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THE AWARE CONSUMER

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GOVERNMENT PERSPECTIVE
Make In India

OPINION
New Medical Device: All Set To Change The Indian Healthcare Scenario

Burgeoning Medical Devices Industry

PLUS REPORT • MY MARKET • THE LAST MILE

VIEW  POINT

BEJON KUMAR MISRA | bejonmisra@consumerconexion.org

The Sun-Shine Sector

In 2017, the government approved the National Health Policy, which envisages the realisation of quality health care through both promotive and preventive practices. Through this Policy, the health care system will be made stronger and registries will be established for diseases of public importance.

CURRENTLY, INDIA IS counted among the top 20 global medical devices market and is the 4th largest medical devices market in Asia after Japan, China and South Koreaand is poised to grow to USD 50 billion by 2025 as per some industry estimates.

The medical device market is dominated by imported products, which comprise of around 80% of total sales. The domestic companies are largely involved in manufacturing low-end products for local and as well as international consumption. Lately, many multinational companies have established local presence by acquiring established domestic companies or starting a new business.

The Indian medical device market offers a great opportunity not only of its size, but also because of encouraging policies and regulations that the Government has introduced. For instance, the government has overhauled the regulatory framework for medical device in 2017 and has brought it at par with international norms by introducing the concept of 'risk-based' regulation. The regulatory licenses issued for import, manufacture or sale of medical devices have been made perpetual in nature to cut down on unnecessary and time-consuming paper-work, in a bid to increase ease of doing business in

India. Foreign direct investment in medical device manufacturing sector is permitted without any prior approval from the government, allowing business to quickly scale-up existing operations by infusing capital or engage in time-sensitive strategic acquisitions. The already robust intellectual property rights regime in India has been strengthened further by tweaking of rules for grant of patent and trademark in the last two years. The Indian Government has also introduced various fiscal measures to promote research, development, manufacturing and import of medical devices. For instance, the Government has incentivized scientific research and development by providing weighted deduction for the expense incurred on that front. There is minimal or no import duty on certain medical devices.

However, like any other country, there are certain challenges in doing business of medical devices in India that must be borne in mind. The first and foremost challenge is price control.The second challenge is the presence of multiple regulators which may make simple tasks, such as rectification of erroneous declaration on the label, quite a tumultuous affair. The third challengeis presence of archaic laws that do not permit manufactures and importers of medical device to promote their product directly to the customer as cures for certain prescribed conditions and illnesses.

Having said that, the Government remains extremely committed and sensitive to the demands of the industry, and, in fact, has earmarked medical device industry as a “sun-shine” sector.

DESKTALK

Message from the Editor-in-Chief

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Need Of A National Comprehensive Policy

MEDICAL DEVICES ARE now a pervasive part of modern medical care.They are in many cases associated with quality of care. In some cases, the use of devices has certainly improved quality. In other cases, devices have been associated with many problems. The approach to quality of devices has depended largely on regulation. Recently introduced guidelines and the amendment in the law will provide adequate guidance for both the manufacturers and competent authorities to manage cases efficiently and appropriately.While these regulations and reforms promise to clarify, unify, and expedite the process of manufacturing and importing medical devices into India, they also pose their own challenges and complications. Understanding the regulatory reforms imminent in India will be crucial for foreign companies looking to enter or expand their business in India's medical markets. It is hoped that the guidelines are implemented and regulated properly with effective outcome.

The era of newer development and technology has decreased the morbidity and mortality of life. The medical development in terms of drugs and devices has brought about the robust change in the life of the people (as offered by the cosmetic treatment, dentist, face and cardiology devices).

Medical devices have extended the ability of physicians to diagnose and treat diseases, making great contributions to health and quality of life. Implementing a full regulatory programme can be very demanding on resources, especially for a developing nation. A good approach to setting a clear direction for all stakeholders is to establish a comprehensive national policy or guideline on medical device.

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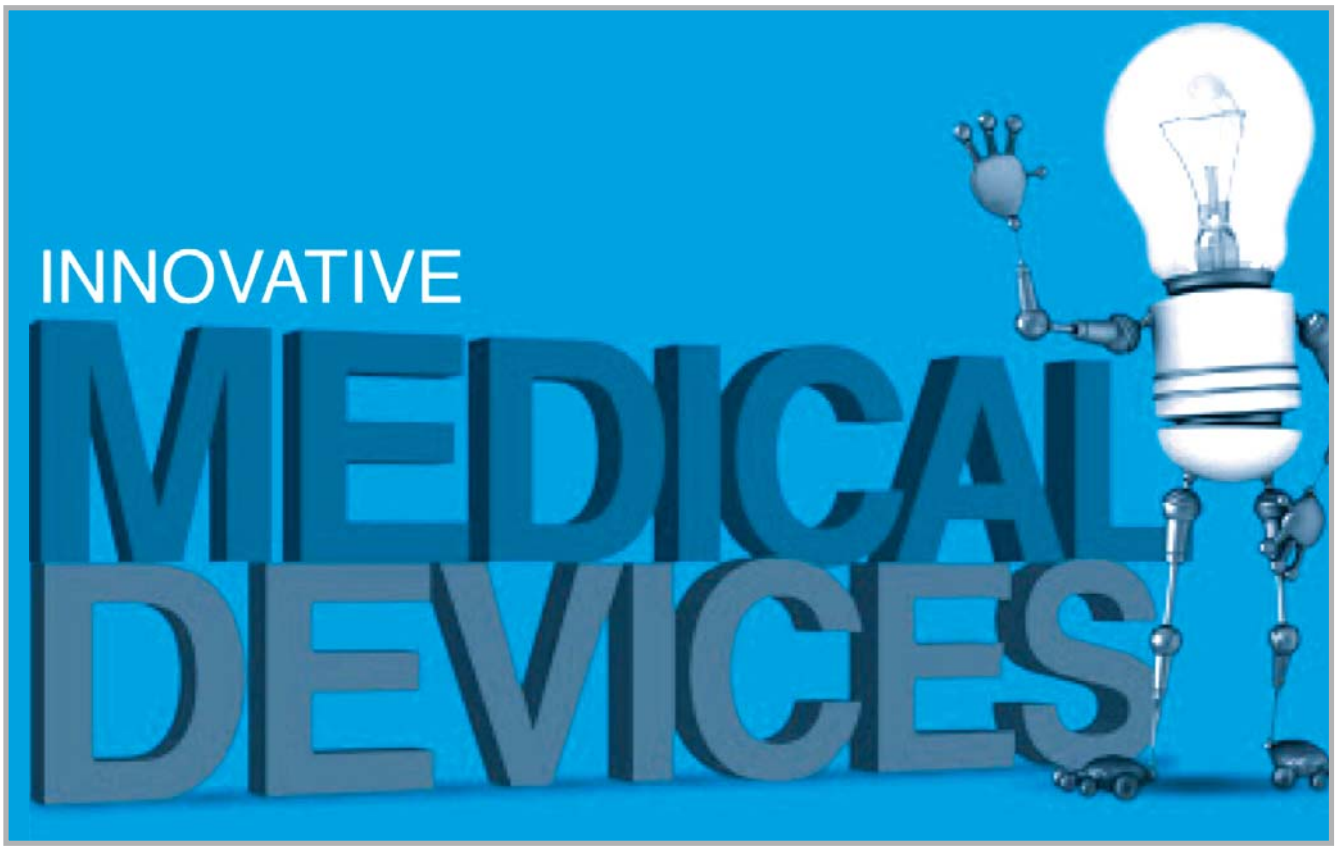
JAGAT PRAKASH NADDA
UNION MINISTER OF HEALTH AND FAMILY WELFARE.

India is deeply committed nationally and globally to achieving all public health goals and also focusing on developing India as a hub for affordable medical devices."

ROUNDUP



PGI Doctor's New Medical Device To Make Biopsy Redundant

With this device, biopsy will become redundant. In biopsy, doctors remove tissues from an organ to examine any pathological abnormality.

THE PGI IN collaboration with the Central Scientific Instruments Organisation (CSIO) and Semi Conductor Laboratory (SCL), Mohali, have developed a device that can spot abnormalities in intestines (ulcers, cancer or wheat allergy).

With this device, biopsy will become redundant. In biopsy, doctors remove tissues from an organ to examine any pathological abnormality.

"We have used a basic principle of physics to detect biological problems in the gut. Indian gut is often unhealthy as there is a lot of

DATA BRIEFING

For instance, footwear priced at less than INR500 attracts a GST rate of 5% and those priced above INR500 at 18%.

inflammation at microscopic level, which translates into poor gut health. Consequently, there is suboptimal absorption of food and suboptimal energy levels," said Dr Usha of gastroenterology department, PGI, who is also heading the project. "Impedance (a type of electrical resistance) is the basic method used in the device that will spot suboptimal gut health," she added.

How does it work?

"The epithelial cells of the gut are tightly packed with each other. If a small amount of current is passed during endoscopy, it will resist the passage of current, which can be seen on the meter attached to the device," Dr Usha said.

"In case a gut is infected, gaps can be seen at microscopic level. A leaky or unhealthy gut can be spotted with the help of the readings on the meter attached with the device. We have made five prototypes of the device and checked its validity and reliability on intestines removed from human bodies during a surgery," Dr Usha added.

The doctor as of now is working on finding a correlation between the buccal (mouth) and gut mucosa (lining of the epithelial cells). "If this works out, endoscopy or biopsy would become redundant and the currents can be passed on to the mouth to detect the health of the gut for early prevention of stomach cancer.

Advantage of device

Biopsy of entire gut is not possible. Therefore, by using small amounts of current, the abnormality can be detected without biopsy in case diseases like cancer.

We can prevent the progress of any gut-related disease and it takes less time as compared to biopsy. The device can also monitor healing of the gut when a patient is on medication.

IIT Kharagpur To Develop Coin-sized Biological Computers For Medical Treatment

IIT KHARAGPUR HAS set up Bioelectronics Innovation Laboratory to develop battery-free implantable medical devices for treatment of brain, nerve, muscle or spinal cord disorders that are untreatable by using standard medical practices.

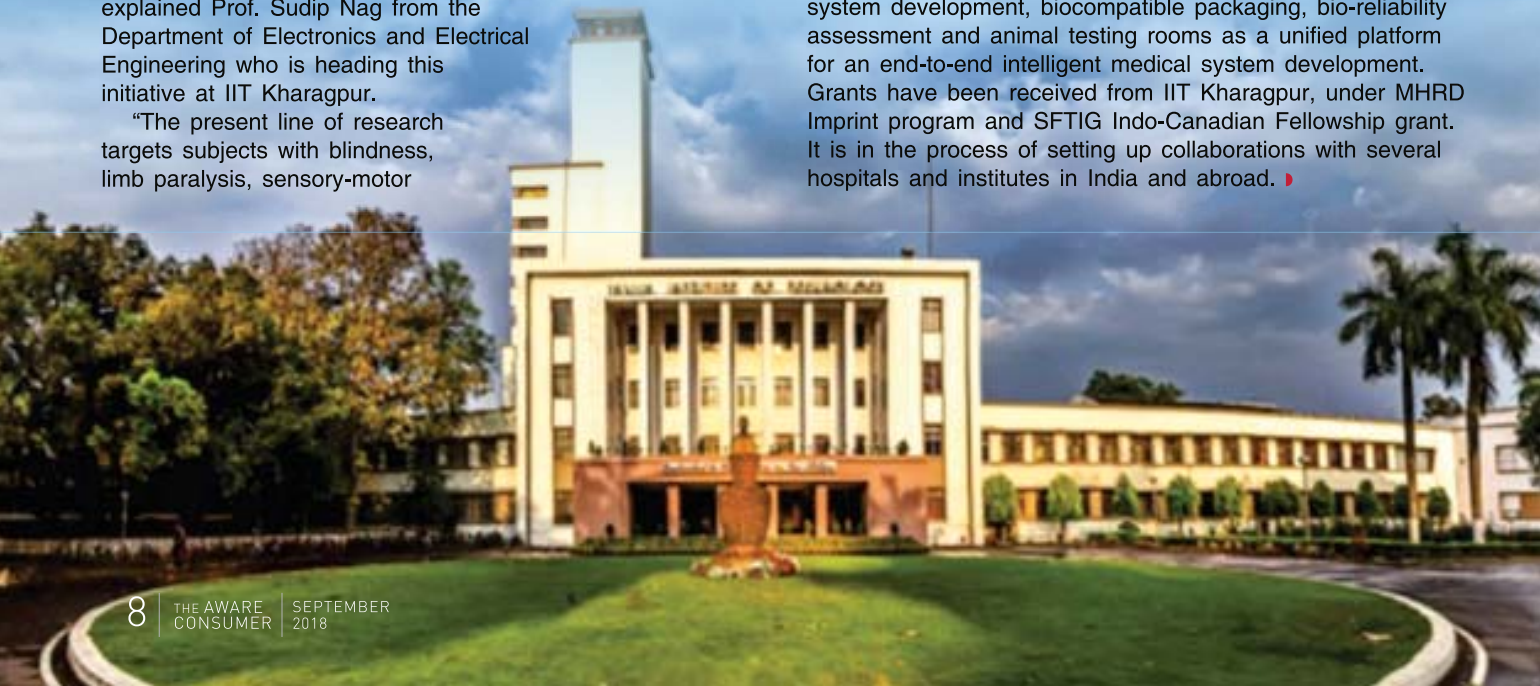
"We aim to implant coin sized electronic chips with wireless energy supply for rehabilitation and prostheses applications. Unlike the standard pace-makers that require a surgery every 5 to 10 years due to limited battery-life, our solutions depend on wireless power transfer and intelligent communication schemes. The novel bioelectronic devices will be able to sense bio-signals, process information to make intelligent decisions, and control diseased organs by electrical methods" explained Prof. Sudip Nag from the Department of Electronics and Electrical Engineering who is heading this initiative at IIT Kharagpur.

"The present line of research targets subjects with blindness, limb paralysis, sensory-motor dysfunction, cognition-loss, parkinsons tremor, epileptic seizures, and even memory-loss."

Bioelectronics utilizes the intersecting knowledge of both electronics and biology. Bioelectronic devices generally target to restore missing neural functions, while utilizing energy efficient and miniaturized engineering systems.

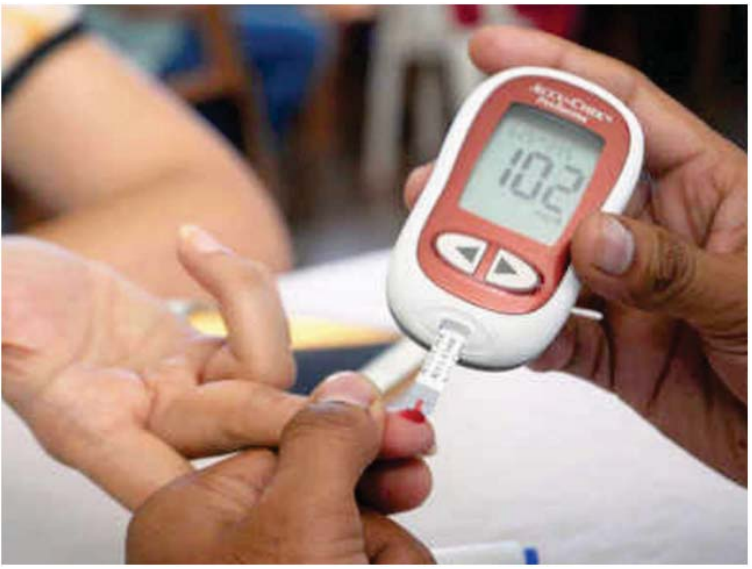
According to Nag, these solutions will incorporate a combination of electrical stimulation, bio-potential recording and neuro-chemical sensing. Also, this will enhance the life-time of implants and reduce the number of surgical interventions.

The laboratory will facilitate energy efficient electronic system development, biocompatible packaging, bio-reliability assessment and animal testing rooms as a unified platform for an end-to-end intelligent medical system development. Grants have been received from IIT Kharagpur, under MHRD Imprint program and SFTIG Indo-Canadian Fellowship grant. It is in the process of setting up collaborations with several hospitals and institutes in India and abroad.



TECH TO THE RESCUE:

Diabetic Tools To Sweeten Quality Of Sugar Control



FROM THE DAYS when we as medical students used to collect urine samples and use the turquoise-coloured solutions to estimate the sugar, (remember urine sugar is proportional to blood sugar), medicine has come a long way.

No one needs urinary estimation, for blood sugar estimation with slick, small and relatively inexpensive glucometers has made life easier.

The ease of the glucometer was necessitated initially for the insulin-requiring patient who needed to know his reading to enable calculation of the next dose instantly. Now this device provides patients security, comfort and independence, for he need not run to the lab and get his venu-puncture repeatedly. In fact we live in an era of patient empowerment and diabetics are now being taught self-monitoring and titration of therapy, to enable closer and simpler monitoring of their metabolic condition. A glucometer is a mobile-sized device, which is battery operated and into which a small chemically sensitized strip is inserted. The patient then pricks himself and expels a drop of blood on to the active portion, the glucometer pings to confirm the upload and within seconds, flashes the blood glucose value. The strip is discarded, the prick is cleaned and the machine put away. A one-time investment, the patient has to replenish the stock of strips and store them perfectly, lest improper handling can result in inaccurate readings. Of immense value to the daily user, the memory on the meter provides the ready reckoner for the treating physician about the glucose history of the patient since his last visit.

This brings us to the introduction of the ambulatory glucose monitor which goes a step further and continuously measures the glucose level. Once a small coin-sized device is installed on the shoulder(relatively painless), the patient goes about doing all his daily routine including shower, exercise etc. While the thin prong sensor in the coin senses and translates the blood glucose level round-the-clock. The central monitor app for this sensor can be uploaded on a laptop/ smartphone/ handled separately and merely by bringing the patient close to it, can immediately reflect the blood sugar value at that moment in time. No repeated pricks, no drops of messy blood and no strips to buy and store. Instant result and spontaneous titration. Now this has another advantage for it provides the amplitudes of glycemic variation through the day and night for the recording and capture into memory continues. There are many patients with relatively normal fasting and post-meal values (glucometer determined), who still have inadequate three months average control (HbA1c). In fact when replayed and collated together, this machine provides a fortnight's readings and a mean graph, day-wise and through the fortnight. This helps to decipher the silent highs and lows which can then be used to tweak treatment to perfection.

Recently introduced, this has added a therapeutic boost which is cost effective.

