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Progressive change

Impetus to Medical Technology through Innovation, Incentivisation and Regulation

A theme paper released at the 6th Medical Technology Conference –
"Medical Technology and its Vital Place in Healthcare in India"

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Foreword

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If India has to achieve universal healthcare for all by 2020, it has to ensure that the four wheels of Healthcare viz. the Healthcare providers, the Pharmaceutical industry, the Health Insurance sector and the Medical technology industry grow in tandem.

Though Medical Technology is vital, it is still the smallest of the wheels. To help it reach its potential it needs smooth flows of FDI, technical and R&D collaborations, a strong incentive to manufacture in India, a robust technological ecosystem to support this manufacturing activity, and an appropriate regulatory regime.

Given these, this sector could be the next trail-blazing story of success from India.

Mahadevan Narayanamoni
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Healthcare and Life Sciences Advisory
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Multiple factors have been impeding the growth of medical technology in India over the last few decades. With several changes on the anvil, including the Drugs and Cosmetics (Amendment) Bill, 2013, the sector is poised for major developmental and regulatory changes.

While the pace of change may be uncertain, its direction is very clear – clear actions to be taken by the payers, providers and the regulator for improved patient outcomes, greater affordability and availability of technology based solutions in healthcare.

Overall healthcare market in India

Healthcare Industry has ridden the global downturn far better than its other industrial counterparts and is regarded as one of the fastest growing sectors in India driven largely by increasing penetration of healthcare across the country, a growing lifestyle disease burden, and continued leveraging of India as a cost effective manufacturing base combined with uninterrupted imports. A segmentation of the healthcare market in India is depicted below:

1

Healthcare Delivery

Estimated size: USD 32 Billion

Includes Government and Private Hospitals

2

Pharma and Biotech

Estimated size: USD 20 Billion

Includes the manufacture, extraction, processing, purification and packaging of chemical and biological materials to be used as medication for humans or animals

4

Medical Technology

Estimated size: USD 4.4 Billion

Includes companies engaged in manufacturing medical devices, equipment, electronics and consumables.

3

Medical Insurance Services

Estimated size: USD 3.7 Billion

Includes health insurance and covers an individual's hospitalization expenses and medical reimbursement facilities

The outlook for these segments of healthcare over the next few years remains strong, with more recent trends such as greater adoption of health insurance (private as well as state-funded) likely to further increase the penetration of healthcare across the country. Financial support in the form of fiscal benefits, technological advancements and policy changes are bound to create a strong opportunity for India to build global competitive edge in the healthcare sector.

Defining medical technology

Medical technology includes the application of organised healthcare knowledge and skills in the form of devices, equipment, procedures and systems designed to address accessibility, affordability and availability of appropriate healthcare solutions. As per the tabled Drug & Cosmetic bill (amendment) 2013, medical devices are expected to be defined as per the GHTF which defines Medical device as

any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article which:

- is intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of diagnosis, prevention, monitoring, treatment or alleviation of disease, supporting or sustaining life, providing information by means of in vitro examination of specimens derived from the human body.
- does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Other definitions across the globe

USA

A medical device is defined within the Food Drug & Cosmetic Act as "...an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

China

The State Food and Drug Administration (SFDA) defines medical devices as any instrument, apparatus, appliance, material, or other article whether used alone or in combination, including the software necessary for its proper application. It does not achieve its principal action in or on the human body by means of pharmacology, immunology or metabolism, but which may be assisted in its function by such means; the use of which is to achieve the following intended objectives:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap conditions;
- Investigation, replacement or modification for anatomy or a physiological process;
- Control of conception.

France

A medical device is a product that must correspond to the following definition of the Public Health Code3 "A medical device is understood to be any instrument, appliance, equipment, material, product, with the exception of products of human origin, or other article alone or in combination, including the accessories and software involved in its functioning, intended by the manufacturer to be used in humans for medical purposes and whose principal intended action is not obtained by pharmacological or immunological means or by metabolism, but whose function can be assisted by such means.
Medical Devices that are designed to be implanted in whole or in part in the human body or placed in a natural orifice, and that depend for their proper functioning on a source of electrical energy or any other source of energy other than that generated directly by the human body or gravity, are called active implantable medical devices.

