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Medical Technology
Shaping Healthcare For All In India

Contents

Foreword

Challenges in access to quality and affordable healthcare persist in large parts of the country despite several positive developments in the recent past.

The Medical Technology industry plays a crucial role throughout the healthcare lifecycle and has been instrumental in transforming healthcare ecosystems across the world. For India too, the MedTech industry offers the potential to address the healthcare issues by using a mix of nascent as well as advanced technologies.

However, the sector has not been able to realize its full potential on account of multiple challenges being faced by the industry. This untapped potential, if unlocked, could help Indian healthcare ecosystem leapfrog over its constraints and provide the required impetus that India needs in realizing its vision of achieving 'Healthcare for All'.

CII and Deloitte have partnered to undertake a study to map the role of medical technology industry in

India's healthcare journey, identify key constraints in the sector's current landscape and propose methods to realize its true potential.

This report is an outcome of an extensive research and several rounds of deliberations with medical device industry experts. We hope that this report will catalyse further discussion and appropriate action by stakeholders to facilitate growth of the medical devices industry and ultimately move towards a healthier India.

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Setting the Context

Importance of Healthcare for an economy

Economic health of a country is strongly dependant on the health and wellness of its citizens. In order to ensure adequate levels of health and wellness, an effective healthcare ecosystem is a prerequisite.

World Health Organization (WHO) has defined basic building blocks of a healthcare system as "delivery of effective, safe, quality interventions; adequately trained and distributed workforce; a health information system that analyses and disseminates reliable data; safe and efficacious medical technologies that are cost effective and accessible; a financing system that raises adequate funds to ensure coverage to the population from any financial catastrophe; and a good governance system to oversee administration of these building blocks."
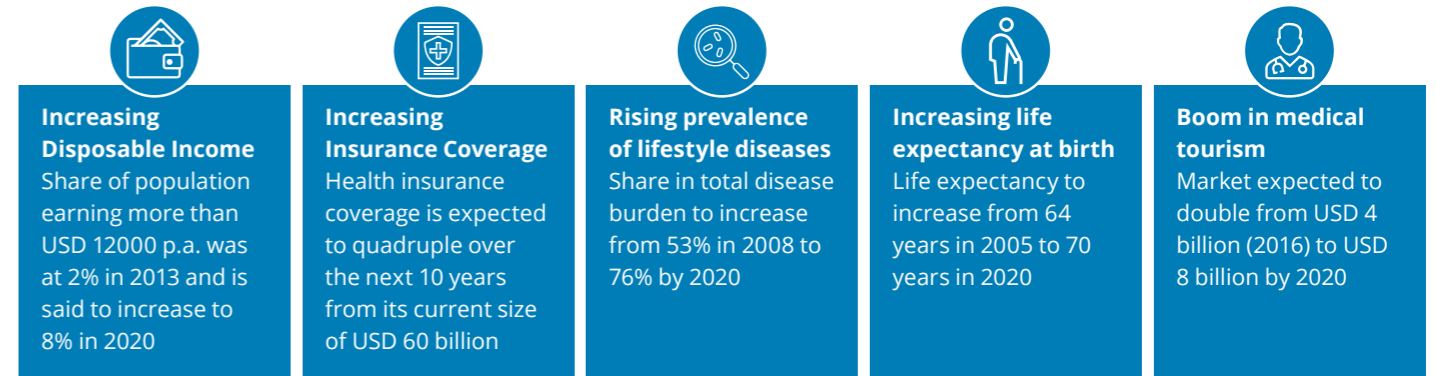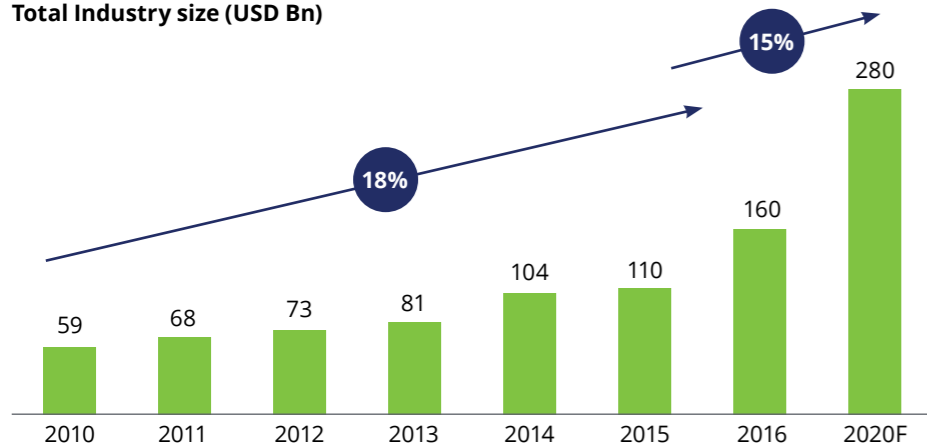
With ~17% of world population and a GDP growth rate of ~7.2%,[1] India is amongst the fastest growing economies of the world. For it to continue on this growth path, access to good quality healthcare services for all its citizens is critical. However, assessments of India's healthcare system— from the point of view of its accessibility and affordability, to its effectiveness and quality —indicate that while we have come a long way, there remains a lot of ground to be covered.

Reality check for Indian healthcare
While the Indian healthcare industry has been growing at a double digit rate and has matured significantly in the last few years, it still faces a number of challenges.

The Indian healthcare sector grew at a rate of 18 per cent from 2010 till 2016 and is expected to advance at a rate of 15 percent during 2016–20 to reach USD 280 billion by 2020[2]. The key factors that have been and will continue to be responsible for growth in the healthcare market include increase in disposable incomes, expansion of health insurance coverage, rising burden of lifestyle diseases due to sedentary lifestyle and increased stress levels, increasing life expectancy, and a boom in medical tourism in India.

Total Industry size (USD Bn)

Increasing Disposable Income	Increasing Insurance Coverage	Rising prevalence of lifestyle diseases	Increasing life expectancy at birth	Boom in medical tourism
Share of population earning more than USD 12000 p.a. was at 2% in 2013 and is said to increase to 8% in 2020	Health insurance coverage is expected to quadruple over the next 10 years from its current size of USD 60 billion	Share in total disease burden to increase from 53% in 2008 to 76% by 2020	Life expectancy to increase from 64 years in 2005 to 70 years in 2020	Market expected to double from USD 4 billion (2016) to USD 8 billion by 2020

Source: India_healthcare_Inspiring_possibilities_and_challenging_journey , 2012 , BMI India Pharmaceutical & Healthcare Report, 2017

However, despite such high growth levels and a growing demand, the healthcare industry in India is still plagued by lack of accessibility, unaffordability, and variable quality of care.

Access to healthcare services
While the metro cities and increasingly other Tier 1 cities have healthcare infrastructure that competes with the best in the world, the tier 2/3 cities and rural areas do not get sufficient care of good quality. With more than 65% of its population residing in rural areas, India cannot boast of a comprehensive healthcare system unless it satiates the healthcare needs of all strata of the society in all geographies. Several measures have been taken by the government of India over the years to strengthen the healthcare infrastructure and human resources for health but India still falls short on several key accessibility measures:

• India has 0.7 beds per 1,000 people, which is well behind the 3.5 beds per 1000 people recommended by the WHO[3]. In comparison the USA has a ratio of 2.9, and China a ratio of 3.8[4]. The healthcare delivery system will need additional 3.6 million beds to reach the recommended capacity.

Number of hospital beds per 1000 people in 2014
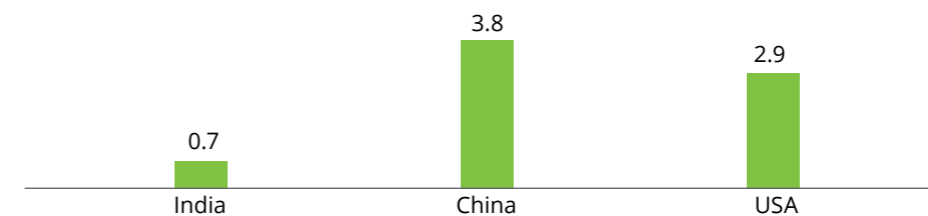
• Lack of skilled service providers is still a constraint in India and the condition deteriorates further in rural areas. The number of physicians in India per 1,000 people is at 0.7 as compared to China at 1.9 and USA at 2.5.[5] India is at half of the global average of 1.5 physicians per 1000 people.[6]

Number of physicians per 1000 people in 2014
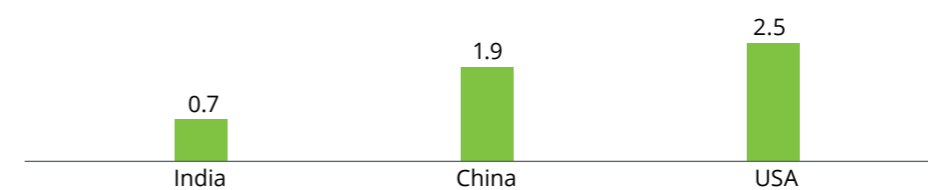
- The share of healthcare expenditure in GDP over the years has been very low and was at 4.8% in 2015[7]. Moreover, the government's expenditure on healthcare in India, at less than one-third of the total, is also quite low when compared to other countries. For example, China and Russia's public share of total healthcare expenditure is more than half.
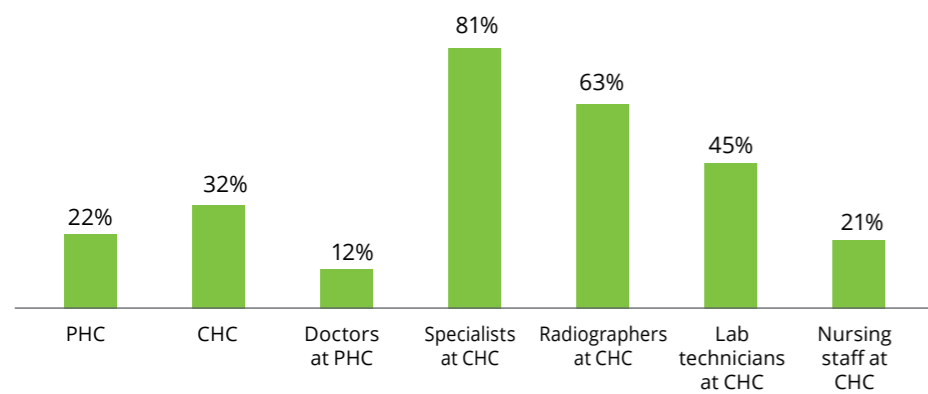
Total Health Spending as a percentage of GDP in 2015