Since diabetes is a way of life, any inexpensive practical aid to make life sweeter for the sugar-free patients is indeed desirable. ✷

Samsung's new ultrasound device delivers 3D images of foetuses

SOUTH KOREAN TECH giant Samsung Electronics has developed a new ultrasound image processing engine to deliver three-dimensional pictures of various organs or of foetuses.

The solution, CrystalLive, was developed in collaboration with Samsung's medical instrument arm Samsung Medison, Yonhap news agency reported.

It is believed that the solution could help doctors improve the accuracy of diagnoses by detecting potential congenital diseases in foetuses.

"We plan to improve the accuracy and efficiency of diagnosis through the CrystalLive engine and speed up our penetration into university-run hospitals, which call for high-level diagnosis," Samsung Medison said in a statement. ◗

FEWER COMPLICATIONS FOR PATIENTS WITH LEADLESS PACEMAKERS

Approximately a million pacemakers are annually implanted in patients to provide electrical stimulation to regulate heartbeat.

A RESEARCH STUDY found that patients with leadless pacemakers are likely to have fewer short-term and mid-term complications than those with transvenous pacemakers.

Approximately a million pacemakers are annually implanted in patients to provide electrical stimulation to regulate heartbeat.

Conventional pacemakers are surgically placed under the skin of patient's chest stretching from the shoulder vein and attaching to the heart.

The wires and surgery lead to complications in the patient.

Leadless pacemakers on the other hand, are devoid of wires and are ten times smaller than the traditional pacemakers.They are placed directly into the heart using a catheter passed through the femoral vein in the leg.

A study compared short- and mid-term complications between 718 patients receiving the Nanostim leadless pacemaker and 1,436 patients with conventional (transvenous) pacemakers.

It was found that patients receiving one type of leadless pacemaker (Nanostim) overall had fewer complications (5.8 percent vs. 9.4 percent). Leadless pacemakers completely eliminated lead and pocket complications, including infection. By comparison, complications among traditional pacemaker recipients included lead complications (3.62 percent), pocket complications (0.42 percent) and infection (1.74 percent). There were no significant differences between the groups in regard to rates of vascular complications, electrode dislodgement and generator complications.

Daniel Cantillon, a researcher said, "The data from this study is encouraging, and we expect complications from leadless pacemakers to continue to decline as the technology improves and physicians gain experience implanting these devices".

The study was published in Heart Rhythm journal.

Smart Stents Can Better Prevent Heart Attacks

Smoking is one of the leading causes for heart diseases. Regular smokers, as well as second-hand/passive smokers, are at high risk of heart disease. Tobacco also contributes to heart conditions by reducing the good cholesterol (HDL) and increasing the bad cholesterol (LDL and Triglycerides) in the body.

The device uses medical-grade.stainless steel and looks similar to most commercial stents

SCIENTISTS HAVE CREATED a 'smart stent' that can monitor even subtle changes in the flow of blood through the artery, and detect the narrowing in its earliest stages - potentially preventing heart attacks.

The device uses medical-grade stainless steel and looks similar to most commercial stents.

It is the first angioplasty-ready smart stent, researchers said. It can be implanted using current medical procedures without modifications.

"We modified a stent to function as a miniature antenna and added a special micro-sensor that we developed to continuously track blood flow. The data can then be sent wirelessly to an external reader, providing constantly updated information on the artery's condition," said Kenichi Takahata, from University of British Columbia (UBC), who led the study published in the journal Advanced Science.

For every three individuals who have had a stent implanted to keep clogged arteries open and prevent a heart attack, at least one will experience restenosis - the renewed narrowing of the artery due to plaque buildup or scarring - which can lead to additional complications.

"X-rays such as CT or diagnostic angiograms, which are the standard tools for diagnosis, can be impractical or inconvenient for the patient," said York Hsiang, a professor at UBC.

"Putting a smart stent in place of a standard one can enable physicians to monitor their patient's health more easily and offer treatment, if needed, in a timely manner," he added.

The device prototype was successfully tested in the lab and on a pig model.

SUPPORT THE CAMPAIGN

LOOK OUT FOR THE RED LINE

BE RESPONSIBLE

Medicines such as Antibiotics have a Red Vertical Line on their pack to indicate that these should be consumed only on doctor's prescription. Always complete the full course as prescribed by the doctor.

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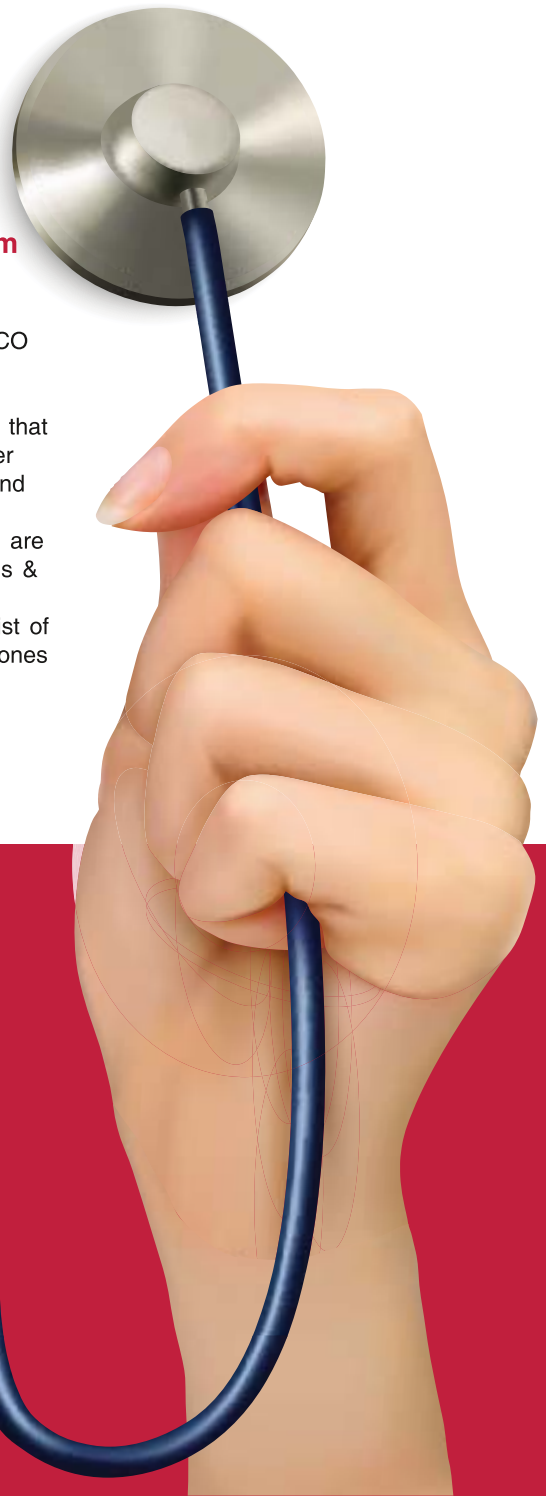
Indian Regulations For Medical Devices

THE CENTRAL DRUGS Standard Control Organization (CDSCO) under the Ministry of Health & Family Welfare (MoHFW), Government of India issued a draft of Medical Devices Rules, 2016 through a gazette notification (No. 724) published on October 17, 2016. Medical devices regulations primarily focused on the quality and safety control to ensure the highest standards assurance of a medical device. It has been classified according to patient risk in different classes (Class A, B, C & D) to ensures that patients have access to high quality, safe, and effective medical devices, by restricting their access to the unsafe and sub-standard products.

The current regulatory system

Laws for medical devices in India are regulated by a part of the Ministry of Health and Family Welfare, i.e., CDSCO under the control of Drug Controller General of India (DCGI). All medical devices follow a regulatory framework that is based on the drug regulations under the Drugs and Cosmetic Act (1940) and Drugs and Cosmetic Rules (1945). At present, a total of 22 medical devices are considered as notified under the Drugs & Cosmetics Act, 1940, and need to be registered with the CDSCO (1). The list of notified medical devices includes the ones used in the following:

- Aesthetics (Breast Implants, Tissue grafts, Dermal Filler, Implants, Injections)



CLASSIFICATION OF MEDICAL DEVICES AND THE COMPETENT AUTHORITY

As per the guidelines in the new gazette, in vitro and other devices used for diagnosis are classified based on their level of risk as follows:

Class A: low risk devices like thermometers and sphygmomanometer

Class B: low-to-moderate risk devices like needles and suction cannula

Class C: moderate-to-high risk devices like ventilator and joint implants

Class D: high risk devices like pace maker and heart valves.

- Blood Storage (Blood Bag System, Bloodlines, Filters, Platelet Storage)
- Cardiology (Annuloplasty System, Heart Valves, Balloon Catheters, Bioprosthetics, Cannula, Cardioverter Defibrillator, Catheters, Access Port System, Cannula, Guide wires, Sheaths, Shunt, Occlusion and Aspiration System, Plaque Excision System, Stents, Filter System, Pacemaker)
- Contraceptives (Condoms, Copper T)
- Dental (Denture cream, Implants, Abutments, Needle, Scaffolds)
- ENT (Hearing Prosthesis, Implants, Ossicular Prosthesis)
- Gastroenterology (Catheters, Feeding Tube Kit, Hernia System, Ligation Device, Stents);
- Gynecology (Catheters, Grafting System, Needles, Tampons, Pelvic Floor Repair System, Stents)
- IVD (Blood Testing, Cell Processing, Filter Sets, Lab Kit, Prep Pads, Stem Cells)
- Neurology (Catheters, Distraction System, Fixation System, Grafting System, Implants, Reconstruction Device, Stents, Guide wires, Catheters)
- Oncology (SIR Spheres), Ophthalmology (Bandages, Catheters, Eye Drops, Implants, Intraocular Gases, Lens, Occluder)
- Orthopedic (Bone Cements, Bone Substitutes, Cervical Plates, Bone Void Filler, Plates, Screws, Cables, Casting Tapes, Coils, Discs, Metal Acetabular Augments, Metal Revision Shells, Femoral Cone, Mesh, Metal Tibial Cone, Fixation System, Grafting System, Haemostatic Powder, Hip implants, Knee implants, Elbow implants, Joint implants, shoulder, Nail system, Tibial Augments, Metallic Anchors)
- Pulmonary (Catheters, Suction System, Tubes, Valve system)
- Spine (Bone Cements, Bone Void Filler, Cages, Cervical Plates, Discs, Fusion Device, Spacer, Fixation System, Implants, Screws)
- Surgery (Catheters, Disposables, Endoscopic Applicator, Tips)
- Syringes and Needles (Blood Transfusion Set, Cannula, Catheters, Infusion Wires, IV Flow Regulators, IV Sets, Needles, Stopcocks, Syringes)
- Urology (Catheters, Stents, Dialysis, Filters, Guide Wires, Stents, Tapes, Tubes)
- Vascular (Cannula, Catheters, closure Device, Elite snare, Embolization Device, Filters, Grafting System, Guide Wires, Occluder, Prosthesis, Reconstruction Device, Sheaths)
- Wound Care and Surgical Dressing material (Bandages, Casting Tapes, Catheters, closure Device, Collagen Membrane, Dressings, Closure Device, Fasteners, Hemostatic Foam, Hemostatic Pads, Mesh, Splint Rolls, Staplers, Surgical Drapes, Surgical Sealant, Sutures).

Wireless medical devices that fail to function as intended can cause harm to patients whose lives depend on them.

IMAGINE RECALLING THE medical device you designed and deployed because the battery could not last as expected. Imagine if an implanted device had to be surgically removed from a patient, whose very life depended on it. In fact, there was recent case in which Implantable Cardioverter Defibrillators (ICD) and Cardiac Resynchronization Therapy Defibrillators (CRT-D) had to be recalled, due to premature battery depletion. If a wireless medical device is designed well to perform the way it should despite the rigors of the real world, this would not happen.

To avoid these occurrences, here are a few tips for medical device manufacturers:

Tune and test the medical device with simulated sensors

IoT medical devices are currently driving

ENSURING MEDICAL DEVICE SAFETY THROUGH DESIGN

by Janet Ooi

innovations in sensors. What have traditionally been in hospitals or clinics, can now be found in home environments, and in more portable forms. More focus is put into the design of medical devices that are non-intrusive, smaller and portable to support this paradigm shift. However, users are not expecting any less from their medical devices in terms of functionality and performance.

Test considerations: Use highly accurate signals to simulate different pathological conditions for sensor tests.

Electronics in a medical device rely on sensor signals as a basis for its control activities and accurate response. It is crucial to verify, tune and test sensor behavior during the product design stage. An arbitrary waveform generator (AWG) can be used to simulate highly accurate and clean physiological signals and variations of ideal signals, which includes infrequent pulses and impairments to simulate and characterize the response of advanced medical devices.

Optimize the medical device battery run time

Technology advancements in portable, wireless medical devices has put greater emphasis on the need to prolong the life of the batteries that power them. Batteries must be small, lightweight and able to accommodate demand for data handling, analysis and other inter-app functions in today's connected world. Accurate characterization of the current profile in batteries then becomes critical at the design stage of the device to satiate the need for lower power consumption.

Test considerations: Use instruments with sufficient current range and bandwidth for accurate current profiling

The battery and power delivery network of a medical device must be incorporated as part of the design test process. This helps device manufacturers better understand battery life expectancy, gain insight into critical events that contribute to power consumption, and experiment with design tradeoffs that can help lengthen battery life. Here are some of the key test challenges to profiling batteries in wireless medical devices:

- Precision at low current
- Wide dynamic current measurement
- Fast data acquisition
- Debug design down to sub-circuit level
- Long operation time

An oscilloscope, DC power analyzer with source measure unit (SMU) or a device current waveform analyzer can be used to effectively test and validate the design of the power delivery network, depending on the dynamic current range and bandwidth of the wireless medical device.

"Proof" the medical device against RF interference

The rise in adoption of connected devices poses serious concerns for patients, as wireless medical devices are forced to compete for connectivity against a myriad of other devices operating at the same frequency. A cellphone's operation could cause an infusion pump to stop working, or a pacemaker could be susceptible to hacks by unauthorized sources.

Such incidents create potential risks to a patient's safety and disrupts effective healthcare delivery. Radio frequency (RF) coexistence testing then becomes crucial to determine the ability of a medical device to maintain its functional wireless performance in the presence of other wireless signals on both the intended and nearby frequencies.

RESEARCH FEATURE

AN OVERVIEW OF THE INDUSTRY

Medical Devices

THE HEALTH CARE industry in India has been one of the country's largest economic sectors, with regard to both employment and revenue. Several diseases such as polio and syphilis have been successfully eradicated. Besides, there is a sharp reduction in infant mortality ratio, malaria, HIV and AIDS-related deaths. In the last few years, the industry has registered a growth of 10% and is expected to reach USD 145 billion by 2018 and over USD 280 billion by 2025.Furthermore, the health care expenditure is likely to witness a rise due to rising awareness, increasing disposable income as well as growing population.

By definition, a medical device is any instrument, apparatus or appliance used specifically for diagnosis, prevention, alleviation of diseases or wellness purposes.

Medical Devices are segregated into six major segments, out of which diagnostics imaging constitutes the largest chunk (from a global perspective), with an annual sales estimate of USD 60 billion in 2015. Next in line is IV Diagnostics, with an estimated 24% share.The global medical devices industry was estimated at USD 228 billion in 2015. At its current growth trajectory, the market is expected to reach USD 332 billion by 2020.

OVERVIEW OF THE MEDICAL DEVICES INDUSTRY IN INDIA

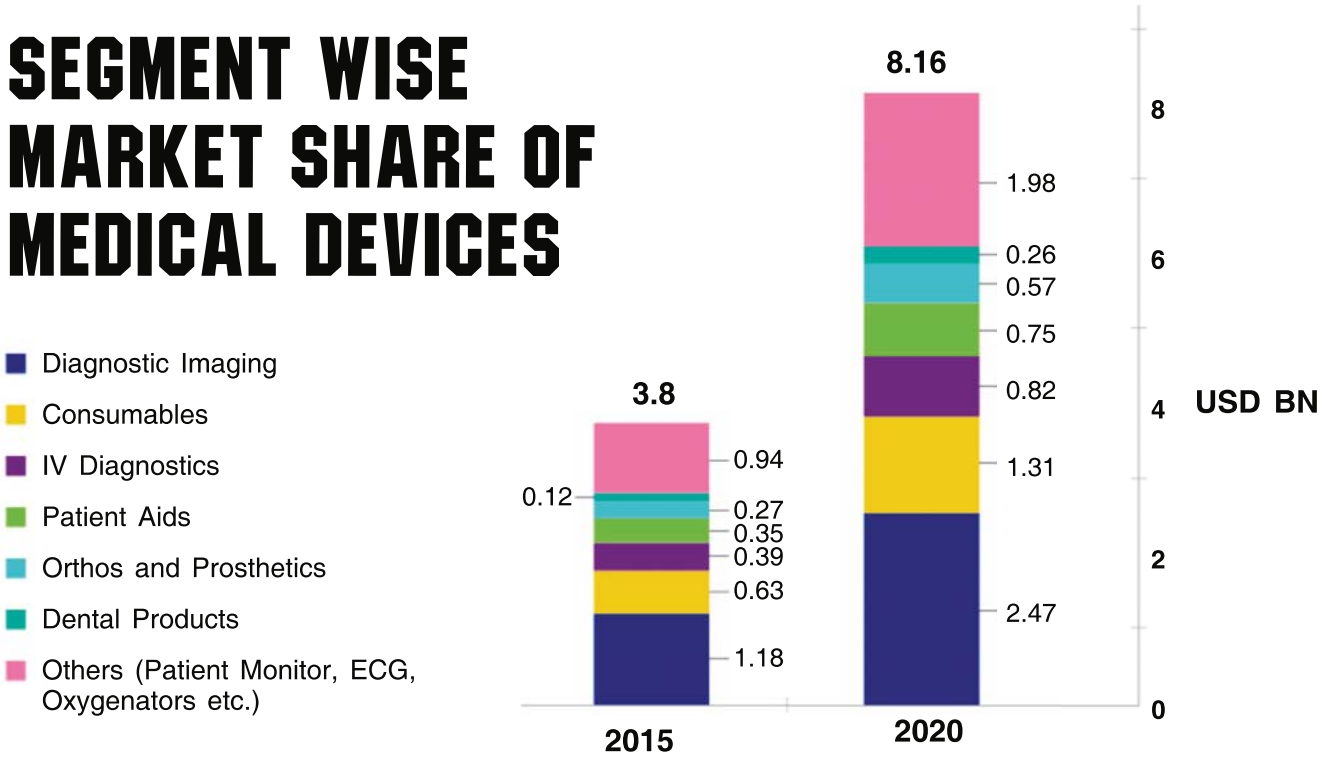
The Medical Devices industry in India is presently valued at USD 5.2 billion and contributes 4-5% to the USD 96.7 billion Indian health care industry. Currently, India has about 750–800 medical device manufacturers in the country, with an average investment of Rs 170–200 million and an average turnover of Rs 450–500 million.