Japan

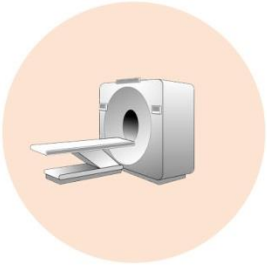
According to the Pharmaceutical Affairs Law, "Medical devices" refers to those equipment/instruments which are intended for use in the diagnosis, treatment or prevention of disease in humans or animals, or intended to affect the structure and functions of the human or animal body.

Profiling the industry

Currently valued at USD 4.4 billion, the Indian medical device and equipment market is expected to grow to around USD 5.8 billion by 2014 and USD 7.8 billion by 2016 growing at a CAGR of 15.5%. India's medical device market is currently the fourth largest market in Asia with 700 medical device makers, and ranks among the world's top 20, according to data from the India Semiconductor Association.

The Indian market remains largely dependent on imports (with three quarters of its equipment and device needs met through imports), often seen by global devices companies as a market for selling their current mature market products (in some cases, even refurbished equipment), mostly developed and manufactured outside of India.

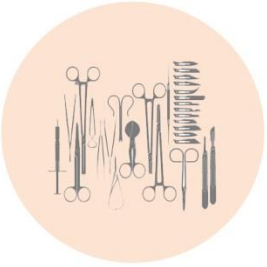
While Tier 1 cities such as Bangalore, Hyderabad and Pune have several companies with focus on medical technology, areas in the North such as Chandigarh, Faridabad, Ballabgarh and Manesar have also developed as manufacturing clusters for medical consumables despite the lack of any specific incentives/ infrastructure support. Several MNCs are now undertaking substantial amount of their product development/ manufacturing in India, particularly to meet local demand.



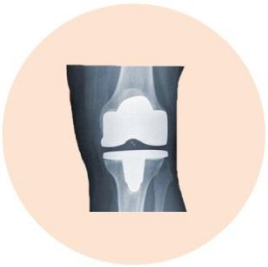
Electro - Medical equipment

Medical technology in general use

Irradiation



Surgical Equipment



Implants

Medical Disposables

Breakthrough innovations in medical technology

In order to remain competitive in the marketplace, companies need to look beyond technology and should be able to offer customized and creative solutions to the end user. Innovation in MedTech is not only confined to product level technology but is supported by two other pillars of innovation – service delivery and operating models. There have been a number of interesting innovations in Service Delivery, Operating Models and Product Lines.

Service delivery innovation

- **GE** launches "experiential lounge on wheels" to provide healthcare services to woman and infants in small towns and villages of Tamil Nadu
- Bangalore based diagnostic start up, **Achira Labs** is building a micro-fluidic platform that provides point-of-care diagnostics
- **Neurosynaptic Communications** provides affordable telemedicine solutions that enable remote communication and monitoring of vital stats such as heart rate and blood pressure via video and audio
- Mumbai based **Biosense** has developed U-Check – a urine dipstick kit through which patients can have their urine samples analysed at home and transmitted to physicians using the mobile phone
- **Forus Health** launched 3nethra – a single, portable, noninvasive prescreening ophthalmology device that can be operated by a minimally trained technician thereby making healthcare services accessible to the rural population.

Operating model innovations

- **Vision Spring** uses the micro-franchise approach to create vision entrepreneurs that aid in the distribution of affordable reading glasses to customers
- **Drishti Eye Care** uses a three tier hub and spoke model which offers primary eye care through telemedicine supported vision centres, screening camps and surgical care at district hospitals
- **Sparsh Nephrocare** operates a chain of "In hospital" dialysis centre focused on making dialysis therapy accessible to patients in Tier II and Tier III cities in India using an s asset light model (a mix of new and refurbished equipments)

Product line innovations

St. Jude Medical Inc. launched its next generation pacemaker in India, a first-to-market Quadripolar pacemaker system that offers more pacing options for patients with heart failure

Vygon India has launched its new Neonatal PICC range across the country through workshops held with the support of the National Neonatology Foundation and intensive care chapters of the Indian Academy of Paediatrics. By ensuring safe vascular access this PICC range plays an important role in reducing morbidity and mortality in infants

Philips India launches "Philips Efficia" - range of infant warmers and incubators meant to reduce infant mortality, BiliChek transcutaneous bilirubinometer phototherapy system and NeoPAP respiratory support solution for neonates

Skanray Technologies has developed a USB-based ECG unit called Cardiskan which converts laptops or personal computers into a 12-channel electrocardiogram system. As a result, rural diagnostic centres can now offer ECGs at significantly low cost.

