FICCI

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Department of Pharmaceuticals
Ministry of Chemicals and Fertilizers
Government of India

PATIENT FIRST

INDIA MEDICAL DEVICE 2018™

'Affordable, Accessible & Quality Healthcare for All'

15 - 17 February, 2018

Bangalore International Exhibition Centre,
Bengaluru

CEOs SPEAK

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तथा संसदीय कार्य मंत्री
भारत सरकार
MINISTER OF CHEMICALS & FERTILIZERS AND PARLIAMENTARY AFFAIRS GOVERNMENT OF INDIA

अ.शा.सं...../ मंत्री (सीएंडफ)
D.o.No...6602..../M(C&F)

Message

It is a matter of great pleasure and pride to convey this message for "INDIA MEDICAL DEVICE 2018" -3rd edition of International Exhibition and Conference on Medical Electronics & Devices sector scheduled to be held from 15-17 February, 2018 at Bengaluru.

With the theme **"Accessible, Affordable & Quality Healthcare for All",** the event would be a positive step towards the development of Medical Devices Sector in India and would also be a platform where the Indian Industry will showcase its strength to an Indian and International audience.

The event has already established itself as a program of repute amongst the healthcare sector stakeholders. Parallel events like the CEO's Forum, Conference, International Regulators Meet, Buyer-Seller Meets and interactive functions will create the right atmosphere for exchange of ideas and for doing serious business.

I am confident that this event will be extremely relevant for the participating companies and I wish them a fruitful participation.

7th February, 2018

(AnanthKumar)

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राज्य मंत्री
सड़क परिवहन एवं राजमार्ग,
जहाजरानी, रसायन एवं उर्वरक
भारत सरकार

सत्यमेव जयते

Minister of State
Road Transport & Highways,
Shipping, Chemicals & Fertilizers,
Government of India

मनसुख मांडविया
MANSUKH MANDAVIYA

Message

INDIA MEDICAL DEVICE 2018 is an initiative of Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India supported by the Federation of Indian Chamber of Commerce & Industry (FICCI) being held from 15-17 February, 2018 at Bangalore International Exhibition Centre (BIEC), Bengaluru.

I am confident that the event will prove to be an excellent platform for the Indian Medical Devices sector to interact with all stakeholders and policy makers. Scientific, Technical and Policy level interaction on the latest developments in the sector will go a long way in charting out a course for the industry in the future.

I extend my greetings to all the participants and hope that there are significant takeaways from this event.

(Mansukh Mandaviya)

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India Medical Device 2018

Affordable, Accessible & Quality Healthcare for All

The Indian Medical Devices industry is currently valued at around USD 4.9 billion and has been growing at an average rate of 17% during the last five years. It is strongly believed that growth will outperform the pace, resulting in the Indian Medical Devices market crossing USD 25 billion by the year 2025.

The main factors for this growth are rising incidence of chronic diseases, increased urbanization and a growing elderly population. The increased awareness about latest technology solutions to augment life and rehabilitation have also given a further boost to the sector. The influx of medical technology has strengthened the existing healthcare infrastructure in various ways right from digitizing medical tests, diagnostics and therapeutic procedures to enhancing the reach of healthcare through Telemedicine and Health IT.

However, the sector has not been able to realize its full potential owing to numerous challenges being faced by the industry. It is imperative for all the stakeholders to converge their efforts and address these challenges to provide the required impetus that India needs in realizing its vision of achieving **'Affordable, Accessible & Quality Healthcare for All'**

India Medical Device 2018 is being jointly organized by the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India and Federation of Indian Chamber of Commerce & Industry from 15th-17th February, 2018 at Bangalore International Convention and Exhibition Centre, Bengaluru. The endeavour is to promote India as a quality manufacturing hub in the Medical Electronics and Device sectors through a platform for manufacturers to showcase their products and technology. It will also provide an opportunity for all the stakeholders of the sector to deliberate on the road ahead and find solutions for the current challenges.

FICCI Medical Device Forum

FICCI had launched the FICCI Medical Device Forum (MDF) to help respond to the requirements of the medical devices industry and create awareness about the opportunities in the sector. Since its inception, FICCI MDF has been working closely with various departments of Government of India viz. Ministry of Health & Family Welfare; Department of Commerce, Ministry of Commerce and Industry; Drug Controller General of India (DCGI); Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers and Ministry of Electronics and Information Technology. The Forum has supported the development of the Medical Device Policy as well as Rules and has also been actively working with the National Pharmaceutical Pricing Authority (NPPA) on the pricing policy for devices.

FICCI has been committed towards an appropriate and balanced National Medical Device Policy that is designed to enable a quick and well-planned acceleration of the sector. FICCI MDF has believed that the policy should acknowledge the sub-segmentation of medical devices into simple engineering and complex engineering, and apply distinct policy treatment, wherever applicable.

The Forum has also been working towards promoting innovative and appropriate technologies through local manufacturing and believes that this will help in development of

custom products suited better to our disease pattern and patient demography thereby reducing the overall cost of delivery. Further, the Forum also advocates the need to develop our own quality control standards specific to Indian context.

Recently the FICCI Medical Device Forum has been merged with the FICCI Medical Electronics Forum to form a FICCI Committee that will include Medical Electronics, Equipments and Devices as well as In Vitro Diagnostics (IVDs). The new Committee will focus on the concerns of all these subsectors and work with the government and other stakeholders to help augment this significant and highly specialized sector of Medical Technology in India.

CEOs Speak

Overview

India has made significant strides in the healthcare sector in past couple of decades. This is reflected in progress made towards achieving lower Maternal Mortality Rate (MMR), Infant Mortality Rate (IMR), Total Fertility Rate (TFR) and other key indicators. However, with 21% of global disease burden and alarming increase in non-communicable and lifestyle diseases, incremental changes will not be enough for providing "quality healthcare to all". In fact, India envisions 'Universal Healthcare' in its National Health Policy 2017 as well as through its recently announced *"Ayushman Bharat"* scheme. Medical technologies through their disruptive solutions have the potential to provide the impetus needed to make our healthcare system more accessible, affordable and sustainable going forward.

The global medical device market, currently estimated at USD 389 billion, is expected to grow at a CAGR of 4.4% per annum. It is a highly innovative and rapidly advancing industry[1],[2] that encompasses various areas like diagnosis, treatment as well as monitoring. However, in India, most of the indigenous manufacturing is restricted to medical consumables and technologically advanced innovation has witnessed low levels of penetration and adoption.