USA	S. Africa	Brazil	Russia	China	India
17.1%	8.9%	8.5%	7.1%	5.1%	4.8%
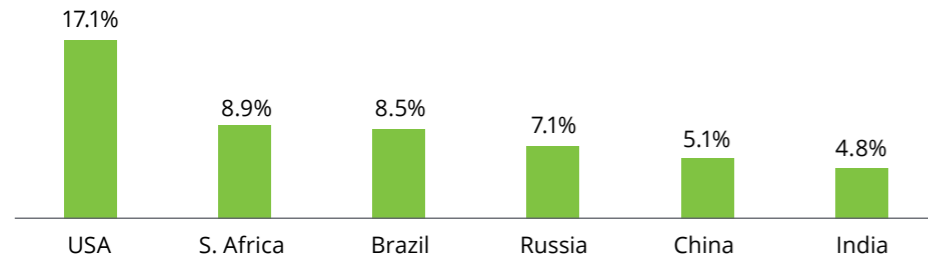
- Due to the health infrastructure being skewed heavily in favour of urban centres, rural areas suffer from an acute shortage of both health centres as well as resources such as specialist doctors. For instance, there is a 22% shortage of primary health centres (PHCs) and 32% shortage of community health centres (CHCs) in rural India.[8] As a result, majority of the beneficiaries in rural India are forced to travel large distances to access quality care.

Percent shortfall of manpower and infrastructure in 2015

| PHC	CHC	Doctors at PHC	Specialists at CHC	Radiographers at CHC	Lab technicians at CHC	Nursing staff at CHC
22%	32%	12%	81%	63%	45%	21%

Affordability of healthcare services

For a country like India, where 1 in every 5 citizens is still below the poverty line, affordability of healthcare services is a major concern. Low insurance coverage and a weak public healthcare system are driving up the average cost of healthcare to families and creating a burden for those with limited resources.

- Despite several financial schemes launched by the government in the past few years the overall health insurance penetration is low. Total number of persons covered under any form of health insurance (public or private) are around 359 million[9] which is ~27% of the total population of India. In comparison, China has more than 95% of its population covered under insurance schemes while USA already had around 91% of population covered under various schemes by the first quarter of 2016.[10]

Out of pocket expenditure as percentage of total health expenditure in 2014

S.Africa	World	Brazil	China	Russia	India
6%	18%	25%	32%	46%	62%
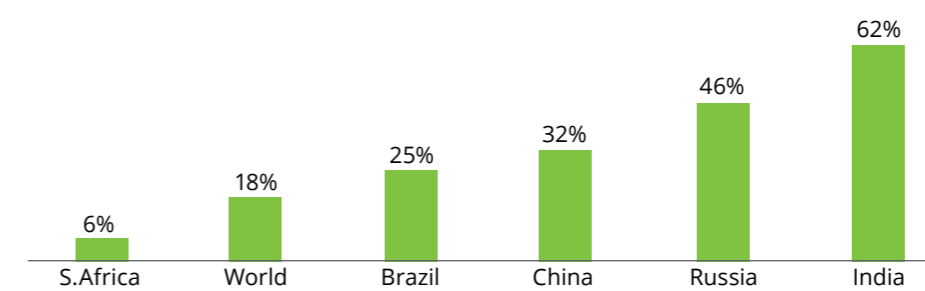
- Out-of-pocket expenditure is 62.4% of the total health care expenditure in the country as compared to the world average of 18.2%.[11]

- Unplanned health expenditure can prove catastrophic by putting significant burden on families. It was estimated that around 60 million people are pushed below the poverty line per year.[12]

Quality of healthcare services

Patient safety and quality of care is a growing concern in the Indian healthcare system. India suffers from higher than average rates of infant mortality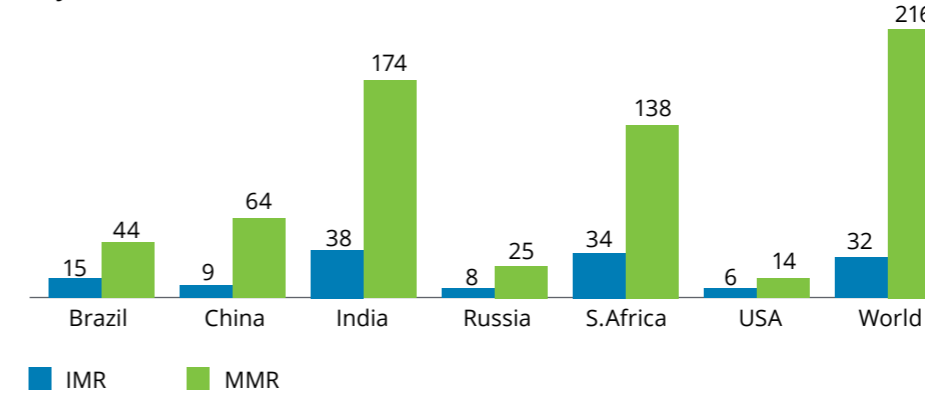, maternal mortality, readmission rates, medication errors, morbidity rates, fatalities due to error, etc. The Infant mortality rate (IMR) of India at 38, is the highest among the BRICS nations, USA and world average[13]. The maternal mortality ratio (MMR) of India at 174 stands just below the world average but is the highest among the other BRICS nations.[14]

With the introduction of National Accreditation Board for Hospitals and Healthcare Providers (NABH) standards in line with the global standards, some large private hospitals have opted to get themselves certified to signal high quality standards. However, accreditation is not mandatory.

Key Health indicators 2015

	Brazil	China	India	Russia	S.Africa	USA	World
IMR	15	9	38	8	34	6	32
MMR	44	64	174	25	138	14	216

■ IMR   ■ MMR

In the public sector, the 'National Quality Assurance Guidelines' prescribe a minimum set of standards that each of the states should meet in order to improve the quality of service delivery in public facilities. However, the adoption of these quality standards in public health facilities has been sluggish and variable across the country.

These challenges are widely acknowledged by the government, healthcare fraternity, providers, payers as well as medical device manufacturers. The government over the years has articulated these issues and has attempted to tackle it through various strategies. The government has also recently released the National Health Policy 2017 where it has emphasized on the vision of **'Healthcare for all in India'.**

### Healthcare for All in India and the National Health Policy

Government defines Universal Healthcare Coverage (UHC) as "ensuring equitable access for all Indian citizens, resident in any part of the country, regardless of income level, social status, gender, caste or religion, to affordable, accountable, appropriate health services of assured quality (promotive, preventive, curative and rehabilitative) as well as

public health services addressing the wider determinants of health delivered to individuals and populations, with the government being the guarantor and enabler, although not necessarily the only provider, of health and related services"[15].
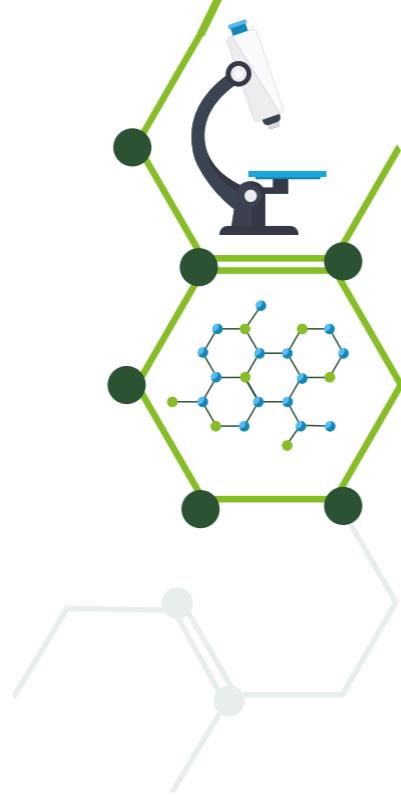
The revised **National Health Policy of 2017,** has refreshed the goals and principles in the context of UHC. The key principles emphasized in the policy include equity, universality, affordability, care quality, leveraging technology / digital health and focus on preventive and promotive health among others.