The manufacturing landscape

The Indian medical devices industry forms a very small part of the total manufacturing industry accounting for only 0.2% of all certified facilities. The high-tech end of the medical device market is currently led by multinationals with extensive service networks; whereas low end equipment and disposables are led by domestic manufacturers because of their cost effective innovations. Collaborative trends across these two segments are visible through deals and acquisitions, setting up of local manufacturing by large international players and other technical alliances.

Local manufacturing impetus by foreign players over the last few years:

Company name	Details
GE Healthcare	Set up a facility in Bangalore to refurbish medical equipment
Nipro Corp	Setting up a manufacturing facility at Pune to produce medical devices, especially equipment to support haemodialysis treatment process
Siemens Healthcare	Manufactures X-ray systems, intensive care systems, hearing instruments, USG and equipment for nuclear medicine at its facility in Goa
Hollister's	Made significant investments in setting up its manufacturing facility for healthcare products in Haryana
B Braun	Besides its suture manufacturing plant in Chennai, B Braun acquired a controlling stake in Hyderabad-based medical devices manufacturer Oyster Medisafe
Terumo	The Company has set up a strong manufacturing base in India for blood bags, seals, component extractors, storage and transfusion sets and services blood centres across the globe

"Issues like lack of R & D, unavailability of raw materials, infrastructure related issues, lack of skilled workers deter Indian companies from investing in domestic manufacturing. The newly tabled Drugs & Cosmetics Amendment Bill states that Drugs and Medical Devices are not comparable but associated issues like Non Conformance (Misbranding, Adulteration etc), Penalty & Punishment (which is very stringent and flat across all categories of devices), Clinical trials etc. should be treated differently than drugs"

Himanshu Baid,
Managing Director,
Poly Medicure Limited

Deals and alliances

Even though the country seems to have lost some of its attractiveness as an investment destination, the medical technology space has seen a spate of partnerships/ acquisitions and collaborations despite the fact that the regulatory landscape for drugs (which includes medical devices) has been a deterrent.

Partnerships	
April 25, 2013. CardioDx, a 2012 Fierce 15 winner, partnered with India's Core Diagnostics to distribute its coronary artery disease test in the country's burgeoning market. Core will administer the Corus CAD test to patients in India, shipping samples back to CardioDx's lab in California for analysis and turnaround.	CARDIODX ⟷ CORE DIAGNOSTICS
M&A	
May 3, 2013. Smith & Nephew to acquire Indian trauma business Adler Mediequip Private Limited and with it, the brands and assets of Sushrut Surgical Private Limited, a leader in mid-tier, orthopaedic trauma products for the India market to supplement their organic growth through acquisitions, and to bring forward a mid-tier offering for these region.	smith&nephew ⟷ Sushrut-Adler Group (SUSHRUT, ADLER)
April 1, 2013. Cardiac Science sells diagnostic cardiology product line to Mortara Instruments for $21M	CARDIAC science ⟷ Mortara
Private equity/VC funding	
Jan 2013. Norwest Ventures invests $11m in Perfint Healthcare for commercialization of its recently launched products, new product development and for expansions into new markets.	NVP NORWEST VENTURE PARTNERS ⟷ Perfint
Sep 2013. Ascent Capital invest $14.7M in Skanray Technologies	ASCENT CAPITAL PARTNERS LLC ⟷
May 14, 2013. Goldman Sachs picks up 49% stake in BPL Medical technologies for INR 110 crore. The fresh infusion will be used to further expand the company's medical device business into areas such as imaging and neo-natal care.	Goldman Sachs ⟷ BPL healthcare caring at its best
May 24, 2013. Villgro Innovations invests in healthcare technology start-up Windmill Health. Villgro Innovations supports and incubates innovators and social entrepreneurs for their early stage of growth.	villgro possible. ⟷ Windmill Health Technologies
May 21, 2013. Medical devices start-up Biosense secures $500K from GSF India & Insitor Fund. The funds will be primarily used to launch a series of products for the healthcare sector.	Biosense adding value to life ⟷ GSF
September 2013: TPG invests USD 23million in Sutures India which manufactures and exports surgical sutures through its FDA approved facilities. The deal has been one of the largest private equity transaction in the Indian medical devices and consumables space so far	TPG ⟷ SUTURES INDIA protecting lives

Challenges facing manufacturers

The industry today is facing an entirely new scenario — one in which regulation is ambiguous but changing, markets are shifting, healthcare is penetrating in Tier II cities, FDI restrictions are increasing, customer landscapes and customer demands are constantly evolving and generating entirely new product/ pricing pressures.

