



THE BOSTON CONSULTING GROUP



Confederation of Indian Industry

MEDICAL TECHNOLOGY: VISION 2025

A \$50 BILLION OPPORTUNITY FOR INDIA

CONTENTS

FOREWORD	4
MEDICAL TECHNOLOGY TODAY, A ROOT CAUSE ANALYSIS	6
STARTING POINT AND THE \$50 BILLION VISION	8
REALIZING THE VISION	10
POLICY AND REGULATION	12
INFRASTRUCTURE AND TALENT	14
FUNDING REQUIREMENTS	16
AWARENESS AND ENGAGEMENT	18
ROADMAP FOR THE WAY FORWARD	19
SUMMARY	22
NOTE TO THE READER	23
CONTRIBUTORS	24

FOREWORD

AN ANALYSIS OF THE global medical technology market growth shows that emerging markets will play a critical role, accounting for more than half of the growth over the next ten years. Besides being important markets that cannot be ignored for global companies, emerging markets are relevant innovation and manufacturing hubs with the share of registrations from emerging markets across Class I, Class II and Class III devices having doubled over the last ten years.

India as an emerging market continues to be relevant to the global medical technologies space, not just from a market point of view, but also as a global hub for innovation and manufacturing. However, India has not reached its true potential, both in terms of the market opportunity as well as in building a hub for innovation and manufacturing.

To build up a roadmap for India to reach its full potential in medical technology, we assembled a think tank to brainstorm and determine the key levers required to be able to unlock the true potential of India. We held a set of workshops highlighted in Insert 1 across Mumbai and Delhi to discuss and debate the right focus areas and develop a roadmap to unlock this potential.

This team, after several months of deliberation has created a roadmap to create a \$50 billion opportunity in the medical technology space in India. Collectively, we have identified six areas to work on to create the right supporting eco-system. We need to create the relevant regulation, put in place systems that enable and reward innovation, streamline the process to invest in manufacturing infrastructure and build trans-border partnerships to bridge capability gaps and accelerate our growth trajectory. Over the longer term, it is important to come together as an industry and drive patient awareness and engagement to clearly communicate the value of medical technology in alleviating pain, restoring health and extending life. This is not possible without the right talent in place and it is up to all of us in the industry to invest in capability development and training to ensure that the talent pipeline for the future is secure.

The roadmap highlights roles for us to play as key stakeholders and it is important that we as responsible stakeholders of the industry react to this call for action to create a vibrant medical technology ecosystem in India.

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INSERT 1 | Brainstorming Workshops held in Mumbai and Delhi



MEDICAL TECHNOLOGY TODAY, A ROOT CAUSE ANALYSIS

THE MEDICAL TECHNOLOGY SECTOR in India was valued at \$6.3 billion in 2013 at end consumer prices and is growing at 10–12 percent per year. However, the sector remains highly under-penetrated contributing 7–8 percent of the healthcare spends vs. pharmaceuticals at 18 percent. We performed a root cause analysis of the Indian medical technology sector to determine why the industry has not captured its full share of the limelight.

We find that the current medical technology industry is in a vicious circle as highlighted in Exhibit 1. The industry is faced with significant lack of clarity in terms of regulation and predictable access to market. This has limited investments in the market which in turn has lead to lower investments in building up the component ecosystem and the technology skills base to support this market. Without a vibrant component manufacturing system, domestic capabilities in innovation and manufacturing are not built leading to the critical enablers to address the market not being in place. This leads to fewer market appropriate products being introduced as the local capability does not exist and therefore a reliance on imported products into the country. As imported products typically address a small part of the market, they have a lower relevance in the government's agenda and hence a limited focus on clear and tangible policy and regulation which can shape the core of the industry.

Addressing this root cause and breaking out of this vicious circle is important as medical technology could play a vital role in strengthening health systems on both the demand and supply side.

Demand Side

There are some critical barriers that limit access of a large percentage of people in India to healthcare and medical technologies in particular. These include: lack of awareness, screening, diagnosis, trained surgeons and affordable technologies. This stems from the fact that the government spends only about 1 percent of GDP on health in a country where the majority is from low income households. The government has recognized these challenges and has taken some measures to address them through schemes such as Rashtriya Swasthya Bima Yojna (RSBY). However, an integrated approach is required to bring together all the stakeholders in the health sector to collectively address all these challenges simultaneously.

Medical technology could play a critical part on the demand side. Access improves as medical technology disaggregates elements of the healthcare supply chain, allowing healthcare personnel to extend their reach beyond the physical catchment area of their facilities. Services such as Virtual doctor (patients diagnosed by doctors over video conferencing facilities) and eICU (remote monitoring of ICUs in resource constrained hospitals) demonstrate these advantages. Additionally

medical technology helps address limitations in physician capacity by automating several elements of the treatment pathway, unlocking demand across the patient base. Finally, by empowering patients, medical technology serves patients under-served by the traditional healthcare setup through applications such as self-monitoring, particularly for conditions requiring chronic care.

Unlocking demand is a critical element to ensure that the industry remains attractive. Traditional limits on access have been driven by availability of trained manpower. Once demand is established and can be served well products will follow to serve the demand. Innovative products will target patient segments to unlock further demand as long as the skill-set is in place to serve the patient. Demand has not been the constraint, the ability to serve the demand has limited the potential.