The industry has steadily grown and witnessed a surge from USD 2.02 billion in 2009 to USD 3.9 billion in 2015 at a Compound Annual Growth Rate (CAGR) of 15.8%. As per industry estimates, the Indian medical devices market will grow to USD 50 billion by 2025. Currently, India is counted among the top 20 global medical devices market and is the 4th largest medical devices market in Asia after Japan, China and South Korea. Equipment and Instruments (surgical and non-surgical) form the largest segment (53% of the Indian medical device industry), constituting about USD 2.7 Billion (2017), while the estimated market size of the consumer and durable segment is USD 1404 million.

With the liberalising of government policies, up to 100% Foreign Direct Investment is permitted in Medical devices through the automatic route. During the period between April 2000 and March 2017, USD 1.57 billion worth FDI came into the country.Taking advantage of this lucrative opportunity, an increasing number of MNCs are setting up their manufacturing bases in India. Some instances include the Becton Dickinson's manufacturing plant in Haryana9 and Philips Medical Systems' acquisition of Medtronics10.

There are a range of Medical Device Clusters that have emerged due to supportive state-level policies as well as the availability of skilled labour. There are a few Medical Device Parks planned across India, including

SEGMENT WISE MARKET SHARE OF MEDICAL DEVICES



What is a medical device?

A MEDICAL DEVICE is any apparatus, appliance, software, material, or other article—whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application—intended by the manufacturer to be used for human beings for the purpose of:\

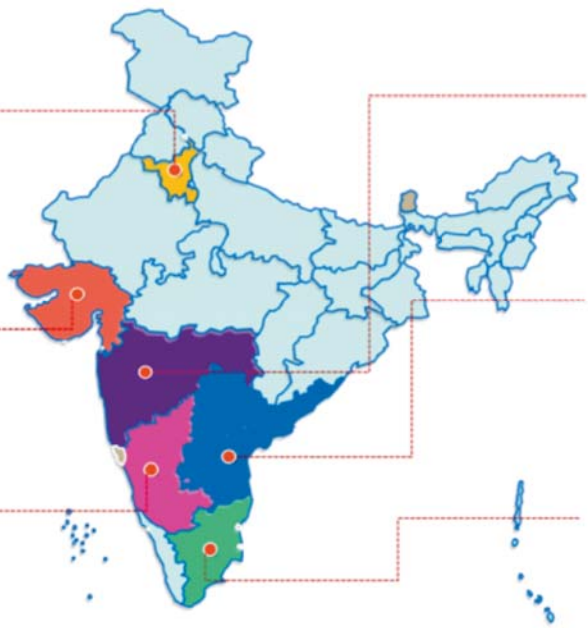
- Diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- Diagnosis, monitoring, treatment, alleviation, or compensation for an injury or handicap;
- Investigation, replacement, or modification of the anatomy or of a physiological process;
- Control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means

Medical devices vary according to their intended use and indications. Examples range from simple devices such as tongue depressors, medical thermometers, and disposable gloves to advanced devices such as computers which assist in the conduct of medical testing, implants, and prostheses. Items as intricate as housings for cochlear implants are manufactured through the deep drawn and shallow drawn manufacturing processes. The design of medical devices constitutes a major segment of the field of biomedical engineering.

Medical device manufacturing requires a level of process control according to the classification of the device. Higher risk; more controls. When in the initial R&D phase, manufacturers are now beginning to design for manufacturability. This means products can be more precision-engineered to for production to result in shorter lead times, tighter tolerances and more advanced specifications and prototypes. These days, with the aid of CAD or modelling platforms, the work is now much faster, and this can act also as a tool for strategic design generation as well as a marketing tool.

Failure to meet cost targets will lead to substantial losses for an organisation. In addition, with global competition, the R&D of new devices is not just a necessity, it is an imperative for medical device manufacturers. The realisation of a new design can be very costly, especially with the shorter product life cycle. As technology advances, there is typically a level of quality, safety and reliability that increases exponentially with time.

For example, initial models of the artificial cardiac pacemaker were external support devices that transmits pulses of electricity to the heart muscles via electrode leads on the chest. The electrodes contact the heart directly through the chest, allowing stimulation pulses to pass through the body. Recipients of this typically suffered infection at the entrance of the electrodes, which led to the subsequent trial of the first internal pacemaker, with electrodes attached to the myocardium by thoracotomy. Future developments led to the isotope-power source that would last for the lifespan of the patient. ◗



HARYANA

Chandigarh, Ballabgarh, Faridabad, Manesar
Low-End Medical Consumables
Companies: Boston Scientific Corp., Becton Dickinson India, Hindustan Syringes, Poly Medicure, etc.

GUJARAT

Ahmedabad, Vapl Industrial Corridor
Pharmaceuticals
Companies: 3M Co., Bayer AG, Meril Life Sciences, Invent Bio-Med, etc.

KARNATAKA

Bangalore, Mangalore
Insulin Pens, Stents and Implants, Medical Electronics
Companies: GE Healthcare, Biocon, Medived, Skanray, Bigtec Labs, Prognosys Medical, etc.

MAHARASHTRA

Mumbai, Pune, Nagpur
Pharmaceuticals
Companies: Johnson & Johnson, Phillips Healthcare, Siemens, Trivitron Co., Smith & Nephew, etc.

ANDHRA PRADESH, TELANGANA

Hyderabad, AMTZ MedTech Park in Vishakhapatnam (AP); Sultanpur (Upcoming in Telangana)
Medical Electronics
Companies: St. Jude Medical, Relisys Medical devices, B Braun, Medtronic, etc.

TAMIL NADU

HLL MedTech Park, Chennai
International Medical Electronics Manufacturers
Companies: Roche, Trivitron, Healthcare, Opto Circuits, Perfint Healthcare, Phoenix Health Systems, Schiller, etc.

Andhra Pradesh MedTech Zone Limited (AMTZ),a park in Sultanpur village (Telangana) and HLL Lifecare Mediparks in Tamil Nadu, Maharashtra and Gujarat.

GROWTH DRIVERS

The demand for medical devices is predicted to rise so as to meet the demands of a growing population. According to the United Nations, India's population is set to touch 1.45 billion by 2028, making it the world's most populous nation.With socio-economic changes such as rapid urbanisation, demographic and lifestyle changes, the society is more prone to lifestyle-related ailments, including diabetes, obesity, stroke and cancer.

Also, out of the total population, the share of ageing population in 2011 was 5.3% and is expected to increase to 6% of the total population by 2021. With an increasingly ageing population, there will be a greater demand for better health care facilities and medical devices.

Also, with a large number of private players making their foray into healthcare, there is a growth in the number of hospitals, diagnostic centres and specialised facilities. Most of these hospitals have their quality and accreditation at par with international standards. 393 hospitals have already received the National Accreditation Board for Hospitals & Healthcare Providers (NABH) accreditation in the last decade.

Government Support

In the last two decades, the Medical Devices Industry has undergone a transformation - from being a domestic-industry- dominated sector prior to 1991 to conversion to import-dependence post - New Economic Policy-1991, to being a non-regulated sector prior to 2006 to regulation of 15 notified devices to the new Medical Device Rules announced in 2017.

The government has taken various steps to ensure that the medical devices sector is considered as significant as the other sectors. To take this further, a task force was constituted to implement a range of recommendations, including the segregation of medical devices from drugs. Currently, only 15 categories of medical devices are regulated as drugs. The new set of regulatory practices aims to remove these hurdles so as to prepare India to meet the Medical devices sector requirements. These new rules shall thus enhance ease of doing business and ensure availability of quality medical devices.

Also, for the very first time, periodic renewal of licenses will not be required. Consequently, manufacturing and import licenses will be valid until it is suspended or cancelled. The rules also aim to promote a culture of self-compliance by manufacturers of medical devices. In addition, the manufacturing licences for certain medical devices are granted without prior audit of the manufacturing site. In such cases, the manufacturer has to do self- certification of compliance with the essential requirements and on the basis of such certification, the licence will be issued.

In 2017, the government also approved the National Health Policy, which envisages the realisation of quality health care through both promotive and preventive practices. Through this Policy, the health care system will be made stronger and registries will be established for diseases of public importance.

One of the most critical policies is the Draft National Medical Device Policy – 2015 that was proposed to strengthen the Medical Devices sector by reducing dependence on imports, thereby giving impetus to the

'Make in India' initiative. Under this Policy, a single-window mechanism will be provided to the industry to not just focus on self-reliance, but also work towards making India the global hub of production in medical devices. Additionally, the Policy envisages interest subsidy for MSMEs, concession on power tariffs, seed capital and minimum or zero duty on raw materials, among others. Currently, the policy is awaiting inputs from stakeholders and their validation.

Impact of GST on the Medical Devices Sector

Medical Devices, including surgical instruments, attract 6% central excise duty and 5% Value Added Tax (VAT) and along with CST, octroi, entry tax etc. comes to more than 13%. With the new Goods and Services Tax regime, the rate is 12%. This new rate is advantageous to achieve lower costs of manufacturing, and thereby proving beneficial to consumers.

Technological advancement and expertise coupled with government support has proved to be advantageous for the sector. With Medical Parks planned in Gujarat, Andhra Pradesh and Maharashtra and emphasis on excellence in Research and Development (R & D), the medical devices industry in India is poised to cross a market size of USD 50 billion by 2025.

The medical devices sector plays a critical role in improving healthcare access. However, the ecosystem is currently not conducive for the sector to drive accessibility and affordability.

In India, the medical devices industry is small, with a disproportionate reliance on imports and a complex regulatory environment

Though the Indian market is among the top twenty in the world by market size, and fourth in Asia after Japan, China and South Korea, however, the per capita spend on medical devices in India is the lowest among BRIC countries at USD 3(USD 7 in China, USD 21 in Brazil and USD 42 in Russia). It is significantly behind developed economies like the USA (USD 340). This current under – penetration of medical devices in India represents a sizeable growth opportunity.

Existent Regulatory environment
Ambiguous, complex and lacking transparency

The policy for the pharmaceutical industry has largely been applicable to medical devices as it so far has been subsumed under the larger pharmaceutical structure. It therefore requires a clear, unambiguous and transparent policy to enable investments and growth.

The industry is largely dependent on imports with most local manufacturers producing products in the lower end of the technology value chain.

Import dependence

Limited availability of technology and funds not enabling indigenous manufacturing

Imports constitute around 75% of the medical devices industry sales in India. A range of factors contribute to this high percentage share of imports

1. An inverted duty structure historically favoring import of finished goods than raw materials /components for medical devices manufacturing

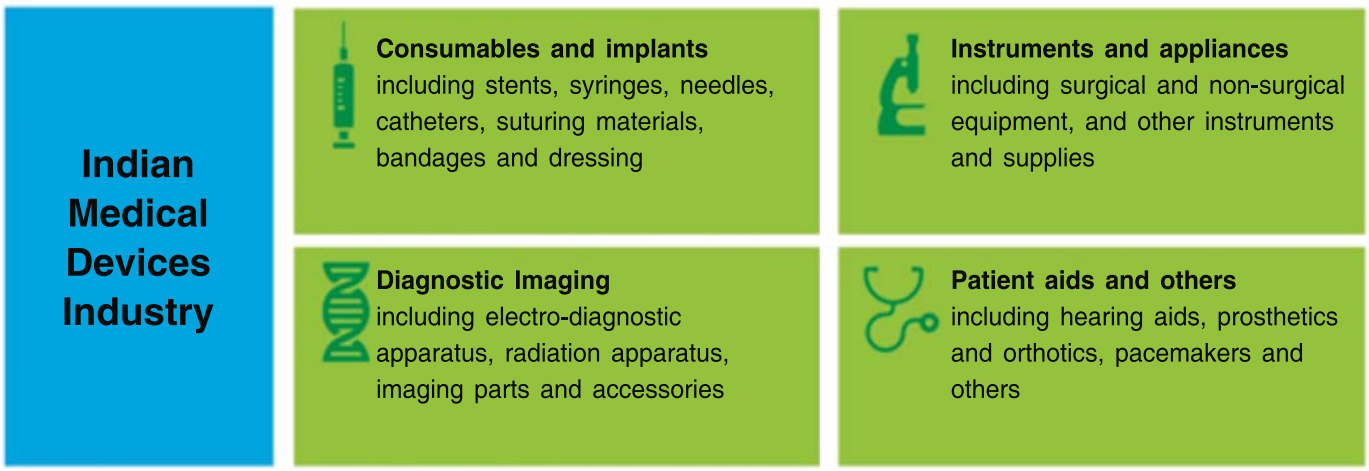
2. Absence of a concrete regulatory framework specific to medical devices constraining investments in the market and, lack of a component manufacturing ecosystem and skills base to support domestic manufacturing of medical devices. In addition, global capacities of multinational firms are also boosting imports

The Indian medical devices industry comprises four segments – consumables and implants, diagnostic imaging, instruments & appliances and patient aids and, others.

In order to bridge the gap existing in medium – high end technology products, an increasing number of multinational companies are establishing and growing their presence in India. Nearly all of the top 40 global medical devices companies today have a presencein the country. The share of multinational firms is around 40% – 50% in consumables and instruments and appliances and, as 80% – 90% in all other.

Exhibit 3: Medical devices industry segments sub-segments. Most multinational companies have their

Exhibit 3: Medical devices industry segments



production base outside India and import their products for the Indian market.

Demand side factors

- **Rising prevalence of chronic diseases resulting in a higher demand for healthcare services:** Non-communicable diseases are expected to comprise more than 75% of India's disease burden by 2025, compared to 45% in 2010
  – India is today referred to as the diabetes capital of the world, with the number of diabetes patients increasing from 38 million in 2010 to 46 million in 2015
  – Around 62 million patients suffer from coronary heart disease (the leading cause of death in India), compared to 47 million in 2010
  – Similarly, around 23 million patients suffer from Chronic Obstructive Pulmonary Disease (the second leading cause of death in India), compared to 21 million in 2010
- **Ageing population:** The share of aged population (>65 years) is expected to increase to 7% (100 million) of the total population in India by 2020, compared to 5% (60 million) in 2010. This would result in a much higher need for healthcare and thus medical devices, both at health facilities and homes
- **Increasing income and affordability, resultingin higher demand and utilization of healthcare services:** The size of the population earning more than USD 5,000 per annum is estimated to increase to around 450 million (~28% of the total population) in 2025 from the current 145 million (~12% of the total population) . This is partly driven by increasing urbanization in India, which is expected to reach 40% by 2030 from the current level of 32%
  In addition, health insurance coverage (Exhibit 4: Demand side factors) is also expected to increase from the current 300 million people to 655 million by 2020.
  As a result, the share of spend onhealthcare as a percentage of total household spend is expected to increase from 7% in 2005 to 13% in 2025.

The Government of India has in recent years, implemented several policy measures to address the challenges of medical devices industry. Some of these include:

- Draft Drugs & Cosmetics Amendments Bill (2015)
- 100% FDI in medical devices under automatic route
- 'Make in India' initiative for promoting indigenous manufacturing
- The development of a quality standardization framework in India that is based on international standards and certifies the quality, safety and performance of medical devices.

Availability of advanced and sophisticated medical technology is creating new markets / applications, increasing the dependence by doctors on advanced medical devices, and is leading to rapid obsolescenceof existing medical technology thereby creating
demand for replacement/up-gradation of products. The Government of India's focus on digital and increasing penetration of mobile and internet (eight-fold in the past decade), are other important factors contributing to rising awareness and demand.

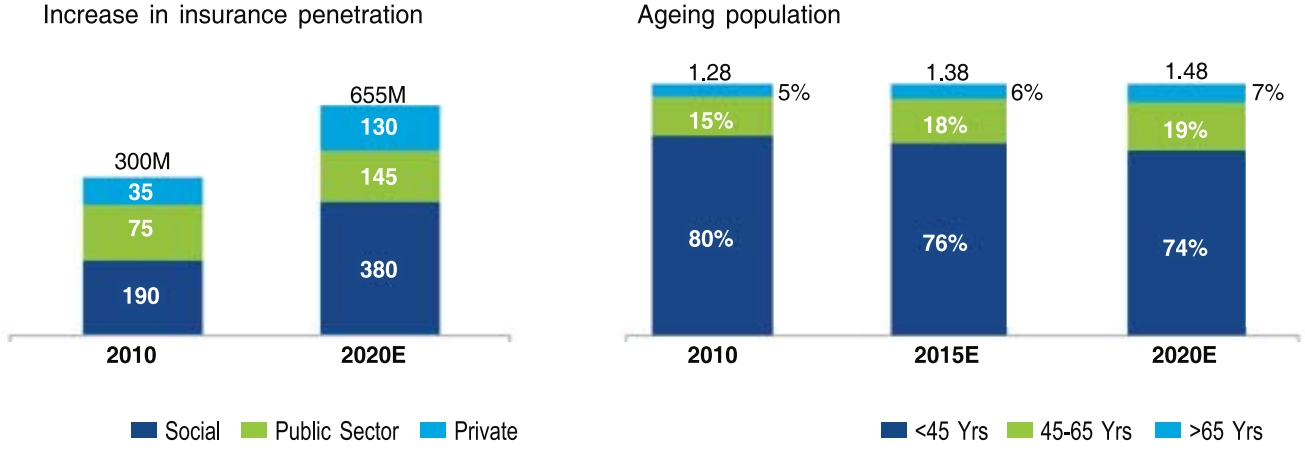
The advent of frugal engineering innovations have led to the recent development of low cost products that are at par with existing products on quality.

Funds/Investments and changing business models

The inflow of FDI in medical devices was USD 90 million between December 2014 to August 2015, post the government permitting 100% FDI under the automatic route.

Several MNCs have been increasing their manufacturing footprint and locating research centers in

Exhibit 4: Demand side factors



Focus on manufacturing in India...

