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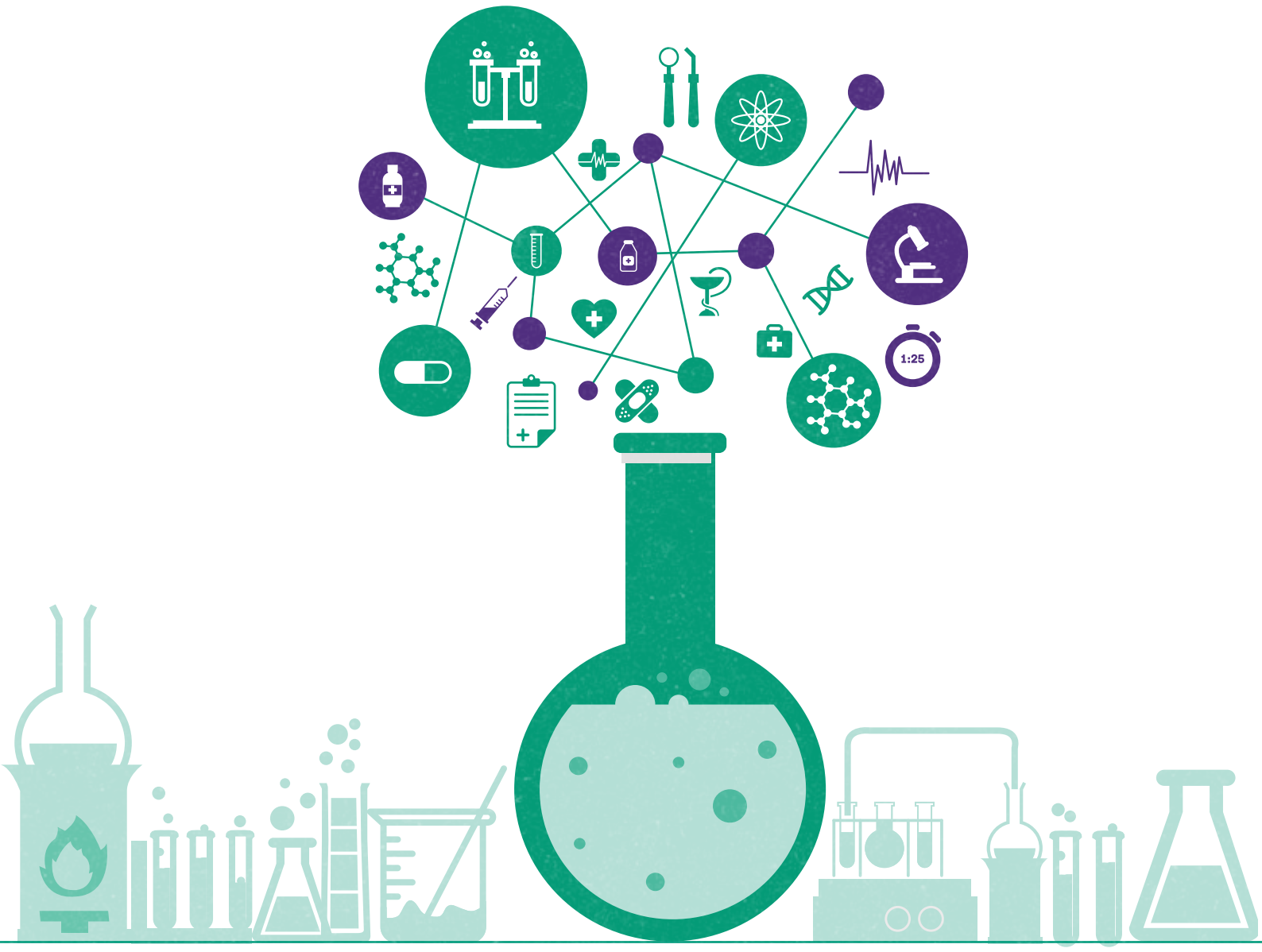
Meeting Challenges: "Tapping Opportunities to achieve $50 bn vision for Medical Technology Sector"