Infrastructure

- Inadequate infrastructure - Power, Sewage, Roads, Transport
- No specific pockets/ clusters for development

Financial incentives

- No clear fiscal incentives to support capital-intensive medical device manufacturing

Manpower and technology

- Strong need for professionals who are well versed in both medicine and technology
- Unsteady supply of skilled workers / outdated labour laws
- Vocational training institutes do not include any specific training in medical technology/ precision tooling.

Regulatory mechanism

- Governed along with drugs which makes regulatory compliance difficult
- Lack of regulatory clarity – be it in terms of market entry, infusion of capital, approval processes, labeling and classification etc.

Access to capital/ FDI inflows

- Unwarranted FDI restrictions owing to incorrect classification with Drugs impeding the availability of foreign capital
- No substantial grants for medical technology

Investment/ access to technology

- Limited focus on development activities
- No significant collaborative activities for development of medical technology to address the needs of a populous nation

Absence of a comprehensive reimbursement system

- No clear reimbursement systems in place.
- Public intervention currently is minimal and basic

Regulatory landscape

At a time when the industry is maximizing its reach, scale and potential to address India's healthcare needs, the government is endeavoring to create a supportive enabling environment. The recently tabled "The Drugs and Cosmetics Amendment Bill, 2013" is expected to recognise the uniqueness of medical devices, equipment, consumables and diagnostic products.

Regulatory bodies active in India:

The CDSCO is the principal authority regulating medical devices in India under Ministry of Health and Family Welfare (MoHFW). However, this body is usually referred to as the DCGI
Companies must register all their products with the DCGI before its products can be introduced into the Indian Market
The State Food and Drug Administrations (one for each of India's states and territories) register all other products, accredit most manufacturing plants, and conduct the bulk of quality monitoring and inspections.

Regulatory status of CDSCO

Central Licensing Approval Authority

Serves as a main body that will classify medical devices

Drugs and Cosmetic Act (DCA)

Regulates the import, manufacture, sale, distribution of 14 medical devices (of over 10,000 generic categories) classified as drugs

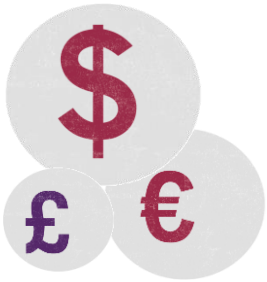
At present, medical devices are not addressed as a separate segment of healthcare, but are governed by CDSCO under Drugs and Cosmetics Act, classifying them as "drugs". However, "force fit" of DCA provisions for medicines to medical devices, lack of a transparent regulatory framework and the ambiguity associated with regards to the regulatory system caused backlogs and delays in the approvals/ other regulatory aspects of critical life saving and life supporting technologies.

Overall, for a healthcare ecosystem to flourish in any economy, it is imperative for the Government and regulatory bodies to recognize that medical technology plays a vital role in the healthcare delivery system and thereby grant it a single window clearance mechanism.

The regulatory impact across the Medtech Industry

Foreign Direct Investment

From November 2011, 100% FDI in the pharmaceutical sector was allowed in brownfield investments (i.e. existing companies) but only with prior government approval (FIPB approval). The policy was, in many ways, a knee-jerk reaction of the government to the spate of M&As in the "pharma" sector and its fear of losing control over essential drugs. This has indirectly placed restrictions on the availability of capital to the devices industry (classified along with drugs) and thereby significantly disadvantaging a sector which was still in its infancy stage and had minimal access to FDI. Timelines for approval/ licenses for medical devices (for manufacturing, registrations and imports) are governed by the DCGI and are characterised by long times for approvals. Industry and Financial Investors hope that the new bill will disengage medical devices from the erstwhile Drugs definition.