New Manufacturing Policy aims to raise manufacturing contribution to GDP from 16% (–USD 0.3 Tn) in 2013 to 25% of GDP (–USD 1 Tn) by 2025

Source: DIPP

The imperatives for the medical devices industry are aligned to the objectives of 'Make in India'

Investments
Capital and technology investments for setting up manufacturing facilities in India

Innovation
India specific innovation to help improve accessibility and affordability of medical devices

Skill
Training and development of human resources for manufacturing, operations and services

Infrastructure
Best-in-class infrastructure in compliance with global standards for supporting high-technology industry

India to serve both the Indian and global markets. Increased funding and investments have also reflected in other supply side changes in healthcare delivery in India, such as:

Overall growth in healthcare infrastructure

- There is a significant increase in the number of hospitals and hospital beds in India. Bed strength had increased from 0.8 million in 2002 to 1.6 million in 2012, and is further expected to increase to around 2.9 million by 2025. This increase has been driven primarily by growing presence of corporate hospital chains, international companies and service providers entering tier 2 and tier 3 cities
- There is an increasing presence of diagnostics laboratory chains focusing on imaging and pathology. It is estimated that there are more than 100,000 diagnostic laboratories across the country, with the number expected to grow at a rate of 15% – 20%
- The healthcare industry is also witnessing the emergence of new formats like chains of multi-specialty outpatient clinics, mother-and-child hospitals, short stay surgery centers, IVF centers, etc., which are driving demand for medical devices

Increasing focus of healthcare providers on quality and accreditation

There has been a strong focus on upgrading medical technology by hospitals and laboratories to comply with accreditation requirements.Around 285 hospitals in India are NABH accredited with 472 additional proposals submitted for accreditation. Similarly, 347 laboratories in India are NABL accredited with 150 additional proposals submitted.

At this critical juncture, the 'Make in India' initiative provides an opportunity to create a 'step change' in Indian healthcare, especially in the medical devices industry.

While the potential of the medical devices sector is acknowledged with its inclusion in the 'Make in India' initiative, it is essential to leverage the initiative to kick-start indigenous manufacturing and realize the twin objectives of accessibility and affordability.

All effort isaimed at understanding the context, constraints and opportunities for medical device players, healthcare providers and key policy makers; exploring the significance of India vis-à-vis other global manufacturing destinations; and aligning 'Make in India' for medical devices with other key government initiatives.

FIGHT THE FAKES

SPEAK UP ABOUT FAKE MEDICINES

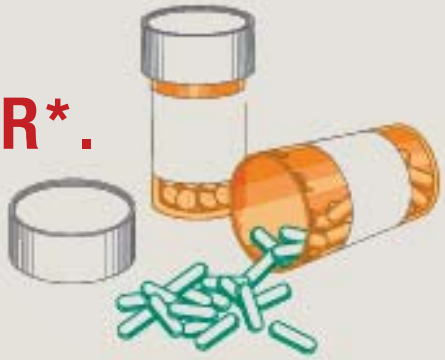
VISIT FIGHTTHEFAKES.ORG

FAKE MEDICINES HARM – NOT HEAL

There are a lot of shady ingredients found in fake medicines that are directly responsible for serious disability and even death. This includes poisons such as mercury, rat poison, paint and antifreeze.

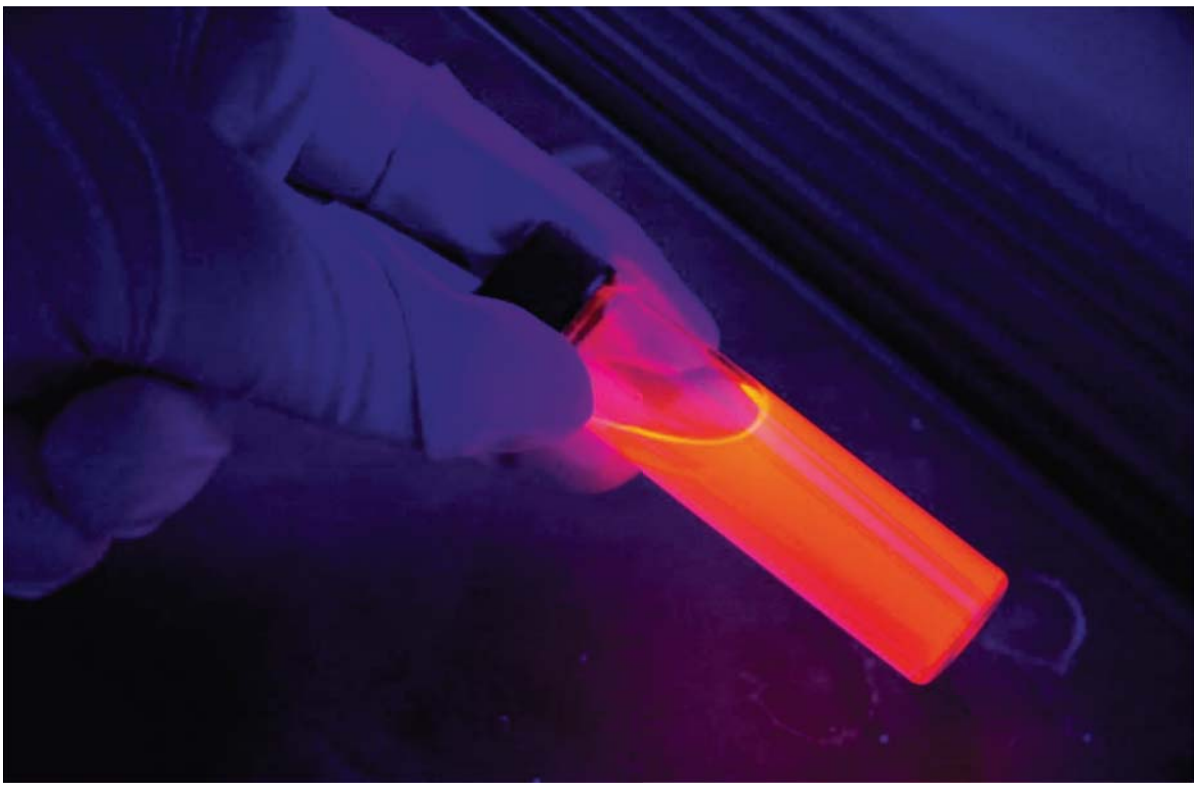
Fake tuberculosis and malaria drugs alone are estimated to

KILL 700,000 PEOPLE A YEAR*.



*International Policy Network

TOP 10 CRUCIAL MEDICAL DEVICE TRENDS 2018



It's important to keep up with medical device trends as these innovative technologies are changing the face of healthcare. Certain themes will influence the decisions of both medical device startups and major healthcare companies. The year 2017 proved to be a landmark for global medical device companies. Technology and healthcare will continue to shape the future of healthcare and 2018 is setting up to be even more exciting.

THE FOLLOWING 10 medical device trends for 2018 are curated from different sources by various experts in the field. Here's a simplified list that quickly breaks each trend down.

1. Small Medical Device Companies Increase R&D Spending

A survey by Emergo completed in Spring 2017 saw that 61% of their respondents with 50 employees or less were planning to aggressively increase their R&D spending. Identifying a need for new devices still under development will be the influencer of their spending decisions, according to ¾ of the respondents. Product development and commercialization are key drivers for small and start-up companies while pricing pressures dissuade larger firms from R&D spending.

More than 72% of all respondents say new R&D initiatives for new devices will begin over the next 12 months. This applies to firms of all sizes and geographic locations but as the survey shows, most of them will be smaller, **startup medical device companies.** Current medical device OEMs spend about 7% of their revenue on R&D, which is more than most industries.

2. Personalized Care

Medical devices aim to make healthcare a more individualized experience for patients. Rather than a mass generalization of a medical condition, these devices will begin to help patients have a customized treatment plan. Currently, 30-40% of patients use medications or therapies where the adverse side effects outweigh the benefits.

Personalized care can solve that problem and offer many other benefits. One of which is that it helps companies discover new potential therapies through data from personalized care devices. This not only helps the patient receive additional benefits but also uncovers demand for devices not yet developed.

3. Disruption from Outsiders

New **medical device trends** allow for healthcare startups to enter the once exclusive market. Rather than a members-only club, the medical device market opens its doors to small and startup companies, allowing them to compete. Even established players are beginning to develop innovative technologies and some partner with the smaller companies who already have them.

The regulatory authority skips analyzing the product and instead focuses on the developing company. If the authority approves the company, they can build safe, reliable and high-quality devices without needing approval on each individual product the company develops.

4. Blockchain-based EHR systems emerge as Blockchain technology surges

Blockchain technologies is a medical device trend that serves a number of purposes, from EHRs and interoperability/security to value-based care models, precision medicine, and patient-driven healthcare systems. It is "a shared, immutable record of peer-to-peer transactions built from linked transaction blocks and stored in a digital ledger." Nodes, or individual computers, store data and create a network with no central entity controlling the data.

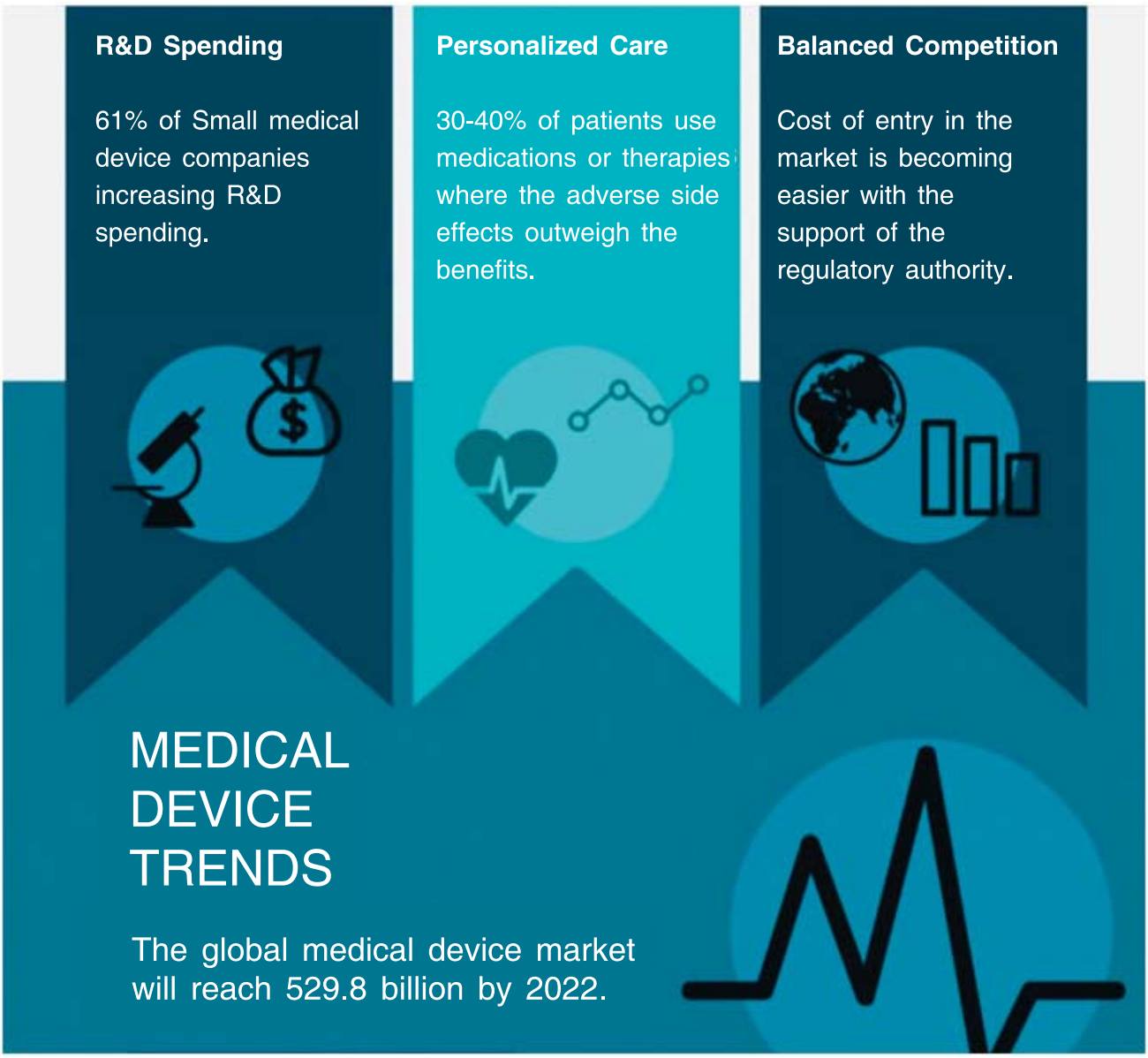
Dhawal Thakur, healthcare research lead at MarketsandMarkets says, "In 2018, several more vendors will be putting forth blockchain-based EHR solutions as one of the major areas of innovation or technological transition." He also states disruptive changes in EHR setup are necessary, resulting in the use of blockchain technologies as a solution for achieving interoperability and overcoming data exchange issues relating to documenting and transferring patient data.

5. Focus on Security Issues

With the rise of **IT in healthcare,** it's certain there will also be a rise in information security breaches. Brendan O'Connor of Service Now says in 2018 there will breaches that impact our physical, personal lives, whether it's a medical device or wearable that is hacked or an industrial IoT device (ie self-driving car) that is compromised. This is **medical device trend** forces governments and companies to take a closer look at their security infrastructure and adjust it accordingly.

6. Cloud Computing

Cloud-based systems offer provider organizations a plethora of benefits: real-time reach even in disaster situations, safer and more efficient big data storage, simple data analyzation and a simplified research process. 'Right Scales 2017 State of the Cloud Report states that cloud adoption sits at 72% with 85% of enterprises already utilizing a multi-cloud strategy, up from 82% in 2016. A whopping 95% of organizations are running applications or experimenting with infrastructure-as-a-service.



Cloud technology is flexible and accessible from a development perspective, and companies can easily scale it up or down as demands change. Cloud software is centrally updated and moves out of the testing environment and into real-world scenarios with ease. Expect healthcare device providers to really utilize this **medical device trend** in 2018.

7. Rise of Big Data and Digital Health

Big data is the new frontier of information management and major **medical device trend** for 2018. It is the infrastructure that captures, stores, analyzes and visualizes vast amounts of unstructured data. Through better analytical systems and the adoption of more intelligent technology, big data can be translated into information that will lead healthcare providers and researchers to possibly predicting when and why patients will be rehospitalized, what the expected therapy response will be and an estimated recovery time.

Dhawal Thakur of MarketsandMarkets forecasts 2018 to be an exciting year for digital health and big data analytics. He says “big data analytics is set to bring about significant advancements in terms of creating a more technology-enabled approach to develop preventive medicine and personalized treatment pathways. Technological enhancements will keep pushing specialized devices for monitoring specific patient biometrics into the market, and IoT devices, coupled with big data analytics, will form the basis of virtual care or telehealth services.”

8. AI-Based Technologies

The adoption of artificial intelligence technology is slow despite the fact of extensive research and successful trials in real, clinical settings. AI-based technology adoption will experience a huge jump in 2018. Experts forecast the healthcare industry will face complex workforce surpluses and shortages leading up to 2030, making the need for AI technology surge.

This **medical device trend** will help by managing data, designing effective treatment plans for patients, assisting with repetitive jobs, precision medicine, creating better pharmaceuticals, helping patients make better lifestyle choices and even analyzing the current healthcare system. The Forrester Research report, Predictions 2018: Digital Will Disrupt Siloed Healthcare Ecosystems, expects these four functional areas to drive the most growth in AI technology: clinical insights and interventions, supply chain management and operational efficiency, customer service and security/risk.

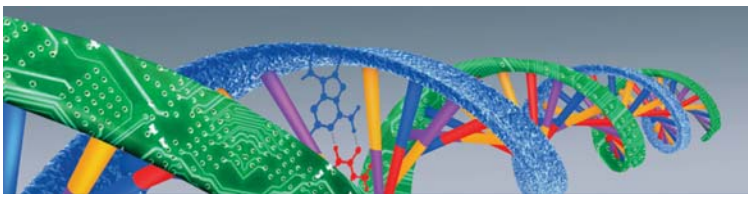
9. The Internet of Things (IoT) Continues to Shape Healthcare

It's no surprise that medical devices, considered an aspect of the IoT, is helping to shape the future of healthcare. This is one of the biggest medical device trends and 2018 is going to be an exceptionally important year in this regard. Higher medical device adoption rates aide in a larger shift towards value, aging populations, and a provider workload increase will increase medical device demand and new security technologies will prevent security breaches (ie blockchains).

10. Pharma/Medtech Combination

New **medical device trends** for 2018 will see the fusion between pharmaceuticals and Medical device companies, two industries who used to operate within their own borders. But now, as we see more medical devices enter the market, more medical device manufacturers need to conduct clinical trials on their devices and are enlisting the help of pharmaceutical companies. Medical device companies, especially startups, leverage the expertise of drug companies to compete in the lucrative pharmaceuticals-device product market.

Expect to see a rise in these combination products in 2018 and beyond. This medical device trend will reveal a revolutionary new level of value for healthcare providers and their patients. This partnership will foster innovative treatment options and continue to motivate Medical device development.



Medical Device Trends Conclusion

These medical device trends will impact the **healthcare IT industry,** which is constantly evolving in its very fluid state. Healthcare executives and IT professionals will be busy keeping up and creating technological advancements, security updates and so much more. The new digitized health ecosystem comes to balance efficient care, convenience, safety, privacy and affordability into one neat little package that is the **innovative Medical Device market.**

As healthcare and technology continue to learn how to work together in a synchronized and effective manner, the benefits to patients and providers will be vast and far-reaching. This union has proven to save more lives, improve the overall quality of healthcare, make healthcare more accessible and foster economic growth, as well as job creation. Only by working together, from the top executives to the patients, will these exciting technologies flourish.

TECH DRIVEN

MEDICAL DEVICE INDUSTRY

Empowering Healthcare Sector

Mukul Kumar Mishra

LOOKING AT THE speed at which India is taking long strides in the healthcare landscape at large, one derives a great sense of satisfaction that the nation is benefitting from factors like medical devices and modern technology.

The Indian healthcare sector is on the cusp of transformation due to a range of factors including technological advancements and high demand of quality and cost-effective medical facilities.

There is a belief that the quality of any healthcare delivery system depends upon three Ds — Doctors, Drugs and Devices. All three are utmost important and needed to achieve the aim of providing healthcare to all.

Neeraj Lal, Vice President and Cluster Head — Bangalore and Karnataka Region, Rainbow Children's Hospitals says, "Medical technology is an integral part of the entire healthcare. For decades now with advancement of technology and increasing sophistication of medical devices, the industry has played a major role in bringing down the incidence of disease and improving the overall healthcare system across the globe."

"Medical devices" encompass any instrument, apparatus and appliance which are used for the diagnosis, prevention, monitoring, and treatment of any disease or malfunction within the body. The medical devices are the sunshine segment of the healthcare ecosystem which makes whole process of diagnosis quick, accurate and an easy task.

