MTaI
MEDICAL TECHNOLOGY ASSOCIATION OF INDIA

Demystifying the MedTech Sector in India

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Message from the Director General

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Director General
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Association of India (MTaI)

Though Medical Technology is an intrinsic part of health care services today, in India, it has realized only a small fraction of its potential. Facing numerous hurdles on account of un-nuanced policies and lack of clarity in the regulatory framework, the industry as a whole has annual revenues of just $4.9 billion. Large parts of the population are not able to avail of its benefits.

To the many challenges the industry is facing, a new one has been added in recent months – that is, arbitrary price control. As the experience of Stents has shown in ample measure, price control does not by itself increase patient access.

To make modern medical technology available to the population, particularly the populace located outside the metro cities, several things have to happen at once. First there is the need to nourish the anemic bed capacity of India. Then there is the need to develop technically skilled human resources in vast numbers. Who can not only utilize these technologies but also counsel and train the end user to employ these. Undifferentiated price control, indifferent to this knowledge, will hit at this training and capacity building contribution of the industry. And may just prove a remedy worse than the disease. Moreover, if the industry is prevented from recovering its expenses and investments, growth and technological advancement will be hampered. This may hurt quality of healthcare outcomes in India as well the fast growing Medical Tourism industry, which already earns for India more in exports than what we spend on imports of medical devices. And which is projected to grow to two and a half times by 2020.

Rather than imposing un-nuanced price control, the government should establish mechanisms to subsidize the treatment of those who cannot afford to pay. This can be done through publicly funded insurance schemes and reimbursement of expenses incurred by the economically weaker sections. Side by side, the industry and all other stakeholders should be engaged in an open dialogue and steered towards voluntary correction of any market anomalies.

Likewise, import substitution being forced upon the industry, either through extraordinarily high duty tariffs or the Preferred Market Access (PMA) mechanism, is likely to ultimately impact the patients only. Rather than import substitution or PMA we must aim at export promotion through the pursuit of quality and thereby achieve global competitiveness. This will give enough time to the companies to expand their technological expertise and nurture the necessary technological eco systems, reaching first for the manufacture of simpler devices, thus enabling sustained growth and reputation building

A similar Sub-sectoring of medical devices, based on engineering complexity is needed for policy and decision clarity.

Tracing the historical origins

A lot of medical devices that doctors and other healthcare professionals use have developed gradually over the decades. Intravenous needles used in the past gave way to flexible venous catheters such as Venflon and Angiocath, because of which repeated needle pricks are no longer necessary. Likewise, silk and catgut sutures that surgeons would need for closing a wound, have now been replaced by salves and staples which close wounds without sutures.

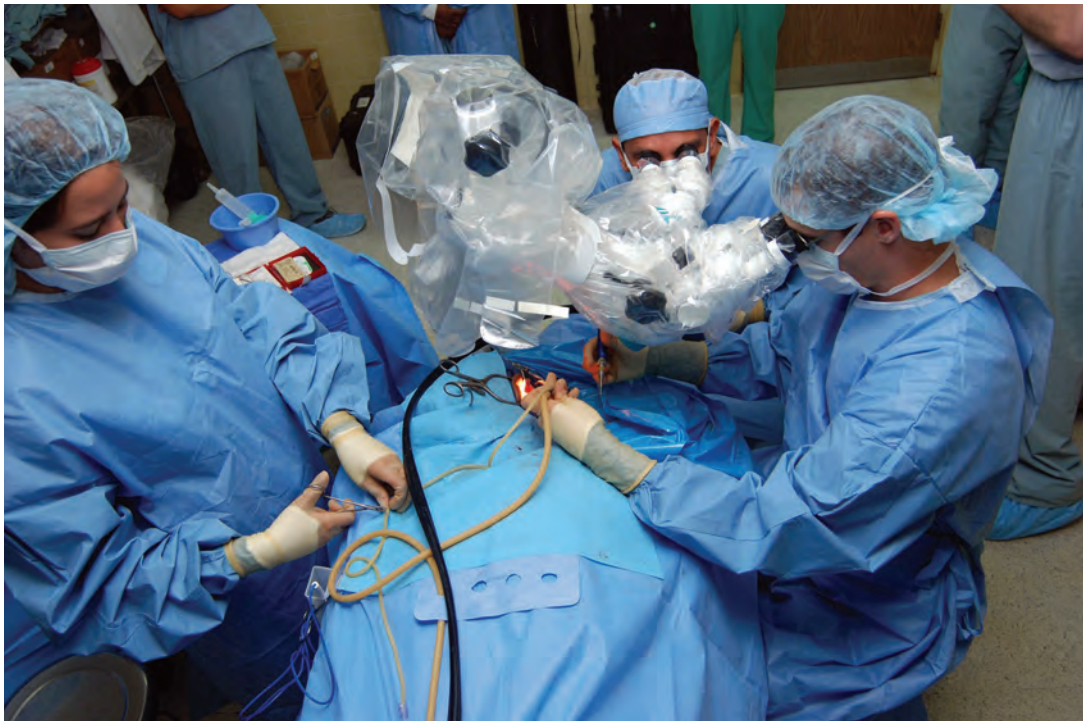
There are numerous medical advances that have made life simpler and more comfortable for both clinician and patient. However, for reasons of shortage of space, we have chosen to elaborate on a few major equipment that have transformed the medical profession in the last half century or so. One such modality is: non-invasive imaging – CT scan, MRI, ultrasound, nuclear scanning, etc. Another is Minimal Access Surgery (MAS), also commonly known as 'Keyhole Surgery'. A third significant area of scientific advancement is the treatment of eye disease – cataract, retina surgery, correction of refractive errors, etc.

Three examples of medical technology that have transformed healthcare are: CT scan and other radiological tests, keyhole surgery including angioplasty and recent eye surgery techniques.