The vision of 'Healthcare for all' is an ambitious one but also an essential one for India. However, the problems of accessibility, affordability and quality are deep rooted and emanate from factors that are structural in nature. Accordingly, solutions that are linear and incremental will take forever to address these challenges. On the other hand, disruptive technological solutions have the potential to leapfrog over some of these issues and push the country towards a more accessible, affordable and reliable healthcare systems in the foreseeable future.
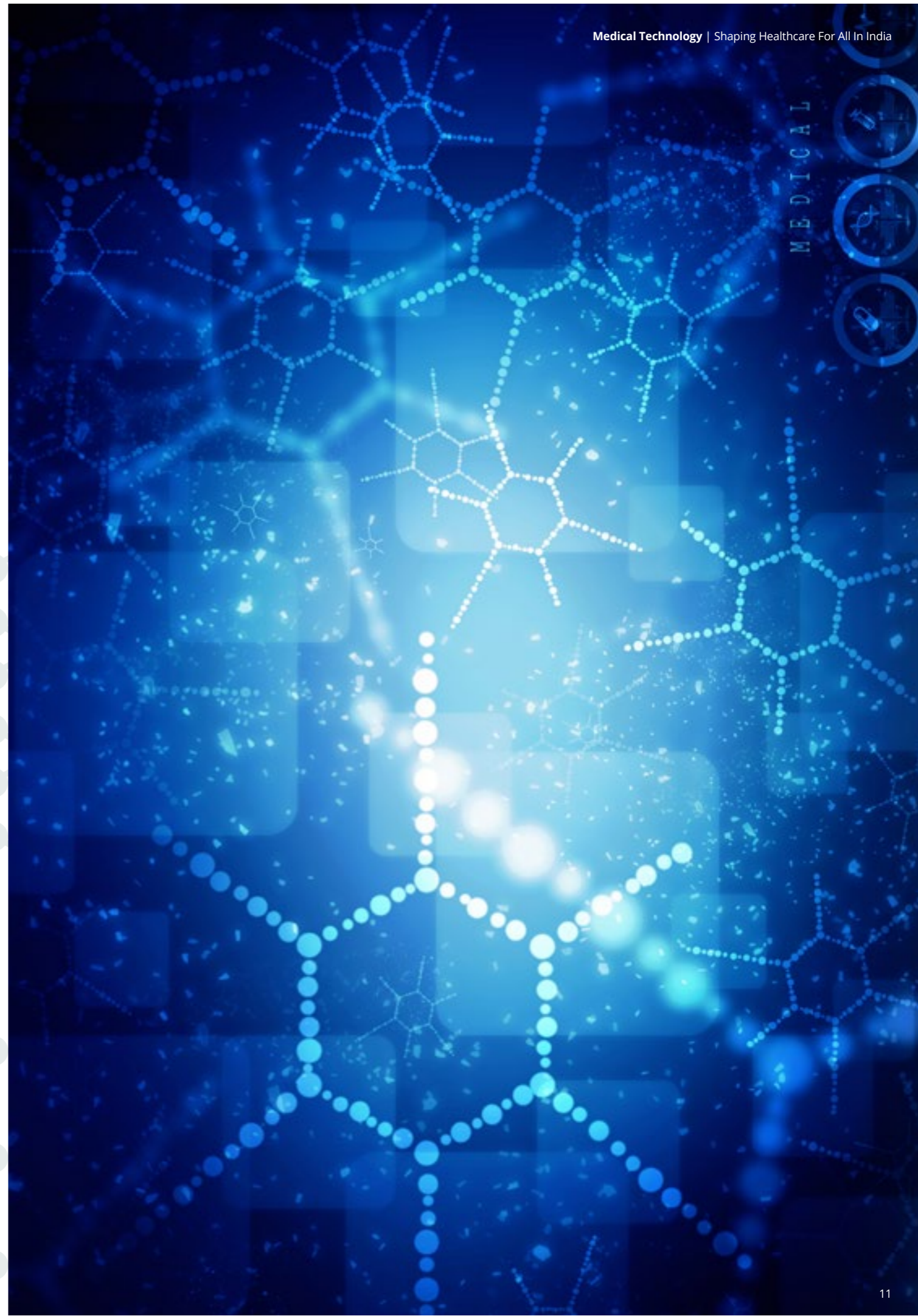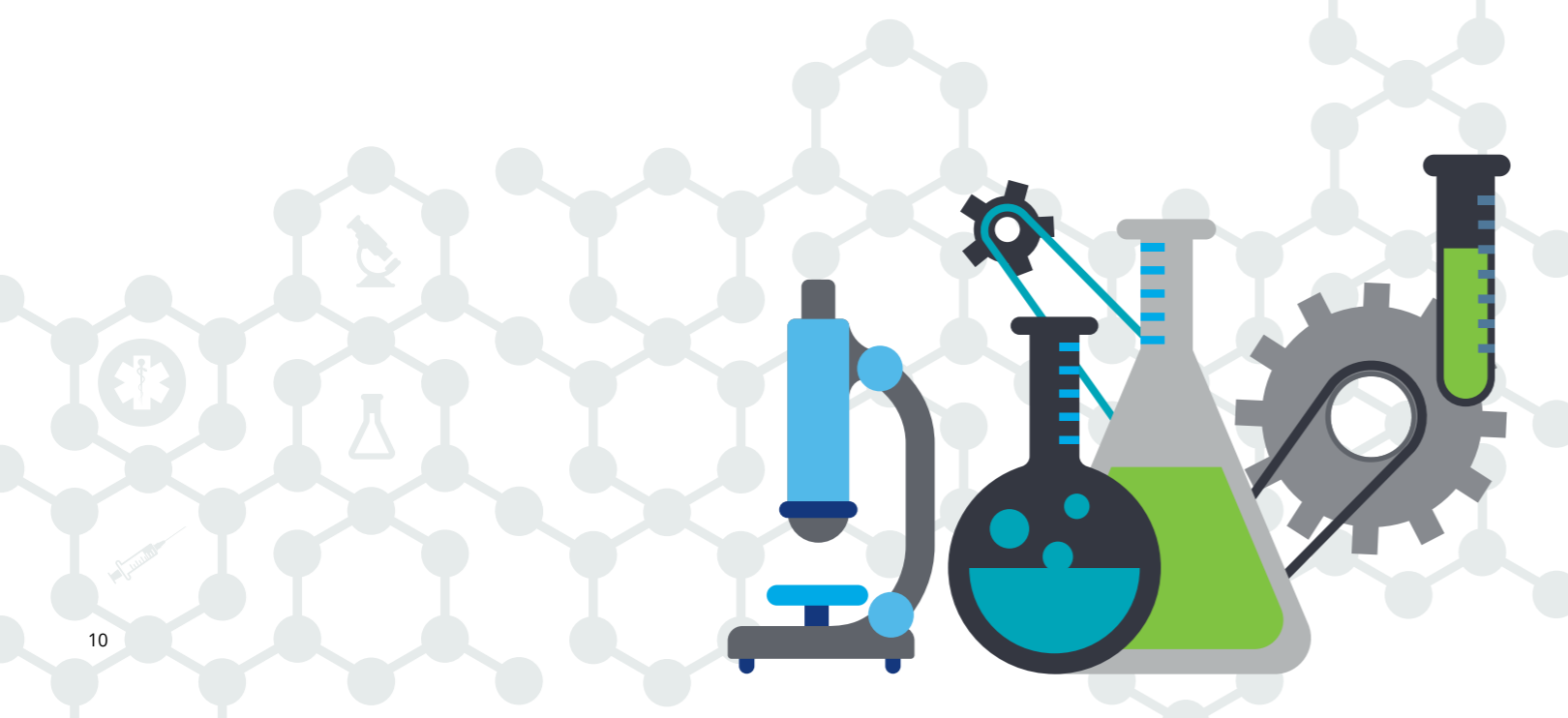
Medical Technology: A Crucial Link in India's Healthcare Ecosystem

MedTech has the potential to address many of the healthcare issues of India
Globally, the healthcare sector is witnessing rapid advancements in how patients are diagnosed and treated and the Medical Technology industry is at the core of this transformation. . The industry is well positioned to revolutionize healthcare in India as well. Using a mix of nascent as well as advanced technologies such as artificial intelligence, remote sensing, 3D printing, E-ICUs, virtual reality, telemedicine and others – MedTech has the potential to help India's healthcare industry overcome many of the challenges faced by it – be it accessibility, affordability or quality.
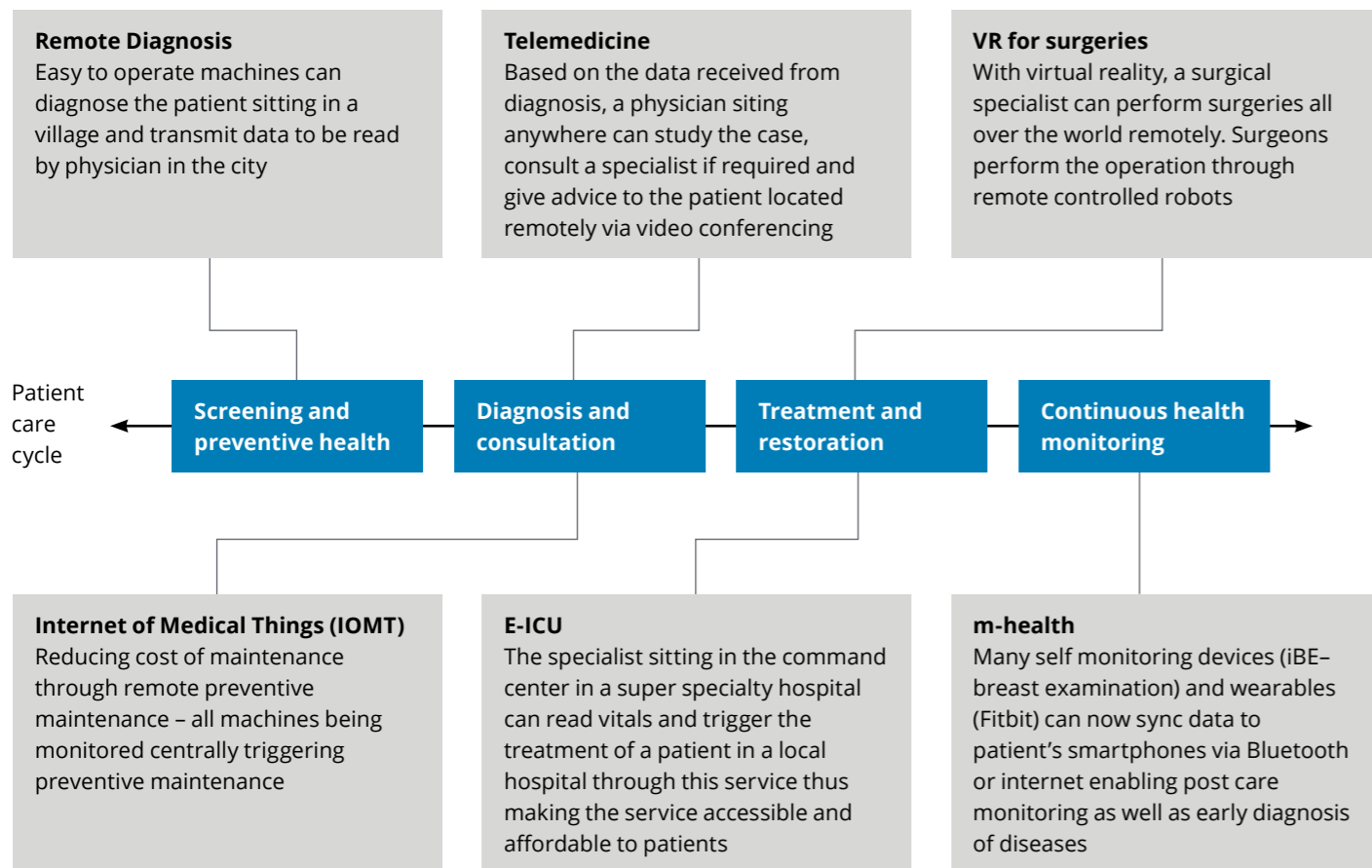
Role of Medical Technology in healthcare