9th Medical Technology Conference – Concept paper

September 2016



Foreword

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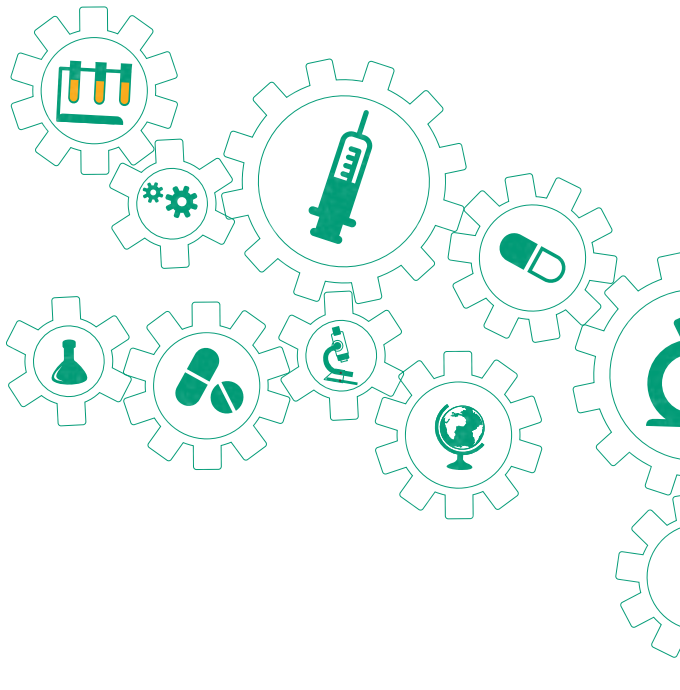
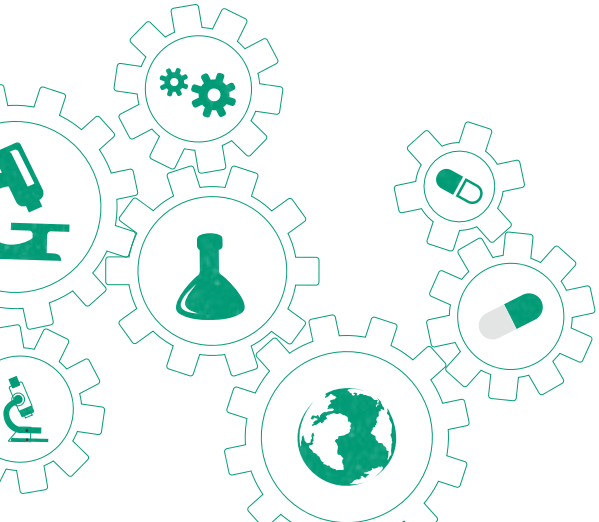
- Home to one sixth of the global population, the demand and need for healthcare delivery and allied services cannot be understated in India. The cost of bridging the gap for medical facilities (especially public infrastructure) and standards in India in line with global averages and norms, is estimated to be at around US$ 25 bn in the next few years. While a lot of this investment is proposed to be undertaken in the private sector, a natural offshoot of the healthcare infrastructure growth is a spur in the demand for allied technologies, medical devices, medical equipment and medical consumables which aid in delivery of healthcare (together referred to as 'medical technology' or 'medtech').
- As a collaborative effort between industry, associations and research groups, the medical technology industry was envisioned to be US$ 50 bn by 2025 and a clear roadmap for achieving this goal was laid out. Exactly two years hence, we have tried to evaluate our progress in this significant vision and growth trajectory. Industry keenly awaits the formalisation of a strong policy document for the sector aimed towards strengthening and supporting the medical device sector in India. This can be done by implementing globally harmonised set of regulations for medical devices and supporting the domestic manufacturing framework for safe, high quality and affordable medical devices.
- While there have been advancements either made or proposed to be made to eradicate the prime roadblocks identified in 2014, the industry continues to grapple with some fundamental issues pertaining to regulatory uncertainty, fragmented nature of the industry, and an ecosystem not conducive enough to foster cutting edge innovation and indigenous manufacturing.
- This concept paper, prepared with the active consultation of members of the CII Medical Technology Council, is an interim review of the proposed vision and roadmap. This is an attempt to provide an insight into the various updates on regulatory, technology and the market fronts in the Indian medical technology sector. The industry currently is heavily import oriented but shares a common vision to continue providing high-end and proven technology products, at affordable cost. The removal of existing barriers for growth will ultimately lead to increased investment into the Indian market by domestic and global players alike, whether in the form of local manufacturing, fostering R&D and innovation, partnerships for skill development, among other things.



Where are we on the roadmap

The idea of a US$ 50 bn market is based on growth of healthcare delivery sector, indigenous innovation and India acting as manufacturing hub for the global industry.

We are currently grappling with complexities in regulation itself over the last two years and have made marginal progress on the way forward.



Regulatory dynamics

Uncertainty and disjointed approach

Reality check

Creating the rule book – the National Medical Devices Policy

One of the least understood sectors, medical technology is currently undergoing an identity crisis with the National Medical Devices Policy, 2015 undergoing multiple iterations and deliberations over the last year. The first impediment of creating an identity of its own is proposed to be removed by de-linking medical technology from the Drugs and Cosmetics Act. The move however, was partially successful as a policy initiative in this direction is still not formalised.

Additionally, multiple hurdles lie ahead of the industry as regulations that are being announced periodically are not well understood on account of any final regulation. There is no 'transitional' view in place. Creating a sense of 'regulation' without actually having a detailed action plan is the primary operational impediment in the med tech industry.

Developments

A few positives, and multiple – not well understood

Multiple discussion forums for industry-government consultative interactions for seeking inputs on the Policy, permitting FDI in the sector through a landmark announcement, reversing the inverted duty regime to encourage local manufacturers, extending the SUGAM portal for medical devices by the CDSCO are all measures which were aimed at creating an identity for the medical technology industry.

But why is the regulation being introduced? The answer to this question, keeping an unbiased view of domestic and international manufacturers and based on a pure reading of the Draft broadly indicates the following:

- Provide safe, quality, affordable medical technology for ultimately improving patient care
- Incentivise local manufacturing – provide access to capital, setting up of med tech parks (the first of which was inaugurated this year), creating a level playing field and encouraging healthy competition, encourage innovations and R&D (ICMR, DIETY, DoP, CSIR, DBT) through a single window for coordination
- Develop export potential through local manufacturing facilities
- Gradually reducing our import dependence – by growing the market to attract scale and investment essential for local manufacturing
- Creation of an autonomous body to give effect to this regulation (Clearances, compliances, monitoring and overall sector promotion)
- Discouraging second hand medical equipment imports
- Setting a price control regime for medical devices
- Developing an institutional framework for R&D

As the Policy itself is in draft stages, a number of departments and governing agencies (CDSCO, D&C, AERB, PNDT, BIS, etc) have come up with their own set of detailed/insufficiently detailed requirements that somewhere aim to capture one or more of the above intentions. However, lack of coordinated discussions amongst these agencies, in the absence of an overall guiding rule book, has led to interpretation issues and high approval times in complying with these interim measures. The industry and the regulator, both find this challenge difficult to deal with in absence of Policy formalisation.

Country's healthcare system is currently 75 percent dependent on imported medical technology. To gradually transition from an import dependent to an export oriented sector, we need to prepare and develop our medical technology ecosystem. This needs to be done before announcing measures and rules for operations so that there is no immediate adverse impact on patient care and quality of care. Interim announcements, without the overall guiding principles in place, should therefore be rolled out only after a well thought out consultative process. As we hear, these efforts are currently ongoing.