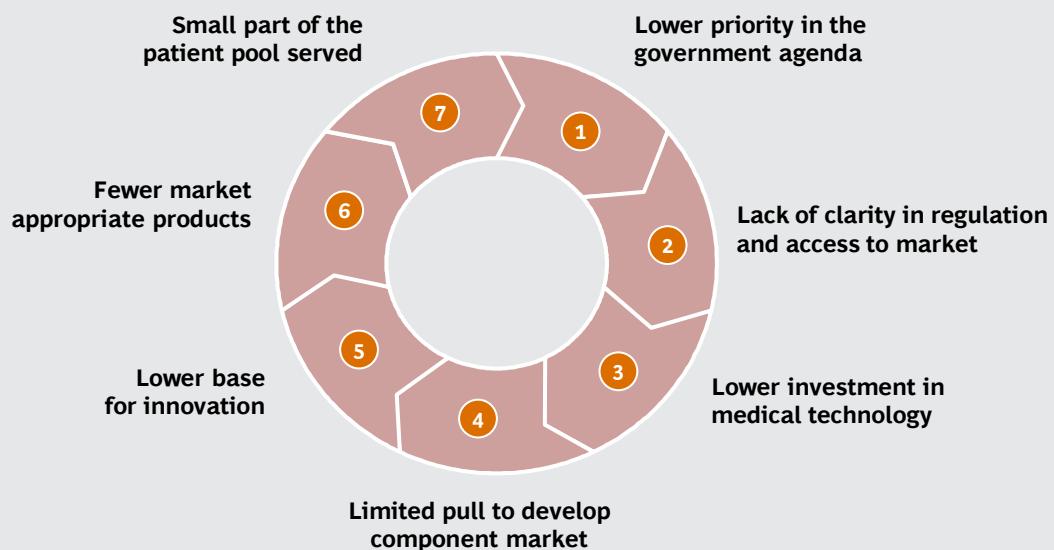
Supply Side

On the supply side as well the medical technology industry has not played the role it could have played in shaping healthcare. Advanced products available are largely imported from developed economies. To ensure that supply constraints are addressed, companies which are present in India, need to adapt their innovation and manufacturing model. In fact, it is probably best that they develop a model suited to India: a model which is

customized to the needs of the country, focuses on addressing key issues of affordability and access, and delivers innovation which is relevant both for India and countries on a similar path of development. Another critical element is getting these innovations manufactured at an appropriate cost for the local market. India has demonstrated competitive advantage across the value chain. Manufacturing costs in India have been known to be up to half the costs of manufacturing in developed markets. However, in medical technologies, in spite of the many advantages, India has not got its fair share of manufacturing. This is primarily because of the challenges in setting up a manufacturing facility in India, the availability of skilled labor and the nascent ancillary industry. Single window clearance is still far away, making the process to manufacture complex and time consuming. Finally, on the supply side, supporting regulation and predictable access to market is vital. As highlighted in the root cause analysis, it limits investment in the space and is a critical element in determining the attractiveness of investments in the country.

Many elements need to come together for India to take its place in the global arena. All stakeholders must play the desired role to make this happen. In this paper, we lay out what is required and the roadmap going forward to ensure India becomes a significant force in the medical technology industry.

EXHIBIT 1 | Vicious Circle in the Medical Technology Industry



Source: CII-discussions.

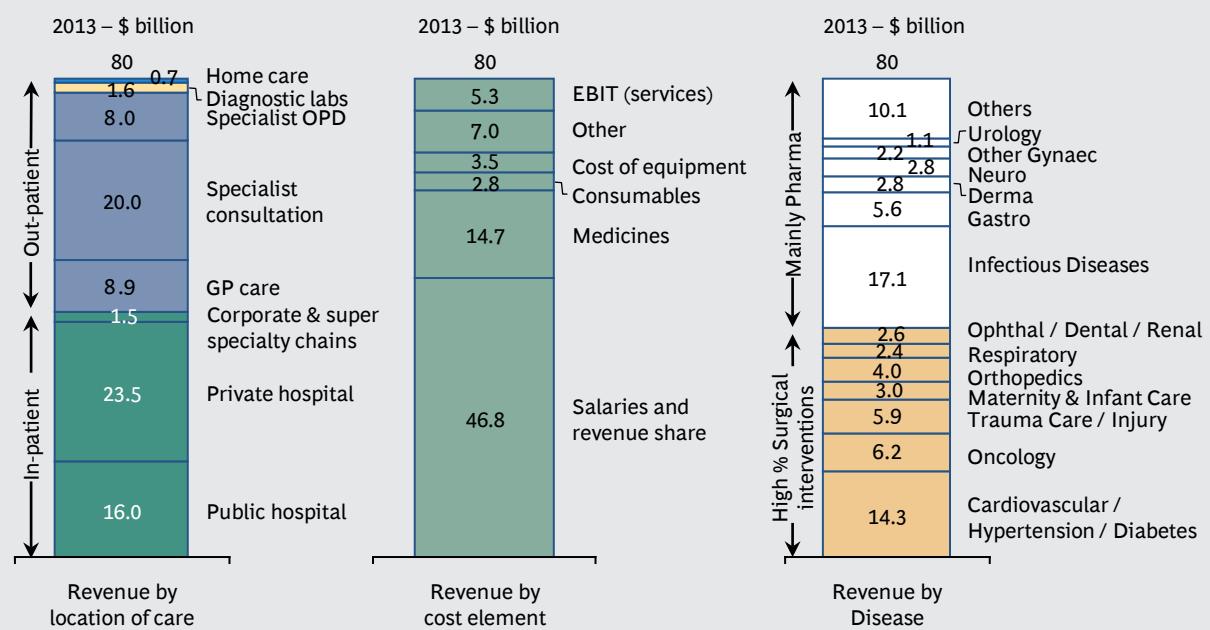
STARTING POINT AND THE \$50 BILLION VISION

INDIA IS A VERY unique market with specific challenges that the medical technology industry needs to recognize. First, affordability and accessibility of medical technologies for Indian patients is much lower. Second, trained manpower to deliver the right care is in acute shortage. And finally, while the disease burden is moving towards chronic diseases, infectious diseases still remain a significant part of the disease burden.