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[1] *https://www.prnewswire.com/news-releases/global-medical-devices-market-2017---us-versus-international-sales-300557677.html*

[2] *https://www.visiongain.com/Press_Release/498/The-global-medical-devices-market-will-reach-398-0bn-in-2017*

Despite the existing challenges, the Indian medical technology sector has witnessed rapid growth in recent years, largely driven by unmet clinical needs and improved focus on domestic manufacturing. Medical devices that represents ~6%[3] of the overall Indian healthcare industry, is presently valued at approx. USD 4.9 billion[4] and is expected to grow to USD 25-30 billion by 2025[5]. Still at a nascent stage, it has found its place in top 20 global medical device markets and is the fourth largest medical device market in Asia, mainly due to the advantage of 'design-to-cost' factor, owing to price-sensitivity in the Indian market. The export of medical devices from India has grown from USD 0.87 billion in 2012 to USD 1.2 billion in 2014[6]. USA has been the chief destination for export and contributes close to 15 per cent of the export trade for India[7].

Multinational companies, especially in several high technology segments, are currently driving the growth of Indian medical devices sector with imported medical devices generating about 75% of the sales[8]. The import of medical devices had grown from USD 2.46 billion in 2012 to USD 2.87 billion in 2016. However, this should not be seen as a deterrent. Some of the most developed markets of the world, like Germany and Singapore, have been entrenched with foreign industry giants from Japan and USA. According to data published by the Government of USA, the import market size for medical devices was USD 23.3 billion in Germany[9] (~39% of its market size) and USD 11.2 billion in Singapore[10] (~51% of its

[4] *http://www.skpgroup.com/data/resource/skp_the_medical_device_industry_in_india_.pdf*

[5] *http://www.nathealthindia.org/pdf/Deloitte_NATHEALTH_Medical%20Devices%20%20Making%20in%20India.pdf*

[6] *http://www.nathealthindia.org/pdf/Deloitte_NATHEALTH_Medical%20Devices%20%20Making%20in%20India.pdf*

[7] *http://www.nathealthindia.org/pdf/Deloitte_NATHEALTH_Medical%20Devices%20%20Making%20in%20India.pdf*

[8] *http://www.skpgroup.com/data/resource/skp_the_medical_device_industry_in_india_.pdf*

[9] *https://2016.export.gov/industry/health/healthcareresourceguide/eg_main_108585.asp*

[10] *https://www.export.gov/article?id=Singapore-Medical-Devices*

market size) in 2017. In order to bring India higher on the global medical technology map, we need concentered efforts, on both demand as well as the supply side.

The Government of India has taken some early steps to boost this sunrise segment in the country. One such step was permitting 100 per cent automatic foreign direct investment in the sector, which helped attract FDI worth USD 1.57 billion during April 2000 and March 2017. Rolling back of import duty concessions for 67 medical devices has also given a boost to the sector. A series of Medical Device Clusters have emerged due to supportive state-level policies and the government is now in the process of setting up Medical Technology Parks across the country.

India has also seen augmentation of the sector as a part of the "Make in India" initiative that provides immense opportunities to local manufacturers and startups as well global players. However, it is important to understand that medical technology is a highly specialized sector covering very diverse and niche sub-segments. So, it may not be viewed from the same lens as that other segments like FMCG or electronics goods. The nature of operations, marketing, supply chains and skill requirements of this industry are very distinct and thus, requires a strategic approach tailored to its requirements.

The year 2017, although has been a significant year for the medical devices sector, from the perspective of policy and regulations as well as industry growth, it has also brought in new challenges that need attention from both policymakers as well as the industry in order to sustain the momentum. The government's move to separate medical devices from drugs in the country's policy framework is indeed laudable. However, the government needs to provide further clarification since there is uncertainty about the impact of new Medical Device Rules and eventually follow this up with a different Act, completely separating medical devices from pharmaceuticals.

Price control is likely to emerge as a major impediment, which is likely to inhibit the growth of medical device industry is India. The recently announced price control policy, while intended to improve affordability, needs reconsideration before further implementation. In its current form, the policy will have limited impact on patient costs and could rather, deprive India of innovations and new technologies in the future, besides restraining sectors like high-end tertiary care and medical tourism. It is also imperative for us to realize the need for appropriate Trade Margin Rationalisation rather than unnuanced caps on device ceiling prices.

It is crucial that strategies and measures adopted by the government provide clarity and assurance, not only to the industry but also to the most important stakeholder who is the end-user of technology i.e. the patient. "Patient-centricity", which has evolved as the key element of an effective healthcare ecosystem does not seem to find adequate focus in the current scenario. This will adversely affect the existing trust deficit in the entire healthcare ecosystem. Hence, we need to be collectively mindful that the ongoing reforms help strengthen patient engagement, safeguard doctor-patient relationship and optimize revenue in the healthcare ecosystem, which is significantly consumer and market driven.

Medical technology has the potential to create a new patient-centric business model that combines devices with big data analytics and artificial intelligence to develop innovative and personalized products. Devices can also provide a unique platform that helps us to consider the appropriateness of treatment, availability of quality healthcare and reduce the pressures of financing and accessibility. It is therefore critical to create the right environment to foster the growth of this sector by coming up with a globally harmonised approach to the regulation of life-saving medical devices.

This White Paper is an effort to bring the voices of the industry to the forefront and re-focus our efforts on creating appropriate environment as well as building patient-centricity in our system. Some of the key industry leaders have shared their viewpoints on pressing issues and presented the solutions that can help us reshape the future of our country's healthcare landscape without hampering the interests of any stakeholder.

The themes shared in the paper are:

- **Lack of Latent Demand and Manufacturing Expectations:** India has been struggling with low healthcare spend and huge gaps in infrastructure. This has led to a lack of latent demand in the sector, hence affecting the need for medical technology. With robust policy reforms and appropriate investments in healthcare infrastructure and delivery, it is expected that there will be an increase in the latent demand of healthcare services. This increase in demand will further provide impetus for growth and advancements in the diagnostics, pharmaceutical, medical devices and other allied industries.

- **Need to Address Policy Asymmetry in Medical Devices Sector:** Medical technology, the smallest wheel of the healthcare continuum, being far more complex than the more deciphered healthcare delivery and pharmaceutical sectors, needs to be given due recognition by our policy makers and thought leaders. The recent pathway to policy reforms, although well intentioned, needs to be reconsidered with a larger vision of providing stability to this highly specialized sector, while keeping with the goals of affordability and access to quality healthcare.

- **Affordability in Healthcare:** It is critical for the government to recognize the advantages of trade margin rationalization over capping of device prices, which can lead to greater transparency and higher affordability. Although fixing trade margins would

restrict how much a product's price can be raised from the import or manufacturing cost, but innovation would still be rewarded.

- **Increasing Insurance Penetration to Augment Access to Innovative Technologies:** Lack of affordability for high-end technology devices among large section of Indian population has been the major cause of low per capita consumption of medical devices. Financing channels, chiefly health insurance provisioning through increased penetration as well as innovation in insurance products to provide coverage for new technologies and procedures that include high-end medical devices is the way forward.