"Medical technology has evolved by leaps and bounds providing a right thrust to surgical processes and treatment procedures. With new advanced technologies, doctors and surgeons can be more accurate, right from early diagnosis to attaining desired outcomes during procedures and surgeries," says **Madan Krishnan,** Managing Director, India Medtronic, a company which deals in medical technology solutions.

Diagnostic equipment is used in medical imaging, a process of creating visual representations of the interior of a body for clinical analysis. Medical imaging is being done with the purpose to reveal internal structures which ultimately help doctors to examine and diagnose the medical condition of a patient.

"Connected care, digitisation, miniaturisation and indigenous innovation in medical technologies are trends that have potential to push boundaries of healthcare delivery in India. Digitisation and connected care are creating possibilities of more efficient management of ICUs and healthcare outcomes in private hospitals," said **Pushpa Vijayaraghavan,** Director, Sathguru Management Consultants.

"Today, medical devices can provide enhanced patient care in remote areas through telemedicine and teleradiology. Advanced equipment technologies such as artificial intelligence and robotics provide higher levels of precision thus increasing the success rate and improving overall quality of care," **Lal** said.

"Technologies such as virtual reality and augmented reality can also be used to simulate real time healthcare environment to provide training to physicians, technicians, and doctors thus eliminating the need for presence of actual equipment for training purposes," he added.

As India's population is on the rise, the country needs a very efficient imaging technology to screen and diagnose patients. Not only that, the growing non-communicable disease among citizens of urban cities is another challenge which makes healthcare providers think about catering people with high-tech medical devices.

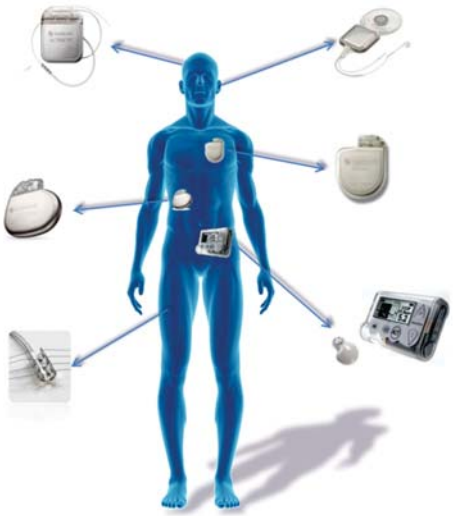
Non-Communicable Diseases (NCDs), such as cancer account for 60 per cent of all deaths in India. The data presents an alarming picture revealing that 68 per cent of cancer patients in India die before five years of diagnosis. In addition, changing lifestyle and food habits also make people vulnerable to NonCommunicable Diseases (NCDs), which are typically treated or ameliorated with medical devices.

"Healthcare providers are now focusing on patient care and enhancing clinical outcomes by adopting state of the art digital technology and advanced medical processes. Embracing and adopting technical advancements at an equipment and procedural level can help elevate clinical outcomes like never before while making it effective, affordable and accessible," said **Dr Dilpreet Brar,** Founder, CEO & MD, medECUBE Healthcare. According to him, some recent developments in the field of medical science with respect to equipment and technologies specific to radiology are:

- New probes (radiopharmaceuticals) are becoming available to diagnose cancer, Alzheimer's etc.
- Molecular imaging can be used to make targetted cancer therapies more effective
- GE and Siemens recently launched their next generation CT machines for Cardiac applications

Siemens launched Magnetom Vida MRI at RSNA in Chicago in November 2017. This MRI can adapt to anatomical and physiological characteristics of patients **Dr Vivek Chail** from icliniq.com says, there are many developments taking place in the area of patient outreach and delivery of healthcare. " There is AI assisted robotic surgery which is helping many patients and doctors perform precision surgeries and reducing the risks involved, with better outcomes. In artificial Intelligence-assisted robotic surgery, an experienced surgeon controls a robotic device and surgery is performed with greater precision and accuracy. This is a benefit in critical areas of medicine like brain and spine surgery where a high degree of accuracy is needed," he added.

GrowthDiagnostic equipment market comprises of organisations which are involved in the manufacturing and marketing of equipment such as computed tomography (CT) scanners, magnetic resonance imaging systems (MRI), X-rays, nuclear imaging (SPECT/PET), mammography devices, cardiovascular monitoring and diagnostic devices, ultrasound devices, and accessories.



Digitisation and the proliferation of IoT-enabled devices present a great opportunity for growth in India. According to the Government's Make In India website, the medical devices industry in India is presently valued at $ 5.2 billion and contributes 4-5 per cent to the $ 96.7 billion Indian health care industry. Currently, India has about 750–800 medical device manufacturers in the country, with an average investment of Rs 170–200 million and an average turnover of Rs 450–500 million.

According to industry estimates, the medical devices market will grow to $50 billion by 2025. At present, India is counted among the top 20 global medical devices market and is the fourth largest medical devices market in Asia after Japan, China and South Korea.

The growth of medical device market is attributed to many factors including burgeoning middle class, improved healthcare infrastructure, increased healthcare spending, etc. In addition, the Government's initiatives like bringing 100 per cent FDI, Make in India concept and building medical device parks, etc, have also given push to this industry.

Challenges

Despite huge potential due to high demand of quality diagnostics services, the Indian medical device market faces several challenges. Foremost among them is country's reliability on imported devices for addressing domestic demand.

More than 70 per cent of medical equipment sold in the country is imported. In addition, lack of compliance standards and coherent policy framework are also jeopardising growth of Indian device industry. Through Make in India concept and Medical Devices Rules 2017, the Government has tried to boost domestic manufacturing market; nonetheless these steps are not sufficient to do away all the obstacles of the domestic market.

Experts believe that in India, pseudo manufacturing flourishes as manufacturers are turning into importers for their brands. Other countries like US, China encourage domestic players to make indigenous products. Domestic players demand the Government should increase the basic customs duty on medical devices in the range of 5-15 per cent to promote domestic manufacturing.

India needs to implement 'Make in India' in its true sense and for that a framework of policies along with strategic roadmap is need of the hour.

"While medical technologies can redefine possibilities and push boundaries, impact on outcomes entirely depends on widespread adoption by public and private stakeholders in healthcare delivery. Majority of the impressive devices indigenously developed are lurking on the sidelines for lack of market maturity and adoption pathways," says **Pushpa Vijayaraghavan,** Director, Sathguru Management Consultants.

MAKE IN INDIA

UNDERSTANDABLY, THE CURRENT inverted customs structure is totally in favour of imports and is detrimental to Make in India.

A lot has been spoken about recognizing the Medical Technology industry as a sunshine sector in the Government's Make in India initiative. The move has been welcomed by the industry with open arms. However, there still exist a lot many gaps to fill, in order to boost the growth of this important sector.

Creation of designated manufacturing zones for medical devices, PPPs, 'Free Diagnostics Service Initiative', Ayushman Bharat Yojana are all opportunities that are set to give impetus to this sector.

On the flip side, there are a lot of challenges that medical device manufacturers are facing and need to be addressed at the earliest. To start with, there is significant room to 'correct' the skewed GST on some of the diagnostics products. e.g. Instruments attract 18%, reagents/consumables at 12%. This rate is too high and should be brought down to 5% in order to benefit the patients at large. Such correction will only give further fillip to manufacturing in India.

The preferential pricing policy and buy India policy are strategic drivers that can, not only positively impact domestic growth but also benefit the consumers as well as stakeholders. However, the policy remains only on paper and needs reconsideration, as the following points have not been considered:

- Preferential pricing for domestic manufacturers based on World Bank norms which allow 15-20% price preference.
- Preference for Indian Certification for Medical Devices (ICMED) /ISO certified manufacturers to boost quality.
- Preference for Design India Certified Manufacturers to boost indigenous development.
- Timely payment against government supplies.
- Penal provision against hospitals that keep exclusionary compliance clause of USFDA certification in tender specifications.
- Incentives for R&D and innovative indigenous product development.

Another very big deterrent to the growth of this sector is our dependency on imports. Even today 70-80% of our medical equipment is imported. Inverted duty structure is at the root cause of this scenario. Currently the medical devices are importable at zero basic customs duty. On the other hand, the components required by domestic manufacturers to manufacture the same in India are

charged 7.5% basic customs duty, thereby penalizing any efforts to make in India. The industry needs the approach adopted by the automobile sector. Today, every single automobile manufacturer is making in India. And this is because the import duty on parts is only about 10% while on finished cars it is upto 90%. So obviously, it makes sense to Manufacture cars in India.

Understandably, the current inverted customs structure is totally in favour of imports and is detrimental to Make in India. The Government is talking of Make in India but its own policies are killing Make in India. It is high time the Govt. walks its talk and corrects its inverted duty structure to encourage Make in India which will not only make healthcare more affordable but also create much needed jobs.

Besides, lack of regulatory systems with global standards and lack of quality product testing are hampering this sector. At present most of the medical devices can be imported by anyone from anywhere without any regulatory checks. There are rampant imports of low cost, poor quality equipment. All these facts pose challenging for domestic manufacturers.

On the positive side, the size of the Indian medical device industry was USD 2.16 bn in 2006 and in little over a decade, It has more than doubled to reach USD 5.2 bn by 2017. As a manufacturer of diagnostic instruments, the direction in which the industry is moving is very exciting! It has steadily grown at a CAGR of 15.8%. As per industry estimates, the Indian medical devices market will grow to USD 50 billion by 2025. Currently, India is counted among the top 20 global medical devices market and is the 4th largest medical devices market in Asia after Japan, China and South Korea.

With a little more support from the Government the medical device industry in India will lead the way in global healthcare!

Niti Aayog To Work On Boosting Make In India For Medical Devices

Prabha Raghavan

IN A MOVE to boost production of medical devices in India, government policy think tank Niti Aayog held a meeting to mull measures like tax-based incentives and caps on distributor and retailer margins of these products. The discussion was held in the run up to a meeting of a committee of secretaries that will be chaired by Niti Aayog CEO Amitabh Kant.

Niti Aayog is working on proposals to incentivise domestic manufacturing of medical devices following orders from the Prime Minister's Office.

The meeting included senior government officials from different ministries as well as industry representatives. It focussed on understanding hurdles in local manufacturing and quality of the devices produced here as well as solutions for the same.

This was a routine meeting to discuss how India can have a complete ecosystem with respect to regulations, import duties and infrastructure (to incentivise local manufacturing). Incentives like tax holidays and providing land at reasonable prices were also discussed.

Another measure discussed was caps on trade margins to bring down prices of medical devices as opposed to capping their maximum retail prices.

The government is looking at amending the Drug Prices Control Order for medical devices and the intention was to go by the trade rationalisation route.For this purpose, the National Pharmaceutical Pricing Authority (NPPA), India's drug pricing regulator, is expected to collect data like the difference between the ex-factory or landed price of various devices and their MRPs.

NPPA in 2017 had already sought such data on the medical devices regulated under the Drugs and Cosmetics Act, including syringes, heart valves and intraocular lenses. So far, trade margin data on stents, knee implants and syringes have been released in the public domain.

In 2017, the government capped MRPs of cardiac stents and knee implants, bringing their prices down by 60-80% for patients.

What can India learn from steps taken by other countries to boost their indigenous manufacturing and exports of medical devices?

For India to establish a firm footing in the global market, a robust policy and regulatory framework is required. China (as a consumption and manufacturing hub) and Ireland (as a major exports hub) provide ideal examples on how to develop a sound policy and regulatory environment for the medical devices industry.

China
(Domestic Consumption + Manufacturing Hub)

Ease of Business
- China FDA allows fast track approval of domestically produced innovative medical devices; New order reduces registration timeframe by half
- Waiver of clinical trials for class I and selected class II and class III products

Financial Benefits
- Reduced corporate tax for the medical device industry from 25% to 15% as it is an ìencouragedî industry
- Extension of tax benefit by three years if investment made in provinces recognized for development of medical devices

Industry Association
- Dedicated associations CAMDI and CMDI for medical devices sector

Proximity to market
- Huge domestic population/market
- Japan and US significant export markets

Driven by domestic consumption, timely intervention by the government to promote manufacturing – reduced corporate tax rate, focus on R&D ecosystem, incentivization for indigenous manufacturing

India can adopt best practices from two very different ecosystems and design a holistic ecosystem for medical devices

Healthcare ecosystem

Ireland
(Major Exports Hub)

Ease of business
- Science Foundation recognizes Medical Devices industry as priority
- Well established medical devices industry in Galway which provides a ready pool of vendors and workers for new manufacturers entering Ireland

Financial Benefits
- Lowest corporate tax rate in Europe of 12.5%

Proximity to market
- Proximity to EU; US companies gateway to Europe

Regulation and IP Protection reforms
- Regulations less stringent for product approvals;
- EU regulations are less stringent than those in US for product approval

Proximity to EU market has been the key driver for the growth of manufacturing set up, ably aided by government interventions including reduced corporate tax rate, easy product approvals, reduced input costs

The move was met with divided responses from domestic and global device makers. Local manufacturers claimed this would give a level playing field to them, while foreign companies alleged it would block innovation in this space from reaching Indian patients.

Other issues discussed during the meeting included the creation of a separate act to regulate medical devices, currently regulated under the Drugs and Cosmetics Act.

“The discussions by and large were a near repeat of earlier discussions at similar meetings hosted by the Department of Pharmaceuticals in Bengaluru and Delhi”, said Rajiv Nath, forum co-ordinator of Association of Indian Medical Devices Industry (AiMeD), a lobby group for domestic medical devices.

According to Nath, the draft medical devices policy has been "lying in limbo" since 2015.

"If Department of Pharma will not play the leadership role or implement the mandate to foster growth of medical devices, we wonder if we are going in circles between policy makers. Meanwhile, we continue to be increasingly import dependent," he said. 70% of the country's medical devices needs are met through imports, according to industry estimates. ◗

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SUNIL KHURANA

1 INTERVIEW

AYUSHMAN BHARAT Will Fuel The Medical Device Market Growth In A Big Way: Sunil Khurana

Shahid Akhter, spoke to Sunil Khurana, CEO & Managing Director, BPL Medical Technologies Pvt. Ltd., Bangalore to know more about the existing challenges in the Medical Device Market. Edited excerpts:

Q What is your take on the Medical Device Market?

Medical device itself is a something which needs to be understood- even consumables, very high end medical electronic products are seen as a medical devices. I feel, for the last several years there has been a very good growth happening in that space. In 1993-1994-1995 timeframe only 3 or 4 MRIs use to come in our country. Now the market has gone up and about 300-350 MRI's are being installed in a year. So the market has really grown big time. There is a lot of thought by the people on going for a preventive health check-up and that is where it has a huge scope and my view is that even today bed ratios are still very low as compared to other developing nations like China where they have more than 3 beds per thousand population. We are sitting at 1.3-1.4 beds per thousand and these are continuously improving because there is participation by a lot of corporate houses, lot of nursing homes are coming up, government is also investing and as we know Ayushman Bharat is going to further fuel the growth big time.

When number of beds increases, everything will increase and medical device is no exception and that is where you will see proportionate growth of medical device happening. In my view, the next 20 years will be a double digit healthy growth.

Q According to you, what are the Medical Device Manufacturing Challenges being faced?

Medical device manufacturing is very interesting. India faces huge issue on the R&D side, very few institutes collaborate with the medical device companies the way it is run in the western countries and then they help to bring a lot of new technologies which are implemented and manufactured in India. The government needs to bring strict curriculum to IITs, attach these institutes with companies who have a lot of aspirations to make big in India. On the R&D side, you really have a problem because it is not well supported and you take a couple of products and unless it reaches a level for commercialisation you try to copy which is not the right way. So R&D is one challenge.

Skilled Manpower is second challenge which I see very clearly, so these two areas if addressed then I think Indian medical manufacturing sector will see a boom.

Q Could you please throw some light on the BPL Journey so far?

BPL started the medical devices somewhere in 1967. So it is well over 50 years now and BPL was the first company to make a medical device in India, the first manufacturer of the medical equipments like ECG and couple of those monitors at that point and time. We kept our focus only to some of those products but 5 years back, those investments from Goldman Sachs in BPL. This inception happened in August 2013 and we are just coming close to 5 years time. We have added lot of verticals now. We have added radiology, where we are now manufacturing X-ray machines, we have ultrasounds and we have also added critical care and in that space we felt that anaesthesia has a big business and is a very needed product in all the hospitals...

India faces huge issue on the R&D side, very few institutes collaborate with the medical device companies the way it is run in the western countries and then they help to bring a lot of new technologies which are implemented and manufactured in India.

Q How would you best describe BPL as a Differentiator?

Our clear philosophy is that selling is very simple. You can sell a product and move on. We feel that products have to be maintained very well so our focus on service is key. We have the best distribution when it comes to medical device distribution side. We have our distributors probably in every corner of India and through these we train our distributor's team to sell and service both. In a very efficient way we make the product up and that is what differentiates us.

Q What are the futureplans of BPL?

Considering that India has a huge and overall income levels are going up we know that healthcare overall space is going to become very big. Today in India about $1.5 billion business is done for diagnostic imaging versus total global, it is more like a $50 billion so what it means is that we are doing about 2% of global business whereas our population is more like a 15 percent. So if everything is equal you have an opportunity to go from 2% to 16%. We want to bring a lot of technologies.

In Make in India, remove those frills which are not needed, bring products which are more affordable and we have also observed that in every country there are couple of good local companies who have done very well. We are very confident that in the years to come we should be the number 1 medical equipment company in India. We don't want to restrict us only in India, we are also trying to set up our overseas division so overall making in India versus bringing something which is made outside will definitely be a better preposition to look at these products.

2 INTERVIEW

India can rule the world through medical device:

Ganesh Sabat

The domestic companies need to grow exponentially as 70-80% of medical device are imported into India.
In an interview withGanesh Sabat, CEO, Sahajanand Medical Technologies(SMT), Surat, shares his vision and plans of expanding SMT's reach across the world. Edited excerpts:

Q Tell us about your foray into the stent making industry?

We are a technology based company that manufacture laser and various other machines to cut and polish diamond. Stents require a laser source to be cut so it was a natural progress for us from laser cutting the diamond to laser cutting the stent.

Our stent is of high quality and we are selling it in 60 countries for more than a decade. We have got more than 500,000 implants across the world. We have started a randomised clinical study in Europe with some of the most renowned cardiologists of the world; this will provide highest level of evidence.

Clinical study started in Netherland which is going to demonstrate the high quality of our product. This will also put forth the name of India as a high quality medical device supplier. We are proud of the study that we are conducting. This will be a landmark study from India.