Industry speak

- Industry involvement and consultative decision making process has been appreciated, though not all results are visible yet. While some announcements have been in line with discussions, some others have turned out to be contradictory to the overall philosophy and guiding principles. Significant efforts are being made to discuss these issues with multiple agencies and forums to resolve interim regulations in the absence of the Policy being finalised.
- Application and registration through online portal was viewed as an encouraging development.
- There clearly isn't a need to reinvent the wheel on Regulation – several examples of countries which have transformed into strong development hubs for med-tech (China, Ireland, Malaysia , Costa Rica) and import dependent economies (such as Saudi Arabia) exist where regulation has been devised for smooth med-tech trade and operations. Several of these economies rely on reference country regulations (IMDRF countries) combined with oversight from a local regulatory body.
- Suggestions by an apex healthcare institution to use a weighted average matrix for classification of devices at one such consultative forum that evaluates products on clinical efficacy, and lastly on affordability (and not just by cost minimisation alone) is a welcome suggestion and may be extremely relevant in the Indian context.
- The demand for medical technology products cannot just be viewed in the light of burgeoning population of the country. It has to be evaluated in the context of available infrastructure to use these products, qualified doctors and technicians to deliver such technology and the relative position of the product in the healthcare technology spectrum. Does the demand for healthcare in the country and the availability of healthcare infrastructure warrant a gamma radiation equipment manufacturer to set up local manufacturing in India? Will we be able to afford such equipment and do we really need this in every hospital in the country when rapid obsolescence in technology may even alter its relevance? Is it absolutely necessary for us to develop low volume but high value products locally in the near term? Several players are already manufacturing (and exporting) high volume and low/intermediate value products in the country and should be incentivised to grow further.
- We talk about segregating medical devices from drugs on one hand and are spending time on industry-government deliberations and collaborations. In parallel, there are discussions to add ~3800 devices under the same regulation, Drugs and Cosmetics Act. This disjointed approach has only created further uncertainty amongst medical device players in the country.

Bringing in the environment factor

Policy in the right direction, practical difficulties galore

Reality check

Disregard for indispensable products and refurbished technology alternatives

Considerable difference in the Draft Biomedical Waste Rules circulated to the industry for comments and the actual Rules put into effect were noted. While moves on automatic approvals, authorisations and several other consultative and thought-out initiatives were welcome, a few imminent and harming non consultative aspects (which may affect not just the 'quality' of care, but also the 'access' to care) such as the following have caused concerns.

- Phase out of chlorinated plastic bags, gloves and blood bags within two years from the date of notification of these rules could have the catastrophic effect of 'no surgeries being performed' since a bio-degradable alternative does not exist and cannot be developed at such a short notice.
- With a clear aim for the inclusion of machines older than three years in the 'Hazardous Waste - prohibited from Import" category, previously unaffordable critical care equipment which became available to several healthcare institutions through the refurbished route (where the clinical life and longevity of the equipment is technically extended through globally accepted OEM standards), may suddenly become out of reach (a matter which is still under debate). First hand equipment would be unaffordable unless government aids in financing these equipment.

Developments

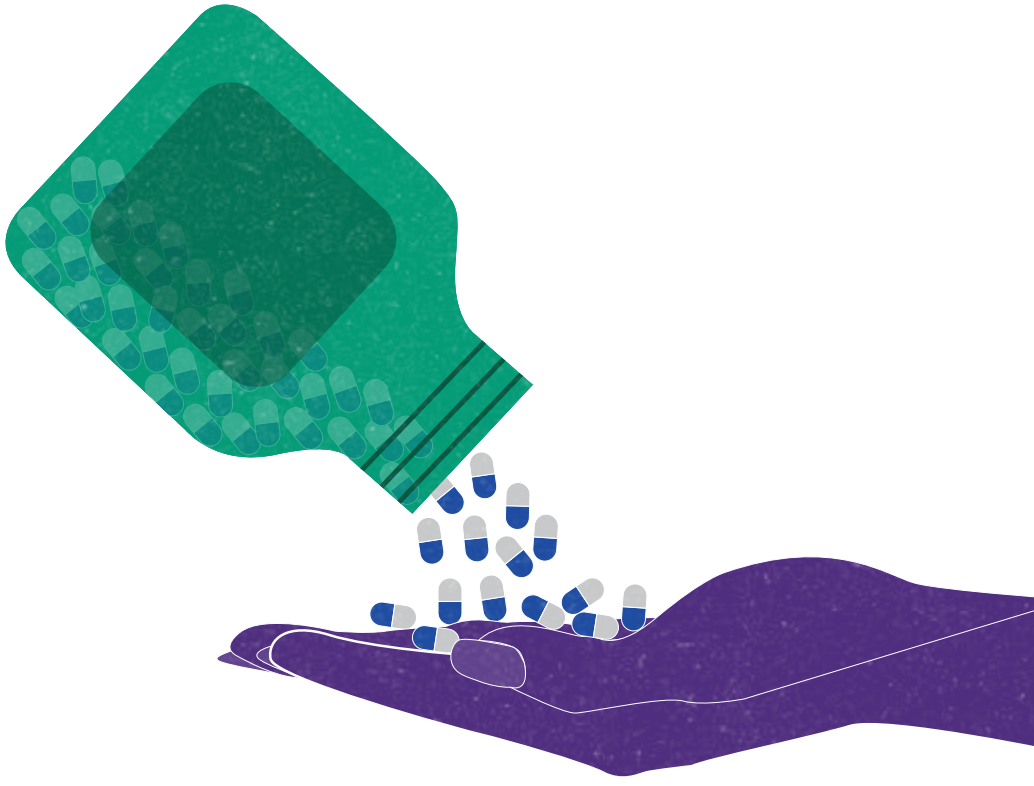
A mixed bag (… biodegradable or not)

Health care facilities (HCFs) have so far segregated biomedical waste (the wastes involved in diagnosis, treatment and immunisation such as human and animal anatomical waste, treatment apparatus such as needles and syringes and cytotoxic drugs) at the individual level in colored bags—yellow, red, blue/white and black according to the category of the biomedical waste. Post the maximum storage period of 48 hours they either treat it in-situ or a worker from a common biomedical waste treatment facility (CBMWF) collects it. The CMBWF then treats the waste according to the colour of the bag. Different colours indicate different types of treatments—incineration, deep burial, autoclaving, shredding, chemical treatment, disposal in a landfill, etc.