International players

Understanding regulation around classification, India-specific labelling and approval of medical devices and equipments has been a key challenge for domestic and international players besides not having any financial incentives (in terms of duties (including CVDs)), infrastructure support and other fiscal incentives. Concerns also exist around the fees associated with the regulatory processes and multiplicity thereof - components of a pack are often individually treated as products thereby multiplying the outgo on fees. Frequent changes in the manner of classification/ India specific-labeling are also issues which most international players are often seen grappling with.

Indian Manufacturers

Domestic manufacturing in India is faced with many challenges that includes considerable time of around 6 to 12 months spent in obtaining the manufacturing licenses which go through the State Drugs Licensing Authority, then to the CDSCO Zonal/ Sub Zonal offices and finally to the CDSCO (DCGI). In doing so, a manufacturer needs to obtain a fresh approval for each brand which not only results in unnecessary delays and loss of potential customers but also places the sector at a disadvantage as compared to its Asian counterpart - China where approvals are required only for generic products and not for every brand. Concerns around the absence of a separate export promotion council and lack of focus on the promotion of Medical Technology Industry are reasons for the country's less than average performance in exports.

Hope on the horizon

Drug & Cosmetics Bill (Amendment) 2013

August 29, 2013. GOI has 'introduced' the much awaited Drugs and Cosmetics (Amendment) Bill 2013 in the Rajya Sabha that provides for setting up of a Central Drugs Authority as an overarching body for regulation of drugs, cosmetics and medical devices. The bill was referred to the Parliamentary Standing Committee (PSC) on Health and Family Welfare and currently awaits approval.

- The purpose of the bill is to bring a comprehensive legislation to cover various aspects of drugs and cosmetics, including regulation of clinical trials and medical equipment sector
- The bill proposes to set up a Central Drugs Authority (CDA) to act as an appellate body for central and state drug controllers and would be a multi-member authority headed by the Health Secretary. Also any reference to the CDSCO in any law other than this Act shall be deemed as a reference to the Central Drug Authority which shall include Central Licensing Authority and State Licensing Authority
- The CDA will access periodically the functioning of the Central Licensing Authority and State Licensing Authority. It shall also recommend to the central government standards for drugs, cosmetics and medical devices, measures to regulate clinical trials, etc.
- The Bill proposes the inclusion of a separate chapter on medical device regulation and clinical trials along with their classification on the basis of GHTF. It also considers the establishment of a Medical Devices Technical Advisory Board with all equipments, devices and electronics regulated under this proposed law
- In line with EU regulatory framework, India will consider the notified bodies to carry out conformity assessment. Clinical trial evaluation of medical devices shall be undertaken as per the guidance laid by GHTF, in case of deviating from the regulation a penalty would be implicated
- Similar to EU & US, manufacturers must obtain certification from notified bodies for quality management, risk management and risk assurance
- Testing and evaluation of medical devices in two government funded laboratories, one for physical testing procedures and the other for chemical and microbial testing procedures
- Apart from setting up regulatory guidelines, industry experts have urged government to establish dedicated centres in the country to oversee the flow of approval, monitoring and certification of medical devices. It will mend the communication gap between agency and manufacturers including domestic and international ones.

Benchmarking best practices across the globe – reimbursement mechanisms

"Affordability and accessibility" are the two major pillars that are highly imperative for the growth of medical technology industry in India. It has been observed that the size of the target population that can afford or have access to such technology is very small. Besides an uncertain regulatory framework, the industry is also struggling with an outdated model of reimbursement for healthcare. That paves way for a robust reimbursement. It has been observed that medical devices are seldom reimbursed by certain government programmes in India with the presence of only a few state specific schemes (for the BPL population) such as Arogyashree (Andhra Pradesh), Rashtriya Swasthya Bima Yojana (various states) and the Bhai Ghahnya Sehat Seva Scheme (Punjab). The primary payer is the patient (75% of the total healthcare spending) with private and public health insurance providers being a close second. Private insurance providers are often characterized by challenges like adverse selection, only risky and expensive treatment burden and complaints of denial of coverage & reimbursement that needs to be addressed.

United States

- In the US, medical devices are approved on the basis of safety and efficacy. They are reimbursed on the basis of novelty and superiority of the product relative to a standard
- Coverage (new device or technology), coding (inpatient/outpatient/durable equipment) and payment are the three parameters for achieving the reimbursement of any device
- Hospital systems are focused on low cost yet improved quality device
- US Government focuses highly on transparency at each stage for the device manufacturer.