As a result the model needs to be different. Developing a customized model is important, not only to design medical technologies to cater to the needs of Indian patients but to create a global platform for innovation in India.

In 2013, the healthcare market as reflected in Exhibit 2 was believed to be \$80 billion of which \$6.3 billion is the component of

EXHIBIT 2 | Indian Healthcare Market — Revenue



Source: BCG analysis.

Note: Numbers have been estimated bottom up and top down for 2010 and extrapolated for latest estimates. Exchange rate USD: INR 58.48

healthcare spending attributable to medical technology. Based on this input, our group brainstormed what could be a plausible vision for the industry in India. Continued growth rates of 10–12 percent until 2025 implies an overall healthcare spend of \$250–300 billion by then. Medical technology maintaining current penetration levels of 8 percent implies a domestic market of \$20–25 billion. Additionally, the focus on local innovation products to drive access and affordability will be an important opportunity and will be equivalent to half of the growth from existing products / business models i.e. an incremental \$10 billion growth by 2025. Globally the medical technology market is expected to be \$600 billion+ by 2025 implying a manufacturing base of \$200 billion by then. We imagine India to capture 10 percent of that share by 2025 in line with China's share today. This will lead to an opportunity of at least \$20 billion by 2025. The build up of the opportunity behind this vision is summarized in Exhibit 3.

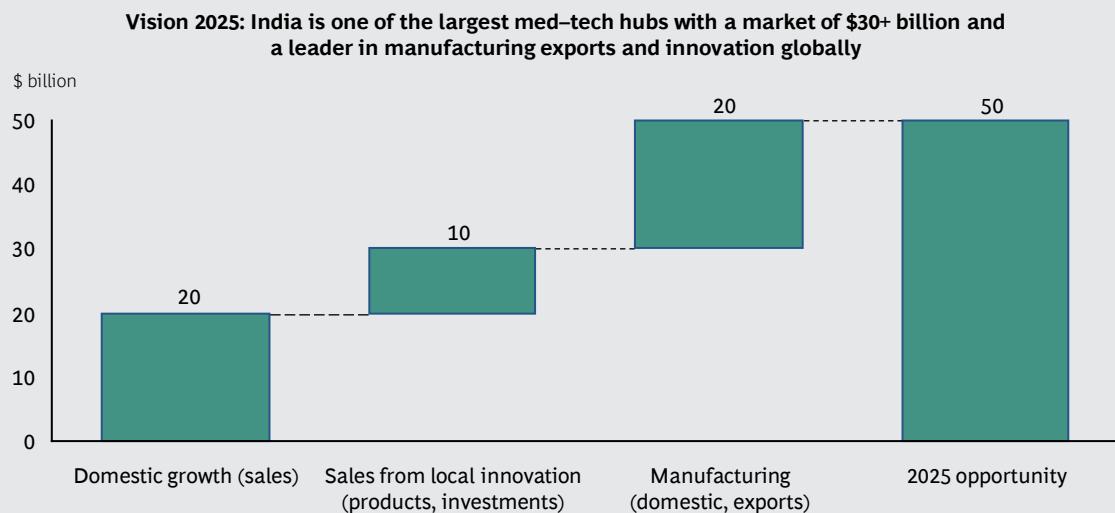
While the sales projection is certainly achievable as it is a CAGR of 14% overall, we debated if an aspiration of \$20 billion in manufacturing is achievable. To test this we studied India's well established strengths in the pharmaceutical value chain. The Indian pharmaceutical market has grown at a CAGR of 13–14 percent in the last five years, ranking

amongst the top five producers in terms of volume of exports to more than 200 countries. In establishing its current position in the global pharmaceutical industry, India has utilized its cost advantage, currently producing drugs at 30–40 percent lower cost than the global players. When testing a new manufacturing model, we fall back on these strengths of India. We put forward a business model that combines low cost manufacturing and focuses on the full medical technology value chain—the objective being to ensure the development of new solutions which address the challenges faced by the industry in India.

We felt that India has the right ingredients to be a significant global player in terms of medical technology manufacturing. While there have been efforts to promote medical technology manufacturing in India, efforts have been distributed and scattered, as a result we don't see India getting the attention it deserves in manufacturing and innovation. In our roadmap we highlight concrete steps to address this which is a combination of communication, partnerships, outreach, regulatory reform and incentives that can help establish India as a hub and global leader in medical technologies.

In the subsequent sections of this white paper, we focus on what is required to realize this tremendous vision for India.

EXHIBIT 3 | The Vision and Opportunity for Medical Technology by 2025



Source: Vision 2025 — CII brainstorming sessions.