1. The Ministry of Environment and Forests released the new Biomedical Waste Management Rules 2016 in March 2016. Key distinctions between the earlier rules and the current rules include:
   - HCF now responsible for pre-treatment of laboratory and microbiological waste, blood samples and blood bags through disinfection/sterilisation on-site in the manner prescribed by the WHO or NACO, regardless of whether final treatment and disposal happens on-site or at a common BMW treatment facility (CBMWF).
   - Use of chlorinated plastic bags, gloves and blood bags to be phased out by the HCF within two years (But do biodegradable alternatives exist?)
   - Ease of approvals: Bedded hospitals will get automatic authorisation and healthcare facilities without beds will get a one-time authorisation.
   - While the earlier rules have no provision for a monitoring authority, the 2016 rules state that the MoEF will review HCFs once a year – a welcome monitoring mechanism.
2. In the latest series of discussions and the outcome of technical committee meeting with Ministry (MOEF) it was communicated to applicants that the machines older than three years will not be considered for approval (NOC) by Ministry. Moreover, Ministry is debating that Critical Care Medical equipment for re-use be placed under "hazardous wastes - prohibited for import" category which would imply that import of refurbished critical care medical equipment into India will not be allowed.

Industry interpretation

- It is important for a country to focus on waste management and environmental impact, and hence the new rules to a large extent were well appreciated as it tries to simplify waste management process and permits automatic authorisations for hospitals/clinics.
- However, directing efforts to ban products that are currently indispensable with no substitutes creates immense uncertainly for healthcare providers to carry on with day-to-day operations. When biodegradable alternatives do not exist, focus needs to shift from pure ban to safer methods of treating waste.
- While natural rubber gloves may be biodegradable, they are known to cause allergies to some people and the world has moved towards using synthetic nitrile gloves.
- The useful life of medical equipment as per various globally accepted methodologies is much higher than the currently envisioned three years; A fact, which can be certified by manufacturers, OEM players, court precedents, our own apex bodies such as AERB (which allows import for pre-owned/refurbished diagnostic equipment which are seven year old or less). Refurbishing processes follow global standard and safe practices where critical parts that have definite life can be fully replaced, thereby extending medical equipment life.



Striking a balance

Import dependence v.s. export promotion

Reality check

Sudden substitution in an import dependent sector

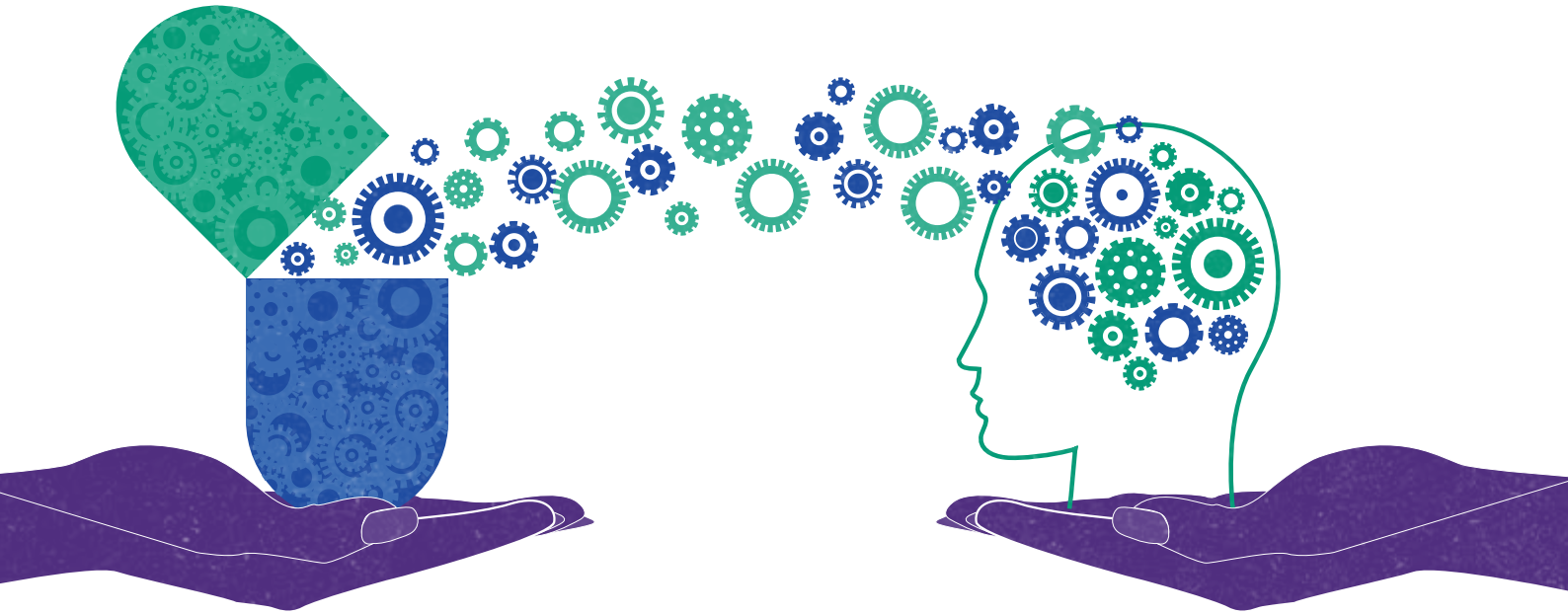
Medtech in India, like several other countries in the world is largely import dependent. Over 75 percent of high end medical devices, critical care equipment are imported whereas large volume and comparatively low end consumables and disposables are largely locally manufactured. While the inverted duty regime is being touted as one of the primary reason for this imbalance over the years, the country's Make In India initiative is being implemented through a 'policy push' to encourage local manufacturing and shift from an import dependent to an export oriented market.

The key issue remains that an import dependent economy cannot suddenly shift to indigenous manufacturing simply through driving policy decisions in a sector such as healthcare. While MNC's are cognizant of the fact that import duties will continue to face pressures, it is imperative to realise that we will not be able to leverage global technology if this were the stand adopted by us. To create a healthy ecosystem in the near term, we will have to grant equal importance to imports and domestic manufacturing with a view to improve clinical outcomes and have continued access to global technology enabling a smooth transition.

