand image for Indian manufactured goods.





Specific measures to showcase the quality of Indian manufactured goods need to be undertaken.

Role of the healthcare Industry

Industry needs to align with the Government initiatives to fully realize the potential of Make in India, leveraging the Government's policy and regulatory changes. While most initiatives have to be undertaken by medical devices manufacturers (both MNC and Indian companies), other key stakeholders (healthcare providers and health insurers) have an equally important role in facilitating the initiative. Additionally, the role of industry associations, funding agencies including PE/VC, incubators etc. is critical in supporting the development of the manufacturing ecosystem.

Medical devices companies

- Develop India as a manufacturing hub: India needs to be viewed as a manufacturing hub for domestic demand as well for international markets covering both developing and the developed countries. Both MNCs and Indian organizations need to leverage local production to cater to domestic demand and international markets.
- Undertake frugal innovation or India based innovation in combination with indigenous manufacturing: Collaborating across Make in India and Innovate in India, the development of India based product innovations that can be manufactured locally could create attractive solutions for both India and other emerging markets. The design and manufacture of products closer to the customer would lead to high quality and cost effective innovations
- Review and revisit India market operating model: Both MNCs and Indian companies need to revisit their operating models for India. Product / segment

specific strategies need to be revisited/created, where low to medium technology products that have a precedence of manufacturing in India can be produced in large quantities to cater to underpenetrated domestic markets. Partnerships with Indian companies by MNCs would improve cost efficiencies and reduce time to market. Partnerships with healthcare delivery players would enable innovative on business models. Additionally, MNCs need to view manufacturing in India as a risk diversification strategy, as ~30% of incremental demand for medical devices would come from India

Healthcare delivery companies

- Form partnerships with manufacturers to design and use new innovations: Healthcare delivery companies need to play an integrated role with medical devices players across multiple areas which could include
 - Partner in formulating new innovations: Being closest to the customer, healthcare delivery companies would be a significant part of the ecosystem specifically in driving India innovation and products aligned to India requirements
 - Support the innovation and manufacturing ecosystem: Healthcare providers need to support initiatives on innovation by the medical devices companies by enabling the testing of and awareness for the products. As these innovations are typically cost effective and result in cost savings, the benefits could be shared among the stakeholder community including patients. This would also support the brand building of Made in India medical devices
 - Form partnerships to improve access and reach leveraging complimentary business models: Business model level partnerships utilizing low cost products and solutions would improve access and reach



Health Insurance players

- Cover diagnostics and screening products outside the IPD settings (including home care etc.) – wider coverage to increase demand: Health insurance coverage in India typically does not include OPD settings. Coverage for screening, diagnostics and monitoring products outside the IPD setting would increase demand for medical devices and also promote prevention and early detection. Health insurance players need to explore possibilities of covering such diagnostics and home care devices, including wearable medical devices, integrated mHealth based devices etc.
- With an increase in insurance penetration, create tiered products that encourage quality and local manufacturing. Also, bringing in quality under reimbursement net: As the penetration of insurance grows, insurance companies can bring in quality of medical devices under the reimbursement net. Indigenously manufactured devices can be provided a higher level of reimbursement under both private and Government insurance programs, thus encouraging local production

Others in the ecosystem (Incubators, accelerators, industry associations, funding agencies including PE/VC, etc.)