Non-Invasive Imaging

Radiological investigation to examine internal body organs have been used for more than a century, with growing effectiveness and lower dose of radiation as the years went by. This meant greater safety for both patient and radiologist (and technician). In the initial phase, the hospital radiology department staff would suffer from symptoms of chronic radiation sickness because of repeated exposure to radiation. Then radiation dosimeters were introduced, lead shielding was made compulsory and finally the concept of ALARA (As Low As Reasonably Achievable) came into vogue. The idea behind ALARA was to expose both patient and health worker to the lowest possible radiation dose without compromising the image quality. Similarly, the need for catering to bed ridden or severely injured patients led to the development of portable x-ray machines.

Yet the need to visualize internal organs such as the liver and kidney in greater detail was being felt increasingly by clinical specialists all over the world.The major transformation in this aspect came in the mid-1970s with the development of CT scan in the US and the first installation in India a few years later. Thereafter, news models were introduced which were more accurate in imaging the internal structures and detecting various illnesses. The MRI first commercialized in the 1980s, followed a similar course. At first, these two modalities were used for diagnosis of brain disorders such as brain tumors, brain stroke, etc but later the applications were expanded to cover the spleen, liver, kidney, etc. Today's CT scan machines are more capable of producing



much more accurate images with lower dose of radiation, within a shorter time and reduced hazard to both patient and healthcare professional.

Minimal Access Surgery

The first experiments with laparoscopic surgery took place in Sweden in 1910-12 on animals and then it was used for examining the chest cavity in human beings. Then in 1985, German surgeon Erik Muhe performed what is believed to be the world's first laparoscopic cholecystectomy (removal of gall bladder) for which he was severely penalized. Within four or five years, however, laparoscopy began to be used widely, and many conventional surgeons got interested. The first series of laparoscopic procedures in India was published in 1990 was published by Dr T E Udwadia, after which the technique began to get widespread acceptance and recognition. This was the consequence of almost 20 years of experimental research. Gradually, as the instruments became more sophisticated, the technique was applied to different parts of the body. Today 'lap-chole' is a routine procedure among surgeons and various terms are used for other procedures such as arthroscopy (to examine the knee), bronchoscopy to look inside the lungs.

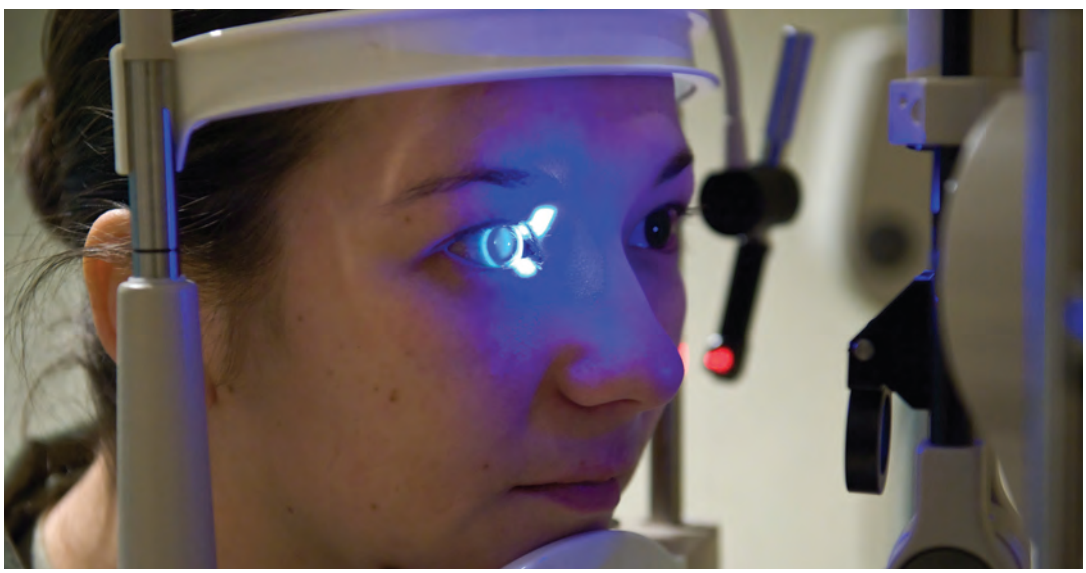
Minimal Access Surgery, also known as keyhole surgery has made operations much safer and comfortable for both surgeon and patient. Angioplasty has restored normal life for many people suffering from serious heart disease.

Angioplasty, which is another widely practiced method for treating heart disease, began in India in the late 1980s. The first series of cases was published in 1987 by Dr Mathew Samuel in Apollo Hospital, Chennai. At that time, the procedure was balloon angioplasty which was able to open up the coronary arteries but not keep them open. Restenosis (repeat blockage) of the arteries was a

common problem, which led to the development of coronary stents within a few years. Stents are very thin metal tubes which would be placed inside the coronary arteries to prevent restenosis. Obviously, this required special catheters and other instruments to insert the stents and retain them in place. However, there would be accumulation of layers of cholesterol, clotted blood and other tissue on top of the stents and they would soon be blocked again! This led to the next scientific advancement: the Drug Eluting Stents (DES) which would release a small amount of an anti-coagulation medicine very slowly. The current vanguard of stent technology is the bio-absorbable stent which rather than remaining inside the body for the lifetime of the patient, dissolves on its own after some months, and thus restores the diseased heart artery closer to its natural state.