- **Non-Compliance to Global Standards and a push for Local Standards:** Obtaining clearance from a regulator or a certifying agency is a critical part of stepping into any new market. Often these processes pose a major challenge to manufacturers who sell in the global market due to the time taken duplication of efforts. We need to work towards a unified global standard or at the very least towards eliminating needless duplication.

ARTICLES

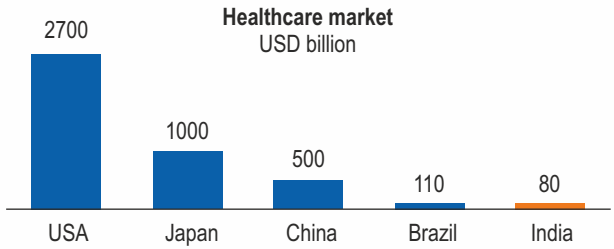
INDIAN HEALTHCARE INDUSTRY: LACK OF LATENT DEMAND AND MANUFACTURING EXPECTATIONS

- ***Mr Sushobhan Dasgupta***, *Managing Director, Johnson & Johnson Medical India Ltd.; VP - DePuy Synthes, Johnson & Johnson Medical Asia Pacific*

INDIAN HEALTHCARE INDUSTRY

Indian healthcare has been constantly evolving over the last decade. Healthcare has become one of India's largest industries - both in terms of revenue and employment generation. Healthcare comprises of hospitals, medical devices, pharmaceuticals, medical tourism, diagnostics, health insurance and medical equipment. Despite strong growth, the Indian healthcare market continues to be significantly smaller compared to other large economies.

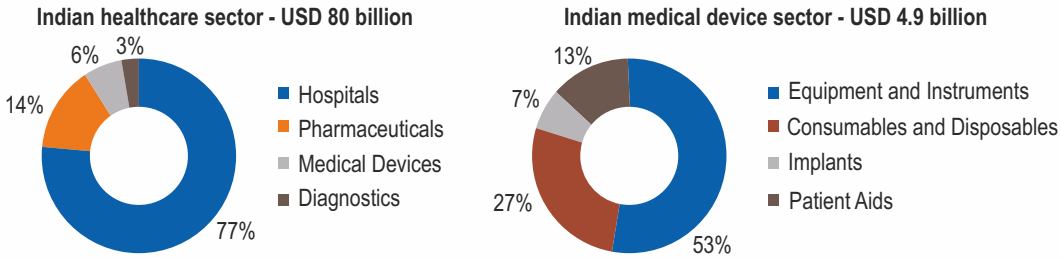
Figure 1: India Healthcare market as compared to the larger economies in the world



Source: IBEF Healthcare Report 2015, SKP analysis

Within the healthcare industry, the Indian medical device sector is estimated at USD 4.9 billion. While the sector is relatively small, it has seen unprecedented growth in the past few years. The sector has grown at a CAGR of 17% during the last five years and is expected to maintain strong double-digit growth of 15% over the coming decade[11].

Figure 2: Sector wise break-up of the Indian Healthcare industry, further break up of Medical Device Sector



Source: IBEF Healthcare Report 2015, SKP analysis

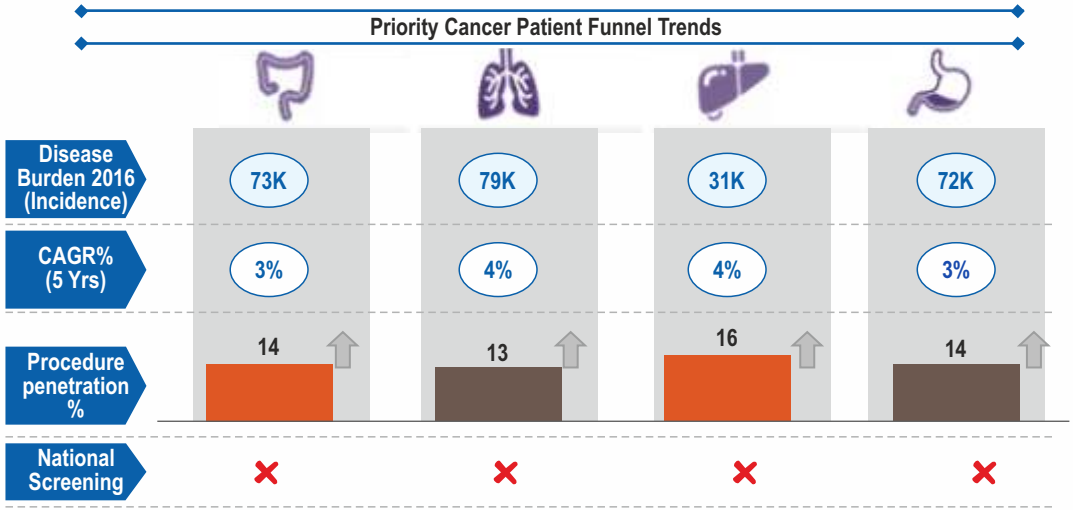
LACK OF LATENT DEMAND FOR SURGICAL INTERVENTION

Latent demand may be defined as the desire or preference, which a consumer is unable to satisfy due to lack of information about the product's availability, or lack of financial resources. In the context of surgical interventions, we would need to look at demand for surgery with respect to the disease burden that exists in the country. Let us take surgical oncology as a case in point (Figure 3). The disease burden is high across all the key organs

[11] *http://www.skpgroup.com/data/resource/skp_the_medical_device_industry_in_india_.pdf*

(intestinal cancer, lung cancer, hepatic cancer and gastric cancer) and has been growing significantly at around 3% to 4%. However, the procedure penetration rates have been quite low, hovering around the 15% mark.

Figure 3: Oncology- Patient Funnel Trends



Key factors that lead to latent demand not being addressed include:

1. Availability of trained Healthcare Professionals (HCPs)
2. Healthcare spending as a percentage of GDP
3. Insurance coverage vs Out-of-Pocket Expenditure
4. Provider trends & access of healthcare to masses

Availability of Trained Healthcare Professionals:

With the large population of the country the challenge faced by India is to be able to develop and train the adequate number of HCPs to be able to meet the requirements posed by the disease burden. Currently, India has an average of 0.7 doctors available for every 1000 of the population as opposed the world average of 3 doctors per 1000 of the population[12]. To match the world average, we need up to four times more doctors than the current numbers. The state of the nurses and paramedical staff is equally challenging.

Figure 4: Comparisons of India vs other countries in Healthcare infrastructure parameters

Per 10,000 population	China	India	Indonesia	Malaysia	Singapore	Thailand	Australia	USA
Health Workforce Density								
Physicians	14.6	6.5	2.0	12.0	19.2	3.0	38.5	24.2
Nurses and midwives	15.1	10.0	13.8	32.8	63.9	15.2	95.9	98.2
Dental	0.4	0.8	0.4	1.4	3.3	0.7	6.9	16.3
Infrastructure								
Hospital beds	39	9	6	18	27	21	39	30

Healthcare Spending as a percentage of GDP:

The global average for healthcare expenditure as a percentage of GDP is approximately 10%, while India is currently languishing at mid-single digits[13]. The recent national health policy has been positive in this regards and stated that the Government aspires to progressively achieve Universal Health Coverage (UHC) thereby ensuring improved access and affordability of quality primary, secondary and tertiary care services.