- Collaborate on India based products and India based innovation: Incubators focused on medical technology and devices should be encouraged to work with industry and academia to foster innovation and entrepreneurship. This would aid in the commercialisation of innovative India based products
- Provide access to patient capital for India based models: Funding agencies including private equity and venture capital firms should promote access to patient capital for inclusive business models to develop India based innovations. These models would cater to underprivileged segments while also encouraging medical devices manufacturing
- Undertake awareness and market building initiatives at the industry level: Industry associations should undertake awareness building initiatives and create platforms to exchange ideas, bring partners together, and facilitate interactions between industry players and regulators



Way forward

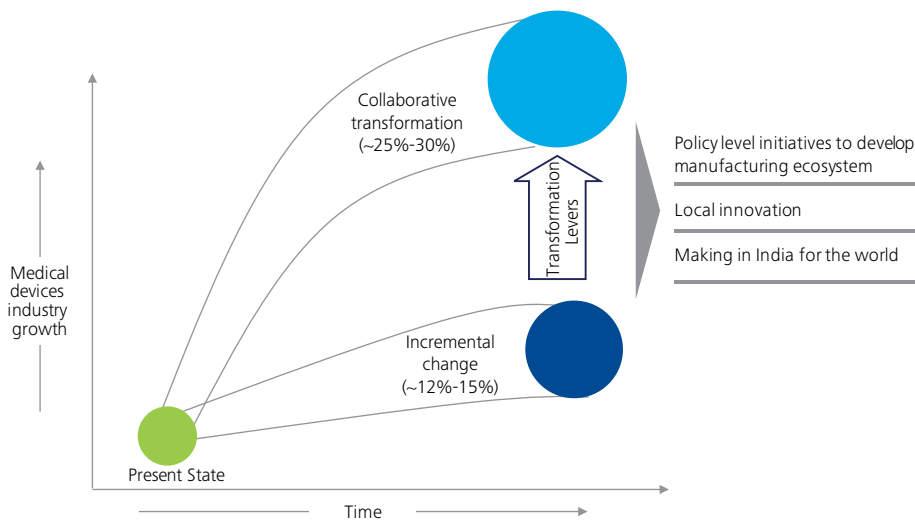
The future depends on pace and extent of changes undertaken

While the Make in India initiative is directionally right, its impact on improving access to affordable quality healthcare depends on how it is framed, developed and implemented over the next few months.

A 'step change' is possible through collaborative

transformation, with key levers being suitable policy initiatives, focus on fostering local innovation and making India a global hub for medical device manufacturing.

Exhibit 26: Present and potential future state(s) of Medical Devices



About NATHEALTH

NATHEALTH has been created with the Vision to “Be the credible and unified voice in improving access and quality of healthcare”. Leading healthcare service providers, medical technology providers (devices & equipments), diagnostic service providers, health insurance companies, health education institutions, healthcare publishers and other stakeholders have come together to build NATHEALTH as a common platform to power the next wave of progress in Indian healthcare. NATHEALTH is an inclusive Institution that has representation of small & medium hospitals and nursing homes. NATHEALTH is committed to work on its Mission to encourage innovation, help bridge the skill and capacity gap, help shape policy & regulations and enable the environment to fund long term growth. NATHEALTH aims to help build a better and healthier future for both rural and urban India.

About Deloitte

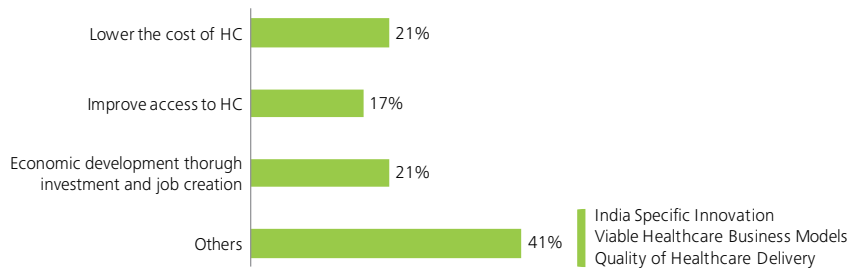
Deloitte drives progress. We advance the aims of our clients and their stakeholders, striving to make them leaders wherever they choose to compete. We focus on making a tangible positive difference by combining strategy with action and delivering measurable impact. We form unique collaborations to find smarter insights, innovative solutions and entrepreneurial ways to move ahead. We invest in outstanding people of diverse talents and backgrounds and empower them to achieve more than they could elsewhere. We believe that when our clients succeed, and when society succeeds, so do we.