Ophthalmic Surgery

Stunning advances have taken place in the past three or four decades in the field of ophthalmology, with particular focus on two areas: cataract surgery, and vision correction. Cataract surgery has advanced in two ways: one, intraocular lens (IOL) which is placed inside the eye after the cataract-affected lens is removed, and two, the technique of phacoemulsification, which enables the diseased lens to be grounded into an emulsion and removed through a tiny incision of just a few millimeters! The first IOLs were implanted by Sir Harold Ridley in 1949 in St Thomas Hospital, London. That model of the IOL was made by the British company, Rayner. But another two decades would pass before the technique became widely accepted. From the 1970s, however, the method was adopted in several western countries and practiced by more and more eye surgeons. While the initial lenses were hard and rigid, new models that were sift and foldable were developed in later years. Phacoemulsification was first developed in the 1960s by New York eye surgeon Charles Kelman, who was said to be inspired by an ultrasound device used by his dentist. In recent years, the technique is being adapted by neurosurgeons to operate on brain tumors!



The other problem of vision correction has also been tackled with hi-tech instrumentation in the past few decades. In 1986, Dr R K Kapoor, a senior ophthalmic surgeon with Bombay Hospital began working with a group of surgeons from the Moscow Eye Institute to correct the severest form of short-sight (myopia). The concept was that by making radial incisions on the cornea, the outermost transparent tissue in the front of the eye, they could alter the focal length of the lens inside the eye, so that thick external lenses would not be required. Though the correction was partial in most cases, the need for thick glasses of -10 to -12 power was avoided. At that time, they would use diamond-tipped scalpels, and the calculation of how deep they should go was rather imprecise. That resulted in a lot of complications and prompted many surgeons to abandon the technique. In later years, however, laser technology enabled exact calculation of how deep the corneal incision should be, and this made it possible to achieve much better results.

Cataract surgery has undergone a revolution in two ways: phaco-emulsification, which requires a tiny incision, and intraocular lens implant, which avoids the need for heavy glasses after the operation.

Healthcare as a whole has come a long way and evolved considerably over the past decades, with numerous technologies available to enhance the welfare of the patient. Medical research has progressed independently in many different directions and would continue to do so in future. It is quite conceivable therefore that amazing devices and technologies would become available in the service of human health before too long.

Yet there is plenty of scope for improvements. As the scourge of cancer spreads along with chronic multi-organ diseases such as high blood pressure and diabetes affects more and more people worldwide, the challenges facing medical science are just as daunting. □

Demystifying the MedTech sector

People normally remember their doctors, hospitals where they get treated but rarely a medical device. To a common man, medical technology means a syringe, a needle or an IV bag; a BP machine or a glucose monitor. However, medical technology is today far beyond this. There are more than 500,000 medical technologies currently available globally which diagnose, monitor and treat virtually every disease or condition that affects lives of people.

Whether outpatient care or the daycare; whether management of life-threatening medical conditions in OT or in ICU, a large number of instruments and technologies are brought into play. From diagnosis through MRI, CT scans to treatment through catheters which go deep into the body; to providing the Vision thru Intra Ocular Lenses, through implants which are installed in the body, to pacemakers which set the heart's rhythm back; to locomotional implants which bring back joy into life for the paralyzed patients to exoskeletons which allow those who could not move to walk again; to beds and chairs which allow dignity to the patients as well as to healthcare workers; to returning the magic of vision to fighting the scourge of human diseases through radiation. To opening up vessels in the heart through stents to closing wounds without suturing; to diagnosing the vital signs as well as to monitoring these conditions from hundreds of kilometers away from the temples of health… that is the mosaic of medical technologies. And it is just a trailer!

Healthcare, today, is on the cusp of a new era when medical technology (MedTech) is changing the face of clinical care. From prevention to rehabilitation, it has changed the way healthcare is delivered. Highly accurate diagnostics to more effective and targeted treatments have already moved into clinical practice with remarkable gains already and the promise of even more to come. Today healthcare has become more comfortable, less damaging and less painful with better final outcomes to the patients as compared to the blind and lengthy procedures earlier.

All of these technologies have been developed over the years on account of tireless efforts of thousands of healthcare experts who have contributed for many years to bring a single product to come into practice. The common thread through all applications of MedTech is the beneficial impact on

health, quality of life and society as a whole. For many patients, medical technologies form an inseparable part of their daily life. Across the world, numerous exciting developments are going on; those technologies hold the promise of even greater success in the complex disease environment.

The life expectancy in India grew from a mere 40 years in 1960 to 63.9 in 2002-06 to 67.3 in 2014. In some states like Maharashtra, Delhi, Kerala and Himachal Pradesh, the expected lifespan at present is slightly above 70 years! This is on account of amazing progress in healthcare technology with a large contribution from medical devices.

Medical Technology is very different from the Pharma sector. It is highly capital intensive with a long gestation period of development and needs continual influx of technology and continuous training of the Doctors & Para Medical Staff to adapt to the new technology. It requires continuous R&D to produce different versions and variations to match different requirements and geographies. Therefore the scalability of MedTech is much slower than that of pharma. It is also different as there are no generics available in the sector.

Can we think of a hospital without these devices and technologies? Can a surgeon of today perform without using these technologies? Will the hospitals still be called the temples of health?

Can we think of a hospital without these devices and technologies? Can a surgeon perform without using these technologies and get the desired results? Will the hospitals still be called the temples of health? Can a country afford to ignore such technologies and can it deprive its citizens of getting the benefits?Medical technology is miracle technology. It is the time for all stakeholders to come forward for a common purpose: improving, extending and transforming people's lives. Let's recognize the uniqueness, nuances and significance of MedTech and how it is making a difference in the healthcare delivery systems. □

Growth opportunities

The Indian medical technology and devices market has been growing at about 15 per cent annually for the past five years and is expected to maintain a similar clip in the coming decade as well. The market encompasses a very wide range of products from the relatively low value items such as surgical instruments or consumables like syringes and needles, to the high value equipment including CT scan machines, cardiac catheterization lab suite, or MRI each of which has a price tag up to Rs 1 crore to Rs 5 crore apiece. In the middle segment, there are implants for knee and hip replacement surgery, electronic measuring instruments like cardiac monitors, artificial lung machines, anesthesia equipment and numerous other items.