[12] *CRISIL research / Apollo investor presentation*

[13] *WHO - World health statistics 2015 / Apollo investor presentation*

Figure 5: Total healthcare expenditure as a % of GDP, with public and private trends

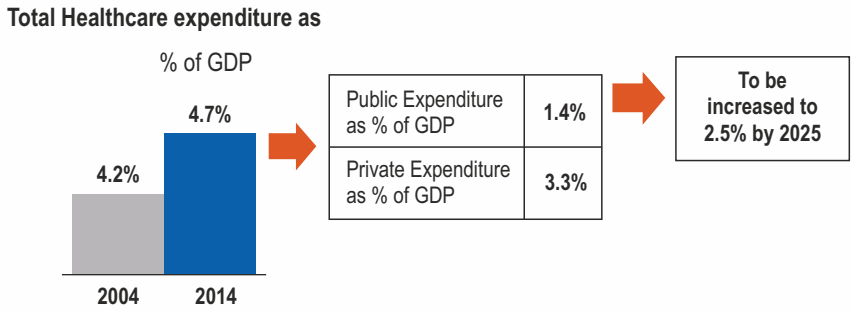
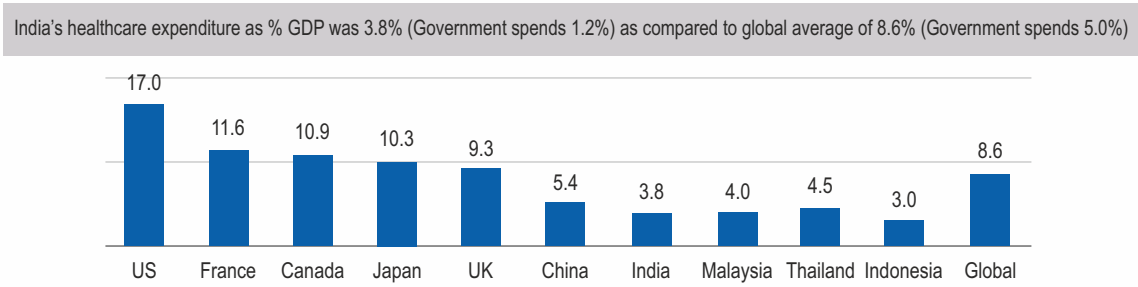


Figure 6: Total healthcare expenditure as a % of GDP, as compared to other countries

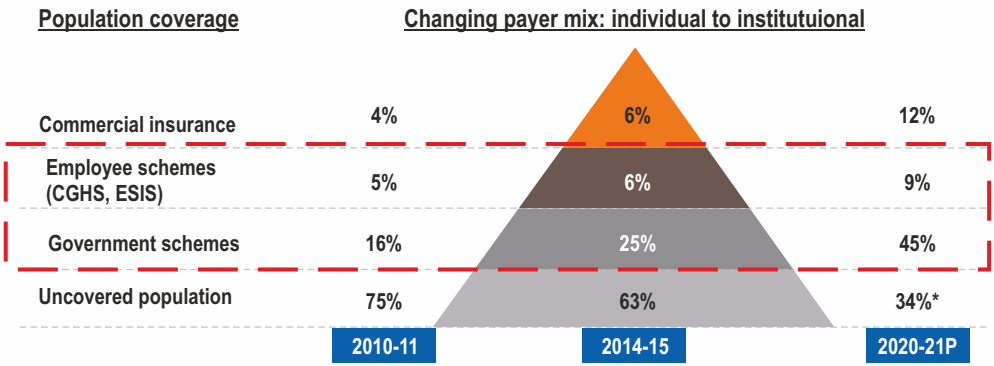


Insurance coverage vs Out of Pocket Expenditure:

High dependence on 'Out of Pocket' expenditure for treatment has been one of the key reasons for slow adoption of innovative technologies. And, it goes without saying that technological innovation requires significant investment. The global coverage of population having health insurance is estimated to be upwards of 80%, while in India we are around the 35% mark. This primarily includes government as well as employee schemes that have smaller reimbursements available to the beneficiary. The encouraging part has been

the consistent growth in the private health insurance sector, which indicates promising progress over the next decade as well.

Figure 7: Insurance trends over the past 7 seven years and future projections



With the recent announcement of *Ayushman Bharat* program, the new National Health Protection Scheme (NHPS) is expected to be game changer, as it will cover 40% of the country's population. Since majority of healthcare services are delivered by private healthcare providers, participation of private sector will be integral in successful delivery of NHPS. Increase in demand in healthcare will also provide impetus for growth and advancements in the diagnostics, pharmaceutical, medical devices and other allied industries.

Provider trends & Access of healthcare to the masses:

The Indian healthcare delivery is highly fragmented in terms of the types of providers and the geographical mix. Taking hospital beds as a measure, India has an average of 1.4 beds per 1000 of the population as compared to a global average of 5 beds for every 1000.

Figure 8: Healthcare delivery is geographically fragmented and is evolving.

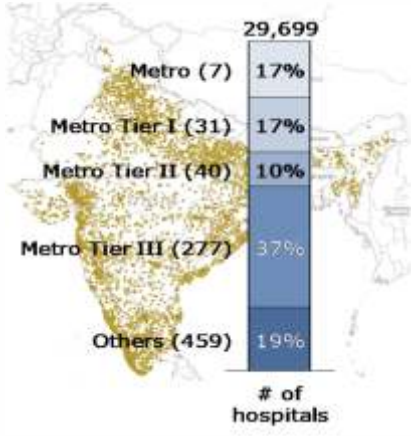


Figure 9: Expansion plans are focused on emerging geographies that will account for 45% of the new hospital additions