Medical Technology is indispensable to healthcare delivery
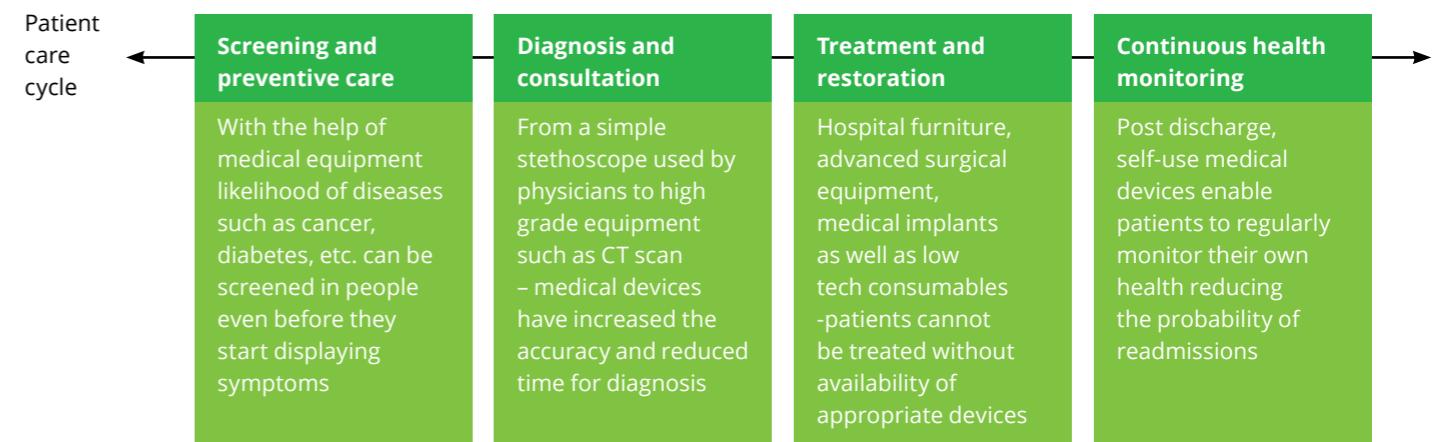Medical technology is an integral part of the entire healthcare lifecycle, from the stage of screening/diagnosing to treatment/care; from restoring patients to normal lives and monitoring their health post treatment. For decades now, with advancement of technology and increasing sophistication of medical devices, the industry has played a major role in bringing down the incidence of disease and improving the overall healthcare system across the globe.

Patient care cycle →

Screening and preventive care	Diagnosis and consultation	Treatment and restoration	Continuous health monitoring
With the help of medical equipment likelihood of diseases such as cancer, diabetes, etc. can be screened in people even before they start displaying symptoms	From a simple stethoscope used by physicians to high grade equipment such as CT scan – medical devices have increased the accuracy and reduced time for diagnosis	Hospital furniture, advanced surgical equipment, medical implants as well as low tech consumables -patients cannot be treated without availability of appropriate devices	Post discharge, self-use medical devices enable patients to regularly monitor their own health reducing the probability of readmissions

Remote Diagnosis
Easy to operate machines can diagnose the patient sitting in a village and transmit data to be read by physician in the city

Telemedicine
Based on the data received from diagnosis, a physician siting anywhere can study the case, consult a specialist if required and give advice to the patient located remotely via video conferencing

VR for surgeries
With virtual reality, a surgical specialist can perform surgeries all over the world remotely. Surgeons perform the operation through remote controlled robots

Patient care cycle ←

Screening and preventive health	Diagnosis and consultation	Treatment and restoration	Continuous health monitoring

Internet of Medical Things (IOMT)
Reducing cost of maintenance through remote preventive maintenance – all machines being monitored centrally triggering preventive maintenance

E-ICU
The specialist sitting in the command center in a super specialty hospital can read vitals and trigger the treatment of a patient in a local hospital through this service thus making the service accessible and affordable to patients

m-health
Many self monitoring devices (iBE– breast examination) and wearables (Fitbit) can now sync data to patient's smartphones via Bluetooth or internet enabling post care monitoring as well as early diagnosis of diseases

Today medical devices can provide enhanced patient care in remote areas by leveraging video conferencing and embedded computing devices which can send and receive data via the internet. By implementing a hub and spoke model, the costly servers and processing units can be placed in a central location while the monitoring can happen remotely and data can be transferred to the central locations for processing.

Complex machinery and devices like MRI and CT scanner are susceptible to breakdown by a simple surge in voltage. Such devices can be remotely monitored to predict failure probability and trigger preventive maintenance action thus saving cost.

Advanced equipment leveraging on technologies such as artificial intelligence and robotics provide higher levels of precision thus increasing the success rate and improving overall quality of care. Technologies such as virtual reality and augmented reality can also be used to simulate real time healthcare environment to provide training to physicians, technicians, and doctors thus eliminating the need for presence of actual equipment for training purposes.

The market for wearables in the form of pedometers, activity detectors, etc. has also increased significantly in the recent past. Such devices when interconnected with other medical equipment, diagnostic equipment, and healthcare analytics platforms can transmit real time data related to a patient's health and vitals which can be used for continuous monitoring of people's health.

Through many such exciting technologies the Med Tech industry is leading the way to address many of the healthcare challenges of India.

MedTech can assist in achieving the priorities set by National Health Policy (NHP)

Based on the priorities and broad principles of equity, affordability, quality etc. set by NHP 2017, medical devices can significantly accelerate India's goal towards universal healthcare . For instance, in the preventive care segment,medical devices have a significant application in screening and early diagnosis of disease. Also, with the use of medical devices in complex procedures, with low success rates earlier, the clinical outcomes have now improved significantly and the overall quality of care has risen. This reduces the lifetime cost of a disease through early detection and reducing readmissions resulting in improved affordability and reduced morbidity.

NHP Principles	How can MedTech help?
Equity and Universality	Medical devices have the ability to reach masses in the absence of physical infrastructure through automation and providing virtual presence thus increasing reach and providing for equity and universality
Affordability	By improving clinical outcomes, early diagnosis of diseases and increased accuracy in treatment - medical devices have resulted in reduction of lifetime cost of disease burden. Through India specific frugal innovation, the price point of medical devices has also come down resulting in reduction of overall cost of care
Patient Centered & Quality Care	Medical Devices can improve quality of care by improving clinical outcomes and convenience of the patients. Many innovative products now are being designed keeping in mind Indian context – infrastructure and skillset
Preventive and promotive health	Medical devices have extensive application in early screening and diagnosis resulting in early detection / prevention and management of diseases. With the help of wearables and mobile technology, people are now more aware and vigilant enabling them to lead a healthier lifestyle

The untapped potential

With majority of demand coming from the metro cities, rural areas which consist of a significant chunk of the population are highly underserved.
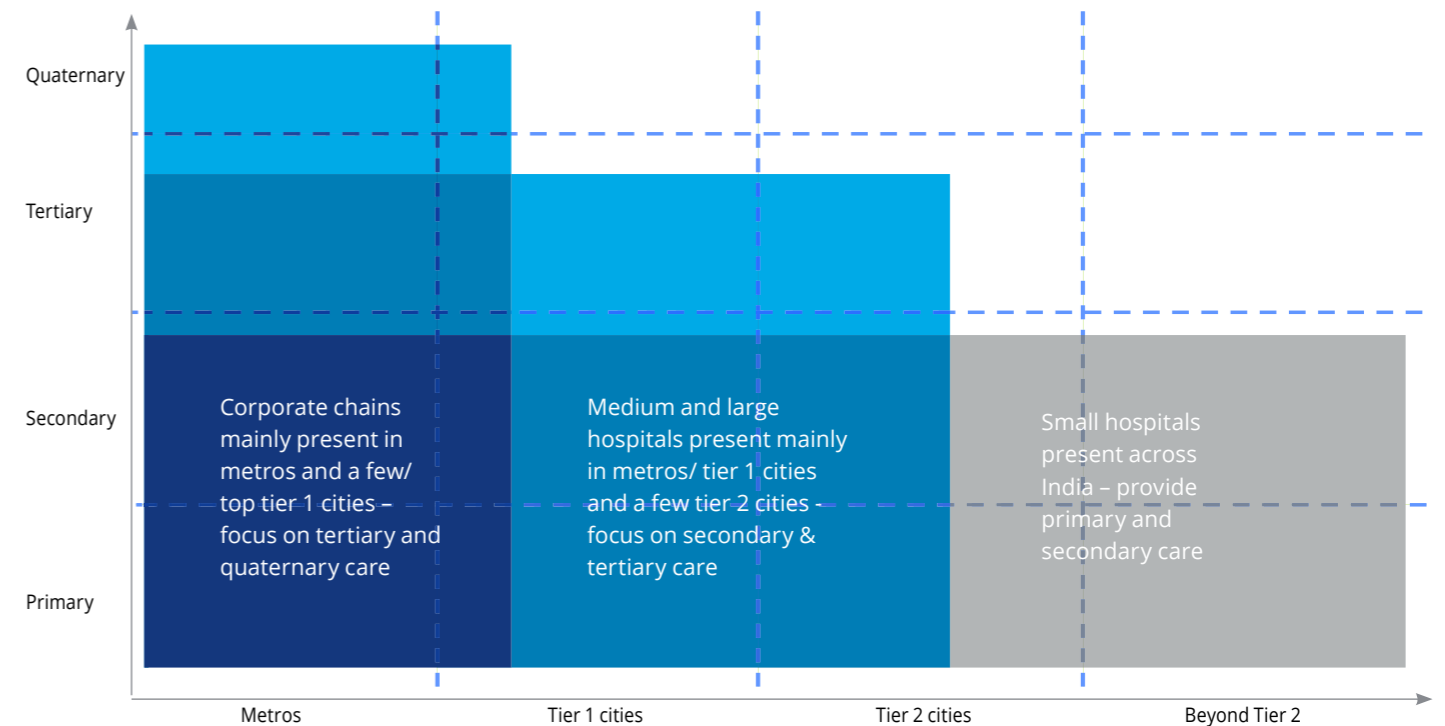The Indian medical device market has grown from USD 2.02 billion in 2009 to USD 4.9 billion in 2016 at a CAGR of 17%[16].