REALIZING THE VISION

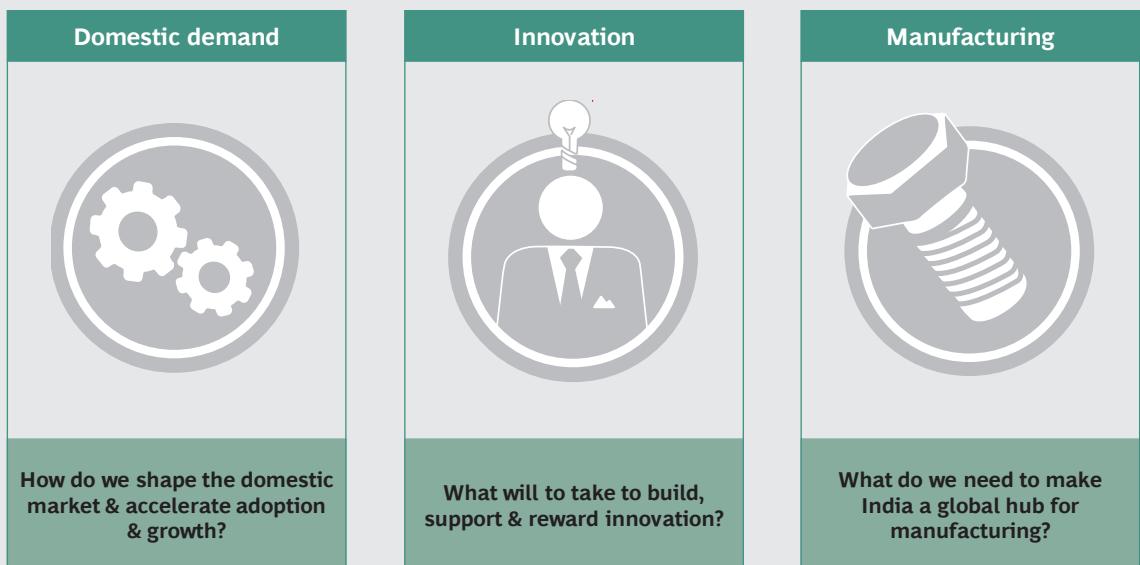
BUILDING THIS LANDSCAPE IN India will require a sharp focus on three key elements i.e. domestic demand, manufacturing and innovation as reflected in Exhibit 4.

To address the “domestic demand” question, a large part of the challenge is to address the issue of access and affordability through a mix of innovative funding models and training programs

to ensure that the right healthcare workers are able to deliver the right therapies to the patient.

For the “innovation” question, we studied international hubs which have successfully built ecosystems that deliver innovation, and reflected on the inputs captured at our brainstorming sessions to synthesize a set of learnings and themes to build the right ecosystem in India.

EXHIBIT 4 | Key Elements of the Vision 2025 that were Discussed and Debated



Source: Vision 2025 — CII brainstorming sessions.

Finally on the topic of “manufacturing”, we looked at the barriers today to determine the roadmap to ensure manufacturing investments in India don’t suffer the delays and challenges they have in the past.

During our brainstorming, we discussed and debated many different elements that need to be in place. These elements were focused on what is required to drive our goals for this vision for the medical technology sector going forward.

We then synthesized these elements into four themes:

- **Policy and regulation:** What regulatory and policy reforms are needed to accelerate the development of the industry?

- **Infrastructure and talent:** Where do we need to invest in infrastructure and talent to ensure the sustainability of the industry?
- **Funding requirements:** Where should we deploy funds to benefit the patient through medical technology?
- **Awareness and engagement:** What needs to be done to communicate the broader contribution of the medical technology industry?

We summarize the challenges across each pillar as reflected in Exhibit 5.

We explore the details behind each and the solutions in the sections of the whitepaper that follow.

EXHIBIT 5 | Summary of Challenges to Address the Vision Across Critical Enablers

	Domestic demand	Innovation	Manufacturing
Policy regulation	<ul style="list-style-type: none"> • Lack of Medtech specific regulation • No clear FDI policy for Medtech 	<ul style="list-style-type: none"> • Unpredictable access to market • Several agencies to coordinate 	<ul style="list-style-type: none"> • Too many agencies for approvals • Difficult to transfer technology
Infrastructure and talent	<ul style="list-style-type: none"> • Poor hospital infrastructure • Lack of trained healthcare workers 	<ul style="list-style-type: none"> • Skill Council playing a limited role • No structured innovation programs 	<ul style="list-style-type: none"> • No hubs to consolidate medtech capabilities • Very few industry training programs
Funding requirements	<ul style="list-style-type: none"> • Limited coverage and reimbursement • Lack of innovative models to support funding 	<ul style="list-style-type: none"> • Small pool of early stage funding • Local innovation does not get required focus 	<ul style="list-style-type: none"> • No manufacturing incentives • Capital costs are high
Awareness and engagement	<ul style="list-style-type: none"> • Irregular media & government interaction 	<ul style="list-style-type: none"> • Lack of communication on innovation globally • Limited global partnerships 	<ul style="list-style-type: none"> • Low advocacy of India as a manufacturing destination

Source: Vision 2025 — CII brainstorming sessions.

POLICY AND REGULATION

WHAT IS NEEDED FROM THE GOVERNMENT TO ACCELERATE THE DEVELOPMENT OF THE INDUSTRY?

GOVERNMENTS OFTEN IMPOSE MARKET access barriers in the form of regulatory controls to protect the domestic industry. The experience of trade liberalization has demonstrated the world over that such policies serve to inhibit innovation in the long term. Prior to 2005, there was minimal regulation of Medical devices in India. Medical devices could be freely manufactured, imported and distributed within the country and yet, there was no noticeable incremental growth in the medical device sector at that time. Regulation has taken the industry a step back, and it is time to take a fresh look at the regulatory environment to determine what needs to change to foster the growth of the industry.

We recommend a series of regulatory and policy reforms to enable the medical device industry to grow and realize its full potential. In this section, we lay out what is needed across each of the pillars of domestic demand, innovation and manufacturing.

One of the most critical regulatory hurdles that acts as a major disincentive to both investment and innovation is the Drugs & Cosmetics Act which regulates the medical technology industry. The proposed Amendment Bill to the Drugs and Cosmetics Act seeks to partially address this by creating a separate chapter for devices, thereby distinguishing them from drugs. This Act needs to be a pri-

ority for the government and once the new Act is passed; new laws will need to be framed to implement the Act. This will require close coordination among all the stakeholders to ensure that the new regulatory regime for medical devices addresses the needs of all stakeholders. Additionally, medical technology and insurance are quite closely linked. Any regulation to spur the growth in healthcare insurance will have a spillover effect on the device industry and is important to consider when building a strong ecosystem.