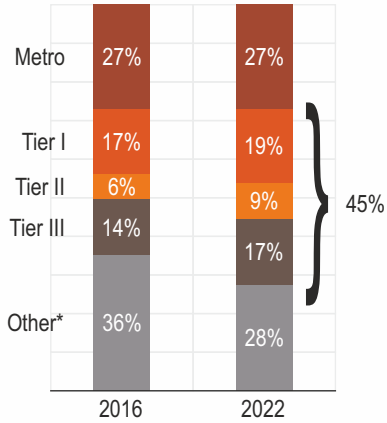
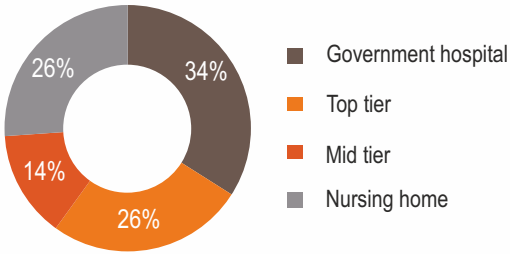
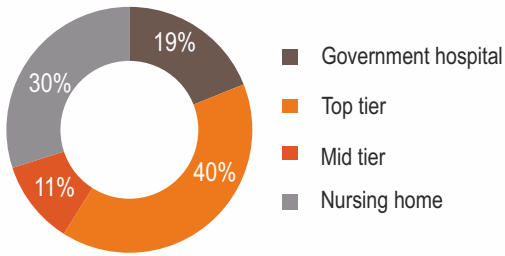


Figure 10: The changing mix of healthcare providers over the last decade with private hospitals taking giant strides

Shares in Healthcare Spending in India, 2005



Shares in Healthcare Spending in India, 2005

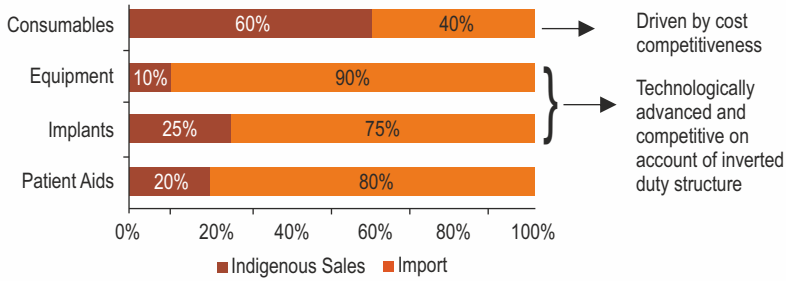


Source: IBEF Healthcare Update (Dec 2017)

LOCAL MANUFACTURING

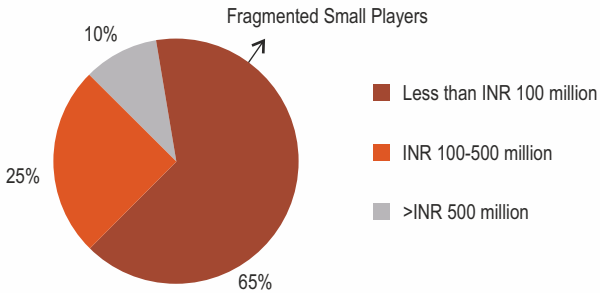
Indian healthcare industry is highly import dependent, and the local manufacturing in fragmented across multiple small players. Supporting local demand for medical devices by expanding provision of services in its public health and healthcare programs can catalyze investments in the country by meeting latent demand of the services, by making them affordable and accessible, commensurate with the objectives of India's National Health Policy 2017.

Figure 11: Segment wise import proportions



Source:Beroe Inc

Figure 12: Highly fragmented domestic Industry



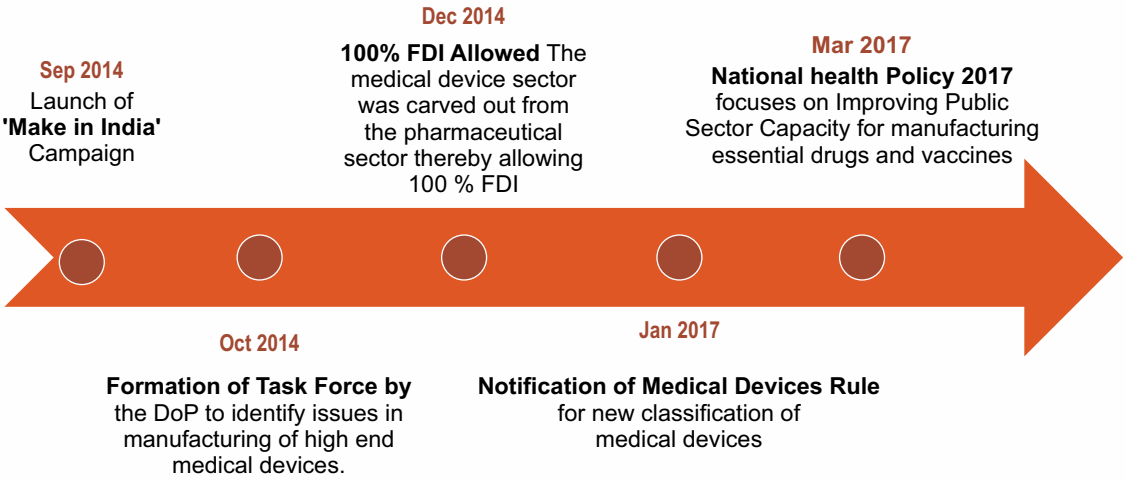
Source: Association of Indian Medical Device Industry (AIMED)

The Evolving policy landscape to support Local Manufacturing:

The policy landscape in India is actively evolving, and the government is taking active measures to ensure growth of local manufacturing. The government launched the 'Make in India' campaign and subsequently formed a task force and initiated the process of implementing its various recommendations such as separating medical devices from the definition of 'drugs' and allowing 100% FDI for brownfield and greenfield investments in the sector.

More guidelines coming out in in the industry where the manufacturing footprint of an organization in India is becoming a significant parameter even in procurement through tendering in government hospitals. Such guidelines are making the MNCs deliberate on setting up manufacturing in India, and at the same time offering an edge to the indigenous manufacturers and hence supporting their plans.

Figure 13: Key Policy trends impacting the manufacturing sector



THE ROAD AHEAD

When we look at the big picture India's healthcare industry is one of the fastest growing sectors and it is expected to reach USD 280 billion by 2020[14]. Indian Healthcare is on an unprecedented growth trajectory with positive developments across all the areas impacting the latent demand, and in turn the local manufacturing requirements positively supported by the policies of government of India trying to strengthen the manufacturing capabilities.

While the sector is currently import dependent with limited or no access to new technology, with the government's improved focus, favorable policies, backed by the regulatory scenario post change indicates the possibility of strong, sustainable and technically sound domestic industry with high quality standards and affordable pricing. The industry can now not only produce high-quality, low-end products but can also manufacture high-end products through the assistance provided by the government (through regulatory and policy changes) and technical collaboration with their foreign counterparts. We are also witnessing some of the larger MNC players in the medical devices space setting up manufacturing operations in India, and in future we are likely to see even more of such practices.

[14] *https://www.ibef.org/industry/healthcare-india.aspx*

Need to address policy asymmetry in the medical devices sector

- ***Mr Probir Das**, Chair, FICCI Medical Devices Forum; Managing Director, Terumo India Pvt. Ltd.*

Introduction:

The medical devices sector in specific and healthcare in general, have been at the forefront of socio-political discourse over the past couple of years. This is a welcome change in a country, which has faced challenges in providing equitable access to healthcare.