While India consists of one sixth of the world's population, its domestic medical devices market represents only 1.7% of the global market[17]. With a per capita consumption of USD 3, India's medical device industry is underpenetrated in comparison to countries like Brazil, Russia, China and USA.[18]

Per Capita Consumption of medical devices (USD) 2016

Global	USA	China	Russia	Brazil	India
47	340	178	43	28	3
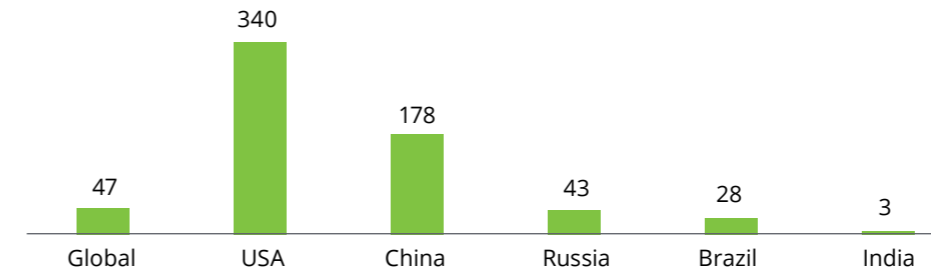
A disproportionate percentage of current demand for medical devices emanates from the metro cities. There is significant untapped demand for medical devices in tier-2/3 and rural areas which presents a huge opportunity for driving growth. However, the key concern remains the huge disparity in the hea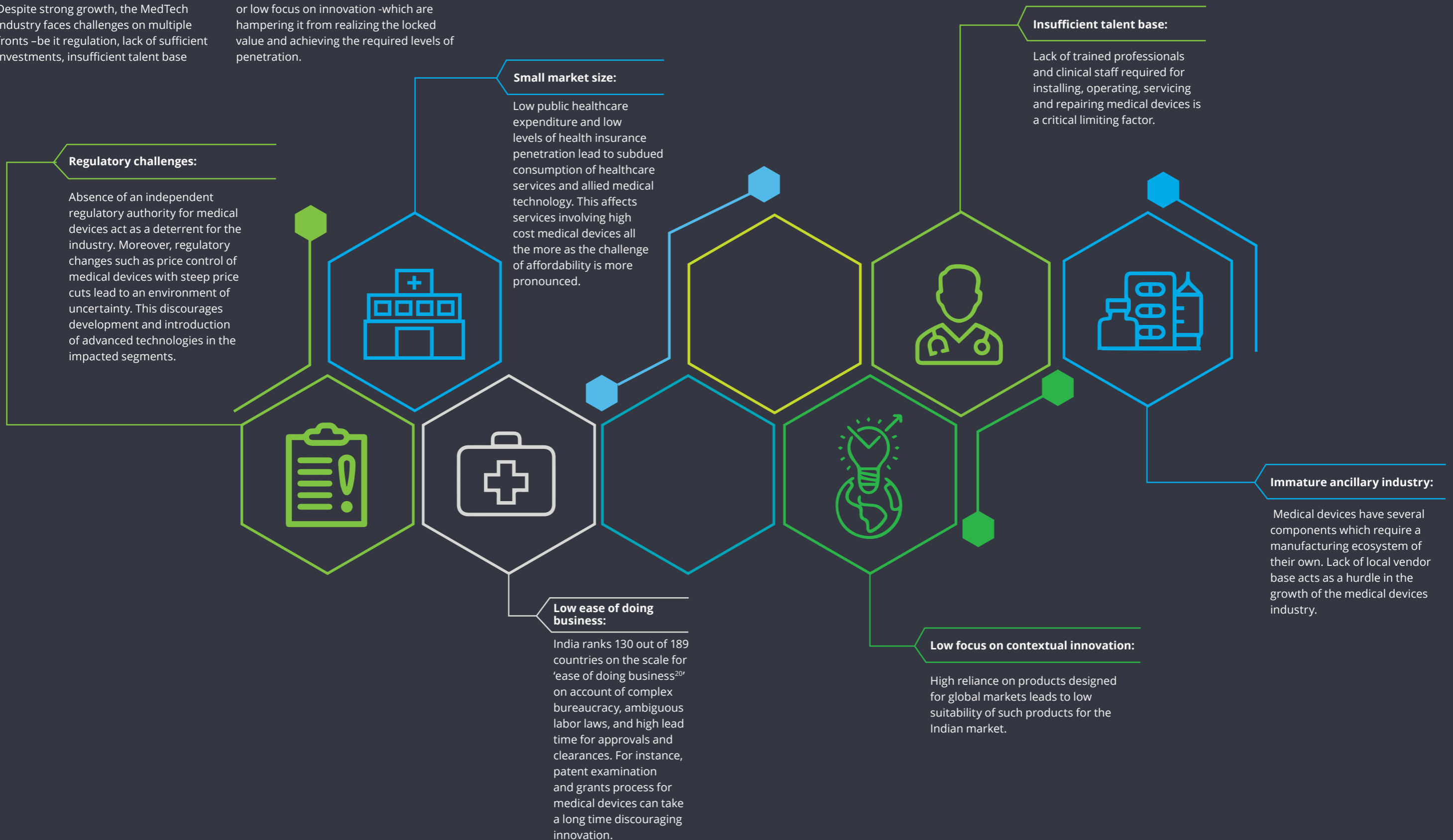lthcare infrastructure in tier 2/3 areas in comparison to the metro and Tier 1 cities. For example, tertiary hospitals, arguably the biggest consumer of advanced medical devices, are concentrated in metro and tier 1 cities. Furthermore, ~70% of the hospital beds and health workforce are in urban areas where only ~30% of the country's total population resides.[19]

Corporate chains mainly present in metros and a few/ top tier 1 cities – focus on tertiary and quaternary care

Medium and large hospitals present mainly in metros/ tier 1 cities and a few tier 2 cities - focus on secondary & tertiary care

Small hospitals present across India – provide primary and secondary care

Key challenges hampering growth of medical devices market in India

Despite strong growth, the MedTech industry faces challenges on multiple fronts –be it regulation, lack of sufficient investments, insufficient talent base or low focus on innovation -which are hampering it from realizing the locked value and achieving the required levels of penetration.
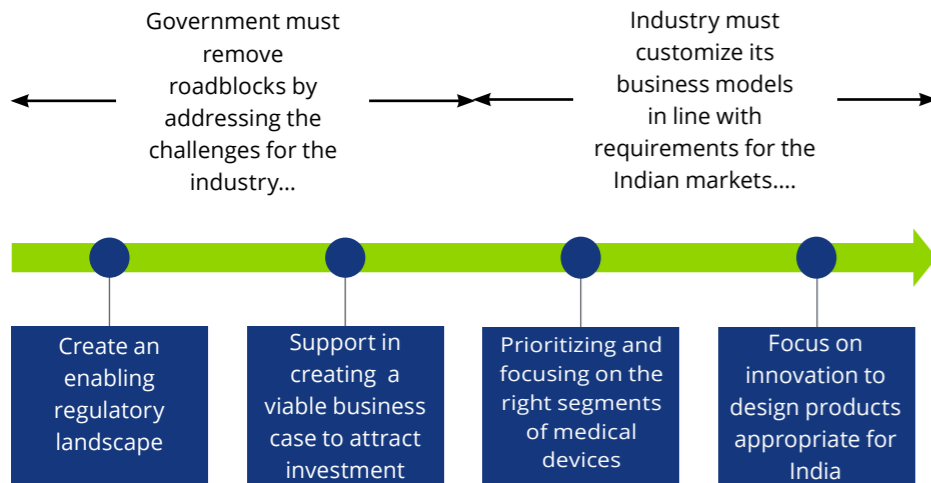
Regulatory challenges:

Absence of an independent regulatory authority for medical devices act as a deterrent for the industry. Moreover, regulatory changes such as price control of medical devices with steep price cuts lead to an environment of uncertainty. This discourages development and introduction of advanced technologies in the impacted segments.

Small market size:

Low public healthcare expenditure and low levels of health insurance penetration lead to subdued consumption of healthcare services and allied medical technology. This affects services involving high cost medical devices all the more as the challenge of affordability is more pronounced.

Insufficient talent base:

Lack of trained professionals and clinical staff required for installing, operating, servicing and repairing medical devices is a critical limiting factor.

Immature ancillary industry:

Medical devices have several components which require a manufacturing ecosystem of their own. Lack of local vendor base acts as a hurdle in the growth of the medical devices industry.

Low ease of doing business:

India ranks 130 out of 189 countries on the scale for 'ease of doing business[20]' on account of complex bureaucracy, ambiguous labor laws, and high lead time for approvals and clearances. For instance, patent examination and grants process for medical devices can take a long time discouraging innovation.

Low focus on contextual innovation:

High reliance on products designed for global markets leads to low suitability of such products for the Indian market.

Medical Technology: Realizing The Potential

The growing healthcare market in India presents a huge opportunity for the MedTech industry. But this potential cannot be realized until both the public and the private sector play their respective roles to overcome the challenges which are inhibiting growth of the industry.

Unlock value for the MedTech industry

Government must remove roadblocks by addressing the challenges for the industry…

Industry must customize its business models in line with requirements for the Indian markets….

| Create an enabling regulatory landscape | Support in creating a viable business case to attract investment | Prioritizing and focusing on the right segments of medical devices | Focus on innovation to design products appropriate for India |

Role of the Government
Government should remove roadblocks by addressing the challenges faced by the MedTech industry from a regulatory and business environment point of view.