Developments

Increase in duties (January 2016)

The customs department has raised import duty on medical devices used for surgical, dental and veterinary use from the current 5 percent to 7.5 percent to help companies manufacture these products in India itself. Besides, the government imposed special additional duty on these items of 4 percent by withdrawing exemptions. Also, basic customs duty will be reduced to 2.5 percent on raw materials, parts and accessories of these items.



Industry Interpretation

- Stakeholders take cognizance in the fact that it is not a desirable situation for a country with over a billion population to be 75 percent import dependent on medical devices.
- Besides affordability of healthcare (which is currently 75 percent out of pocket), the three pillars of medical technology remain safety, quality and efficacy of devices. At present, there is no nodal agency for assessing and evaluating technology in India. Product performance reports are a globally accepted means of showing efficacy of medical technology, an aspect which has not found the same degree of importance in drafting policy and regulation. Trying to make things cheaper simply through import substitution without judging a product on quality may create morbidity and mortality traps. A hurried move on import substitution and following a procurement based approach may therefore encourage quality-adjusted products to flood the market to comply with regulations. Precision technology do not warrant local manufacturing and can continue to remain import oriented products. Making them dearer through additional duties will neither encourage local manufacturing nor will they be incentive enough for existing manufacturers to supply the limited quantities in India. In other words, a one-size-fits-all approach may not work here.
- Building know-how is not a short/medium term investment. Are we aiming to become a manufacturing hub for borrowed technology? Technology, globally, is centered in a few pockets of excellence. A free flow of such technology across borders during the interim period (while we develop local R&D and develop substitutes), combined with a focus on disease management and product efficiencies are critical. Import substitution could, and most likely should, be done in a phased manner while leveraging on global technology in the interim.
- Tax and customs framework and reform should focus on seamless and cost-effective procurement of samples for R&D and innovation, tax incentives for in-house R&D centres, exports benefits similar to what was done for the software industry in India.

Focus on efficacy of devices and quality of clinical outcomes

Examples of medical devices policy reform and regulation in import dependent economies can be taken, which use International Medical Device Regulators Forum (IMDRF) harmonised guidance documents on basic regulatory practices as reference. This helps countries maintain focus on global standards for quality and clinical outcomes and direct local efforts only towards creating access and smooth market operations to deliver healthcare to patients, while choosing to be import dependent.

Impact of 'NLEM' inclusions

Moving backwards towards a 'drug' treatment

Reality check

Counter-productive to Make in India

Technology pricing spiraling downwards is a global trend including in the med tech space. But do we see the benefits being passed on to the patient?

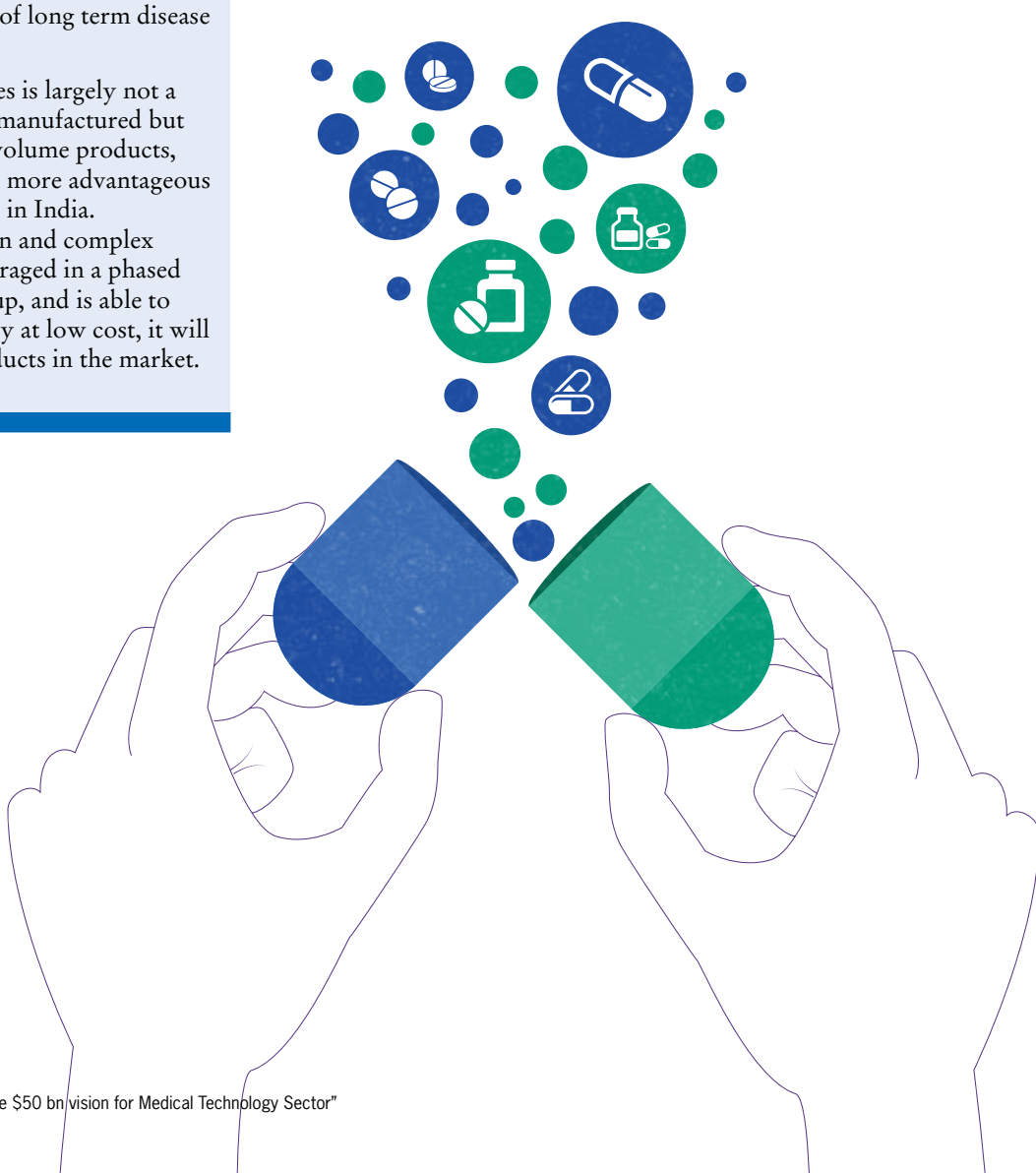
Understanding the complex distribution and marketing channels along with planned quality check on procedure reimbursements will be critical to co-evaluate when assessing any form of price control. Factors such as longevity of the product may reduce in their significance, discourage innovation and reduce access to better outcomes if a pricing barrier is imposed. A pricing barrier may have a direct effect in the form of 'quality and disability adjusted products' entering the market which may defeat the higher purpose of long term disease management.