India's demographic dividend hinges upon the wellbeing of its society. However, this dividend can be completely wiped out by impending threats like NCDs, which is likely to account for 75% of India's disease burden by 2030, and may result in USD 5 trillion loss to the economy. Thus, it is important that the Government is recognising the need for Universal Healthcare Delivery even though it has been unable to provide adequate budgetary provisions.

Medical technology, the smallest wheel of the healthcare continuum, being far more complex than the more deciphered healthcare delivery and pharmaceutical sectors, has not been given due recognition by our policy makers and thought leaders. It is high time we realize that without the apt application of the latest innovative medical technologies, the healthcare objectives of our country surely cannot be met.

Relevance:

Medical technology in India is disproportionately small vis-à-vis other key markets e.g. China's per capita consumption of medical devices is estimated at USD 178, Brazil's at USD 28, Russia's at USD 43 while for India, it is estimated at USD 3[15].

Globally medical technology is estimated at USD 389 billion market[16] with India contributing only ~1.3% to it. Uniquely, 60% of share of this market belongs to less than 50 top global players, and the last half decade has seen mega M&As to further consolidate this. Perhaps the reason for this consolidation is the huge sectorial dependence on legacy know-how and need for massive financial staying power and incremental innovation driven high resilience to quick obsolescence.

Further, though very often parallels are drawn between pharmaceuticals and medical devices manufacturing, very little of medical devices, apart from the low risk and non-complex devices, can ever be compared to pharmaceuticals. Quality of medical devices relies on their continuous improvement, unlike the blockbuster nature of pharmaceuticals, and hence its manufacturing requires a far larger and continuous plug-in into medical research, an innovative bio-design community and a commensurate nimble component supply ecosystem. It is imperative for the stakeholders to understand these unique needs in order to create any meaningful policy interventions for high risk, high complexity sub-segments of medical devices.

Current Scenario:

Currently there is an absence of a nuanced, cogent, outcome focused and stakeholder consulted policy. In the absence of this policy, and deep policymaker understanding

[15] *Statista, Medical devices expenditure per capita*

[16] *https://www.prnewswire.com/news-releases/global-medical-devices-market-2017---us-versus-international-sales-300557677.html*

regarding the various diverse sub-segments of this sector, there have been well intentioned, yet disjointed ineffective movements to regulate prices, increase of import duties and sporadic formation of MedTech parks and a lack of a complete ecosystem approach for sub-segment focussed sectorial development. Price control of coronary stents and knee implants have seemingly brought investment in this sector to a naught to only USD 173 million in this fiscal, as compared to USD 439 million in 2016[17]. Several engagements between leading MedTech park providers and global investors also seem derailed, and the overall global sentiment for India as an attractive medical device investment destination has taken a massive hit.

However, there are silver-linings too. The government's industry aligned effort of adopting New Medical Device Rules, providing operational ease from a regulatory standpoint, and the most recent budget announcement of Rs 5 lakh health cover provision for 10 crore Indian families are excellent developments. These now need to be taken to the next level swiftly – through a Medical Device Act and by effectively operationalizing the Health Insurance Program, respectively.

[17] *https://www.telegraphindia.com/india/fdi-fall-and-medical-device-cap-coincide-201699*

10 Gaps and Recommendations:

SL. NO	GAPS	RECOMMENDATIONS
1	Lack of a MedTech Vision 2030 Document	Vision document that balances the following: • Policy continuity and stability • sub-segmented approach • quality of care provision & treatment outcome • cost of delivery • leveraging the global ecosystem • sub-sector nuanced innovation capability • marrying MNC innovation capability with indigenous low cost manufacturing
2.	Current price control approach neither creating affordability nor access	• Globally benchmarked health technology assessment and value based healthcare approach, incentivising innovation. • Trade margin rationalization
3.	Un-sub-segmented, hence unclear Manufacturing expectations	• Sub-segment nuanced, capability linked manufacturing expectations. We need to plot our expectation map on capabilities that we can use now and what we need to build over the next decade. • High quality MedTech creates employment in provider segment (which is the 3rd largest employer in India). If we compromise quality for speed to force create manufacturing bases, it will adversely impact quality and ruin the provider sector growth and job creation potential.

SL. NO	GAPS	RECOMMENDATIONS
4.	Archaic Import substitution focus led import duty increase	• No country is import independent in medical devices; even China which is a far larger market and a net exporter of medical devices imports 70% of its domestic consumption of medical devices. Yet it recently reduced its import duties from 4.3% to 3%. • For those sub-segments those are currently produced in India at globally exportable quality, the import duties may be kept at current levels, but for those sub-segments that are not, duties must be brought down to create lower cost access to patients, expansion of product usage, job creation under provider segment, and eventual market expansion led domestic manufacturing.
5.	None or very limited Innovation / Bio-Design facilities	• Given Indian healthcare delivery is unique and low cost, India can become the exporter of frugal innovation globally. Currently the bio-design led MedTech innovation centres are just too few. The Policy must emphasize on significant scaling up of such centres.
6.	(Even with New Rules) Medical Devices fall under Drugs	• The Rules are a great start, but we need to quickly get legislative support and form a Medical Devices Act, completely separating medical devices from Pharma.

SL. NO	GAPS	RECOMMENDATIONS
7.	MedTech parks are in places without ecosystem support	• Map the existing medical devices manufacturing rich zones (e.g. Bawal – Faridabad, Bangalore, Trivandrum, Pune, etc.) and provide them with Park Status along with common facilities (testing, QA/QC, Sterilization, Packaging, Advanced Warehousing, etc.) • Provide attractive tax breaks for global company mega-projects to attract manufacturing investments. • Align med tech parks to centres of medical excellence and research.
8.	Small sized market. General texture of market is treatment quality ungoverned	• Quick and time bound operationalization of Central Government Health Cover (National Health Protection Scheme of Rs 5 lakhs for 10 crore poor families) • Creating standard treatment guidelines • Creating outcome registries
9.	Risk of a non-globally aligned, protectionist, local quality system	• Globally the standards for medical devices are ISO (devices) & IEC (electronics). • There seem to be movements in India to create standalone parallel quality systems (e.g. ICMED)

SL. NO	GAPS	RECOMMENDATIONS
		• This will cut India off from a global supply chain, hurt Make in India for the world, and create a low quality perception about India in global markets. • Hence, this should be prevented and focus should instead be increased to improve ISO / ICE appreciation and scalability.
10.	Lack of a single window system / general EoDB challenges	• Currently to set up a new facility, approximately 35 different licenses may be required. • Create a consolidated facilitation desk (under DOP or DIPP) and create a single window touch point.