The market size at present is about $ 4.9 billion (approximately Rs 30,000 crore), which is a tiny part of the total healthcare market of about $ 80 billion but this is likely to record substantial growth in the coming years. Hospital administration professionals often say that a large multi-specialty hospital of 100 beds or more needs as many as 2,000 different items on a daily basis. Thus, the growth of the medical devices market is closely connected with the expansion of healthcare delivery systems in the country.

Apart from the metro cities, hospitals are being built in Tier-II and even Tier-III towns like Indore, Coimbatore and Madurai. These are relatively underserved and offer excellent opportunities for future growth.

Healthcare delivery growth

New hospitals are being built at a rapid pace all over the country, and many existing hospitals are being expanded in many places. There is also a spate of acquisitions of new properties by for-profit hospital companies, nearly half a dozen of which have become publicly listed in the past two years.

Along with large hospitals, single specialty hospitals and diagnostics chains are also making ambitious plans to grow their business.

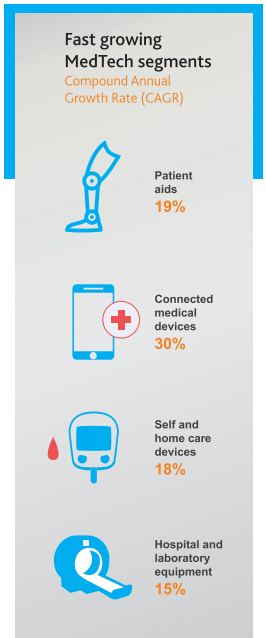
Apart from the metro cities, hospitals are being built in Tier-II and even Tier-III towns, some of which are state capitals, district headquarters or business centres like Indore, Coimbatore, Madurai and so on. These were relatively underserved regions where healthcare is concerned and a number of large and medium hospital companies are reaching out to the people here.

An important aspect of in-patient hospital outcomes are the medical devices and consumables, used either in the Operating Room, the ICU or even in the regular wards. The utilization of high-value medical gadgetry is relatively more in the OR and the ICU. Since many hospitals being built in recent years have a higher proportion of ICU beds, this trend also favours a higher growth trajectory for medical devices.

Disease patterns

India carries a two-pronged disease burden. On one hand, the scourge of MDR

(multi-drug resistance) TB, malaria and other infectious diseases are taking a heavy toll on the health of people. On the other hand, the rapid growth of non-communicable diseases such as diabetes, high blood pressure, PCOD (polycystic ovary disease) and cancer that used to afflict the affluent sections of Indian society have travelled down the social ladder to affect more and more people. While effective treatments are available for most of these, they also require a lot of monitoring of health parameters. Lot of people living with diabetes have to check their blood sugar at least once a day, and high blood pressure patients often need to take their readings at home. All of these are likely to swell up the demand for various use-at-home-medical devices in the years to come.



Public Private Partnership

The need for harnessing the funding capacity of the private sector in healthcare and the necessity of making healthcare services affordable for the maximum number of people has given rise to the concept of the Public Private Partnership in healthcare delivery. This throws up the possibility that access to healthcare and the demand for medical devices could increase exponentially and in tandem, if the PPP model could become an industry standard.

Health Insurance

In the current scenario in the country, where 70-80 per cent of the healthcare expenditure of individual patients is borne by the family itself, affordability is a major question.

While the spread of health insurance is much lower than that in the developed countries such as US, about 25 per cent of the Indian population is covered by some kind of health insurance. This includes publicly funded schemes such as Rashtriya Swasthya Bima Yojana (RSBY), which is operated by the Central Government and State Government-sponsored schemes like Yashaswini in Karnataka and Arogya Raksha in Andhra Pradesh. Likewise, privately funded insurance schemes run by non-life insurance companies such as ICICI Lombard and Bajaj Allianz are expanding steadily year after year.

Technological advances

While hospital growth and increasing affordability among the burgeoning middle class, which currently stands at about 300 million people, offers tremendous opportunities for growth for medical devices in India, technological advancement is creating new avenues for this sector. Thus, portable ECG machines, from which the results can be transmitted to a major hospital with greater ease than before, has enabled healthcare professionals to offer their services at locations far removed from the hospital itself. Bausch & Lomb introduced Intra Ocular Lenses which could go thru 1.4mm incision thus helping in faster recovery especially for the diabetic patients in the country. Vygon brought in catheters as thin as threads which became the life-lines for millions of babies worldwide. Stryker allowed dignity and safety to patient in transportation through patient assist beds and chairs which could climb steps.

The list is long. Companies from all across the world delivered some spectacular advances in patient care. ◻

Challenges and threats

As mentioned earlier, the medical device market in India is worth $ 4.9 billion (Rs 30,000 crore) approximately but is highly fragmented. This is a relatively small component of the total healthcare industry size of about $ 80 billion. To put it another way, the annual per capita consumption of medical devices and consumables in India is about $ 3 as compared to $ 45-70 in middle income countries such as Brazil and Russia.