A. Create an enabling regulatory landscape
Due to absence of a specific legislation for medical devices in India, in the past, the industry had been largely unregulated. Only 23[21] types of devices are considered "drugs" and are notified under the Drugs and Cosmetics Act including cardiac stents, catheters, intra ocular lenses, heart valves, orthopaedic implant among others. Product approvals, policies, clinical trials, and import licences of these notified medical devices are governed by the Central Drugs Standard Control Organisation (CDSCO) headed by the Drugs Controller General of India

(DGCI). Moreover, various sub-segments of medical devices be it low tech consumables such as bandages or high end equipment such as MRI machines have been viewed with the same lens from a regulatory point of view.

However, the government of India has, over the last few years taken several measures to bring more focus on the MedTech industry. Most notable amongst these is the passing of the 'Medical Devices Rules, 2017' which are set to come into effect from 2018. These rules seek to regulate import, manufacturing, distribution, and sale of a wide variety of medical devices. They have also sub-segmented devices on a risk based categorisation. Moreover, the rules propose a single-window online portal for processing all applications of import, manufacture, sale or distribution, and clinical investigation of medical devices.

While these steps have been appreciated by all stakeholders, the government may also consider the following:

• **Set up an independent medical devices authority and a separate legislation for medical devices:** which can define and set the standards, provide approvals, and establish monitoring mechanisms for medical devices.

• **Faster patent approvals:** The government should enable robust IP protection framework and fast track grant to eligible patents. Grant of patents in some cases can take more than 2 years which hampers the overall innovation process.

B. Support in creating a viable business case to attract investment
The sector has not been able to attract the expected levels of funding despite various initiatives taken by the government.
MedTech industry is capital intensive with a high gestation period for investment. Various facets such as bolstering the local manufacturing landscape, driving innovation through R&D, building the ancillary industry, and producing skilled staff for the industry require huge amounts of capital. Hence it is crucial that the government supports in creates an enabling ecosystem which draws investment from both domestic and international players.
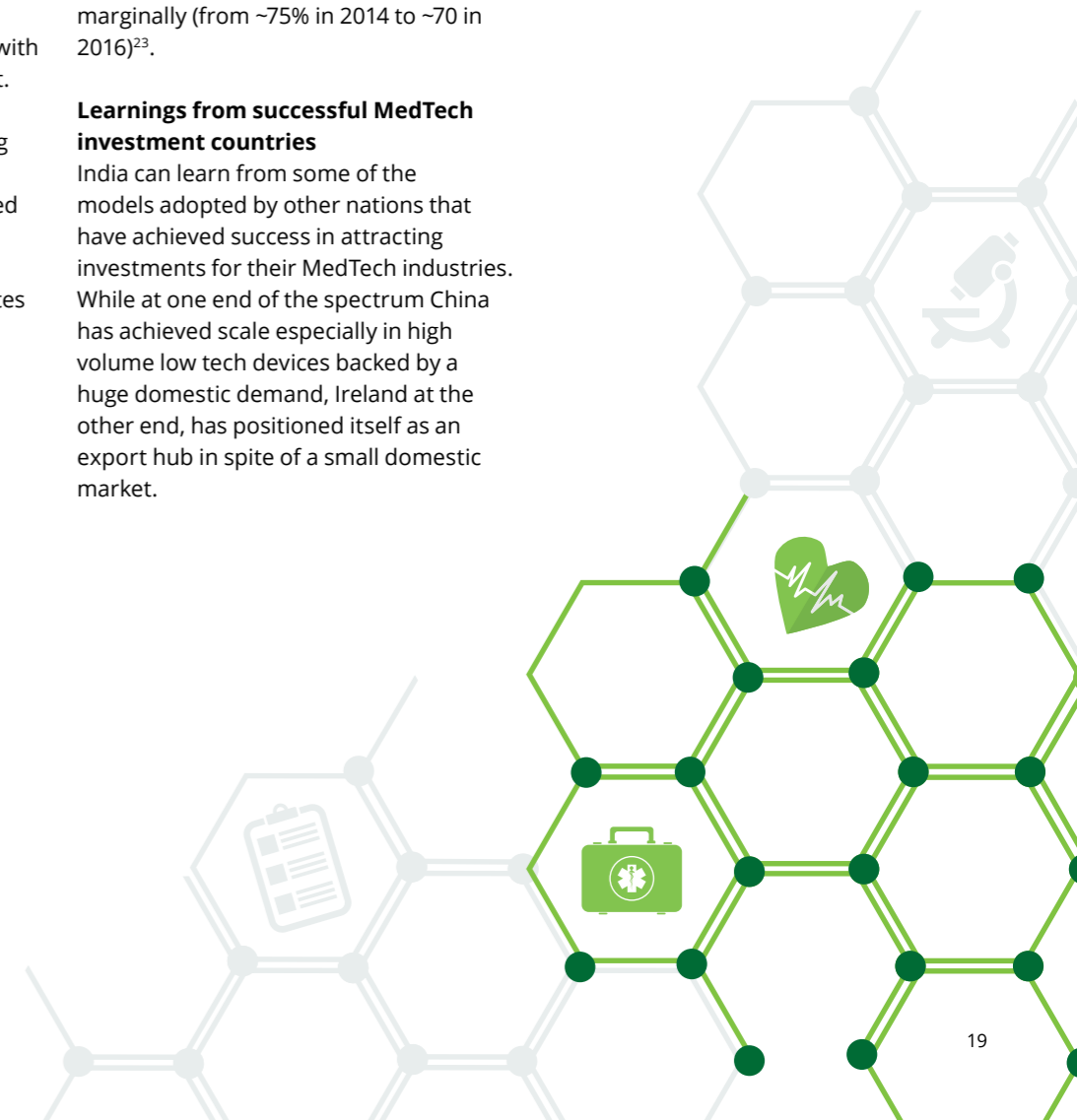
The government in the recent past has taken a number of measures to promote investment:

• Promoting Make in India (MII) for the medical devices industry;

• Allowing 100% FDI under the automatic route for medical devices;

• Correcting the inverted duty structure for select medical devices;

• Setting up of MedTech parks in three states and testing labs in two states.

In spite of these steps, the investment flow in the sector has been modest at best. Total FDI in the sector in the 9 months following the allowance of FDI (from Dec 2014 to Aug 2015) was just USD 85 million that is just 0.5% of the total FDI and about 5.4% of the healthcare FDI in India.[22] Despite the increased emphasis on Make in India campaign, reliance of the sector on imports has reduced only marginally (from ~75% in 2014 to ~70 in 2016)[23].

Learnings from successful MedTech investment countries
India can learn from some of the models adopted by other nations that have achieved success in attracting investments for their MedTech industries. While at one end of the spectrum China has achieved scale especially in high volume low tech devices backed by a huge domestic demand, Ireland at the other end, has positioned itself as an export hub in spite of a small domestic market.

	🇨🇳 **China** **Manufacturing Hub**	🇮🇪 **Ireland** **Export Hub**
Public Health Expenditure spurring domestic demand	56% of total health expenditure	66% of total health expenditure[24]
Healthcare insurance coverage providing affordability	>95% of total population[25]	>98% of total population
Access to large global markets spurring export demand	Japan and US significant export markets for China	• EU market a major export destination for Ireland
Financial incentives acting as catalysts	• Extension of tax benefits by 3 years if investment made in provinces recognized for development of medical devices • Corporate tax rates of 25%[26]	• Lowest corporate tax rates of 12.5%[27] • 25% refundable tax credit on R&D expenditure
	Manufacturing low end high volume products. However, trying to move up the value chain	Growth spurred by a huge export led market (especially in EU) and timely government interventions on the regulatory front

Source: Deloitte analysis, World Bank Data

Some common traits observed in the above models include:

• Significant public share of health expenditure,

• A high percentage of population covered with health insurance,

• Access to mature foreign markets, and

• Relevant financial incentives.

India could also adapt relevant features of successful models from these countries to help improve attractiveness of its business models.

Providing financial incentives is an effective lever which could catalyze investment. The Medical Device industry has been advocating for certain incentives to ensure reasonable returns especially in the initial few years such as:

• Extended tax holidays for domestic manufacturing,

• Weighted tax deductions for R&D investments, and

• Incentivizing exports for medical devices[28].

Supporting local demand for medical devices by expanded provision of services in its **public health and health insurance** programs is another initiative that can catalyze investments in this industry. This will not only help in offsetting India's low per capita usage of medical devices, but will meet latent demand for these services by making them affordable and available to a large number of hitherto untapped population; thereby overcoming some of the challenges of the public healthcare system and realizing the goals of access, equity, and universality as articulated in India's National Health Policy, 2017.

The Government is already exploring avenues to collaborate with the private sector through **Public-Private Partnership (PPP)** models to extend healthcare services to its population which will indirectly give a fillip to the medical devices industry. Enabling these partnerships through flexible governance structures and operating models that work needs to be prioritized.

> **Public-Private partnership models impacting demand for Medical Devices**
> Government under the National Health Mission has announced 'Free Diagnostics Service Initiative' aimed at providing a minimum set of diagnostics to the underserved people in India. The program under the National Health Mission has also recognized an integrated approach for prevalent non-communicable diseases (NCDs) – hypertension, diabetes and cancer - wherein emphasis would be given to screening and testing for select chronic illness "all year round". Such government mass screening programs will go a long way in giving a fillip to the In-Vitro Diagnostic (IVD) industry.

Role of the Industry
Industry should customize its business models in line with requirements for the Indian markets.

A. Prioritizing and focusing on the right segments of medical devices
Domestic manufacturing of medical devices can provide significant benefits to the economy. However, Indian MedTech stakeholders need to prioritize areas and have a segment wise strategy towards manufacturing.