Q How is SMT different from other stent manufacturing companies?

There are 10 to 15 companies that are manufacturing stents in India. We are the first company to manufacture and commercially sell stents in India.

We are very proud that we bought this critical technology to India because around 300 million people are going to suffer from cardiac disease as per Cardiovascular Society. There will be huge burden on India and stent is the backbone where you can provide critical patient care.

We are competing with really large companies like Abbott, Boston and Medtronic who have got a lot of financial and political power. The competition is really huge. We have to really work on advanced technology and compete with the state of art product. So our focus is to come up with better products than so that we can survive in this field.

Q How much importance do you give to R & D?

Our company is primarily focussed on R&D because we are a technology based company. We have invested heavily in R&D. Today we are contributing almost 10 percent of our revenue into R&D. Recently we have set up an R&D facility in Ireland to bring many different technologies that will address the healthcare needs of India.

Q What are the challenges that you face?

Stents have a huge developmental cost and it is not a typical generic product. That developmental cost means we would have to put a lot of money into R&D. It is an industry where international cardiologists are focusing a lot on the advancing technology. Every day you have to invest into R&D. Now as an Indian company, my biggest market is in India. If we don't have profit in India then how do I invest into R&D. This will also affect the Indian companies.

The pricing should not be cost plus profit; they should always take into account the developmental cost and a lot of the ongoing R&D that we are supposed to do to stay ahead of the competition.

Our company is primarily focussed on R&D because we are a technology based company. We have invested heavily in R&D. Today we are contributing almost 10 percent of our revenue into R&D.

Q Are there any merger and acquisitions plans?

We have not done any merger and acquisitions but as the scale will go up we are going to look at two kinds of acquisitions. One is the technological acquisition and another is the acquisition to expand our geographical base.

We are growing pretty fast in Europe and we believe that we are going to start our operation in US very soon. These kinds of growth will provide us opportunities to acquire some companies for sales and marketing purpose or for technology purpose. In next 2-3 years we are planning to have some acquisition.

Q Where do you see SMT in next five years?

Our future goal is to become the number one medical device player in India. It is a clear-cut thought process that we have across the company. We will need a lot of support from the government. Medical device is a nascent industry in India but worldwide it is the biggest potential that India should look at. Like pharma industry India can rule all over the world through medical device.

Government has come up with the 'Make in India' policy. At this point of time we really don't know what benefits we have. The awareness of benefits will help us aggressively address the medical device challenges. 70-80% of medical device are imported into India which means that the domestic companies need to grow exponentially. For this we will need a lot of support from the government, clear cut policies, clear cut support system so that make in India gives us a great platform but at the same time the government and the industry need to work out a lot of things to make it highly successful.

3 INTERVIEW

There Is Complete Policy Vacuum For Medical Devices In India:

Probir Das

In an interview with Probir Das, Director, Medical Technology Association of India, Gurgaon, talks about opportunities and challenges faced by the medical device industry in India. Edited excerpts:

Over the last 20 years we have seen that the bed ratio, the number of beds per 1000 population, the per capita bed is 0.7 percent which was the same 15-20 years back. The healthcare delivery infrastructure is low and if we don't scale it up, we will continue to be on the marginal side of the global medical devices market.

Q Where is India placed in the medical device manufacturing?

The medical devices global market size is about $500 billion and that in India is about $7 billion, so we are talking about being 1.3 percent of the total medical devices market globally. From a size stand point, we are a small contributor but from a growth stand point we are a good contributor because if you look at the global market it is growing at 4-5 percent annually, whereas in India we are growing roughly at 12-14 percent depending on which end of technology you are.

Q You have spent more than 25 years in the medical device industry. Your views on the problems and challenges.

We are a constrained environment country and if we are able to solve the medical devices driven healthcare problems in India, we would be able to really scale them up and take them to the world. So that is a huge advantage from a global standpoint. Also, when we look at the global standing of medical devices in India we need to keep the comparison of global consumption versus local consumption in medical devices or healthcare.

Over the last 20 years we have seen that the bed ratio, the number of beds per 1000 population, the per capita bed is 0.7 percent which was the same 15-20 years back. The healthcare delivery infrastructure is low and if we don't scale it up, we will continue to be on the marginal side of the global medical devices market. One has to keep in mind that the medical device industry is almost an ancillary industry. In the last 27 years the quality and care available in India has gone through a good massive shift.

Q What are the challenges that your see?

The biggest challenge that I see is the fact that we have a complete policy vacuum for medical devices, there isn't a national medical devices policy in place and a lot of actions are being taken incoherently. Though the intentions are really good but no clue on what is the long term ramification of several one of them. For example: Make in India is going to attract people to come and manufacture in India and the government has an expectation that the global companies should come and manufacture here but at the same time there is no single window clearance. The other challenge is that the market is extremely fragmented, if you look at delivery in India-hospitals can be a 5 bedded or 2000 bedded and the quality, delivery skill and bandwidth of these are extremely divergent and the medical device industry has to fit that. So we would like to see some market consolidation.

Q What needs to be done?

The first thing that needs to be done is to have a medical devices policy at least then there would be some stability in decision for the next 10-20 years. Secondly I think we really need to get of this bandwagon of import substitution and focus on export promotion or global competitiveness because in several industries right after the independence we tried to import substitution and none of them have worked, medical devices is far more complex so we need to fit a part of the global ecosystem. Else import substitution is going to cut us off from the global system and that is not going to be good for the Indian patients. Third thing that needs to be done is having very structured and focussed incentivisation for R&D and new product development should be made available for local manufacturers, local entrepreneurs and large firms at global companies to come and invest in local product development.

सत्यमेव जयते

Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Government of India

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Pyush Misra
Director,
Consumer Online Foundation

Is There Accessibility To Affordable And Quality Healthcare In India?

THERE HAVE BEEN countless debates in policy circles on healthcare costs and how India is fighting against fiscal deficits, to assure healthcare access to all. However, the truth is, access to healthcare is poor and The Lancet in its latest study emphasizes this aspect. India ranks 145th among 195 countries in terms of quality and accessibility of healthcare, behind its neighbours China, Bangladesh, Sri Lanka and Bhutan.

While, India suffers from lack of doctors and clinics, in case of epidemics and diseases like tuberculosis - patients are either never diagnosed or diagnosed too late. The Prime Minister's recent speech in London, blaming doctors and pharma companies for distorting prices, has made the Union government's stance clear to now go for price caps of medical devices.

Though the government's goal has been to ensure all Indians have access to life-changing medical technologies and preserve innovation, yet the recent price controls on coronary stents and knee implants have created a challenging environment for the medical devices industry. This move has not benefited the patents in any manner. In my opinion, the measure to price capping will result in making latest global innovation a distant dream for the larger community.

Instead, to increase affordability of devices, I believe the government should adopt an effective alternate model – trade margin rationalization (TMR). It is imperative to focus on TMR as it imposes a cap on the margins across the value chain, rather than capping price of devices.

Though the government has considered TMR, yet its decision to calculate basis the landed cost has now got India's $60 billion healthcare industry in an apprehensive mood. Recommendations have been made to the government for trade margins to be calculated on the point of the sale i.e. - the distributor, rather than on the

Imposing price controls on medical devices will not reinvigorate India's long-ailing healthcare system

Medical Devices Under Price Control

While Indian healthcare sector is predicted to grow by $ 280 billion in size by 2020, the country is still lagging behind in healthcare sector, especially when it comes to medical treatments, high mortality rates, lack of awareness and malnutrition, amongst other.

landed cost of devices. While price caps disincentivize innovation - fixing trade margins would restrict how much a product's price can be raised from the import or manufacturing cost, yet innovation would still be rewarded.

The issue of poor healthcare access now is increasingly being questioned at all levels and has put pressure on prices of medical devices. This has troubled the medical devices industry, as innovation in healthcare is one of the prime elements to save thousands of lives, every year. Price capping and a series of hateful remarks against research-based foreign medical device companies have led to a sense of distrust and confusion among patients, who deserve the best healthcare and access to medical innovations. However, where is the proof that price control has helped the patients and will meet their long-term needs?

In this battle it is important that we involve all stakeholders across the value-chain, and more scientific approaches such as TMR will facilitate differential pricing for innovative medical technologies. Ideally, TMR should be allowed, instead of serving all stents on a single plate and thereby, compounding healthcare problems. Price cap has put a substantial roadblock to the element of options for patients in medical devices and technology. Ideally, healthcare manufacturers should be allowed to do what they do best – go all out with innovation that is for the greater good of people.

Time and again, the key stakeholders of the industry – physicians and health experts have voiced their concern over price capping, by terming it 'counterproductive'. I believe, these research-based foreign medical device manufactures must work with the government for a transparent mechanism, that benefits patients and addresses concerns around unethical practices in the healthcare delivery system.

In such a scenario, this will not only bring immense setback to the industry, but also seriously maim the prime target group - the patients. It would inevitably limit the choices available to doctors and leave patients at the mercy of what is available, rather than what is necessary. It is because the domestic industry is still at a nascent stage – not prepared enough to cope with the growing demand of treating modified diseases that are resistant. This means there is a need for a regime that nurtures healthy competition, apart from encouraging all the members, to learn from one another. If this doesn't happen, the wealthy will just get better access to quality healthcare, while poor patients will have to compromise and live with sub-standard medical devices and technology.

Price-Control : A Regulatory Philosophy That Fundamentally Dents The Image Of A Country

India's $5 billion medical device market may be going through an existential threat.

INDIA'S $5 BILLION medical device market may be going through an existential threat. The Indian healthcare industry has been registering a double-digit growth rate, with a CAGR of 17% in the last five years. However, India's drug pricing authority – the National Pharmaceutical Pricing Authority (NPPA), notified the Medical Devices Rules, 2017, which has come into effect from January 2018, allowing the NPPA to notify 15 medical devices as drugs, effectively bringing them automatically under price control regulation.

In their book, Forty Centuries of Wage and Price Controls by Robert Schuettinger and Eamon Butler, first published in 1979, vividly documents a four-thousand-year historical record of economic catastrophe caused by price control policies. In its very essence, price control – a populist regulatory device, seldom works for a nation's economy, its consumers or its regulatory philosophy. In the case of NPPA, it fails to achieve the very purpose for which it is being imposed – better access to drugs and medical devices.

Pharmaceuticals are often characterized as making windfall gains at the expense of hapless patients, which is often used as a justification for imposing price-controls. However, academic research shows that more than four-fifths of the value created by new drugs flows to patients in the form of health benefits, and less than one-fifth flows to manufacturers. New drugs and medical devices do generate

*By **Avirup Bose,** Associate Professor and Assistant Director,*
Centre for International Trade and Economics Laws, Jindal Global Law School

financial rewards for their innovators, but also decades of healthy life to patients, improving the overall life-expectancy of a nation.

Unfortunately, Indian regulators – like the NPPA, for example do not perform a cost-benefit analysis of how imposition of price-control measures would discourage investment, innovation and job-creation in the Indian pharmaceutical industry – something that the Indian government is vocally committed to promote.

On balance, by cutting short the price of drugs and medical devices, the regulator could ensure that innovation falls by even more. Crude price-controls would severely stifle introduction of new drugs and devices in Indian markets. A report by IMS Health – a leading Indian healthcare market research agency, reveals that price-control measures by NPPA has ensured a 75% decline in new drug launches since 2011. The statistic would be similar for medical devices, if the NPPA continues to subject the medical device market to the same failed regulatory strategy.

With drastically reduced margins of profits, drug and device manufacturers would have less incentive to reach rural markets. This is precisely the reason why price-control as a strategy fails to protect the very people for whom its introduction is justified by the regulatory agency. Rural poor and low-income households (even in tier II and III cities) are deprived of the availability of price-controlled drugs and devices. In an IMS Health report – "Accessing the Impact of Price Control Measures on Access to Medicines in India", finds that – there is no significant penetration of price-controlled drug molecules in rural markets. Furthermore, the study finds that consumption of price-controlled medicines in rural areas have dropped by 7% in the past 2 years. Imposition of price-control mechanisms on the medical device market will lead to the same results, disproportionately affecting the most vulnerable sections of the Indian medical consumer.

Moreover, what is most draconian of the NPPA's price-control strategy, is it adopts a "one price fits all" strategy. The NPPA does not distinguish between advanced technologies, within the same medical device, product class and subjects newer technology medical devices to the same price-control measures as older technology products, resulting in technologically advanced stents to be sold at a greater loss, than the older technology products.

Given that NPPA has extended such price-controls over additional medical devices, firstly cardiac stents and then on orthopedic implants (and have now announced it may add price-caps on three more products) - it has affected the way foreign firms visualize the Indian medical device market. The lack of predictability in India's regulatory strategy has ensured

Ramifications Of Rationalizing Trade Margins Of Medical Devices From Landed Cost Will Have A Catastrophic Impact On Indian Export

PROMINENT PUBLIC HEALTH experts and industry insiders are of the opinion, if India isn't cautious in the method of calculating trade margin rationalisation, it may face implications on its exports of medical devices.

India's Export-Import policy is constantly under the scanner of the south Asian countries and there have been far too many pieces of evidence. For instance, immediately after the price capping of stents by the Indian government, Pakistan, Sri Lanka and Bangladesh followed suit and got a similar line of price control.

In February 2017, India slashed the price of coronary stents by 80%. Immediately, in the same month, Pakistan's senate committee on health directed the health ministry and the Drug Regulatory Authority of Pakistan to formulate a pricing policy on stents within a month.

Consequently, in April, Bangladesh too joined the bandwagon; the Directorate General of Drug Administration, contemplated bringing down the current price by half. 6-months later, Sri Lanka followed suit – the prices of the bare-metal stent and the drug-eluting stent was reduced at a similar rate.

This clearly proves that any Export-Import policy which GOI will try to

that foreign suppliers take an overall bearish view towards the entire Indian medical device market. Further, the NPPA, can deny manufacturers to withdraw their supplies from the market to avert a public health crisis using section 21 of India's Drug Price Control Order (DPCO).

Price-control as a regulatory philosophy fundamentally dents the image of a country which is desirous of making it an international manufacturing and investment destination. For example, the US Trade Representative (USTR) is considering to revoke India's special tariff status – under the US's 'Generalized System of Preference' (GSP) – which provides preferential treatment to its exporters from developing countries, including duty free entry of certain goods, chemicals, gems and textiles. In 2017 India was the biggest beneficiary of GSP with subsidies worth $5.6 billion – a status it may lose given NPPA's price-control strategy.

Price-control and health care should not be confused. Slashing prices of drugs and medical devices is a lazy quick-fix which has no commensurate reduction in medical expenses for Indian patients. Since February 2017, when the price of stents were slashed by about 85%, hospitals have started leveraging margins on consumables and services to offset stent price margin losses, with negligible benefits reaching the final consumer. Strangely, the regulator's answer to that problem seems to be considering price control on more medical devices and consumables! In-spite of Indian drug prices being one of the lowest in the world, out-of-pocket expenditure of Indian patients on healthcare is as high as 61%.

India, where two-thirds of the population is denied quality healthcare needs a comprehensive healthcare plan. No doubt that medical expenditure is increasing, but not because of super-normal profit made by pharmaceutical companies but because of profiteering by some private hospitals, and a host of other reasons. Recently, the Competition Commission of India has found that a prominent hospital chain had marked up price of syringes by over 525% for their inpatients. Doctors' consultation fees, cost of operation procedures, diagnostic tests, hospital bed rentals – all add up to the rising cost of medical expenditure for Indian patients. For which the Indian government needs to spend more on healthcare. Currently, India spends around 2.5% of its GDP on healthcare, which is way too less compared to China, Brazil and many other countries. Furthermore, as per the 2018 Global Healthcare Access and Quality (HAQ) index, India is 145 among 190 nations and ranks lower than neighboring Bangladesh, and even sub-Saharan Sudan and Equatorial Guinea.

implement is clearly pursued by the neighbouring countries.

Albeit, India is considering trade margin rationalisation as an alternative mechanism to price control, the medical device industry is concerned whether the calculation will be balanced and agreeable. The neighbouring countries may again take a page out of India's book and implement similar margins by including only the landed cost. If these countries exporting Indian medical devices also demand a landing cost based selling price, it will be catastrophic for 16 billion USD worth Indian drugs/ device export of India.

"The market-based price control mechanism of DPCO 2013 evolved from the past learnings of imposing price control. For instance, when the DPCO in 1995 practised cost-based price capping, it impacted both patients and the industry. There was no new entrant in the market nor any production capacity, as a result, the competition was stagnant, implicating growth and innovation. More importantly, industries ability to invest in enhancing capability building was curtailed. All these are well documented in National Pharmaceutical Pricing Policy 2012. Hence, the government should refrain from going back to the past landed cost/ manufacturing cost-based price capping mechanism and tear down the nascent medical device industry as was the case for bulk drugs," said Avirup Bose, Associate Professor, Jindal Global Law School.

The National Medical Regulatory Authority of Sri Lanka has also initiated the process of trying to match the prices of import with that of the country of origin and other SAARC countries. Subsequently, the Bangladesh Government is also planning to control margins from landing cost for imported medicines. If GOI opts to calculate only the landed cost and the margin, the Indian subsidiaries operating abroad may also suffer and the off-shore subsidiary level expenditure will have to be cut-off severely, affecting Indian export.

"A global company's subsidiary should be viewed as a domestic firm, with added costs not borne by the typical domestic firm, for purposes of the Trade Margin computation. Trade margin rationalization should be based on a comparable PTT (Price to trade) and not landed cost basis in the case of imports, as it does not consider other intermediate expenses such as training clinicians on the technology, providing technical support to clinicians or patients for the product, investment on creating therapy awareness and skill development of clinicians, financing sales and collection costs in India, paying Indian corporate taxes, and other normal expenses for developing and serving the Indian market," said, Ritesh K Singh, a Public Health Expert and Group Chief Economist, Raymond Limited.

Trade margin rationalization based on Department of Pharmaceuticals report on high trade margin rightly addresses the issue of high trade margin escalation as the reason for MRP enhancement. If trade margin proposal is implemented, it is estimated to reduce the MRP by 73 %. This will not only bring inpatient affordability but also allow access to quality healthcare. It will keep the door open for innovation and capability enhancement of the clinicians on newer technologies.

So, adopting this proposal to calculate from the first point of sale would encourage innovation, increase affordable access to quality care, support skilling and training and have a significant impact in reducing prices for patients, thereby enhancing India's competitiveness edge. This presents a win-win situation for all.

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Useful Medical Insights

Or Just More Data?