Manufacturing costs of medical devices is largely not a factor of where the product has been manufactured but is essentially a factor of 'scale'. High volume products, which provide economies of scale, are more advantageous and cost effective when manufactured in India. Indigenous manufacturing of precision and complex technology products should be encouraged in a phased manner. If local manufacturing is set up, and is able to develop parallel/competing technology at low cost, it will create a healthy pool of alternate products in the market.

Recent announcements

Mere extension of drugs, yet again

Thwarting all efforts made in the last decade to segregate medical devices from drugs, we have seen some recent regressive pronouncements where a medical device has again been classified as a drug and has been included in a list of essential drugs. Recently, two categories of stents were included in the National List of Essential Medicines (NLEM). The Health Ministry added drug-eluting Stents (DES) and bare metal stents (BMS) to the NLEM 2015 list in a notification released in July 2016. The National Pharmaceutical Pricing Authority is expected to notify the new price for these stents after due deliberations.



Industry interpretation

- By pushing the Make in India programme on one hand, and simultaneously introducing talks around price regulation, even before the manufacturing plan has been implemented, the Government has created a significant sense of uncertainty amongst medtech players in the country. Restriction on pricing (as against market-driven pricing) may render a market unviable for companies to pour in capital. This move may witness a stalling of new product launches/investments until there is further clarity on the subject.
- An important financial factor to consider is the low levels of insurance penetration, inefficient reimbursement systems and high inventory management costs (associated with just in time inventory practices) which all add to the indirect cost of providing devices in India. A lot of this burden is indirectly borne by the medical device companies, a fact which goes completely unaccounted for.
- Methodology and criteria used for pharma need not be applied to medical technology for inclusion in the NLEM. Both are different, be it in terms of formulations, mode of administration, targeted therapy area, key diseases etc. Coronary stents is a category and not a product, just like antibiotics or vaccines which are a category of medicines with different drug molecules within them, which can be essential. The Government has yet again treated medical devices as a mere extension of drugs.
- In the long run, if enough manufacturers are allowed to smoothly establish operations in the country, market forces will automatically determine the most suitable prices for products and devices. This is not an area which demands an intervention from apex bodies and the government in the current stage of development of the industry. Drug pricing was introduced in pharmaceuticals nearly a decade after the country had established a large indigenous manufacturing base and was an export surplus sector. We seem to have hastily applied the pricing restriction much earlier in case of medical technology.
- If the Government transitions policies to a direct procurement mode and purchases some 'essential' products in significantly large quantities, it could result in significant cost savings. This, as against a reimbursement mechanism, which typically has significant inefficiencies, is a great alternative to any form of pricing regulation and could create an immediate financial saving.
- In India, the medical technology industry is highly fragmented and lacks a sole large aggregator. The US is able to absorb high costs largely because the insurance companies act as the aggregator providing reimbursement and hence possess significant buyer power. Within ASEAN countries like Thailand or China, Government assumes the role of an aggregator to a large extent. This allows consumption to increase, and automatically attracts suppliers. India lacks this mechanism to a large extent, resulting in over 80 percent 'out of pocket' healthcare expenditures.
- India is a highly fragmented and diverse medical technology market where multiple options exist around safety, quality and efficacy. Saturation in urban areas, lack of adequate access/demand in rural and semi-urban areas, may lead to a push of medical technology products with alternating combinations around quality and pricing. Setting up accurate objectives of price control, before selective implementation, are critical for the medical technology framework in the country.
- Globally, pricing regimes are derived through a scientific system of Health Technology Assessment and the same benchmarks can be used to model it in the Indian context.

Standards and compliances

Cornerstone of any medical technology ecosystem

Reality check

Approvals, without a clear governing body

As a global quality reference point, a CE or FDA approval is often regarded as the primary approval criteria for products (much like pharma). An add-on local approval, without diluting the efforts and by fully leveraging on the outcomes of the CE/FDA approval is all that the country needs at this point of time without re-inventing the entire wheel.

Drug marketing code, paradoxical again

The UCPMP Code was brought into force to deal with ethical pharmaceutical marketing practices. However, it is once again being recommended that medical technology be brought under its purview. This was done without a careful thought about the difference in nature and stage of these two industries, bringing us back squarely to the root cause of regulation and segregation from pharmaceuticals. For technology that is new, developed mostly outside the country, if it cannot be explained to doctors, technicians and practitioners, it puts us back at the starting point on the R&D roadmap.

Developments

Quality of a medical technology product is perceived through certifications and approvals. While Regulation is being finalised there are no deliberations/discussions around developing infrastructure and quality of testing similar to CE/FDA locally. Raising our credibility in global markets through appropriate quality certifications is the key if we have to compete in the global arena. In select areas of consumables and low precision devices, we are already globally competitive. This is largely because the manufacturers, with their own funds have invested sufficiently to seek and abide by globally accepted quality standards and certifications (in most cases, CE approvals at the very minimum).

Free sales certificates (used as means of preventing sale of banned products) are denied by the Indian regulators for products not notified within the existing Act (only a handful of the several thousand devices currently are notified). We end up losing the export marketing potential of these products in most countries.