European Union

- Primarily, the health care expenditure in the countries is quite high (i.e.12%) when compared to India (4-5%) of the GDP.
- A large chunk of healthcare funding is dependent on statutory health insurance in both public and private health care services

Germany

- Healthcare expenditure is anywhere between 12-14% of the GDP, and the government aims to provide high quality treatment on cost effective basis
- The Government prefers to diversify insurance landscape with more competition which allows patients more options based on fees and services.

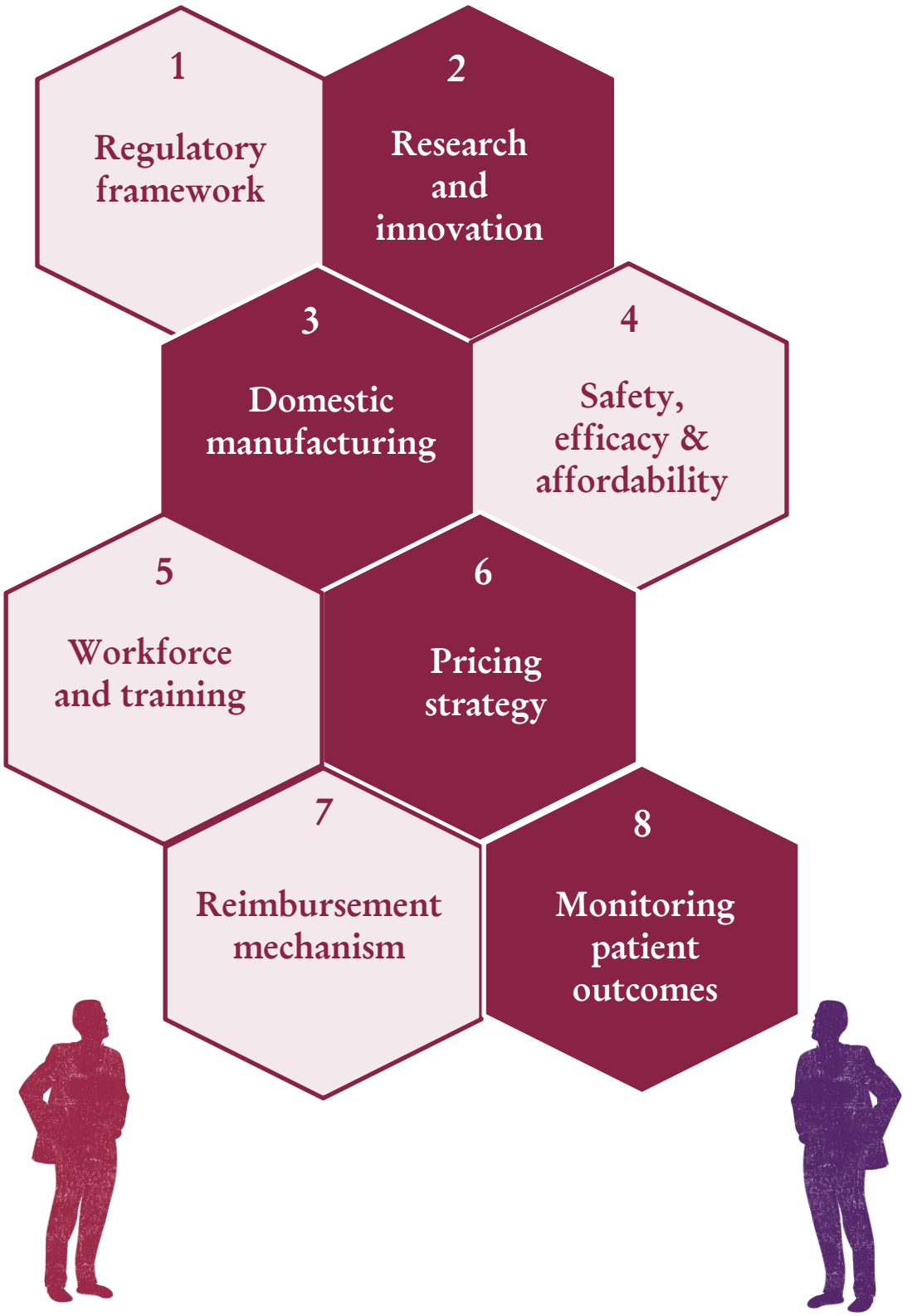
France

- Like other EU members, the healthcare expenditure by government is significant at 12% of the GDP
- The government has consistently reduced the reimbursement rates and tariffs for both drugs and medical devices.