Domestic Demand

These regulatory reforms need to be accompanied by appropriate reimbursement policies. Price controls serve as a major deterrent to stimulating innovation as research based companies are unable to generate a fair return on their investments. At extremely low price points, companies are not able to import their products into India, thereby denying patients access to the latest life saving technologies. The industry is nascent, accounting for less than 8 percent of the total healthcare spending in India. To continue to attract investments, this nascent industry which has long gestation periods should be allowed to let market forces regulate prices and should not be clubbed with the pharmaceutical industry for price control.

Innovation

To drive innovation what is required is a unified regulatory body that can approve bringing new products to the market quickly. The process today is quite unpredictable and requires the involvement of numerous government agencies to bring a new product to market. For example registering a product requires India specific labeling requirements that are better suited to drugs and only serve to add a huge cost burden to medical device importers. These challenges have imposed enormous costs, delays and operational challenges on developer companies wishing to bring the latest innovative lifesaving technologies to India. Capacity is limited of medical device experts within the Central Drugs Standard Control Organization (CDSCO) as the majority are trained in drug regulations. Additionally, transfer of technology was highlighted as particularly challenging in the current policy framework. Clear guidelines on royalty fees, the tax implications and procedural simplicity would go a long way in helping companies to transfer technology going forward.

Manufacturing

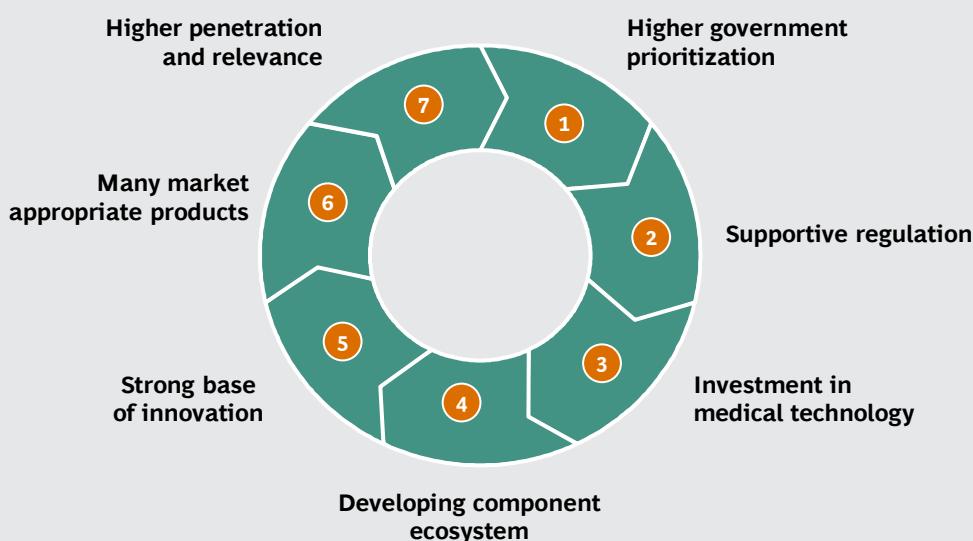
When it comes to manufacturing it is important to formulate a policy that would ad-

dress the complexity that comes with setting up manufacturing units in the country. Multiple approvals from several agencies leads to significant delays on projects and tremendously impacts the predictability and timeliness of new projects. State-wise regulations complicate matters further. Single window clearance for not only setting up the manufacturing facility but also for day to day operations would go a long way in addressing the primary concerns of investors in local manufacturing in India (be it MNC or Indian companies).

Further, it is important to create incentives to enhance the attractiveness of the business case. As we know, the cost of capital in India today is high, traditional incentives in terms of tax holidays will go a long way to spur investments.

Soft loans will encourage investment in domestic manufacturing capacity as well. Finally, there is a need to establish parity in duty structures for imported raw materials and imported medical devices, such that imported raw material / component does not attract higher duty than the imported finished device.

EXHIBIT 6 | Regulation can Kick-start a Virtuous Circle



Source: CII-discussions.

INFRASTRUCTURE AND TALENT

WHERE DO WE NEED TO INVEST TO ENSURE THE SUSTAINABILITY OF THE INDUSTRY?

WHILE POLICY STREAMLINING WILL help, setting up a medical technology business in India remains challenging as finding the right infrastructure and talent to support operations in India is difficult.

In this section, we lay out what is needed across each of the pillars of domestic demand, innovation and manufacturing.

Domestic Demand

On the topic of infrastructure, as we all know today, the critical bottleneck is the hospital infrastructure and trained healthcare workers. It is important that the industry invests in training programs for healthcare workers to ensure the right talent and capacity is available to ensure medical technology uptake can keep up with demand. Several companies have already done this. For example, training centers for radiologists, training programs for lab technicians are innovations which companies have done to bridge this talent gap in healthcare skills. A number of training and education centers being set up by private companies have imparted skills on how to use new medical technologies to public and private doctors and surgeons. It is important for the government to partner with the industry and build broader skill development programs to help build the talent base required to ensure medical technology takes off.

When it comes to improving health delivery companies can play a significant role too. Investing for the long term by creating pay-per-use models can help address the capital challenges that are associated with healthcare delivery infrastructure.

Further, companies can expand their talent development initiatives by partnering with NGOs, state governments and other partners that work at the primary and secondary care levels. These partners have access to a large segment of society at the middle and bottom of the pyramid that cannot easily access tertiary care which in turn drives the demand for medical technologies. The industry can play a critical role in imparting new skills to these healthcare providers to help them identify patients with chronic diseases and referring them to hospitals and clinics that offer suitable treatments. While the return per patient may be lower, the volume of sales derived would meet the dual objective of expanding access and affordability and generating new streams of revenue.

Innovation

With regards to innovation, the skill set for medical devices which is a combination of electromechanical and design skills have not been nurtured. Courses that feature medical technology fundamentals which create the base for innovation are few in India today.