Industry speak

- Fundamental difference between pharma and medical devices is that pharmaceuticals largely falls under business to consumer (B2C) segment while medical devices come under the business to business (B2B) segment. Hence, it may not be appropriate to extend the same levels of stringency in marketing and promoting medical devices to healthcare providers.
- New technology (such as that available in radiation, robotics etc) cannot be brought into India unless the users and providers of the technology are educated about its benefits and usage. We cannot, yet again, use the same paintbrush across pharmaceuticals and medical technology when it comes to marketing practices. Each of these health care sub sectors are at very different stages of evolution.
- A high duty on imports with a parallel push on exports is a double edged sword without appropriate quality benchmarking for the medical technology industry. We restrict our ability to procure technologically advanced products, and without a quality benchmark in place, we restrict our ability to export. As a trade practice, this will not be acceptable in global markets.
- Good quality is not a subjective comment. If our regulation does not give confidence that their approval is good enough, it brings us back to the root cause of regulation.
- The indigenous market is characterised by a co-existence of contrasting players– those who have invested in technology and quality and supply globally marketable products and those who provide low-cost and low-quality products in the market.
- There is no eco-system and infrastructure to conduct the level of quality testing similar to CE/FDA, locally. Ultimate goal is to innovate and develop locally, manufacture and procure locally and serve globally. All we need is the right framework in place to achieve this in the long term. As a first step, the Gujarat Government has already approved the setting up of the country's first medical device testing lab to be housed at Gujarat Food and Drug Control Administration (FDCA) office at Vadodara

Patient access and reimbursements

Background

Improving Patient Access

Unlike pharmaceuticals or many other industries, 60 percent of global medtech market is controlled by a few large players. Medtech is far more complex and requires physical, financial and clinical infrastructure. Only in the presence of all these can any player successfully set up base in a country and conduct smooth operations, provided there is also a strong local demand. With significantly lower average per capita spend on healthcare compared to other countries, the per capita spend on medical technology (which is essentially a subset of healthcare drawing its demand from beds/infrastructure) is lower too. Without a visibility on healthcare infrastructure development, which is the primary need, in the next five years, the demand for medical technology cannot be ascertained with accuracy.

Long term view on re-imbursement costs

Re-imbursement policies should focus on long term medical costs incurred by the patient and not the immediate surgery/product prices alone. While a low cost product may be preferred, one fails to notice the recurring costs owing to repeated patient hospitalisation due to clinical outcomes/lifecycle related issues. In the absence of a quality re-imbursement mechanism coupled with imposition of price barriers, products that are quality and longevity adjusted may seep into the system.

India has a complex healthcare delivery system where there is a huge gap of quality and service between a tertiary care provider and a primary health center, and also between public and private hospitals. The higher we go up in the value chain of technology, R&D plays a key role making the cost prohibitive. Thus smaller providers cannot afford and therefore may rely on refurbished alternatives. Providers also get squeezed between insurance schemes and cash patients, where they are forced to provide same quality of care at subsidised cost based on the schemes. There is always a price and quality mismatch wherever these intersections play out.

Industry speak

- The key objectives of healthcare delivery should be to provide quality care at affordable pricing. It is always crucial to understand, who pays for healthcare? Patient or the social security system.
- Public healthcare expenditure in India currently stands at c.1.1percent of GDP, significantly lower when compared to most developed and Asian economies. Even if this increases to 2-3 percent of GDP, as envisaged in the National Health Policy 2015, with slight impetus on improving universal healthcare, the medical devices sector would stand to gain significantly, provided there is a focus on installing quality benchmarks
- While there have been reimbursement programs introduced and an expected growth of ~20-25 percent in private and commercial insurance, it may not be adequate to bridge the gap between the current out of pocket spend and the desired reimbursement levels for a country of our size.
- A national policy for health insurance, currently being envisaged by the Government, if efficiently implemented, can plug several of the gaps and loopholes in the current reimbursement framework.
- In determining the pricing for procedures, there is a need to evaluate quality benchmarks and focus on positive clinical outcomes.

Developing the med tech ecosystem

A parallel initiative, demanding equal impetus

Reality check

In determining our ability to set up and service our healthcare ecosystem, while lack of qualified physicians and availability of beds are core areas of improvement, building a medtech ecosystem requires focused infrastructure (in the form of medtech parks) and specialised skills.

Setting up the first medical technology park

Andhra Med Tech Zone (AMTZ), established under Andhra Pradesh Government has finally received approval for funding by the state cabinet on 1st June, 2016 for setting up Asia's first dedicated medical device park at Visakhapatnam in the state. A second such park is also being envisaged to set up in the State of Gujarat which would complement the first upcoming medical device testing lab of the country at Vadodara. These measures are already paving the way for development of similar such ecosystems throughout the country, as envisioned in the NMDP.

Qualified pool, but are they trained enough

While we produce a healthy pool of engineers, PhDs, there is a lack of industry-academia interaction to develop such individuals as specialists with appropriate practical training. Physicians need to be better trained on using medical technology which will reduce the burden on the industry that currently invests significant capital and efforts in upskilling physicians and technicians and creating awareness about new medical technologies and products (through CME's and other training programs).

Developments

Currently, several companies including established domestic players often hire PhDs or engineers at entry level and develop talent through internal programmes and training, unlike what happens in developed countries that have formalised knowledge teams to connect industry and academia to provide practical training as part of regular curriculum. While there are a few incubation centers to help in prototyping or design testing, a full blown commercial self-sustained ecosystem to aid in scaling up manufacturing is missing.

A key agenda in the proposed NMDP is to develop medical device parks, knowledge networks with industry partners, set up skill development committee, incubation centers, promote international knowledge exchange programs etc.

Industry speak

Implementation of the NMDP vision on training the medical technology sector is key and India can draw upon best practices followed worldwide to develop skill base.

- Formalised training programme to connect industry with academia is of utmost importance for the life-saving medical technology/healthcare sector. Countries such as the US have an active board NIH (funded by the government) which operates through 27 institutes each with a specific agenda of research and provides training opportunities with itself, universities and industries.
- It is important to identify the most critical medical devices needed for the country, and chalk out a framework and ecosystem to sponsor and encourage select local players based on capability and know-how to innovate and develop these devices.
- To promote and fund innovation and clinical testing, create appropriate guidelines and integrate regulation with pre-clinical and clinical testing.
- Create shared infrastructure to support medtech innovation e.g. raw material supplier base, innovation parks, testing services – mechanical, electronics, material safety, contract manufacturing.
- Specialised courses for medical device engineering and training courses designed around medical technology imparted by educational institutions with industry level internships for atleast 40 percent of the course period.