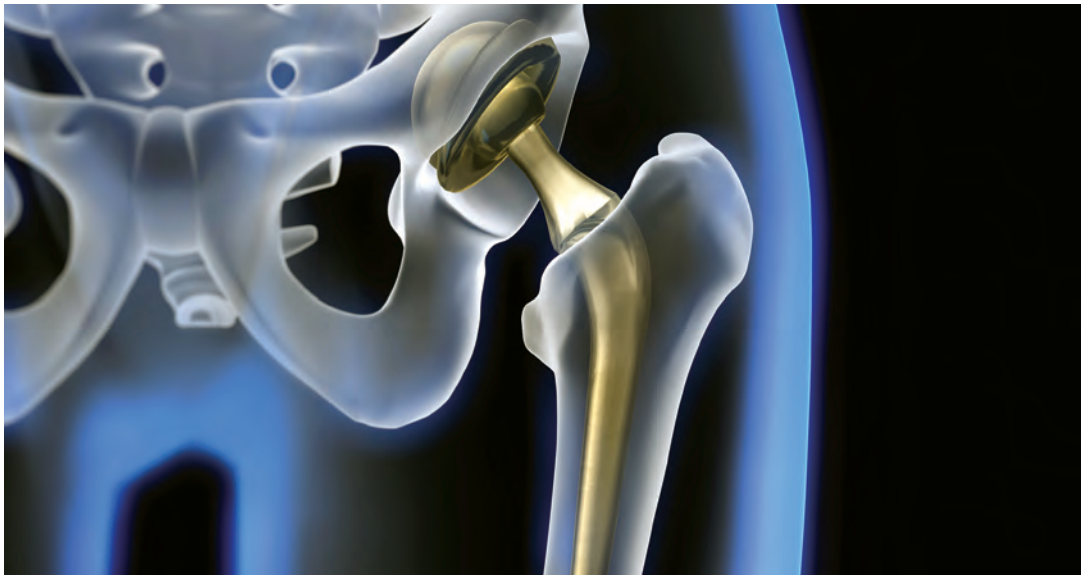
There are strong reasons why the medical devices industry in the country has not expanded to its full potential. These include:

- Non-distinctive regulatory structure
- Price control
- Draft legislation pending
- Custom duties increases on products not import substitutable in near future
- Preferential Market Access which failed in a contiguous sector, being reintroduced
- Growingly conflicting signals to Foreign Direct Investment
- Inadequate public spending on healthcare
- Poor insurance coverage

Regulatory structure

At the moment, there is no fitting regulatory framework for the MedTech sector in India. The sector is governed by a number of diverse laws, administered by several regulatory authorities controlled by different ministries. Since the range of medical devices is very wide, and includes some items that have to go inside the body for long duration, these items come under the ambit of Drugs And Cosmetics Act, as well as the Drugs and Magic Remedies Act, both of which were supposed to take care of medicinal products. In addition, there is the Consumer Protection Act, which not only covers the goods of all kinds but also services provided by doctors and hospitals. Since medical devices are used by doctors and healthcare professionals in providing healthcare services, these products are also covered by the Consumer Protection Act, 1986. Fixing responsibility for an adverse outcome on a medical device or determining the damage caused by such a device requires that suitable quality control benchmarks be created beforehand. The lack of these leaves the medical device companies open to unsupported claims for compensation in the event of a lawsuit. The patient is also left with inadequate cover against poor quality.

The un-nuanced application of the Legal Metrology act similarly goes against the cause of global harmonization which the government has unequivocally endorsed and which is vital to uninterrupted availability of critical medical devices in the country.



In a nutshell, the many laws which impact the medical device sector and the many departments which impinge upon it make for inter-organizational delays, interpretation issues, higher costs and lower ease of doing business.

Unlike pharmaceuticals in which there is a system of licensing and approval for manufacture as well as marketing, there is no such system for medical devices. Besides, there is no system of clinical trials, mechanism for post-marketing feedback or even reporting of adverse effects. Since 2006 , there has been an ad-hoc attempt to regulate the medical devices on par with pharmaceutical products. This has presented its own challenges both to the industry as well as the regulator.

Price Control

This classification of these devices as "Drugs" brought them under the purview of the DPCO (Drug Price Control Order) which is administered by the NPPA (National Pharmaceutical Pricing Authority). Therefore, they have been subjected to the same kind of price control that medicinal products are subjected to. The price control regime for medical devices which began with coronary stents last year, has now been extended to include knee implants as well!

The industry has recently observed an exercise to fix the ceiling price of a category of medical devices (Coronary Stents and Knee implants) with no consideration to Health Technology Assessment (HTA) which is the logical methodology to determine the reimbursement &/or pricing of a given medical device in a given healthcare system backdrop. The desired impact in form of increased access and increase in number of angioplasty procedures is yet to be established. It is also of the strong view that the use of Para 19 of the DPCO to bring elective medical devices under price control is not justified.

Medical technology is a capital-intensive industry with long gestation periods, with many years of research. Different versions of the same device have to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be produced and innovations have to be made continuously. Hence, this sector needs a nuanced approach, rather than a "one size fits all" kind of regulatory policy.

A step in the positive direction is the setting up of the Medical Technology Advisory Board (MTAB) in 2016 under the aegis of the Department of Health Research (the new name for the ICMR). This would help to establish the system of HTA, which examines the real value of a technology or device in terms of the health outcome which the technology brings about. Pricing based on HTA therefore makes much more sense than that based on input costs.

Though the system of Preferential Market Access is well intended, it works to restrict healthcare access to a majority of people in the country; it should instead be implemented gradually over several years into the future.

Draft Legislation pending

In 2015 the Central Government came out with a draft legislation for medical devices after nearly a decade of meetings and consultations. However, before the new laws could be guided through the legislative labyrinth, the CDSCO (Central Drug Standards Control Organisation) published a new set of guidelines for marketing and selling of medical devices: The Medical Device Rules, January 2017, which have been notified and are likely to come in to effect from January 2018. While the concern of CDSCO to better regulate more of the devices is understandable, the time given to the industry to prepare for the implementation of these Rules is too short. While the industry wants a greater adjustment period, which will also help it iron out the outstanding issues, it reiterates its demand of the necessary Legislation preceding the Rules.

Customs Duties

Import duties on medical devices and equipments were increased almost across the board by 7.3% in January 2016. Since, most of the items affected were falling in the 11.6% range which has gone to 18.9% now, it means an effective duty increase of 62.7%. For products where the ability to import substitute is still far away, the high custom duties should be rolled back to the earlier figures.