Current structure of Medical Devices in India
The Indian medical devices industry can be classified into four broad segments – consumables and implants, diagnostic imaging, instruments & appliances, and patient aids & others with each segment having distinct characteristics in terms of category of players, usage of technology, target markets etc.
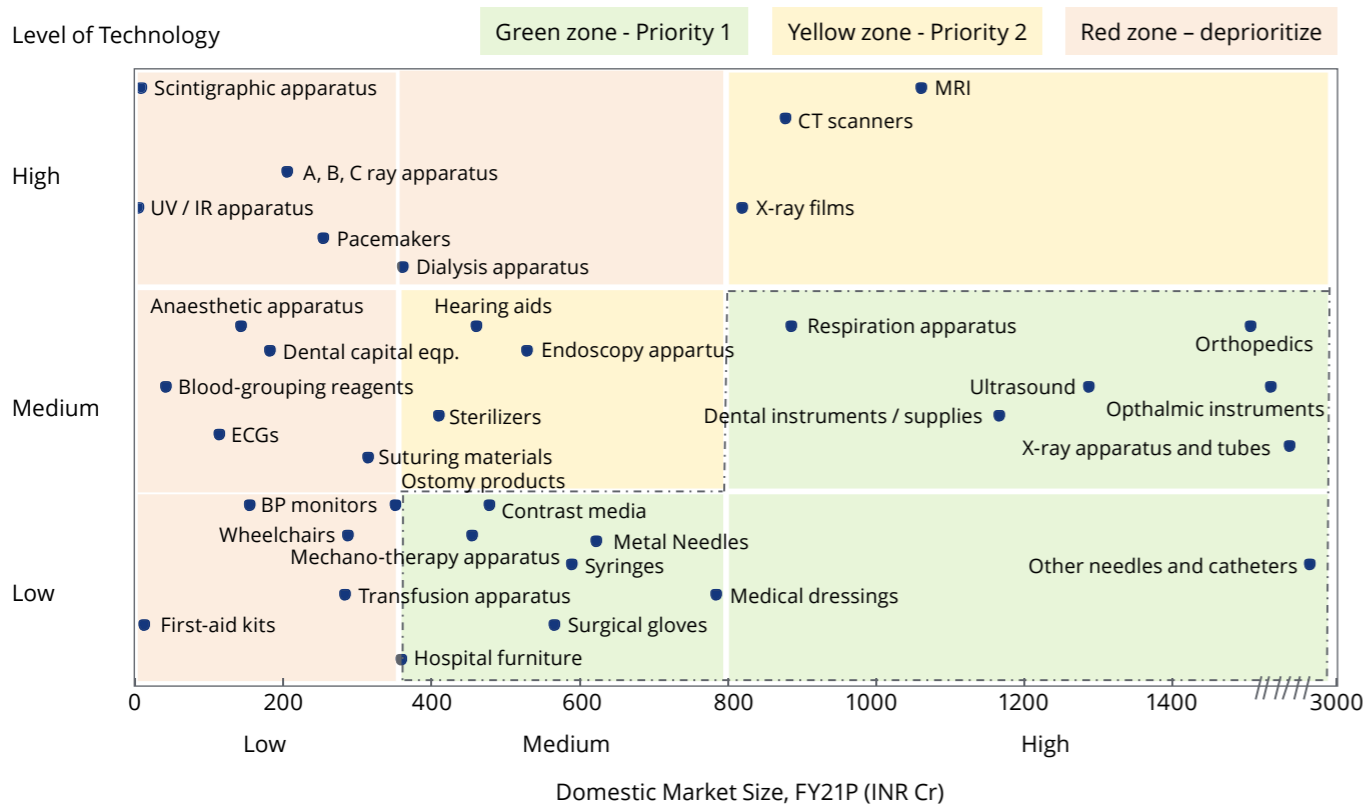
Domestic manufacturing of medical devices in India is currently a small and fragmented industry with presence of both domestic and MNC players. While most domestic players operate largely in the low-tech and high-volume segments, the high end segments are dominated to a large extent by MNCs. Moreover, import dependence is higher majorly in mid to high-tech segment of the medical devices – diagnostic imaging, instruments and appliances, patient aids and others.

	Key Products	Technology	Industry Structure
Consumables and implants	Stents, syringes, needles, catheters, suturing materials, bandages and dressing, implants	Low-medium technology segment	Domestic and MNC players
Patient aids and Other devices	Hearing aids, prosthetics and orthotics, pacemakers & others	Medium-high technology segment	Mix of MNC and domestic players
Diagnostic Imaging	Electro-diagnostic apparatus, radiation apparatus, imaging parts and accessories	Medium-high technology segment	Mainly MNC players with few domestic players with 'local innovation'
Instruments and Appliances	Surgical & non-surgical equipment, other instruments & supplies	Medium technology segment	Mostly MNC players

Prioritization of segments

Various sub-segments of medical devices need to be treated differently as they involve varying levels of sophistication. Moreover, these segments also vary widely in terms of volumes and price points. Accordingly, the industry needs to have different strategic plans vis-à-vis each sub-segment. For instance, most products in higher technology segments usually have a long lead time for development, require large investments, and need a talent base with specialized skillset. On the other hand, low tech segments such as bandages, dressing etc. can be set up and scaled up rapidly with moderate capital.

Medical device manufacturing: play in the right areas

Level of Technology

| Green zone - Priority 1 | Yellow zone - Priority 2 | Red zone – deprioritize |

Domestic Market Size, FY21P (INR Cr)

Green zone - Priority 1	Products with low to medium sophisticated technology could be quick wins and immediate focus areas. Focusing on them could impact the import bill significantly	Total Imports (2016) = INR 8300 Cr – i.e. **46% of total imports for MedTech in India**
Yellow zone - Priority 2	Products with low to medium sophisticated technology could be quick wins and immediate focus areas. Focusing on them could impact the import bill significantly	Total Imports (2016) = INR 2600 Cr – i.e. **15% of total imports for MedTech in India**

Source: Deloitte analysis, BMI research

One of the ways India can select potential areas to focus on is to prioritize manufacturing of low and mid-tech products which have a significant scale (medium to high) such as Needles, Catheters, X-ray apparatus, Dental instruments, X-ray apparatus, Ophthalmic instruments, etc.

On the other hand, high-tech low volume devices such as CT scan and MRI machines would require a longer term outlook. Efforts should be made towards developing required capabilities and the necessary ecosystem for their manufacturing in the medium to long term horizon.

B. Focus on innovation to design products appropriate for India

India is a vast country with an uneven distribution of wealth and resources. Many parts of the country still lack basic amenities such as uninterrupted power supply, proper roads for transportation, and robust communication systems. Moreover, availability of skilled manpower remains a challenge in smaller towns and rural areas.

Across industries, companies that have accepted these realities and modified their products and services to suit these conditions have been successful. The medical device industry however has a high import dependence wherein products that reach the market may not necessarily be designed for Indian market conditions.

In recent years, both MNCs and domestic players have started driving innovation in complex areas such as patient monitoring, point of care screening, and diagnostics and have adapted their products to better suit the market needs. The focus has been on:

- Using frugal innovation techniques to create devices that are more affordable whilst meeting threshold quality requirements

- Designing products sans 'bells and whistles' resulting in cost reduction while retaining the core functionality

- Making devices that are easy to operate and hence can be deployed in areas with inadequate supply of skilled technicians

- Creating compact and energy efficient devices which can be deployed even in small centres in remote areas

Medical device players creating customized products for Indian market

Company	Case in point	Product description
GE Healthcare	Compact CT Scanners which consume less power	GE Healthcare developed a CT scan system that uses 40% less power, produces less radiation and is 40% cheaper than imported equivalents. It has a substantially smaller size (can fit in smaller clinics and hospitals) and a higher throughput (scan time is 28% faster).
Skanray Technologies	Affordable X-ray imaging systems	Skanray created a high frequency digital x-ray machine that can cater to the needs of both large hospitals as well as small clinics. The cost of the device is a fraction of that of the imported machines. This wireless device is extremely light-weight and can be easily manoeuvred in congested hospital settings.
Philips Healthcare	Accessible and affordable cardiac care in tier II & tier III cities	Phillips Intuis, an advanced entry-level catheterization lab, is helping provide affordable cardiac care in smaller cities and towns in India. It has a live image guidance technology which can help vascular specialists to decide, guide and confirm the right therapy for their patients in real time.
Cura Healthcare	Affordable digital radiology systems for all resource settings	Cura manufactures direct digital radiology systems that can be floor-mounted, ceiling-suspended, or retrofitted and are suitable for both small hospitals and large healthcare institutions. Moreover, it is powered by just 15 amp and can take up to 50 images without power.

Company	Case in point	Product description
Poly Medicure	Innovative 'single use' medical devices	Poly Medicure produces over 125 different types of medical devices at 5 manufacturing plants in India. It is the largest exporter of single use medical devices in India. In addition to manufacturing, it also invests heavily in designing in India and holds more than 140 patents in various countries and has around 350 pending patent applications.
Meril Life	Affordable cardiovascular devices	Meril has developed new concepts in engineering employing novel designs, drug delivery technologies (for stents & balloons) and affordable catheter-based systems that effectively bridge the gap between countries with ailing populations and struggling health care needs.
Transasia Biomedicals	In-Vitro Diagnostic (IVD) for India	Transasia Biomedicals Ltd is India's biggest IVD company. Since 1991, it had adopted the 'Make-in-India' concept with indigenous manufacturing of sophisticated, state of the art blood analyzers and reagents.
Sahajanand Medical Technologies (SMT)	Affordable coronary stents	SMT, India's biggest stent manufacturer, has been successful in manufacturing affordable stents of world class quality. It has successfully introduced biodegradable polymer to the coronary stent industry, a highly sought after technology in India as well as globally.

Many global medical device players have also set up large R&D facilities in India which are driving innovation

Company	R&D facility
Boston Scientific	Boston Scientific has set up a 100,000 square feet R&D, training and commercial centre in India to develop products suitable for Indian and Asian markets and to train physicians to use them effectively. The focus of the facility is to create market appropriate products for unmet clinical needs.
Medtronic	Medtronic has set up a captive engineering research and development centre in Hyderabad providing support to global business units for improving procedural outcomes and developing future products. This 90,000 sq. ft. lab has 230 highly qualified engineers and is equipped with state-of-the-art technology.
Covidien	Covidien has set up a 40,000 sq. ft. R&D centre in Hyderabad, India with an aim to tailor products to local market needs, increase speed-to-market and develop breakthrough platforms.
Stryker	Stryker has set up a global R&D centre in Gurgaon for developing next generation technologies and high-end medical devices. The centre also operates as a global talent hub, where Indian surgeons and engineers are trained on latest technologies.