The first medtech park is a step in the right direction to create an ecosystem. However, the success depends on multiple factors such as replicating the model in other states, regulation, clinical testing, skill development etc

Global Examples

Seoul National University Hospital in Korea:

The medical technology industry has tied up with large healthcare institutions to set up medtech incubation centers to promote new development, prototyping etc. Such ecosystems provide ready access to patient population for samples, doctors for inputs, clinical engineers at a single location. They also provide highly specialised training for biomedical staff in niche areas of expertise/product areas providing opportunities for such engineers to be either absorbed back by manufacturing industries or in the hospitals.

A* Singapore:

A med tech import dependent economy, has a similar model where A*Star (Agency for Science, Technology And Research), EDB (Economic Development Board) come together to focus on providing training to medtech industry on specialised skill sets. They have invested in such models and ecosystem to enable them to become hubs for R&D and manufacturing in future and encourage several start up ideas to culminate into indigenous medtech companies

The outlook

Medical technology as a sector is unique and not exclusive in terms of its inter-linkages with the healthcare service providers. Accordingly, any view taken on the sector needs to be inclusive and should take into account the dependence on healthcare infrastructure, healthcare delivery and reimbursement/insurance penetration.

- **Payer cum provider:** Government has to take the role of a payer or a provider or a combination of both. Till the time uncertainties around the state of public infrastructure, shortage of capacity, inefficient reimbursement mechanisms are resolved, it becomes arduous to devise inclusive strategies for medtech, which is largely import dependent and survives mainly through private and foreign capital.
- **Clarity of purpose of regulation:** Through this current phase of policy formalisation, all stakeholders including the government have to be mindful of the end objective of this regulation, whether it is - curbing of imports versus reduction in imports, selective price control versus market forces determined pricing, indigenous manufacturing only vs coexistence of MNC manufacturing, own technology vs borrowed technology, focus on quality vs focus on price, independent regulation vs harmonising with global regulation, single body of regulation vs multiple bodies for regulation, etc. A course correction will be required at each stage if we digress from any of the stated objectives. Each of these entails a completely different strategy and approach to be taken in the short, medium and long term.
- **The demand factor:** Medical technology consumption market in India is much lower than that of China or other Asian counterparts rendering it unattractive for several large foreign or domestic players to formulate India-centric strategies. All issues such as pricing, environmental laws, quality/certification, lack of skilled knowledge base that have been discussed in this paper, necessitate a clarity in vision for medtech clarity in vision for medtech in the medium and long term and the need for structured programs to develop and grow the market
- **Regulation and implementation timelines:** Once a vision is established, the most important step is to create a single cohesive body to control regulatory policies around the sector which should solely take ownership of all issues and announcements affecting the sector. While the Government has initiated steps in this direction through the draft Policy, it is also important for it to be implemented in a timely manner. Industry is not against regulation and no industry enjoys a free market devoid of regulation or governing principles. Appropriate regulation is the key and players will automatically tune their strategies in line with the same. Market will carve out a demand supply mechanism for itself and pricing will be a natural output of a dynamic market. We have seen it happen in other sectors in India, and will see it happen in the medtech sector.
- **Incentives to foster innovation:** Financial support to encourage and develop medical technology right from innovation through to testing and eventual manufacturing whether through a technology fund or through capital subsidies, tax exemptions in medical parks, etc, is essential.

What prevails currently, is a sense of uncertainty for domestic and international players alike, indicating a need for radical and fast paced regulatory initiatives for the sector. Preparing the eco-system for this radical change - setting up of the legal framework, enforcement (from both industry and government ends), improving infrastructure and reimbursements are some of the steps that will help the market automatically thrive. Above all, 'access' to 'safe', 'quality', 'affordable' healthcare will definitely improve and the patient will benefit.

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About Confederation of Indian Industry (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 organisation, playing a proactive role in India's development process. Founded in 1895, India's premier business association has over 8000 members, from the private as well as public sectors, including SMEs and MNCs, and an indirect membership of over 200,000 enterprises from around 240 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 specialised services and strategic global linkages. It also provides a platform for consensus-building and networking on key issues.

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CII Medical Technology Division (MTD) has been proactively working on the key industry issues with the Government, involving all the Stakeholders of the Medical Electronics, Devices, Equipments and technology Industry. The division has been a nodal point of reference, providing a forum for dialogue with the Government and companies from the healthcare technology sector.

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

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

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Abbreviation

A*Star	Agency for Science, Technology And Research	**FDCA**	Food and Drug Control Administration
AERB	Atomic Energy Regulatory Board	**FDI**	Foreign direct investment
AMTZ	Andhra Med Tech Zone	**GDP**	Gross Domestic Product
BIS	Bureau of Indian Standards	**HCF**	Health care facilities
BMS	Bare metal stents	**ICMR**	Indian Council of Medical Research
BMW	Biomedical Waste	**IMDRF**	International Medical Device Regulators Forum
CME	Continuing medical education	**MNC**	Multi-national corporation
CII	Confederation of Indian Industry	**MoEF**	Ministry of Environment & Forests
CBMWF	Common biomedical waste treatment facility	**NACO**	National AIDS Control Organisation
CDSCO	Central Drugs Standard Control Organisation	**NIH**	National Institutes of Health
CE	The letters "CE" are the abbreviation of French phrase "Conformité Européene" which literally means "European Conformity"	**NLEM**	National List of Essential Medicines
CSIR	Council of Scientific & Industrial Research	**NMDP**	National Medical Device Policy
D&C	Drugs and Cosmetics Act	**NOC**	No Objection Certificate
DBT	Department of Biotechnology	**OEM**	Original equipment manufacturer
DES	Drug-eluting Stents	**PNDT**	Pre-Natal Diagnostic Techniques
DIETY	Department of Electronics & IT	**R&D**	Research & Development
DoP	Department of Pharmaceuticals	**UCPMP**	Uniform Code of Pharmaceuticals Marketing Practices
EDB	Economic Development Board	**US**	United States
FDA	Food and Drug Administration	**WHO**	World Health Organisation

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