[17] *https://www.telegraphindia.com/india/fdi-fall-and-medical-device-cap-coincide-201699*

Affordability in Healthcare

- ***Mr Madan Rohini Krishnan***, *Vice President – Indian Subcontinent, Medtronic PLC*

For the first-time in India's history, we have seen an unprecedented level of focus on healthcare. Recently, we saw a series of announcements and programmes aimed towards quality and affordable healthcare for all, from the Government of India, with the release of National Health Policy, Medical Device Rules, Price Capping of Stents and the path-breaking National Health Protection Scheme i.e. Ayushman Bharat. Of all these announcements, price capping of stents has been the most debated topic as it relates to the cost of healthcare in India.

Its a well-known fact that topic of 'cost of healthcare' is of a constant debate and discussions world over. Some progressive countries have been able to differentiate between the cost and the value of healthcare. The difference is, where one looks only and only at the cost of healthcare without a view on outcomes or benefits; while for the other, looks at the outcomes for the patients and the healthcare system along with the cost and strives to find a balance.

Healthcare in India faces challenges of 3As – Awareness, Access and Affordability. One needs to look at solving all three challenges together to find real benefits flowing to the patients and ascertain the end result of patient outcomes. The need to address 3As

holistically becomes profound for medical devices as they are used for surgical treatment unlike drugs. While industry supports government's efforts to address two elements of the 3As - Access and Affordability, the price capping of stents has not resulted in meeting these objectives. A recently released study from IQVIA-AdvaMed suggested that the reduction of stent prices did not lead to a surge in number of angioplasties and the reduction of prices almost 85% did not result in corresponding reduction in the overall procedure cost for patients.

Moving forward, we need actions which address the root-cause of the challenges of affordability that primarily revolves around the channel margins, at the same time bring systemic solutions to the challenges of Access and Affordability.

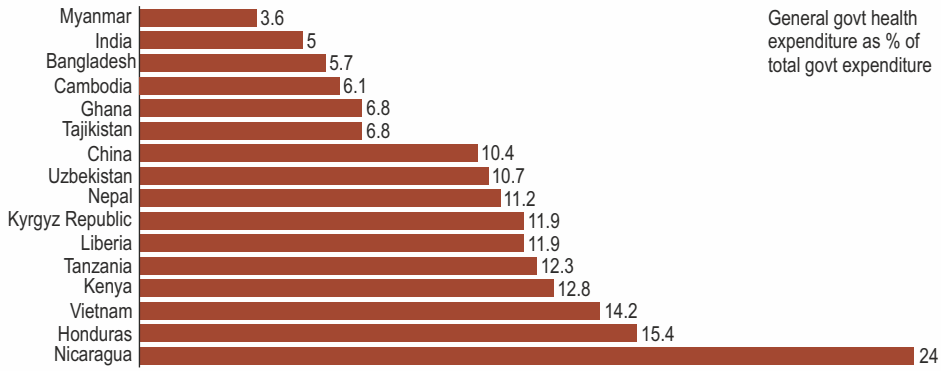
- The challenges on the channel margins were brought up through the data published by NPPA a year back. The Channel Margin i.e. Trade Margin is the difference between the price at which the manufacturers/ importers sells to trade/ hospital and price to patients/MRP. In the short term, trade margin challenge can be addressed by adopting the recommendations from the "Report of the Committee on High Trade Margins in the Sale of Drugs," from the Department of Pharmaceuticals. The report suggested implementing 'Trade Margin Rationalization' can lead to greater transparency and higher affordability at the same time help patients to gain access of innovative therapies.
- In the longer term, we need to evolve more scientific approaches towards evaluating the value of medical technology through real-world evidences, patient outcome research or registries or health technology assessments. These evidence based approaches eventually will help create a solid foundation for the government's vision of providing 'Quality and Affordable Care for All'.


Increasing insurance penetration to augment access to innovative technologies

- ***Ms Shobha Mishra Ghosh***, *Assistant Secretary General, FICCI*
- ***Mr Amit Mookim***, *General Manager – South Asia, IQVIA*

While the Indian economy has pursued a path of expansionary growth and development, it has not yet been able to achieve the goal of providing universal access to healthcare. The government has been facing various challenges as it seeks to provide citizens with affordable and equitable access to high quality healthcare, including procedures involving innovative medical technologies.

India lags behind most developed as well as comparable low and middle income countries on health expenditures as percentage of GDP. Compared to India's 5% (including both



Source: World Health Organization, World Health Statistics, 2017

government and private expenditure), China spends 10.4% of its government budget on health. Vietnam spends 14.2% and Nicaragua a huge 24%[18]. India's relatively limited investment in healthcare has resulted in inequitable access to supportive health infrastructure that enables successful provision of necessary healthcare services.

Despite a double-digit growth rate of the medical devices market, the Indian per capita consumption of medical devices remains significantly low at ~USD 3.0[19]. It is much lower than the global average per capita consumption of USD 47, apart from the per capita consumption of developed nations like USA and Germany. Lack of affordability for high-end technology devices among large section of Indian population is the key reason for this low per capita consumption.

Financing is one of the most critical determinants for quality healthcare infrastructure of a country. It is closely linked to the provisioning of services as well as the quality of outcomes. The current landscape of health financing in India is largely characterized by out-of-pocket payments, with tax breaks provided for health insurance. The National Sample Survey data shows that Indian households are increasingly relying on their own income and straining their savings to finance healthcare expenses. This holds true for both rural and urban households.

The overall out-of-pocket spending for households has risen significantly over the past decade. Studies show that 67% of all expenditure on health is out-of-pocket and of this, 63%

[18] *http://www.livemint.com/Opinion/YrcGbLpfbqrWH55xAzehUM/Why-India-ranks-below-Liberia-in-global-healthcare-rankings.html*

[19] *http://www.nathealthindia.org/pdf/Deloitte_NATHEALTH_Medical%20Devices%20%20Making%20in%20India.pdf*

is on out-patient expenditure[20]. The high burden of out-of-pocket expenditures on health in India pushes almost 63 million people below the poverty line every year.

Although the public sector spending accounts for less than a quarter of the total health spending in India, it has a major role in terms of planning, regulating and shaping the delivery of health services. The Centre and state governments have, over the years, launched various schemes and reforms for financing healthcare in the country, mainly through social health insurance. However, these public health insurance schemes have not been associated with lower health burden for the average household as measured by total real out-of-pocket health expenditure, catastrophic health expenditure or impoverishment caused by health expenses.

In 2017, the coverage of the *Rashtriya Swasthya Bima Yojana* (RSBY) was increased from Rs 30,000 to Rs 1 lakh, reinforcing insurance as the long-term strategy for healthcare financing by the government. This has now been supplemented with an even larger step by the government - the new National Health Protection Scheme (NHPS), under '*Ayushman Bharat Program*' - which gives a coverage of Rs 5 Lakhs to 10 crore families, estimated 50 crore beneficiaries.