Wearable Devices

A new review looks at the booming industry of measuring 'every breath you take and every move you make'

"DESPITE THE FACT that we live in an era of 'big data,' we know surprisingly little about the suitability or effectiveness of these devices," says lead author Dr Jonathan Peake of the School of Biomedical Sciences and Institute of Health and Biomedical Innovation at the Queensland University of Technology in Australia. "Only five percent of these devices have been formally validated."

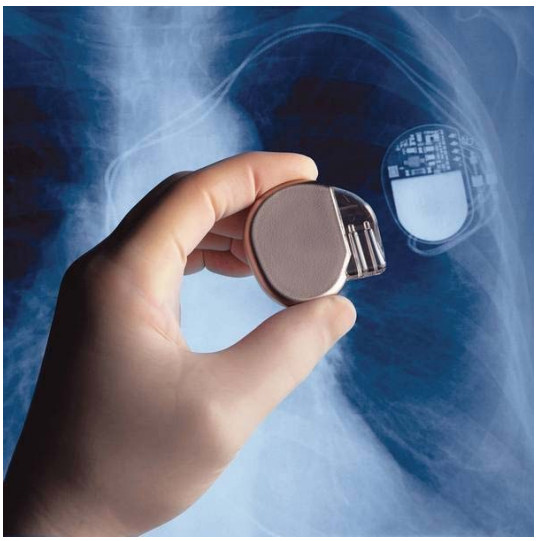
Information was reviewed on devices used both by everyday people desiring to keep track of their physical and psychological health and by athletes training to achieve certain performance levels. The devices -- ranging from so-called wrist trackers to smart garments and body sensors designed to track our body's vital signs and responses to stress and environmental influences -- fall into six categories:

- devices for monitoring hydration status and metabolism
- devices, garments and mobile applications for monitoring physical and psychological stress
- wearable devices that provide physical biofeedback (e.g., muscle stimulation, haptic feedback)
- devices that provide cognitive feedback and training
- devices and applications for monitoring and promoting sleep
- devices and applications for evaluating concussion

Key issues were investigated, such as: what the technology claims to do; whether the technology has been independently validated against some recognized standards; whether the technology is reliable and what, if any, calibration is needed; and finally, whether the item is commercially available or still under development.

Technology developed for research purposes generally seems to be more credible than devices created purely for commercial reasons.

"What is critical to understand here is that while most of these technologies are not labeled as 'medical devices' per se, their very existence, let alone the accompanying marketing, conveys a sensibility that they can be used to measure a standard of health," says Peake. "There are ethical issues with this assumption that need to be addressed."



Though it appears that no one has hacked into a pacemaker in order to hurt the person in which it resides, it's not out of the realm of possibility, and it's something healthcare digital security executives are working to prevent.

For example, self-diagnosis based on self-gathered data could be inconsistent with clinical analysis based on a medical professional's assessment. And just as body mass index charts of the past really only provided general guidelines and didn't take into account a person's genetic predisposition or athletic build, today's technology is similarly limited.

There is particular concern about those technologies that seek to confirm or correlate whether someone has sustained or recovered from a concussion, whether from sports or military service.

"We have to be very careful here because there is so much variability," says Peake. "The technology could be quite useful, but it can't and should never replace assessment by a trained medical professional."

Speaking generally again now, Peake says it is important to establish whether using wearable devices affects people's knowledge and attitude about their own health and whether paying such close attention to our bodies could in fact create a harmful obsession with personal health, either for individuals using the devices, or for family members. Still, self-monitoring may reveal undiagnosed health problems, said Peake, although population data is more likely to point to false positives.

"What we do know is that we need to start studying these devices and the trends they are creating," says Peake. "This is a booming industry."

In fact, a March 2018 study by P&S Market Research indicates the wearable market is expected to generate $48.2 billion in revenue by 2023. That's a mere five years into the future."

A number of areas for investigation have been highlighted in order to develop reasonable consumer policies around this growing industry. These include how rigorously the device/technology has been evaluated and the strength of evidence that the device/technology actually produces the desired outcomes.

"And work for a final question: Is wearing a device that continuously tracks your body's actions, your brain activity, and your metabolic function -- then wirelessly transmits that data to either a cloud-based databank or some other storage -- safe, for users? Will it helps us improve our health?" asked Peake. "We need to ask these questions and research the answers."

India's Medical Devices Industry:

CHOOSING AN INVESTMENT MODEL

OPPORTUNITIES IN THE Indian market: India relies on imports to supply its healthcare system with medical technology. The medical tourism and luxury healthcare markets are among India's fastest-growing industries, which create significant demand for specialized, high-tech medical equipment. There is consistent demand for surgical instruments, cancer diagnostics, orthopedic and prosthetic equipment, imaging, orthodontic and dental implants, and electro medical equipment.

Industry challenges in India: Medical device regulation in India only apply to certain product categories. However, India's underdeveloped regulatory framework is a significant obstacle for foreign manufacturers of regulated device types. The weak rupee makes it difficult for some medical device companies to remain profitable in this market, particularly for manufacturers competing with low-cost Chinese products. Also, foreign manufacturers will also encounter significant competition from American, European, and Japanese companies.

HOW INDIA COMPARES TO OTHER MARKETS

	INDIA	Compare to UNITED STATES	Compare to CHINA
Population	1,251,695,584	321,368,864	1,367,485,388
Primary language(s)	Hindi	English	Chinese, Mandarin
Total healthcare spending	$93 billion	$3 trillion	$574 billion
Healthcare expenditures total (% of GDP)	4.7%	17.1%	5.5%
Healthcare expenditures per capita	$75 (USD)	$9403 (USD)	$420 (USD)
Expenditures on healthcare	Government: 30% Private: 70%	Government: 48% Private: 52%	Government: 56% Private: 44%
Size of medical device market (USD)	$3.5 billion (USD)	$147.7 billion (USD)	$8.7 billion (USD)
Number of hospital beds	0.7 per 1000 people	2.9 per 1000 people	3.8 per 1000 people
Age distribution	0-14 years: 28% 15-64 years: 66% 65 years and over: 6% (2015 est.)	0-14 years: 19% 15-64 years: 66% 65 years and over: 15% (2015 est.)	0-14 years: 17% 15-64 years: 73% 65 years and over: 10% (2015 est.)
Life expectancy at birth	Male: 67 years Female: 69 years	Male: 77 years Female: 82 years	Male: 73 years Female: 78 years
Currency	Rupee	US dollar ($)	Renminbi yuan (¥)

Foreign business now have more freedom to invest in India's medical devices industry than ever before.

In 2015, India's medical devices industry was opened up to 100 percent foreign direct investment (FDI) via the automatic route. But the scope for investments was restricted by the narrow definition of medical devices in the Drugs and Cosmetics Act, 1940.

This year, the government clarified that medical devices will no longer be defined by the Act and widened the range of items defined as 'medical devices' in the FDI Policy. These two measures greatly expand the scope for FDI into India's medical devices industry.

India presents an attractive market opportunity for global medical device manufacturers, but the country has never been able to fully tap into its potential as a domestic manufacturing base. Despite having a medical device market that ranks in the world's top 20, the industry has a long history of being under-resourced.

Foreign companies looking at India's domestic medical device industry should, however, be careful when planning their entry strategy. The type of entity a firm selects, and the state they choose to locate it in, is influential, and a thorough understanding of the industry's various regulations is absolutely necessary.

Foreign direct investment

When foreign entities invest in India, their investment will go through one of two FDI routes, which affects the amount they are able to invest and the investment timeline. The two routes are:

- The government route – For investment in business sectors requiring prior approval from the concerned federal ministry or department, and
- The automatic route – For investment in business sectors that do not require prior approval from the government.

Meanwhile, the list of medical devices that can now attract FDI are as follows:

- Any instrument, apparatus, appliance, implant, material or other articles, whether used alone or in combination, plus any software tool, intended by its manufacturer to be used especially for human beings or animals for diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder.
- Any product or software that will assist diagnosis, monitoring, treatment, alleviation of, or assistance for, any injury or handicap, investigation, replacement or modification or support of the anatomy or a physiological process, supporting or sustaining life; disinfection of medical devices, control of conception and which does not achieve its primary intended action in or on the human body or animals by any pharmacological or immunological or metabolic means, but which may be assisted in its intended function by such means will now be considered as medical device irrespective of its status in the eyes of the drug regulator.
- Any accessories to such instruments, apparatus, appliance, material or other articles, a device which is reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended to be used for examination and providing information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body or animals.

Accessing India's medical devices industry through an indirect route remains attractive to foreign firms. India is heavily reliant on foreign imports: over 80 percent of its medical devices and equipment are outsourced from other countries, particularly from the U.S.

Licenses Required for Import, Sale, Manufacture, and Loan of Medical Devices under the Drugs and Cosmetics Rules, 1945

License for or Registration Certificate	License Form (Template)	Application Form	Relevant Rule	Licensing Authority	Timelines From the Date of Application
Certificate of registration of the foreign manufacturer and the medical devices to be imported (Registration Certificate	Form 41	Form 40	Rule 24-A	Drugs Controller General of India (DCGI)	9 months
Import of Notified Medical Devices	Form 10	Form 8	Rule 21	DCGI	3 months once Registration Certificate is granted
Import of Notified Medical Devices for examination, test or analysis	Form 11	Form 12	Rule 33	DCGI	No time period prescribed
Permission to import new Notified Medical Device for clinical trial or marketing	Form 45	Form 44	Rule 122-A	DCGI	No time period prescribed
Permission to conduct clinical trial using new Notified Medical Device	Form 45	Form 44	Rule 122-DA	DCGI	Six months
Permission to manufacture/ import new Notified Medical Device after satisfactory clinical trials	Form 45	Form 44			No time period prescribed
Retail sale of Notified Medical Devices	Form 21	Form 19	Rule 61(2)	State Drug Licensing Authority	No time period prescribed (usually between three to six months)
Whole sale of Notified Medical Devices	Form 21-B	Form 19	Rule 61(2)	State Drug Licensing Authority	No time period prescribed (usually between three to six months)
License to manufacture Notified Medical Devices	Form 28	Form 27	Rule 76	For Notified certain specified Medical Devices – the DCGI. For other Notified Medical Devices – the State Drug Licensing Authority	No time period prescribed (usually between three to six months)
License to manufacture a Notified Medical Device for the purpose of examination, test or analysis when no manufacturing license under	Form 29	Form 30	Rule 89	For Notified certain specified Medical Devices – the DCGI. For other Notified Medical Devices – the State Drug	No time period prescribed (usually between three to six months) No time period prescribed (usually between
Loan License (manufacture in facility owned by third party)	Form 28-A	Form 27-A	Rule 76-A	For Notified certain specified Medical Devices – the DCGI. For other Notified Medical Devices – the State Drug LicensingAuthority	No time period prescribed (usually between three to six months)

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Although the changes in FDI policy will go some way to improve the sector, there are a number of other problems that could deter foreign investors from manufacturing in India. High tax rates imposed on domestic manufacturers have made investment unappealing to some foreign companies, especially given the comparatively low amount of tax levied on imported medical goods.

It is, therefore, hardly surprising that foreign firms often choose to access India's medical market without establishing a direct presence – many companies establish factories in neighboring China and export devices into India.

Importing into India

Accessing India's medical devices industry through an indirect route remains attractive to foreign firms. India is heavily reliant on foreign imports: over 80 percent of its medical devices and equipment are outsourced from other countries, particularly from the U.S.

Medical device companies that have already been approved in the U.S., Europe, Canada, Japan, or Australia are able to legally sell in India. Prior to starting the import process, firms must prepare and submit a technical dossier: documents that clearly detail the type of devices intended for import and their associated risks.

Devices with higher levels of risk to patients, and which necessitate greater control for safe use, will require a longer dossier and will further be subject to stricter checks. Should the dossier be found to lack all relevant information, it will likely be rejected.

If a company does not have a branch office in India, it will have to contract an importer that possesses a valid import license. Doing so is often a difficult process for companies that have not sourced a consultant, and should not be completed without first conducting a thorough due diligence of the prospective candidate.

Local regulations

Whether a foreign business intends to invest in India, or import into India, it will need to take time and patience to navigate the Drugs and Cosmetics Act, 1940, the Drugs and Cosmetics Rules, 1945, and the Medical Device Rules, 2017.

A peculiar feature of the Indian medical device industry, historically, has been that it was largely unregulated, aside from certain types of medical devices. The Medical Device Rules, 2017, which came into effect on January 1, 2018, should fill this legislative void.

There are, however, plenty of other regulatory challenges that require diligence from multinational businesses. Certain medical devices in India are subject to additional scrutiny: "Notified Medical Devices" are governed by the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. From January 1, 2018, they have been also subject to the Legal Metrology (Packaged Commodities) Rules, 2011 – they were previously exempt from this compliance.

These Notified Medical Devices are overseen by the federal government and state governments, and require licenses or permissions for the manufacture, import, distribution, and sale of medical devices.

The list of Notified Medical Devices are as follows:

- Disposable Hypodermic Syringes;
- Disposable Hypodermic Needles;
- Disposable Perfusion Sets;
- In vitro Diagnostic Devices for HIV, HBsAg, and HCV;
- Cardiac Stents;
- Drug Eluting Stents;
- Catheters;
- Intra Ocular Lenses;
- V. Cannulae;
- Bone Cements;
- Heart Valves;
- Scalp Vein Set;
- Orthopedic Implants;
- Internal Prosthetic replacements; and,
- Ablation Devices.

In addition, the following substances are regulated as "Drugs" under the Drugs and Cosmetics Act, 1940 and administering Rules, 1945:

- Blood Grouping Sera;
- Skin Ligatures, Sutures, and Staplers;
- Intra-uterine devices (Cu-T);
- Condoms;
- Tubal Rings;
- Surgical Dressings;
- Umbilical Tapes; and,
- Blood/ Blood Component Bags.

India's domestic market

India – a key player in the global pharmaceuticals industry, under which medical devices used to be covered – is underperforming.

Medical devices in India hold a market share worth US$5.2 billion presently, contributing around 4 to 5 percent to the US$96.7 billion healthcare industry in the country. India has about 750–800 medical device manufacturers, with an average investment of US$2.7 to 3.1 million (Rs 170 to 200 million) and an average turnover of US$7.09 to 7.87 million (Rs 450 to 500 million).

Despite such figures, India's medical devices sector is expected to see unprecedented growth over the next decade. By 2025, the industry is projected to be worth US$50 billion. This can be attributed to the country's growing middle class, an increase in the number of hospitals, and, consequently, a greater need for sophisticated medical devices and better healthcare.

(Editor's Note: This article was originally published in January 2015, and has been updated to include the latest legal and regulatory developments.)

New Medical Device All Set To Change The Indian Healthcare Scenario

What the government and the medtech sector must do to reap the benefits of this revolutionary legislation

THE NEW MEDICAL device rules which came into force from January 2018 has finally given the medical devices and in-vitro diagnostic devices (IVD) industry a distinctive regulatory identity.By delinking devices from drugs, the multitudes of devices used in the country today, from the humble to the complex have potential to come under the ambit of rules to ensure patient safety, quality and performance parameters of devices sold within the country.

Given that 80% of the devices are imported, the legislation has an important role to play in creating a level playing field for domestic and foreign manufacturers. The legislation is also propitious for achieving the main goals of the National Health Policy 2017 that calls for addressing the changing priorities in Indian healthcare, mainly bridging the accessibility and affordability gap.

While the present regulation is still an amendment to theDrugs and Cosmetics Act, 1940, the Parliamentary Standing Committee for Health and Family Welfare has actively sought comments and concerns to revive the bill for a stand-alone legislation for medical devices, which has been under discussion for a couple of years now. Widely anticipated to be tabled in the Parliament this year, the singular act of medical devices, if passed, will hoist India's regulatory framework for the sector on par with mature global economies.

Irrespective of the outcome, the new medical device rules currently en vogue has set the right frame of reference for the medical technology (medtech) sector.

With a phased approach in the works, the rules in the present form gives scope for introducing new products as the implementation continues. In a few years, it is expected that

the regulation will span the entire medtech devices and IVD manufactured in the country.

The central government is keen to get the regulations off the ground, and unlike other regulations in the past, there is no scope for withdrawal or postponement. In another unique scenario, the regulation is consistently pushing for empanelment of the notified bodies – a welcome sign for the industry to increase their competitiveness and market potential with regulatory compliance.

The success of the legislation, however, hinges on addressing a few implementation bottlenecks, as voiced by the industry.

What are the roadblocks to successful implementation of the regulation?

- **Creating the right ecosystem:**

The primary concern in implementation is the establishment of an ecosystem for the notified bodies, which will shoulder the burden of evaluating regulatory compliance. The process so far, is not going as speedily as expected.

- **The state vs. the center debate:**

Like in the sister industry of pharmaceuticals, the efficacy of any legislation laid down by the central government depends on the involvement and co-operation of the state governments.

The present legislation is based on the licensing model with a one-time audit and no in-built surveillance mechanism to measure continued compliance. Sampling is also expected to be conducted by the central licensing authority (the **Central Drugs Standard Control Organization**) or the respective state licensing authority (the state **Food and Drug Administration**s) themselves.

There are still on-going debates among stakeholders if this is the right approach for implementing the legislation, as this is unlike any other regulatory model in the world.The CE mark, for instance, is earned after a rigorous surveillance every year, along with surprise inspections and audits by accredited third-party organizations to ensure non-partisanship.

- **Infrastructure issues:**

The “Make in India” program has spurred the founding of medtech parks around the country, with promise of the government support in the form of land allocation and subsidies to encourage growth of the domestic medtech industry. However, the relatively slow pace of infrastructure development of these parks is delaying the domestic industry from setting shop. In the face of the anticipated withdrawal of large players as an effect of price control, this may have larger implication on the availability of devices in the country.

- **Industry awareness:**

While dominated by large players and multinational corporations, the domestic medtech landscape also comprises small and medium players and startups vying for bigger market shares. While these players have a bird's-eye perspective of the regulation and the compliance requirements, there is a general lack of in-depth understanding of the rules.

This creates a problem – the scope of the regulation is automatically limited to the 22 device types that were already under mandatory control. To advance further to higher levels of manufacturing, domestic players must comprehend the scope of requirements in Schedule 4 and 5, which pertain to the manufacturing of medium to high risk devices.

Possible solutions

- **Overcome policy uncertainty:**

The new medical device rules were framed with the intention of making the domestic industry on par with global manufacturing practices.

While the policy has the right intent for addressing multiple aspects of this paradigm shift – encouraging domestic manufacturers, boosting innovation and R&D (research and development), the industry is looking for an assurance on follow-through at the basic level. For instance, fixing land allocation and electricity connections, and a clarity on the exact subsidies provided at medtech parks.