Denmark

- Healthcare expenditure is 9.5% of the GDP
- Healthcare coverage caters to the whole population and claims would not be denied under the guise of "pre-existing" condition.

Conclusions-
Building blocks for progressive change



Conclusions

Covering the holistic needs and requirements of the payer, provider and the regulatory forces is a top priority issue. Set out below are our conclusions on way forward for the industry, from experience-based learning, best practices from around the world and insights from industry leaders. Over time, addressing the points highlighted herein should help reshape the medical technology industry in India, put India on the global map as a provider of innovative and cost-effective medical technologies and ultimately lead to improved patient outcomes.

Clarity in regulation

- The Drugs and Cosmetics (Amendment) Bill, 2013 should ensure development of regulatory guidelines and protocols around safety, efficacy and affordability and reduce current levels of ambiguity in regulation around licenses, new product approvals, classification, imports etc.
- Adequate stakeholder involvement and consultations for correct and effective interpretation and implementation of the statutes from day one
- Build adequate infrastructure and manpower capabilities for the regulating authorities which are trained to handle complications and intricacies surrounding medical devices
- Allow automatic FDI in the sector, enabling domestic players to raise capital, bring in technologies and ultimately compete strongly

Emphasis on Innovation

- Foster collaboration across multiple vendors to arrive at the most efficient and cost effective product – goal being adoption of the most fit-for-purpose product rather than a brand
- Incentivise technical innovations around portability, cost and efficacy through mandatory outlay towards R&D activities
- Innovations around technologies for remote diagnostics and home-based care can go a long way in addressing the healthcare needs of India

Impetus to domestic manufacturing

- Infrastructure development/ cluster based approach – identify at least two clusters in North and South India with specific tax based incentives and low cost funding support
- Specific export based incentives to be provided so that capacities can be built to cater to export markets
- Backward integration is the key to long-term competitiveness in med-tech manufacturing; ancillary industries and raw material suppliers have to thrive along with the technology clusters

Safety, Efficacy and Affordability

- Monitoring mechanism to track comparative effectiveness of alternate technologies. Patient is at the centre of an intricate mechanism of devices, clinicians and other elements – safety of the product and the patient
- Laying down specific safety guidelines for each class of products and establishing an agency for regular testing and monitoring of safety

Workforce and Training

- Building a trained workforce for development as well as maintenance needs of this sector. Biomedical engineering training and certification programmes to be offered as an option in the ITI institutes training curriculum
- Mandatory training hours through industry designed programmes for clinicians – in terms of prescription and/ or usage of the medical technology

Getting the correct pricing strategy

- In some ways, an appropriate reimbursement mechanism should address issues around affordability. Providers should be required to constantly work towards lowering costs, without compromising quality (which the regulatory and safety framework will address). Cost, in medical technology, is tightly linked with design and product innovation which we touched upon earlier
- Using refurbished equipment in a regulated and safe manner should also provide a credible and affordable alternative to payers. Appropriate product approval framework is paramount to ensuring patient safety here

Conclusions

Reimbursement mechanisms

- The role of the government has to shift from provider to payer. Latest Five Year Plan (2012-17) proposes an ambitious expansion programme of healthcare related services including doubling the level of public health spending to 2.5 % of GDP and increasing health insurance coverage from 25 % to 75 %
- GOI and other stakeholders should aim to reduce out-of-pocket payment up to 40% in the coming years
- Making health insurance schemes accessible to the majority of the population by initiating micro-insurance plans or community-based health insurance
- Reduction of insurance premiums for higher penetration, focus on speedy clearances/collections in the current reimbursement schemes in the BPL sector
- Government can consider group coverage to make provision for private sector group employees

Patient Outcomes

- Usage of technology along with a resource pool to analyse and evaluate existence evidence and data. Having a framework to measure outcomes driven by technology will go a long way in giving clinicians the confidence in using innovative products (be it entirely new devices or cheaper yet efficacious local alternatives)
- A robust after-sales service network is critical to ensuring that devices are in the condition required to deliver the right patient outcomes