Additionally, since the custom duty regime in the neighbouring countries (Nepal, Bangladesh, Sri Lanka, Bhutan, Pakistan & Maldives) is now much lower than in India, the differential in duties created is likely to lead to the smuggling of many of the low-bulk-high-value devices. If that happens, not only will the Government lose revenue but also the patient will be beset with products without adequate legal and service guarantees.

There is an urgent need to do the micro analysis of the sub-sectors to know the requirements. Care also must be taken that the duty level does not go way beyond what is there in the neighbouring countries and that quality deficient manufacture doesn't find their way in to the market.

A process of incentivization (including lowest possible tariffs on raw material & components), research & development, skill development, greater health expenditure or better insurance coverage, low regulatory costs, assurance of predictable policy, will benefit the cause of Make in India rather than custom

duty increase. Through custom duty increases, which are almost all passed on to the patients, we will only tax the patients to subsidize manufacturing.

Preferential market access

With the intention of promoting local manufacture of medical devices, the government has put in place a system of PMA (Preferential Market Access) according to which public hospitals and healthcare institutions are expected to give preference to products manufactured in India over the imported items. Though the measure is well intended, it works to restrict healthcare access to a majority of people in the country.

Almost 70 per cent of the products (by value) are imported and the rest are manufactured within the country. This also varies depending upon the subcategory of medical equipment: while in some simple consumables the import is about 40 per cent (and domestic manufacturing is 60 per cent), the proportion of imports goes up to as high as 90 per cent in the case of sophisticated devices e.g. 90 per cent of some implants (such as those used for knee and hip replacement etc.) and 80 per cent of patient aids are imported.

This is because MNCs who are manufacturing these products have developed high technology devices through painstaking research over many years, even decades. Though many of these companies have a strong manufacturing foot print in India and export their Made in India devices they also bring their High tech products to India though they are manufactured elsewhere.

As mentioned earlier, manufacturing of this long-gestation-period medical device industry needs deep pockets, continual influx of technology and

simultaneous readiness of product - specific technological eco systems. Indigenous, quality manufacture may not necessarily always mean lower cost. The score often depends on component manufacturing Eco System.

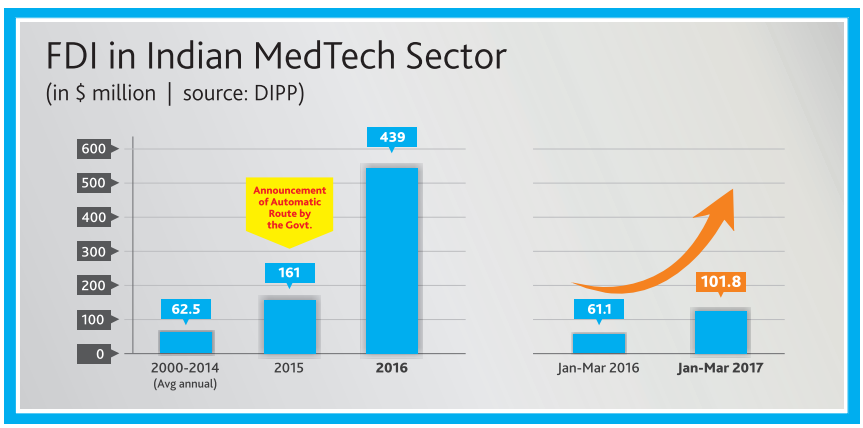
The spectrum of medical device is so diverse - from Cannulae to Cyclotrons and from Syringes to Sternum Saws - that even countries which have been pursuing the manufacture of medical devices for years are making only a small spectrum of what they consume locally. (They, of course, export this product mix robustly).

For these MNCs to produce a larger spectrum of these devices in India, the domestic demand must increase substantially. By merely ordering public healthcare institutions to buy indigenously manufactured products the growth of technology as well as quality may get compromised.

One of the ways to bring foreign direct investment (FDI) into the country's medical devices sector is to reduce the regulatory permissions to make such investments.

Foreign Direct Investment

One of the ways to bring foreign direct investment (FDI) into the country's medical devices sector is to reduce the regulatory permissions to make such



investments. By bringing FDI on the automatic route for this sector the Government has given a booster dose to this sector. The steady surge in FDI, since the decision to bring it on the automatic route is demonstrative of the potential of this sector and what ease of doing business for the relevant communities and global participation can accomplish. But Market Shrinking Measures like Price Control & PMA will hurt FDI growth.

Inadequate public spending

As it is widely known, the number of new hospitals being constructed through public funding is much smaller than those being built in the private sector. The imperatives of the government's stated mission of Universal Health Care (UHC) require that the primary care network be expanded in most parts of the country at a frenetic pace. Access to Healthcare would improve and along with it the demand for advanced technologies. □

The way forward

As discussed in the earlier sections, the MedTech industry in India has a remarkable opportunity for growth and expansion but faces rather daunting challenges that currently hold it back. Hence, MTaI would like to recommend a few steps that could help the sector break free from its shackles and realise its full potential.

Separate regulatory framework

There is a crying need for a separate regulatory mechanism for medical devices, instead of extending the current systems designed for Drugs, and making it applicable to medical technologies as well. All the background work for a separate legislation has been completed; several drafts have been prepared and circulated among various stakeholders. Now it requires steering through the legislature on priority.

This will make it possible for the government to set up a suitable regime for regulation and quality control of medical devices.

The process of permissions and approvals is divided between different ministries on account of different acts applicable to the devices sector. To avoid procedural delays and hurdles, there should be a system of single window clearance, while the different arms of government should coordinate with each other to work out a consolidated approval for the concerned companies. This will drive Ease of Doing Business and promote growth of the sector.

> Ideally, price control should not be imposed on medical technologies at all. If it is to be imposed, it should have the proper checks & balances and should not blanket cap for all generational categories.