Annexure 1: Key Primary Survey Findings

Benefits of Make in India

Respondents believe healthcare affordability (21%), economic development (21%) and improving healthcare access (17%) are three significant benefits of the Make in India initiative

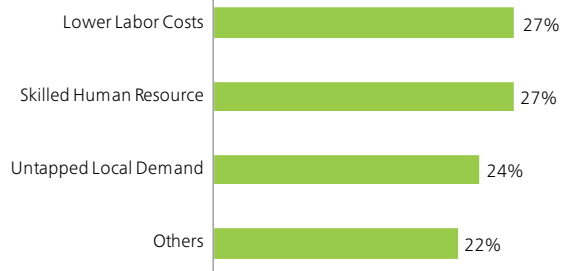
Survey – Benefits of Make in India



India's key competitive advantages

Respondents believe lower cost of labor (27%), skilled human resource (27%) and untapped local demand (24%) are three major competitive advantages of India for the 'Make in India' initiative

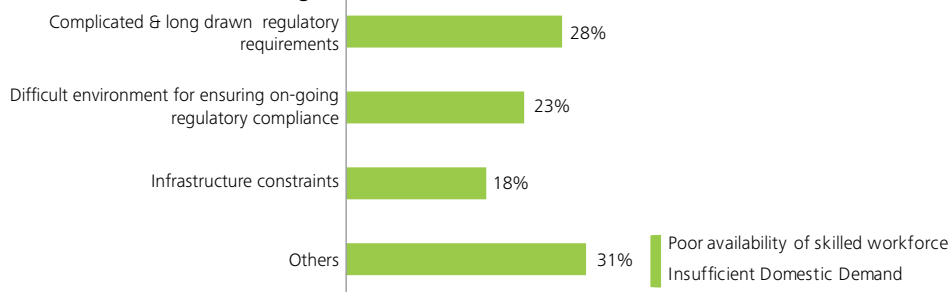
Survey – India's key competitive advantages



Reasons for low level of indigenization

Respondents believe that complicated legal regulatory requirements (28%) and poor compliance implementation (23%) are two keys reasons for low levels of indigenous manufacturing in India

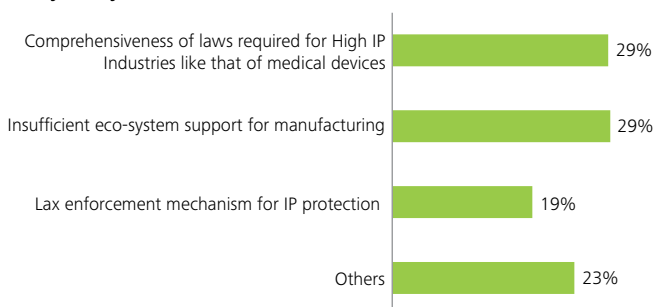
Survey – Reasons for low level of indigenization



Key tactical bottlenecks

Respondents believe comprehensiveness of laws required for IP (29%) and poor ecosystem support (29%) are two key tactical bottlenecks that hinder medical devices manufacturing in India

Survey – Key tactical bottlenecks



Annexure 2: List of participants

Primary interactions and survey

The authors would like to thank the following contributors for providing value inputs to the team during primary interactions:

- Antony Jacob, Chief Executive Officer, Apollo Munich Health Insurance Co. Limited
- Balasubramaniam M, Chief Executive Officer, Cura Healthcare Private Limited
- Dr. Om Manchanda, Chief Executive Officer, Dr. Lal PathLabs Limited
- Dr. Shubnum Singh, Chief Executive, Max Institute of Health Education and Research
- Himanshu Baid, Managing Director, Polymedicure Limited
- Milind Shah, Vice President, South Asia, and MD, Medtronic India Private Limited
- Pavan Choudary, Managing Director, Vygon India Private Limited
- Sameer Garde, Philips India
- Sanjeev Vashishta, CEO, SRL Diagnostics Limited
- Shri C K Mishra, Additional Secretary, Ministry of Health and Family Welfare
- Shri K L Sharma, Joint Secretary, Ministry of Health and Family Welfare
- Sushobhan Dasgupta, Managing Director, Johnson & Johnson Medical India
- Varun Khanna, Managing Director, Becton Dickinson India Private Limited
- Vijay Paliwal, Managing Director, Janak Healthcare – A Midmark Company

The authors would also like to thank the following organization(s) for participating in the primary survey:

1. Apollo Hospitals Enterprise Limited
2. Apollo Munich Health Insurance Co. Ltd.
3. Boston Scientific India Private Limited
4. Fortis Healthcare Ltd.
5. GE Healthcare
6. Johnson & Johnson Medical India
7. Karl Storz Endoscopy India Private Limited
8. Medtronic India Private Limited
9. Max Healthcare
10. N M Medical India
11. Peerless Hospital
12. Siemens India

End Notes

- 1 Statista, Medical devices expenditure per capita
- 2 Deloitte Analysis
- 3 NCBI, Healthcare costs and medical devices
- 4, 5, 16, 17, 18, 20, 22, 23, 24, 25, 26, 27, 28
BMI Espicom, India Medical Devices Report Q3, 2014; Deloitte analysis
- 6 MDDI online
- 7 International Diabetes Foundation, National Health Profile 2010
- 8 IBID
- 9 Indian Study on Epidemiology of Asthma, Respiratory Symptoms and Chronic Bronchitis (INSEARCH), 2012 and Lung India, 2013
- 10 EIU, Global Demographics
- 11 Social health insurance schemes in India, Ministry of Health and Family Welfare
- 12 Global Institute Report
- 13 India Healthcare Report, CII
- 14 Business Standard, April 2014 – Lack of regulation haunts India's test labs
- 15 NABL accreditation data
- 19 CII report on Medical devices industry
- 20 BMI Espicom, India Medical Devices Report Q3, 2014
- 21 Recommendations of the Task Force on the Medical Devices Sector in India, Dept. of Pharmaceuticals, GOI, 2015

Contacts

Deloitte



Charu Sehgal

Leader- Life Sciences and Healthcare
Deloitte Touche Tohmatsu India LLP
csehgal@deloitte.com

P S Easwaran

Partner
Deloitte Touche Tohmatsu India LLP
pseaswaran@deloitte.com

Gajendra Mohan Jha

Manager
Deloitte Touche Tohmatsu India LLP
gjha@deloitte.com

NATHEALTH

Anjan Bose

Secretary General, Healthcare Federation of India
(NATHEALTH)
Anjan.bose@nathealth.co.in

Deloitte refers to one or more of Deloitte Touche Tohmatsu Limited, a UK private company limited by guarantee, and its network of member firms, each of which is a legally separate and independent entity. Please see www.deloitte.com/about for a detailed description of the legal structure of Deloitte Touche Tohmatsu Limited and its member firms.

This material and the information contained herein prepared by Deloitte Touche Tohmatsu India Private Limited (DTTIPL) is intended to provide general information on a particular subject or subjects and is not an exhaustive treatment of such subject(s). None of DTTIPL, Deloitte Touche Tohmatsu Limited, its member firms, or their related entities (collectively, the "Deloitte Network") is, by means of this material, rendering professional advice or services. The information is not intended to be relied upon as the sole basis for any decision which may affect you or your business. Before making any decision or taking any action that might affect your personal finances or business, you should consult a qualified professional adviser.

No entity in the Deloitte Network shall be responsible for any loss whatsoever sustained by any person who relies on this material.

©2016 Deloitte Touche Tohmatsu India Private Limited. Member of Deloitte Touche Tohmatsu Limited