> **Ultimately, medical technology providers and healthcare providers need to work with patient outcomes and cost-effective care in mind. The government has to play the role of a key enabler, taking care of product approval framework, safety guidelines, FDI policy, reimbursement mechanisms, med-tech clusters for indigenous manufacturing, R&D benefits and up-skilling the workforce. This would provide a strong platform for med-tech and healthcare operators to collaborate on and innovate, delivering what payers need and deserve.**

- Mahadevan Narayanamoni

Appendix: Abbreviations

BPL	Below Poverty Line
CDA	Central Drugs Authority
CDSCO	Central Drugs Standard Control Organization
CLAA	Central Licensing Approval Authority
CVD	Countervailing Duty
DCA	Drugs and Cosmetic Act
DCGI	Drug Controller General Of India
ECG	Electrocardiogram
EU	European Union
FDI	Foreign Direct Investment
FIPB	Foreign Investment Promotion Board
GDP	Gross Domestic Product
GHTF	Global Harmonization Task Force
GOI	Government of India
INR	Indian National Rupee
ISA	Indian Semiconductor Association
ITI	Industrial Training Institute
IVD	In Vitro Diagnostics
M&A	Mergers and Acquisitions
MNC	Multi National Corporations
MoHFW	Ministry of Health and Family Welfare
OPD	Out Patient Department
PSC	Parliamentary Standing Committee
R&D	Research and Development
SFDA	The State Food and Drug Administration
USD m	United States Dollar in Millions
USG	Ultrasonography

About CII

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 over 118 years ago, India's premier business association has over 7100 members, from the private as well as public sectors, including SMEs and MNCs, and an indirect membership of over 90,000 enterprises from around 257 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. Extending its agenda beyond business, CII assists industry to identify and execute corporate citizenship programmes. Partnerships with civil society organizations carry forward corporate initiatives for integrated and inclusive development across diverse domains including affirmative action, healthcare, education, livelihood, diversity management, skill development, empowerment of women, and water, to name a few.

The CII Theme for 2013-14 is Accelerating Economic Growth through Innovation, Transformation, Inclusion and Governance. Towards this, CII advocacy will accord top priority to stepping up the growth trajectory of the nation, while retaining a strong focus on accountability, transparency and measurement in the corporate and social eco-system, building a knowledge economy, and broad-basing development to help deliver the fruits of progress to all.

CII's Medical Technology Division aims at adopting a collective stakeholder approach to give impetus to Medical Technology in India by building a collaborative platform of domestic and international players, with a focus on continued innovation, local manufacturing with appropriate fiscal incentives and pertinent regulations governing this sector.

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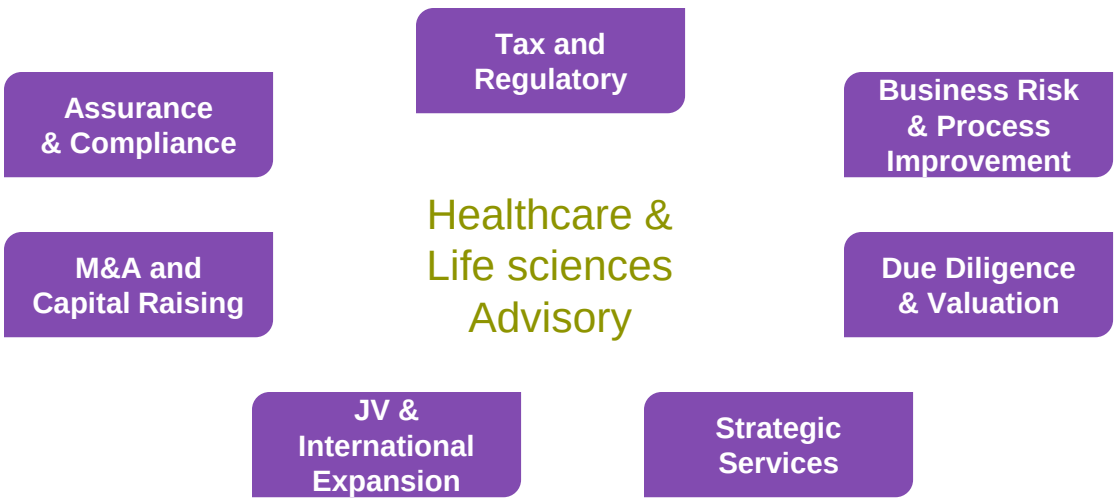

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