The industry has not participated in developing this skill, and has tapped the engineering talent mainly for service and maintenance. A few companies have developed innovation hubs, but the initiatives are localized and the talent often only sees a small part of the innovation process that goes into bringing a product to market. Targeted short, medium and long-term interventions in the Indian education ecosystem, combined with global internship programs which expose students to the full innovation process will go a long way in building an innovation talent pool in India. Coverage of these programs must not be limited to Tier I cities but also percolate to Tier II and III cities. Companies investing in such programs will lead the curve in securing the best talent in advance and broaden their recruiting pools.

Manufacturing

Finally, on the topic of manufacturing, the first area to work on is the designation of areas as manufacturing hubs for medical technology. Once established, facilitative joint ventures, licensing agreements and public private partnerships with the government can foster a dynamic domestic medical technology manufacturing ecosystem. Some of this has begun and needs to be encouraged. This is similar to the work done in the past by IT Hubs or Export hubs for Pharmaceuticals. Designating areas with the right infrastructure i.e. power, water to support medical technology manufacturing will be critical.

Several countries have built similar medical technology hubs and India could follow a similar model. As Asia's leading location for medical technology, Singapore is home to over 30 medical technology companies which have set up commercial-scale plants to produce medical devices for the regional and global markets.

The medical technology industry in Singapore almost tripled its manufacturing output from S\$1.5 billion in the year 2000 to about S\$4.3 billion in the year 2011. Over the same period, its manpower base more than doubled from about 4,000 to 9,000. By the year

2015, the medical technology sector targets to achieve S\$5 billion in manufacturing output.

Singapore achieved this by designing hubs and providing tax holidays to attract investors. Beyond the setting up of hubs, government agencies such as the Singapore Workforce Development Agency (WDA) and the Employment and Employability Institute (e2i) worked closely with industry partners to enhance manpower capabilities through customized training programs and skills upgrading schemes.

Industry too can play a major role, sponsoring or at the minimum guaranteeing job placements for diploma and graduate courses with specialization in medical technology. This will help attract young talent to the industry and help bridge the talent gap.

It may be pertinent to note the Ireland example here. Eight of the world's ten largest medical device companies are located in Ireland. The sector employs over 24,000 people in 160 companies and generates sales in excess of €6 billion annually. Over half of the medical technology companies based in Ireland have dedicated R&D facilities.

This continued investment by industry has stimulated the emergence of an indigenous cluster of over 100 innovation-led companies along the entire Medtech value chain. This has led to a pipeline of people and supporting infrastructure and a virtuous circle of investments following past investments.

Ireland policies have been pro-business, low tax with successive governments taking action to sustain Ireland's business environment. Additionally, world-class academic institutions in Ireland collaborate with MNCs and workers and managers have developed high level skills and experience in MNC manufacturing facilities. Finally, the Industrial Development Authority (IDA) under the Ministry for Enterprise, Trade and Employment works in close partnership with new and expanding manufacturing operations, ensuring that they have the facilities, resources and contacts needed to sustain a competitive edge in their industry.

FUNDING REQUIREMENTS

WHERE SHOULD WE DEPLOY FUNDS TO BENEFIT THE PATIENT THROUGH MEDICAL TECHNOLOGY?

WHEN IT COMES TO a vibrant domestic ecosystem, affordability is a critical barrier that limits access in India. A large part of India pays out of pocket and with the government spending at about 1 percent of GDP on healthcare, the total pool of money available to the healthcare industry is limited. Economically viable models to reach the full population of India have been challenged in terms of the price points of lower income patient segments. While there are plans in place to step up government spending significantly in the next few years, this cannot meet the cost burden of providing healthcare to 1.2 billion people alone.

In this section, we lay out what is needed across each of the pillars of domestic demand, innovation and manufacturing.

Domestic Demand

The Government has developed the basic infrastructure in terms of healthcare delivery centers, medical colleges, and paramedical manpower. The Medical technology sector can help optimize the use of these funds by not only adding to this infrastructure, but also improving management and operational efficiencies by building physician skills, developing operating protocols and implementing systems to deliver better results using existing resources. Several such partnerships have been developed by medical

device companies and industry associations, which are in place and in pipeline to partner with the government to enhance access and affordability. However, the government also needs to demonstrate a commitment to work with the private sector.

The government can enhance funding to healthcare by reforming its reimbursement programs and systems. The government needs to partner with the industry to streamline its reimbursement system and move towards evidence and outcome based pricing and faster approvals. Additionally, there are several state health insurance schemes that provide some coverage for tertiary care which includes medical technologies. The administrators of these schemes need to engage more actively with insurance companies and medical device companies to not only understand the value of new life saving technologies, but also to explore the world of non / less invasive treatments which are less traumatic for the patients.

Finally, to further enhance funding, innovative financing models will be required to increase access and affordability. India has witnessed a great deal of innovation in this area over the past decade. This includes patient access programs for cancer drugs, tiered pricing for HIV / AIDS therapies, and loan schemes for costly devices and insurance products for cardiac therapies. Medical

device companies now offer loans to patients with low interest rates to help ease the financial burden of costly therapies. These schemes help address a lot of challenges around access and affordability which limits the growth of the industry today.

Innovation

Local solutions will grow the market, increase access and affordability and at the same time reduce India's dependence on imported medical technologies. Medical device companies have begun to adapt their global knowledge and expertise to pioneer local solutions to meet India's unmet medical needs. Some examples of local innovations include the portable ultra ECG machine which has enabled communities to access diagnostic care. However these innovations are few and far between. Relevant innovation for the Indian market in the medical technology space has been limited.

In our discussions, we found that MNCs have not invested in local innovation, and directly import products into the market. Local companies have not invested in R&D, with R&D levels less than 1 percent of sales vs. 6–7 percent of sales for global companies.