Another aspect is to streamline the licensing process to ensure that manufacturers who already possess reputed international certifications can obtain the Indian mark easily. Currently, a domestic manufacturer with a CE mark must undergo nearly the same regulatory grind as a new manufacturer, a rather discouraging measure.

- **Revamping “Make in India”:**

Medical electronics is slated as a critical aspect in the new manufacturing policy for electronics, expected to be released in 2018. Both the industry and the government should work together to clear implementation bottlenecks to ensure they reap the benefits of the policy.

- **Promoting startups:**

The healthcare startups have gained tremendous private equity and venture capital attention over the past year and this trend is expected to intensify in the coming years.

On the other hand, the medtech startups face a funding crunch unless the solutions they provide are unique and innovative. In the interest of promoting domestic manufacturing and bridging the accessibility-affordability gap, the state governments should set-up schemes to fund the medtech startups.

Conclusion

The Indian medtech sector is at a crossroad. While it is too soon to evaluate the trajectory of the legislation, implementation issues are already coming to the fore. With a firm hand on weeding out policy concerns, the disturbances in compliance are expected to be temporary. The most crucial aspect is for the industry and the government to establish an open dialogue to sort out discrepancies and concerns. The state governments will perhaps play the most crucial part in ensuring successful implementation of the legislation.

Medical Devices in 2030

WHILE THE OUTLOOK for medical device companies appears positive, unsustainable healthcare costs and new competitive forces threaten to alter the future industry landscape. If today's manufacturers fail to stake their claim in the evolving value chain, they risk being caught in the middle and becoming commoditized. Staying ahead means offering value beyond the device and solving healthcare's problems – rather than contributing to them.

Reinvent, reposition, reconfigure!

Thedaysofsimplymanufacturingadevice, andselling it to healthcare providers via distributors, have long vanished. Value is the new byword for success, prevention the preferred clinical outcome, and intelligence the new competitive advantage. Here we discuss the pathway to success in 2030 for medical device companies, following a three-pronged strategy:

Reinvent

Medical device manufacturers should take acloser look at their existing organizations and reinvent their traditional business and operating models to adapt to the future, by:

- integratingintelligenceintotheirportfoliosandofferings, to positively influence the care journey and connect with customers, patients and consumers
- deliveringservicesbeyondthedevice,andintelligence beyond these services – a true shift from cost to smart value
- investinginenablingtechnology–makingtheright choices to support a wide range of parallel business models tailored by segment to customers, patients and consumers (prospective patients) – and, ultimately, the financial ambition for the organization.

Reposition

It is equally important to prepare for the future byconsidering an 'outside-in' perspective.

In 2030, the external environment will be extremely dynamic and medical device companies need to reposition themselves in the newly envisaged competitive landscape, to cope with tumultuous forces from:

- newentrants,includingcompetitorsfromunrelated industries

Mapping Learnings from Other Countries with India

Developed countries, such as those mentioned below, have robust public health insurance frameworks that account for a majority of healthcare benefits and fund a large chunk of the hospital care costs. Inherent to this system is transparency and predictability in the provider pricing of healthcare services – one of the key elements missing in Indian healthcare at present. Some of the best practices taken from other countries which can be replicated are as follows:

Parameters	USA	France	UK	India
Product based reimbursement/ co-payment	Patient shared billing with government and insurers	Case-mix system of reimbursement based on treatment in public or private hospitals	Fixed annual budgets by local clinical commissioning group (CCG's) along with regional Strategic Health Authorities (SHA's)	Mostly out of pocket expenses - Patient shared billing with government and insurers
Bundled/ Package Rates	Fixed procedure fee based on diagnosis-related groups (DRG) payment system	Fixed procedure fee based on French DRG payment system	Fixed procedure fee based on DRG payment system, except few cases paid as unbundled rates	Procedure fees deviate based on hospital, quality of device and region
Device Pricing	Covered in package rates	List of reimbursable products and services covers both generic and branded products with incremental value	Manufacturer's free to set prices but have to negotiate with CCG's	Price capping for stents, implants market forces drive the prices for all other products
Price Capping	Capping at healthcare provider fees	Capping at healthcare provider fees and device fee	Capping at healthcare provider fees	Initiated capping at device fee
Value proposition from the country	Incentivize hospitals to shorten surgical time and length of stay	Differentiate between novel brands with incremental value	Controls hospital budgets allowing free competition in product prices	

- newtechnologies,astechnologicalinnovationwill continue to outpace clinical innovation
- newmarkets,asdevelopingcountriescontinuetheir high growth trajectories.

Reconfigure

The traditional medical device value chainwill rapidly evolve, and by 2030 companieswill take on significantly different roles. Following their reinvention and repositioning, medical device companies will need to reconfigure their respective value chainsand define their place therein. Multiple value chain 'configurations' will exist, requiring companies to make fundamental strategic choices. As somewhat evidenced today, manufacturers will continue to link themselves directly with patients and consumers, or combine with providers or even payers through vertical integration.

Value chain reconfiguration choices will not be straight forward, and are likely to differ by company segment (device area, business unit, geography). This will be further complicated by the fact that the value chain itself will be dynamically evolving, as a result of other companies attempting to reconfigure and meet their strategic aims. The right choices, however, will create significant value for the end user – and help the company avoid a future of commoditization.

Industry executives need to challenge conventional thinking, and reimagine the roles their companies will play in 2030. Accordingly, they will need to reconfigure today's organization to shift from being a participant in the value chain to being a solution provider for sustainable healthcare costs.

The evolving value chain

Making a power play across the medical device value chain of the future

Traditionally, medical device companies have delivered value primarily through manufacturing and selling their products. But as pressures on the healthcare system mount, there are foundational shifts in the care delivery model, and as a result, the industry value chain is up for a drastic overhaul.

In the new normal, companies will need to step out of their conventional manufacturing role. Services and data intelligence will need to be integrated with products to offer holistic solutions, requiring a 'power play' across the value chain – strengthening existing business-to-business (B2B) plays and creating new ones, while introducing business-to-consumer (B2C) plays. These power plays will likely include a continuous slew of deal activities – mergers and acquisitions (M&A), strategic alliances and partnerships.

Medical device companies will ultimately seek to play a larger rolein the value chain and get closer to customers, patients and consumers. Done right, this will not only add new revenue streams for them, but also contribute to shorter, cheaper, and fewer hospital visits – and thus lower healthcare costs.

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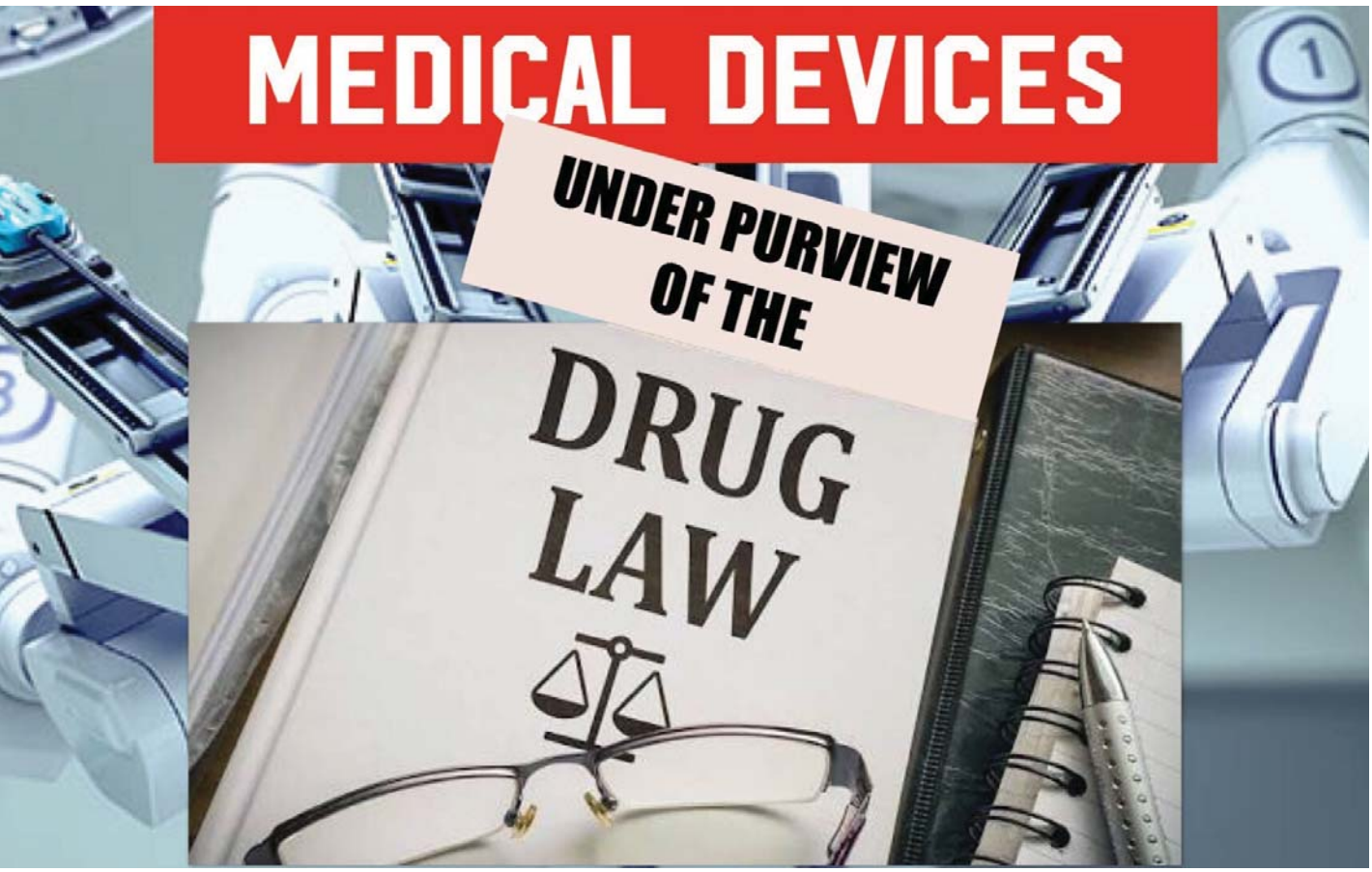

In a move to regulate quality of high-end medical devices and equipment such as implants, X-ray machines, MRI and CT scan equipment, and dialysis machines, the health ministry has proposed to expand the list of devices under the purview of drug law.

THE CENTRAL DRUGS Standard Control Organisation (CDSCO), the drug quality regulator under the ministry, has suggested to add eight new categories of medical devices under the definition of drug, which will be directly regulated under the Drugs and Cosmetics Act. At present, only 23 medical devices qualify as drugs and are monitored for quality by the Drugs Controller General of India (DCGI).

All other medical devices are sold without any quality checks or clinical trials. The latest proposal would mean companies will have to do trials in India, submit safety data and meet other such regulatory requirements to seek before seeking approval for selling such high-end critical products.

The list proposed by CDSCO includes implantable medical devices, MRI equipment, CT scan equipment, defibrillators, dialysis machines, PET equipment, X-ray machines and bone marrow cell separator. The regulator has proposed to notify these eight categories of medical devices as 'drugs,' under Section 3 of Drugs and Cosmetics Act.

"This will be notified in the official Gazette of India and it will come into force after a period of twelve months from the date of its publication," the regulator said in a public notice inviting comments from all stakeholders by mid-July. The move assumes significance as increasing number of such products are entering the market with several variants and brands.

Many of these products are life-saving devices, priced exorbitantly and used in critical care. Medical device market in India is pegged at around $7 billion, growing annually at 10-12%. Estimates show medical technology sector has the potential to touch $50 billion by 2025.

Currently, India imports around 80% of the medical devices.

New rules to make medical devices

Those planning to set up a plant for manufacturing medical devices in the state would now have to apply for licence under the new Medical Device Rules, 2017 implemented in January this year. Earlier, the licence was issued under the Drugs and Cosmetics Act, 1940.

"The licences already issued under the Drugs and Cosmetics Act for manufacturing medical devices will stay the same," the newly appointed medical device officer for the state, Amal Kumar, said.

He said the licences under the new rule would not need periodical renewal for manufacturing and import and would remain valid until they are either suspended, cancelled or surrendered. The licensee would have to pay a retention fee every five years for the licence to remain valid. An online portal — Sugam — by Central Drugs Standard Control Organization (CDSCO) has been launched to provide online services for granting licences for manufacturing, import, clinical investigation, sale and distribution of medical as well as in vitro diagnostics (IVD) devices.

"Now, a total of 598 items are in the list of medical devices," said Kumar, adding the 2017 rules also include surgical sutures, bandages, dressings and staples, disinfectants, ligature and mechanical contraceptives. Setting new standards for the requirement to manufacture medical devices, they have been classified depending on the risk involved into four classes — low (Class A), low moderate (Class B), moderate high (Class C) and high (Class D).

"The application for manufacture of Class A or Class B medical devices will be assessed by the state licensing authority whereas the application for manufacture of Class C or Class D medical devices will be assessed by Drug Controller General of India (DCGI)," Kumar said.

He further said there were three plants in the state — two in Patna and one in Hajipur — for manufacturing devices under Class A and B. "The manufacturing sites will have to be inspected not less than once a year to check they are conforming to all the terms and conditions for the licences. Manufacturers are expected to follow stringently the quality management system while manufacturing medical devices," he added.

Rationalising profits: Govt plans cap on trade margins of medical devices

The government plans to bring down prices of commonly used medical devices by capping the trade margin at 30% on the first point of sale, a move likely to trim irrational profits made by distributors, wholesalers, retailers and even hospitals by selling such products to patients.

The government think tank Niti Aayog has suggested that in order to make medical devices and services affordable, rationalisation of trade margins may be considered and, on high volume medical devices, up to 30% margin may be allowed over the manufacturer's price at the first point of sale. The proposal was discussed at a meeting with the prime minister's office recently.

The Niti Aayog has also started consultation with other stakeholders including medical device manufacturers and public health groups on the issue. It has also recommended the standing committee on affordable medicines and health products to come up with a list of medical devices, where volumes are high and industry profits can be curbed to apply the cap on margins.

At present, India imports over 75% of all its medical device needs and around 80% of the imports include high-end products used in critical care.

At present, medical devices are largely out of government price control. Just four items — cardiac stents, drug eluting stents, condoms and intra uterine devices — are in the National List of Essential Medicines and fall under government's purview.

Apart from these, only knee implants have been recently brought under price control and the remaining medical devices are under no price regulation.

"It was suggested that consumables, diagnostics and devices may be considered for price control under provisions of DPCO and DPCO be amended to encompass all medical devices and other health products," an action plan shared during the meeting with PMO said.

While medical device manufacturers have welcomed the government's move to cap trade margins, they are debating on the official definition of the 'first point of sale' in the case of imported devices.

IPC Issues First 'Standards For Medical Devices - A Reference Document' To Provide Information On Quality Parameters

Nearly eight months after the implementation of the Medical Device Rules 2017, the Indian Pharmacopoeia Commission (IPC) has brought out the first reference document for medical devices manufactured and sold in the country. Framed mainly on the basis of MD Rules, the 241-page draft rule book is expected to provide manufacturers, licence holders, regulators and healthcare professionals with requisite information on regulatory and technical requirements under one umbrella.

In addition to the new MD Rules, the document is based on the standards adopted in Indian Pharmacopoeia 2018, British Pharmacopoeia, Japanese Pharmacopoeia, European Pharmacopoeia and the Bureau of Indian Standards.

Currently, India's medical device sector is dominated by multinational companies, which is evident from the fact that about 80 per cent of the sales are generated by imported devices. Though many multinationals have set up operations in India over the years, a majority of them

focus on distribution of imported devices and support functions. The MD Rules 2017 were framed around the guidelines of the Global Harmonisation Task Force to ensure that the Indian norms are on par with those in vogue globally. Medical devices, both indigenously produced and imported, now have to conform to the best international practices of manufacturing. Against this backdrop, the new reference document will come in handy since the industry is growing at a rapid pace and there is need for an easy-to-access guidebook on regulations and export-import guidelines.

The draft document is likely to be modified as the IPC has requested industry experts and other stakeholders to submit their comments and suggestions on it. Comments can be submitted till September 1, 2018. The documenthas elaborate sections on classification, registration process, grouping and labelling. More than 20 pages are dedicated for classification of devices and quality parameters.

The reference manual is the latest step from the Union health ministry to ensure the reliability of medical devices available in the domestic market. Plans are afoot to bring all implantable medical devices and other critical medical equipment under the purview of the Drugs and Cosmetics (D&C) Act 1940 and the Central Drugs Standard Control Organisation has notified the list of devices to be regulated under the Act. Apart from all medical implantables, the list includes defibrillators, bone marrow cell separator, dialysis and X-ray machines as well as PET, CT scan and MRI equipment.

While welcoming these positive moves, the domestic industry representatives continue to make a pitch for creating a separate act to regulate medical devices. A draft medical devices regulatory bill has been lying with the health ministry since 2016.

"The law to regulate medical devices needs to be passed and stakeholder consultation for the draft created by the health ministry needs to be expedited as clearly medical electronics are not drugs and a misfit in current legislation of D&C Act," says Rajiv Nath, forum coordinator of Association of Indian Medical Device Industry.

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PAVAN CHOUDARY, Director General of the Medical Technology Association of India (MTaI), a non-governmental organization.

The significance of the medical technology industry is not fully appreciated, and the sector is under-prioritised, according to industry representatives.

"The healthcare sector rests on four pillars—hospitals, pharmaceutical industry, health insurance industry and the medical technology industry. The last of these is the least understood of all yet most significant for enhancing quality of healthcare, and has direct implications for patient outcomes.

The recently presented NITI Aayog action agenda recognizes the significance of global companies' presence for the domestic industry to compete with and grow. Import substitution as a focus of policies needs to be replaced with greater efforts directed towards ensuring global competitiveness through export promotion and meeting global quality standards."

SANJAY BHUTANI, Director, MTaI.

"The policies must factor in the existing gaps in the domestic manufacturing industry, and promote ease of doing business by way of reduced inter-organizational delays, enhanced start-up industrial finance, simplified regulations such as single-window clearance, and greater investment in infrastructure. We endorse the Trade Margin Rationalization Report of the Department of Pharmaceuticals, provided unique and deserving sub-sectoral nuances are given due consideration."

URVASHI PRASAD, Public Policy Specialist, Office of Vice Chairman, NITI Aayog.

"There is a need to look at medical devices holistically, and not through narrow prisms of singular initiatives and policies."

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