Price Control

Ideally, un-nuanced price control should not be imposed on medical technologies at all. If it is to be imposed, it should have the proper checks & balances and should not blanket cap for all generational categories. Price control slapped in a haphazard manner, without taking in to account the dynamics of the Healthcare sector, as proven in the case of Stents, will bring no better access for the patient and may just end up smothering this dynamic and vital industry.

Make In India

The government's push towards Make in India is unquestionable. However, it is impractical to plan to make in India the entire range of products. This we-will-make-all approach has the risk of missing out on building competencies that are vital for sustained growth, survival and reputation building for the industry. Countries which have improved their manufacturing footprint in medical devices have moved forward progressively with their product mix. In fact the objective to Import Substitute should be replaced with the aim of achieving

Global Competitiveness (through export promotion & global quality). Make in India should be implemented in a phased manner, allowing sufficient time for new and advanced technology to be brought into the country. It should focus on those devices that can be manufactured in India in the short term, rather than the advanced technologies for which the ecosystem and know-how may not be available within India for several years into the future.

Though this sector is not employment intensive it can really help in employment generation in a surrogate role: through Healthcare Worker training. Besides the Vacancies of Doctors and Nurses, the number of allied HCW vacancies is huge. About 65 lakh vacancies exist in allied healthcare such as Dental technicians, Medical laboratory technicians, Emergency Technicians, Phlebotomists, Serologists, Sonographers and Radiographers and many others. Almost all HCWs are trained and made patient-ready by the MedTech industry. This contribution of the sector should not be inadvertently compromised through any policy.

> There is a crying need for a separate regulatory mechanism for medical devices, instead of extending the current systems designed for Drugs, and making it applicable to medical technologies as well.

Level Playing Field

The Preferred Market Access (PMA) system should be restricted to those items which are already being manufactured by Indian companies. To implement this across the board, would be detrimental to patient interest. Besides, the public hospitals should also buy the products of the best quality available in the market, rather than just be guided by origin of manufacture.

Taxes and Customs Duties

The customs duties regime should be designed in such a way that it does not affect the availability of quality critical careproducts. There is an urgent need

to do the micro-analysis of the sub-sectors. Wherever import substitution of an acceptable quality level is not likely in the near term, a duty roll-back to previous levels should be made. Besides the duty structure should be at par with the tariffs in the neighboring countries so that the duty differential does not lead to a possibility of smuggling.

Another point to note is that even in segments like consumables where countries like China have near self-sufficiency, they have had to reduce duties from 4 per cent to 3.3 per cent for several products. Nuances in deciding tariffs are necessary to make sure that it should not so happen that the manufacture of medical devices actually hapens in the distant future whereas the cost is paid many years in advance by the patient.

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Sub-sectoring medical devices, based on engineering complexity, is a must for policy decision and clarity.

Health Technology Assessment (HTA)

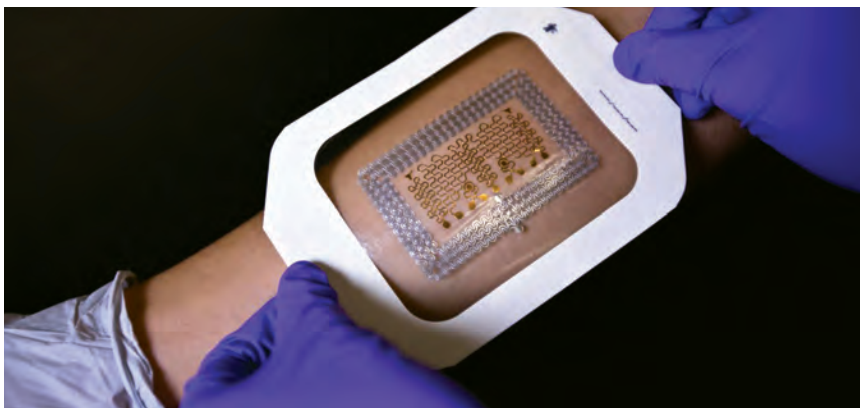
The government must initiate a process by which ICMR/ DHR is established as the sole authority for HTA in the country. Any HTA request for any medical technology by any government body should be routed through the proposed MTAB (Medical Technology Assessment Board) under the aegis of ICMR/ DHR. This will also ensure a holistic assessment of the situation and therefore help in the formulation of a process which will better safeguard the overall interest of the patient, without making the industry unviable.

Fiscal incentives and Infrastructure for R&D

To give India a sustainable leadership in the medical technology space, the Government needs to provide fiscal incentives and infrastructure for medical device innovation and R&D.

Scale up demand

Real time scale up of universal healthcare to expand bed capacity of India is required. it will automatically increase medical device penetration and market size. ◻



MedTech of the future

In other sections of this report, the point is emphasized that progress in medical technology is continuous and gradual, often taking a decade or more to traverse from laboratory to marketplace. At the same time, for every new technology that actually reaches the market, there are many that fall by the wayside, for a variety of reasons – feasibility, ease of use, training requirements, cost to the end user, etc.

Lab on chip device for blood plasma separation

Blood plasma separation has to be done to subject the liquid component of blood to a number of diagnostic test for various diseases. Until now, this process would be done in a laboratory, using sophisticated equipment and it would take a considerable amount of time. Through a process named acoustophoresis, the RBCs concentrate at channel center (node) and cell free plasma collects at walls (antinode) which is separated by a trifurcated channel.

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The proposed techniques have potential application in Point-Of-Care diagnostics and can help in accurate assessment and diagnosis of diseases. These devices will increase the quality, reproducibility, and reliability of the assay results. The cost-effective, self-driven capillary-driven plasma separation device will serve resource poor settings such as rural areas and military camps. The high-throughput acoustophoretic device will help in continuous monitoring of plasma analysis in ICU patients.