Lack of early stage funding was identified as a key factor limiting innovation. Incentives have not been in place to reward developing market appropriate products. Early stage funding for pioneering, cost-effective, good-quality, safe and efficacious local innovations including local incremental innovations is the need of the hour. There are minimal offerings for seed funding to early-stage start-ups / companies as investors do not often foresee eventual realization via IPO or sell-out of the company.

The government also needs to create incentives which encourage local innovation and R&D in India. A good example of the setting up of a conducive environment is what is being done at the Biotechnology Industry Research Assistance Council (BIRAC). Apart from funding research, BIRAC backs IP, business development and networks to cre-

ate partnerships. The focus is on biotechnology within health care, agriculture, green technology and industrial processes. BIRAC is financed by the Indian government and the private sector, and has provided funding of more than U.S. \$200 million for research.

While encouraging the development of market appropriate products will solve part of the problem, we must recognize that there is a large market in India that still remains government funded. For many companies, this market has been difficult to access because of the overwhelming focus on price and not value. Here too, the government could play a tremendous role in encouraging innovation. By shifting the procurement process to a "value based" system where the government rewards manufacturers who innovate and deliver value in the healthcare system will create a tremendous impetus to local innovation. Access to a portion of the public spending on healthcare will encourage players to develop local products relevant to the Indian market and spur the domestic demand.

Manufacturing

Finally, when it comes to manufacturing, it is important to recognize that the manufacturing business case in India is challenging. While labor cost is lower, capital investment and productivity of the labor are critical limiting factors to the manufacturing business case. Combined with approval delays, this makes the manufacturing environment quite challenging for entrepreneurs and MNCs. Access to low cost capital through soft loans would be critical to be able to spur investments in the sector. This combined with the tax incentives and single window clearance highlighted in the regulation section would certainly build a stronger business case in India.

Attracting large global companies will create a base which will then build up the components ecosystem. This in turn will enhance local capabilities and will help local companies build up their access to components and will greatly enhance the manufacturing capability in India.

AWARENESS AND ENGAGEMENT

WHAT CAN BE DONE TO CREATE AWARENESS OF THE CONTRIBUTIONS OF THE MEDTECH INDUSTRY?

LITTLE IS KNOWN ABOUT the medical technology industry in India today. Even estimates of market size vary significantly. Pricing is not transparent to the consumer leading to a general perception is that it is dominated by large imports from foreign multinationals that are self seeking and profit making. Little has been done to address this perception. In reality, most global companies are making large investments in India today, bringing in new innovative technologies, India specific products and services, training and education, as well as investing in local manufacturing and R&D centres. Local companies suffer from the stigma of poor quality but in reality sell their products globally to growing satisfaction of their international clients.

In this section, we lay out what is needed across each of the pillars of domestic demand, innovation and manufacturing.

Domestic Demand

The industry needs to make a concerted effort to communicate its value proposition to the government, patients, media, NGOs and other stakeholders. Companies need to invest in direct to consumer communication to increase disease awareness and health seeking behavior among Indians. AdvaMed's (Advanced Medical Technology Association) communications and advocacy campaign is a step in the right direction. This needs to be supplemented by local indus-

try bodies organizing regular media and government interactions with industry leaders to increase awareness and understanding of the role of the medical device sector in advancing access to healthcare in India.

Innovation and Manufacturing

Attracting foreign investment in India in R&D and Manufacturing has been challenging, particularly because of limited awareness of the advantages of India.

The first step would be to prove the business case in India with case studies of concrete examples of cost competitiveness. Combining this with incentives to build up the business case for example, preferential access in government reimbursement or tax incentives for local manufacturing could create an attractive package for investors.

The second step would be to reach out to countries where bi-lateral dialogue is taking place and through appropriate industry bodies, organize the outreach so that the India value proposition reaches the right ears. Finally, we need to ensure the right contacts can be made locally to ensure that the execution of the investments take place smoothly. Putting in place such a structured communication and engagement plan would be critical to ensure India gets its fair share of manufacturing and innovation investments. It is critical to remember that other countries will be competing for this investment too.

ROADMAP FOR THE WAY FORWARD

AS A PART OF this white paper we discussed the starting point / outline of a potential medical technology roadmap in India. In addition, we studied best practices and ideas put forward at our brainstorming sessions to synthesize a set of principles toward creating a vibrant medical technology ecosystem in India. We consolidated these elements into a roadmap as reflected in Exhibit 6 which we highlight for the acceleration of the medical technology space in India.

At the core of this roadmap lies the foundation of a vibrant ecosystem. We highlight four “quick wins” and two longer-term initiatives which will help develop this ecosystem.

Quick wins are initiatives which participants at our brainstorming felt should be implemented within the next 12 months as they felt that these are crucial for the further growth of the medical technology industry.

A. Medical Technology Relevant Regulation

1. We must have regulations that are dedicated, predictable, transparent, globally harmonized and appropriate for medical devices. It could preferably be based on a separate medical device regulatory act and governed by an independent regulatory body with specialized regulators. If that is not