Emerging economies like India that seek to promote access to medical technologies should consider supporting a private medical insurance system that can coexist with public funding for low-income segments. Such dynamics provides the capacity for a system to absorb costs associated with advances in medical technologies and services and enable wider

[20] *https://thewire.in/220070/poor-will-not-true-beneficiaries-worlds-largest-health-programme/*

penetration of innovative products. It is apparent that NHPS will bring significant growth opportunities for private health insurers in the short as well as long term. Later on, these players can innovate further and provide coverage for screening, diagnostics and monitoring products outside the IPD settings. Health insurance players need to explore possibilities of covering such diagnostics and home care devices, including wearable medical devices as well as integrated mHealth based devices etc.

As the penetration of insurance grows, insurance companies can expand their reimbursement net beyond conventional devices like implants, thereby facilitating access to innovative best-in-class technology. Indigenously manufactured devices that are at par with imported medical technologies, can be provided a higher level of reimbursement under both private and government insurance programs, thus incentivizing local production.

Non-Compliance to Global Standards and a push for Local Standards

- ***Mr Nanda Kumar Subburaman,*** *CEO, Perfint Healthcare Pvt. Ltd.*

Patient needs to be at the core of medical device regulatory policy, processes and systems. The primary expectations from regulations and regulatory process is to provide assurance to the patient and the physician that the product is effective and safe for the intended use. Its absence leaves patients and device users with unverified claims of performance and safety by the manufacturer.

The regulatory policy and processes should be scientific and simple, well documented and understood, quick and cost effective to encourage device manufacturers and technology providers to continuously innovate and introduce new products that benefit the patient. Complexity, lack of transparency and prohibitive cost of regulatory processes simply discourage commercialization of inventions.

Further, in a globalized world, the credibility of the regulatory clearance should be such that it enables manufacturers to supply their products globally rather than limiting it to country of their origin.

A medical device regulatory body needs to look at three key aspects before clearing a product:

a) Effectiveness of the product for its intended use

- Design Control Process - Whether the manufacturer is aware if his specifications would address the intended use and whether they have a robust realization process to create a product that meets these specifications.
- Risk Management - Whether the manufacturers understand the clinical risks arising from use of the product and whether these risks are adequately mitigated through product design
- Verification and Validation (V&V) Process - Whether the manufacturer has validated that the specified product addresses the intended use effectively
- Whether the marketing claims are clearly justified and supported by the outcome of the above V&V process

b) Safety of the product

- Whether the manufacturer knows the potential electromechanical and electromagnetic concerns and if these concerns have been addressed adequately. (IEC 60601-1 standards)

c) Quality Management System (QMS)

- Whether the manufacturer has a comprehensive, well-documented, rigorously implemented and monitored management process that is under continuous improvement, to ensure that the products consistently comply with the clearance provided. - (ISO13485 or ISO9001, in case the design is involved)

- Whether the QMS drives the management to recognize, capture and analyse issues arising during product usage and take effective corrective and preventive action including notifying regulatory bodies, product recall etc.

The above three aspects are critical before clearing any product for market use. Every country, or a region like EC, has its own regulator and regulatory clearance process. A manufacturer needs to obtain clearance from the respective regulator to place his product in any market. This duplicity of efforts takes time, effort and money and thus poses a major challenge to manufacturers who sell in the global market. Various regulators have acknowledged this concern and effective steps are being taken to eliminate duplication of efforts. Some of these steps are:

- Most regulators rely on the IEC standard for product safety and recognize the certification of compliance to IEC provided by notified bodies or certification bodies.
- Some of the oldest and most followed regulators in the world (USFDA, Japanese PMDA, EC, Health Canada, Australian TGA, Brazil) have come together to harmonise the process of certification and surveillance of the manufacturers' QMS into a single certification called **Medical Device Single Audit Program (MDSAP)**.
- Many countries accept USFDA or CE or such clearance and only insist on registering the product through a domestic entity (a legal agent), before they are placed in their country. The legal agent is accountable for compliance in the territory.

Hence, the trend is towards a unified global standard or at the very least towards eliminating needless duplication of efforts.

In this background, we are seeing the emergence of a new QMS standard called **Indian Certification for Medical Devices (ICMED) Scheme** in India and a call by various manufacturers to treat this certification at par with product clearances like USFDA and CE. There are two points that merit serious discussion and consideration at the policy makers' level:

- Is another Indian QMS standard or certification needed at this stage when initiatives like MDSAP have become a reality? Or should India work with the certifying bodies to make it economical for Indian manufacturer to certify to an MDSAP?
- Would an ICMED or an equivalent QMS certification be considered equivalent to a product clearance like CE Marking or USFDA?

The answers would be obvious to a buyer and a patient, and to manufacturers who consider their product to be good enough to compete globally.

With regard to product certification in India, the Government of India has introduced Indian Medical Device Rule (IMDR) to certify products based on the risk category through an accreditation body and certification agencies authorized by the accreditation body. While it is expected that any country that develops its own regulatory standards, would want to treat it at par with the USFDA or PMDA or CE clearance, it is difficult to see such a product being automatically approved to be placed in other advanced markets like the US or Europe or Japan. In this context, it would be prudent for the Indian regulator to not to insist on a mandatory Indian approval for such products that are cleared by other reputed regulatory bodies, but instead build credibility over the next several years to obtain global recognition so that Indian manufacturers benefit globally from an IMDR clearance.

Lastly, the credibility of the regulator lies in its ability to enforce compliance. The process of post market surveillance is a crucial part of the credibility building process, which is currently almost non-existent in India. Indian regulators need to understand the importance of this process since it would help them to devise a robust rule-based surveillance process. This will also encourage voluntary and fearless compliance in an uncomplicated and transparent manner, while severely penalizing violators. It is more often the failure of surveillance that leads to continued adverse events and loss of trust than the original clearance process. Monitoring our post market surveillance would benefit both, the patient and the physician, in the long term. Even as we perfect the IMDR process over the next several years, a rigorous post-market surveillance process should be implemented with urgency. This would help Indian medical device manufacturers gain their rightful place in the global supply chain.

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About FICCI

Established 90 years ago, FICCI is the largest and oldest apex business organization in India. Its history is closely interwoven with India's struggle for independence, its industrialization, and its emergence as one of the most rapidly growing global economies.

A non-government, not-for-profit organization, FICCI is the voice of India's business and industry. From influencing policy to encouraging debate, engaging with policy makers and civil society, FICCI articulates the views and concerns of industry, reaching out to over 2,50,000 companies. FICCI serves its members from large (domestic and global companies) and MSME sectors as well as the public sector, drawing its strength from diverse regional chambers of commerce and industry.

The Chamber with its presence in 14 states and 10 countries provides a platform for networking and consensus-building within and across sectors and is the first port of call for Indian industry, policy makers and the international business community.

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