Moreover, many start-ups have come up in the medical technology space which are creating market suitable offerings and disrupting the industry landscape.

Start-ups in MedTech playing an important role in addressing India's healthcare challenges

Company	Product	Product description
Sattva	Fetal Heartrate Monitor	Fetal Lite is a portable, lightweight device that can take an electrocardiogram of a foetus during labour. It can work in low-resource settings and can be operated by a layperson as it gives easy to understand alarms in case of foetal distress.
Coeo Labs	Ventilators	Coeo Labs has designed a device to tackle ventilator-associated pneumonia in premature babies and patients on ventilators, a major cause of death in roughly 40 per cent of patients on breathing support in India. Currently in the prototype stage, this device is set to be launched at a price point 30% cheaper than competing devices.
Wrig Nanosystems	Hemometer	Developed a mobile phone-sized device called TrueHb Hemometer to measure hemoglobin in a few minutes.
Forus Health	Neonatal retinal scanner	3nethra neo screens prematurely born babies who could potentially have a condition wherein abnormal blood vessels grow in the retina. This condition can result in permanent blindness of the child, if not detected and treated early.
Remidio	Retinal Imaging system	Fundus connects to a mobile phone camera to take pictures of the central part of the retina to diagnose diabetic neuropathy. This device is battery operated and can be installed even in remote centers. The images can be transferred in real time to a physician's phone for consultation.
Cardiotrack	Cardiotrack sensors – Remote health diagnostic	A portable and digitized diagnostic solution which enables instantaneous cardiac monitoring and flow of information through Android-based smart devices between a physician and a cardiologist. This technology which costs less than half of an ECG machines solves the problem of accessibility as well as affordability.
Axio	Haemostatic emergency dressing	Traumatic bleeding is one of the biggest cause of death is road accidents in India. Axio's haemostat works on adhesion rather than absorption technology and can be applied easily on external wounds to stop profuse bleeding. This product is robust, affordable and can be easily administered by a layman.
Tricog Health Services	Cloud based ECG machine for faster diagnosis	Tricog Health services has designed a cloud-based ECG machine which enables the doctor to takes a patient's ECG, send the information to a centrally located hub where the results can be interpreted by a qualified expert. The reports are then transmitted back through mobile phone. This increases the speed of the diagnosis and increases access.

Indian entrepreneurs have realized that developing products and solutions that bridge the gaps in the Indian healthcare system can lead to long term financially viable businesses. However, researchers and entrepreneurs require an ecosystem which can support them through the early stages of discovery and development in order to successfully launch the products and go-to-market.

The administration in the recent past has been instrumental in extending support for innovation in this space. In June 2017, the union cabinet has announced a USD 250 million initiative under the National Biopharma Mission to fund biotech start-ups in the area of medical devices, bio-therapeutics, etc. and create bio-clusters to help build next generation of healthcare technologies. The government could further consider setting up **R&D incubation centres** in collaboration with premier institutions to encourage innovation in the area.

Providing momentum to this wave of innovation bodes well not only for the growth of the Indian MedTech industry but also for progressing the overall healthcare landscape of the country.

Medical Technology Shaping Healthcare for All: Summary

For long, India has struggled to provide quality affordable healthcare to all its citizens. While the challenges in achieving this are well known, adopting the conventional route for creating adequate physical infrastructure, building a medical and paramedical resource base and achieving high quality standards would require huge investments and timelines that a developing country like India can ill afford.

The disruptive power of technology has completely transformed landscape in various spheres of life. It has changed the ways humans communicate, travel, socialize, store, and access information and many more. Medical technology has the potential to do the same for healthcare by leapfrogging over the current infrastructural, skill based, geographical and affordability constraints.

Medical Technology can bridge the distance between the care provider and the patient thereby helping patients in remote areas access specialist and specialized equipment present in large cities far away. Technological advancements in the fields of health monitoring and diagnostics can help in detecting health issues early on thereby reducing overall cost of care and enhancing wellness levels of the society. Similarly, technological interventions are rapidly increasing the precision and efficacy of treatment modalities thereby improving clinical outcomes.

However, to realize this opportunity at scale rather than as isolated, fragmented initiatives, both the government and the industry will need to make concerted efforts.

The government should streamline the regulatory and business ecosystem in a manner that makes operating in India more attractive and simpler for both the medical device players as well as investors. Some of the key areas where government could intervene include:

- Setting up an independent authority for medical devices and enabling faster grant of patents

- Supporting local demand of medical devices through public health and health insurance programs as well as by collaborating with the private sector through PPP models

- Providing relevant financial incentives for the industry

- Supporting innovation in India by providing capital and infrastructure support to MedTech start-ups

The industry needs to customize their business models to suit Indian markets. Medical devices segments which provide sizeable opportunities and require moderate level of technological expertise to produce should be prioritized for manufacturing in India. For High-tech low volume segments, efforts need to be directed towards developing the necessary ecosystem and capabilities for their manufacturing in the medium to long term horizon.

Finally, the MedTech industry in India should embrace the path of innovation so that its products and solutions are tailor-made for the opportunities and constraints of the country.

If India is able to be self-reliant in Medical Technology sector and capitalize on this Medical Technology revolution, by ensuring all stakeholders play their respective roles, it would stand a good chance of realizing its vision of providing healthcare to all its citizens.

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The Confederation of Indian Industry (CII) works to create and sustain an environment conducive to the development of India, partnering industry, Government, and civil society, through advisory and consultative processes.

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CII charts change by working closely with Government on policy issues, interfacing with thought leaders, and enhancing efficiency, competitiveness and business opportunities for industry through a range of specialized services and strategic global linkages. It also provides a platform for consensus-building and networking on key issues.

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About CII Medical Technology Division

CII Medical Technology Division (MTD) has been proactively working on the key industry issues with the government, involving all the stakeholders of the medical electronics, devices, equipment and technology Industry. The division has been a nodal point of reference, providing a forum for dialogue with the government and companies from the healthcare technology sector.

The CII MTD, which represents 70% of Med Tech manufacturers in India, has very active participation of medical technology companies from India and abroad. It is dedicated to the advancement of medical technology, improvement in patient care and driving high-quality cost effective health care technologies for India.

The division is working with a vision of expanding access to quality healthcare, generating employment, manufacture, boosting exports and increasing further foreign exchange inflows, thus advancing economic growth and social outcomes.
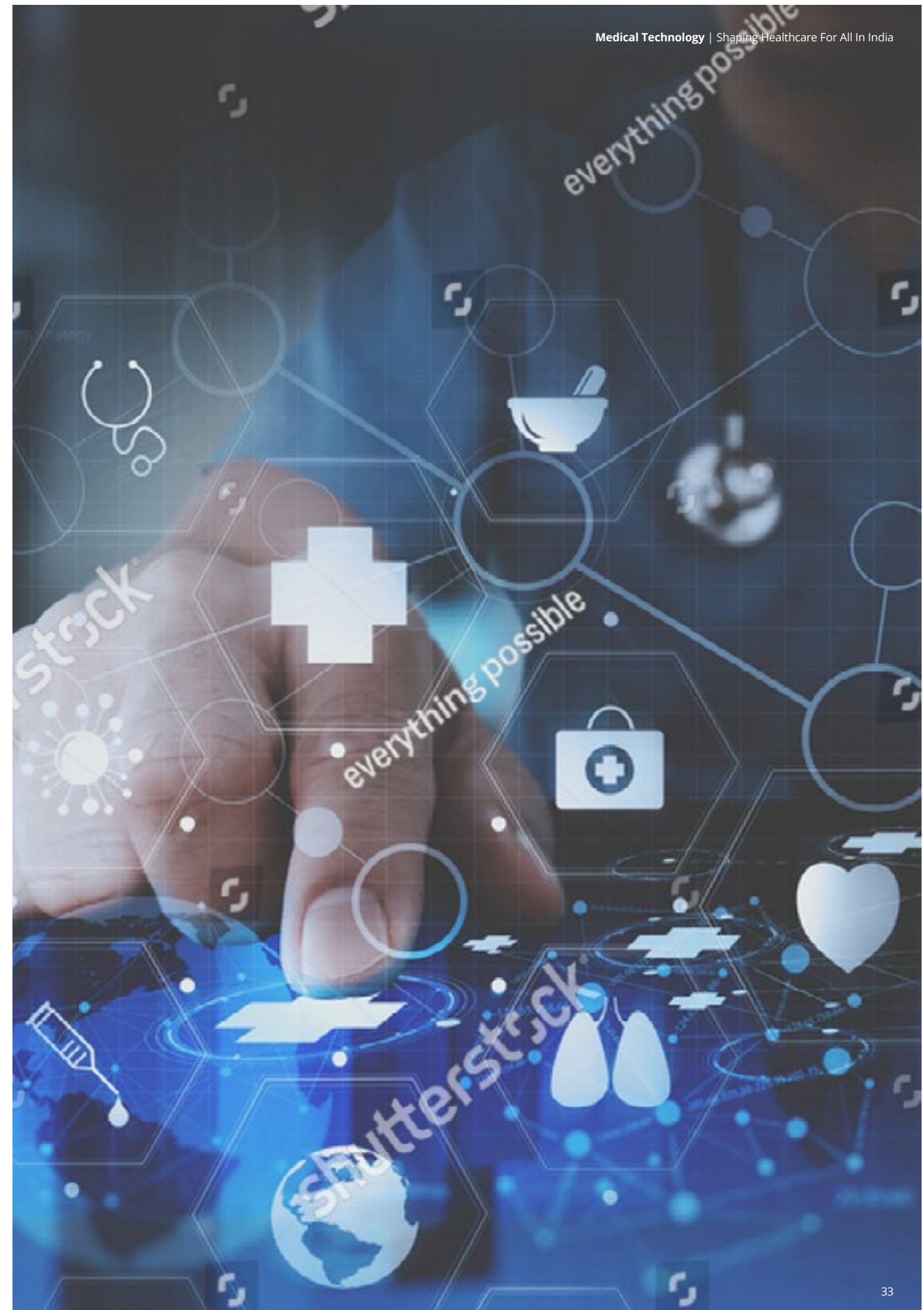
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