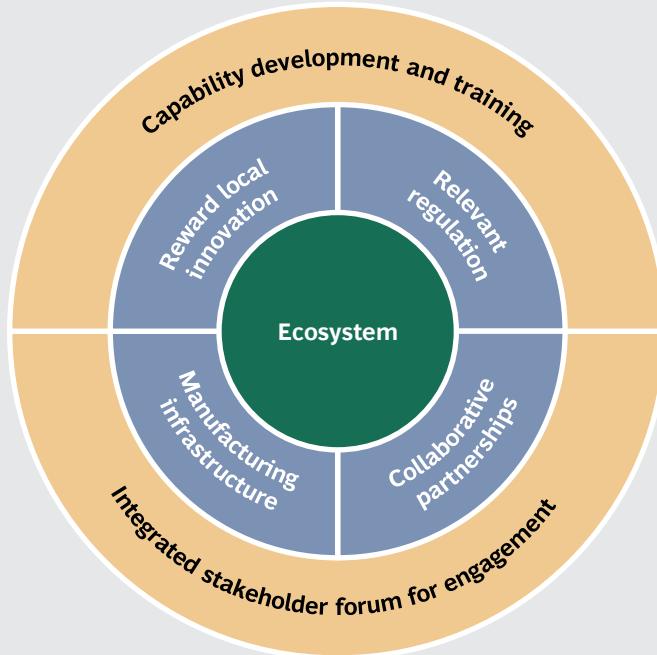
achievable in the short term, at the very least, we recommend the Government to include industry inputs and pass the Drugs & Cosmetics Amendment Bill 2013, which can then provide a starting point to separate medical devices from drugs and pharmaceuticals.

2. Create a “one–window” institution to ease the regulatory burden for the industry and reduce the bureaucracy associated with approval for development, technology transfer and manufacturing.
3. The government has to promote transparent and evidence based pricing and reimbursement policies. It needs to develop a dynamic procurement mechanism for assessing the clinical outcomes and cost effectiveness of a medical technology to determine its merit for inclusion in public insurance schemes.
4. Government should table discussions on a PPP framework for operationalization of partnerships as well as discussions around training and accreditation, particularly when it comes to healthcare workers.

B. Reward Local and Market Relevant Innovation

1. A National Innovation Policy linked to our disease profile is required and should be

EXHIBIT 6 | Roadmap for a Vibrant Medical Technology Industry in India



Source: Vision 2025 — CII brainstorming sessions held on December 2013 and April 2014.

organized in a way that we reward results in innovation which are locally relevant in India.

2. Expand initiatives like BIRAC to medical technology; these initiatives should be broadened to cover more research and support more local innovation. These schemes should provide seed capital, viability gap funding, co-fund start-up projects and support the commercialization of innovations.
3. Government should create strong incentives for commercialization of ideas by creating access to reimbursement in the government funded schemes using a value based approach.
4. Provide a longer term view (10 yrs window) for 200% weighted tax deduction on approved expenditure on R&D activities as the gestation period is high in this industry.

C. Build Manufacturing Infrastructure

1. Streamline the process of setting up manu-

facturing facilities in India by designating medical technology hubs with the right infrastructure in place to support complex medical technology manufacturing.

2. Create training hubs around these manufacturing hubs to ensure a ready supply of trained talent to support these hubs. Industry to assure recruitment from these hubs.
3. Provide manufacturing incentives for example, tax support, low cost funding to spur investments and to make the business case attractive.

D. Collaborative Partnerships

1. Close coordinated working with our academic institutes to build global partnerships with medical technology companies who don't have access to India. Need to select 3 institutes which will drive this collaboration with industry.
2. Create industry sponsored programs between local and global industry on joint collaboration projects using rela-

tionships with specific trade bodies and industry fora.

3. Address the capability shortfall in crucial areas holistically by building select partnerships in procurement, testing, calibration and clinical trials which limits the extent of investment in innovation in India.

E. Capability Development and Training

1. Industry and academia should jointly define the expectations from new graduates. Based on these requirements, the academia must put together a curriculum designed at developing the desired skill sets.
2. Academia should cultivate a culture of collaboration on campus by providing the necessary platforms for interaction with industry. Universities must facilitate interaction between the students of medical technology and business management to ensure cross-pollination of knowledge.
3. Healthcare Sector Skill Council to take as a priority the development of the medical technology skillset. This should form part of their mandate and drive the right talent

development initiatives. Allocate funds to set up Centers of Excellence for medical technology training.

F. Integrated Stakeholder Forum for Meaningful Engagement

1. Coordinated awareness effort of multiple stakeholders led by an industry body to ensure that the benefits of medical technology innovation in the country are well understood by all.
2. Global task force to promote India as a manufacturing and R&D hub globally through targeted specific fora to build bi-lateral dialogue.
3. CII will further need to coordinate between all stakeholders to take the Vision 2025 forward, and it is vital that this effort starts soon.

SUMMARY

In this white paper, we have outlined the opportunity for the medical technology industry in India. Getting things right could lead to a \$30 billion domestic market opportunity as well as setting up the right manufacturing capabilities could spur an additional \$20 billion manufacturing opportunity for the Indian medical technology space.

However to get there, a lot needs to happen. The government needs to streamline regulation to make operating in India simple. The industry needs to innovate its business model, and innovate across the value chain to serve Indian customers better and unlock the latent value in the Indian market. It is important that all stakeholders take steps to create an ecosystem that supports innovation and ensures a revamped business model that works in India and can serve as a template for innovation globally.

Finally, India's traditional strengths in manufacturing can deliver tremendous value if unencumbered from the regulatory and operational challenges that manufacturing investments in India face today.

A roadmap has been developed to address the challenges faced by the industry. At its core, this roadmap focuses on fostering a vibrant ecosystem and streamlining the regulatory process. This will have to be supported by a set of quick wins such as supporting innovation, creating manufacturing hubs and building partnerships. A set of longer-term initiatives outlined in the roadmap around talent and awareness and engagement will need to be acted upon soon to ensure a vibrant medical technology segment is promoted and focused on in India.

NOTE TO THE READER

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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.

CII is a non-government, not-for-profit, industry-led and industry-managed organization, playing a proactive role in India's development process.

Founded in 1895, India's premier business association has over 7200 members, from the private as well as public sectors, including SMEs and MNCs, and an indirect membership of over 100,000 enterprises from around 242 national and regional sectoral industry bodies.

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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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, Equipments 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 has very active participation of medical technology companies from India and abroad 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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