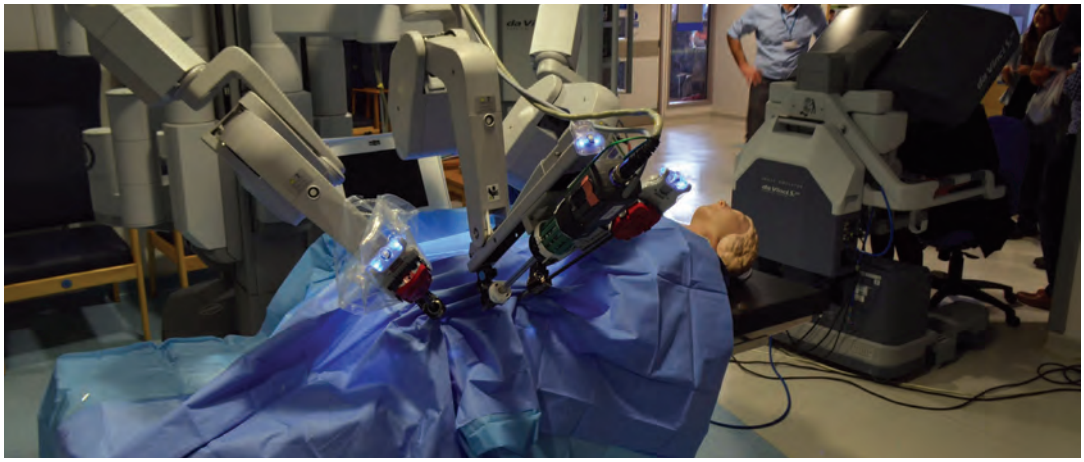
The device has not yet been commercialized, but research projects are underway at IIT Madras and IIT Mumbai.

Robotic surgery

In surgery, as in many scientific and technological endeavors, precision is of paramount important and this is where robots often score over humans. Robotic surgery has come into India a few years ago, and is slowly being used in treatment of cancer of the head and neck, lung, colon and rectum apart from some gynecological malignancies.

Robotic surgery offers some clear advantages over conventional surgery – reduced blood loss, faster recovery from the operation, shorter stay in hospital and less likelihood of post-surgical depression.

Internationally, thousands of cancer patients have been treated with success using the da Vinci Surgical System created by Intuit Surgical, an American company. It was approved by the US FDA several years ago. The cumulative worldwide figure for robotic surgeries conducted till 2015 was 625,000.



In India, the technology is still at a nascent stage, with about 47 hospitals, spread across about 20 metro cities, conducting the procedure. Until recently, there were just about 250 surgeons trained in this technology, and they had conducted about 4,000 surgical procedures between them. Compared to 3 million cancer patients in the country who need surgery, the number treated till now is miniscule.

The US-based Vatikutti Foundation has embarked upon a major campaign to popularize the technology in India as well as to train as many surgeons as possible in different parts of the country. Apart from training of surgeons in robotic procedures, the Vatikutti Foundation is also working with the manufacturing company to work about special price points at which the system can be installed at government medical colleges and public healthcare facilities. They have a target of making the system at 20 new hospitals in India by the end of 2018.

Automated Respiration Monitor

A portable device that looks like a wrist watch is promising to change the way pneumonia is diagnosed and managed in children under five years of age. The prime indicators of improvement or worsening of a child's condition are an increased breathing rate and shallow breathing.

On World Pneumonia Day (November 12) 2015, Royal Philips, the international electronics giant, introduced a device known as the Children's Automated Respiration Monitor, which can give an accurate picture of how a child is breathing. This is crucial in deciding whether a child's pneumonia is getting better or worse, and whether the child is going to live or die.

An estimated 935,000 children die of pneumonia and lung infections worldwide each year, and almost 90 per cent of them are in low and middle-income countries. In India, too, some reports claim that 2,500 children die each year. The device has an excellent potential for making a huge difference in the healthcare outcomes in the under-five age group.

Philips has plans to manufacture the product at its factory in Chakan, near Pune, and it will be exported from here to other countries as well. Since the

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product is the first of its kind, Philips is working both with local end users, as well as key stakeholders in the global health community to ensure that the monitor design and functionality will meet their needs on the ground.

3D bioprinting for tissues and organs

Recent advances have enabled 3D printing of biocompatible materials, cells and supporting components into complex 3D functional living tissues. 3D bioprinting is being applied to regenerative medicine to address the need for tissues and organs suitable for transplantation.

Compared with non-biological printing, 3D bioprinting involves additional complexities, such as the choice of materials, cell types, growth and differentiation factors, and technical challenges related to the sensitivities of living cells and the construction of tissues.

"When printing human tissues and organs, of course, we need to make sure the cells survive, and function is the final test. Our research indicates the feasibility of printing bone, muscle, and cartilage for patients. We will be using similar strategies to print solid organs," says Anthony Atala, one of the scientists working on this technology.

Nanorobots living in our blood stream

In the distant future, microscopic robots on the nanoscale could live in our bloodstream and prevent any diseases by alerting the patient when a condition is about to develop. They could interact with our organs, measure every health parameter and intervene when needed.

Though still an emerging field of science, nanoparticles are gaining something of a reputation as potential multitools for combating things like infections, cancer, type 1 diabetes and even opening up the blood-brain barrier. But they generally can't be simply inserted into the body and left to their own devices, which is why we're seeing the development of techniques aimed at getting them to where they need to go.

Health Sensors – portable diagnostics

If smartphones could be used as biosensors and wearable devices enabling patients to measure almost any health parameter at home, much health-related information would be available at the user's home. This way, patients would have a chance for a better health management. Lifestyle could also be gamified with these devices to make it healthier. These can measure oxygen saturation; pulse variability, ECG, EEG and even more.

Like the tricorder in Star Trek, portable diagnostic devices do not only measure health parameters but also help diagnose the patient using smart algorithms or quick, digital access to medical professionals. The advantage that these developments can bring to telemedicine in a qualified-manpower-deficient country like India can well be imagined. □

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