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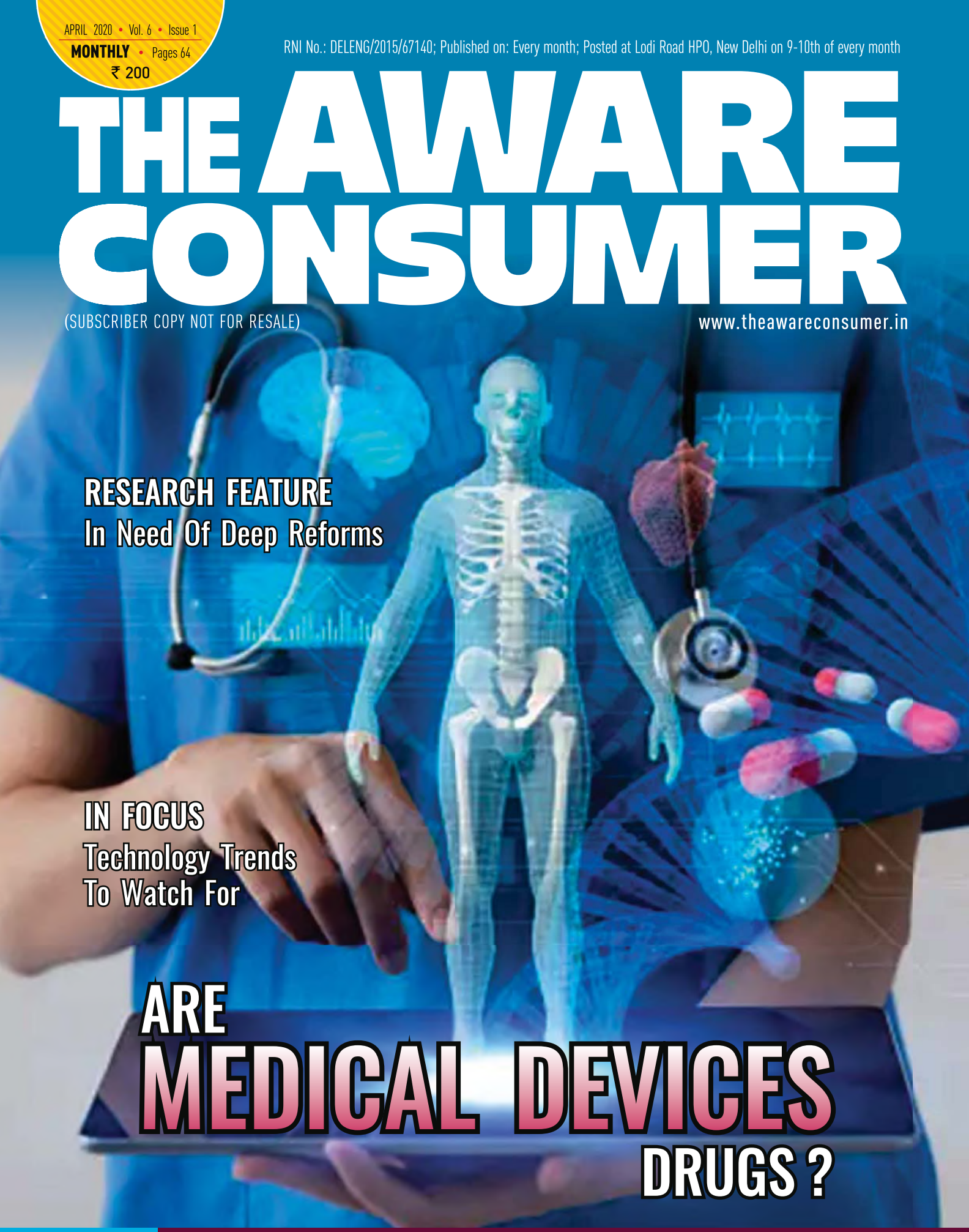

RESEARCH FEATURE
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IN FOCUS
Technology Trends To Watch For

ARE MEDICAL DEVICES DRUGS ?

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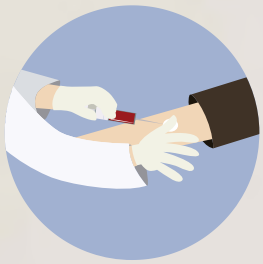

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QUALITY IN PATIENT CARE

VIEW  POINT

BEJON KUMAR MISRA | bejonmisra@theawareconsumer.in

Are MEDICAL DEVICES Drugs ?

As per the recent notification of Ministry of Health & Family Welfare, all medical devices sold in the country will be treated as drugs and would be regulated under the Drugs and Cosmetics Act of 1940.

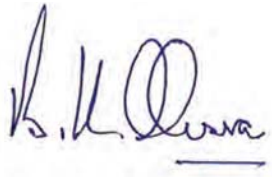
ARE MEDICAL DEVICES drugs? Can we have the same rules for what common sense tells us are engineering and technology-based goods as pharmaceutical products?

The recent notification by the Union Health Ministry notifying medical equipment used on humans as drugs under Section 3 of the Drugs and Cosmetics Act with effect from April 1, 2020; set us thinking. While the aim of ensuring all medical devices meet specific standards of quality and efficacy, and making medical device companies accountable for quality and safety of their products is certainly welcome; one is perplexed as to how the same rules that have failed to enforce stringent quality standards on pharmaceutical companies will work to enforce strict compliance by medical device industry which as best is fragmented with thousands of small players? Aren't the parameters followed by medical device industry different from drugs right from manufacturing to marketing?

The objections raised by the medical device industry also seem valid. We import around 80 percent of the medical devices and have a mounting import bill. The idea behind including the medical devices industry in the Make in India initiative was to provide the local manufacturers the much-needed impetus to grow. The Indian startups in the space are high on innovation and technology and are working to fulfill the needs of the masses, developing quality products that are at the same time accessible and affordable. However, the indigenous industry has to compete against MNCs with deep pockets. The government policies till now have encouraged both the MNCs and local manufacturers to adopt the import route and all this has led to the failure of the industry to become self-sufficient.

Given its potential for export and its importance to boost the growth of the healthcare sector, It is imperative that the medical devices industry be accorded the importance it deserves and be treated as a separate entity with its own dedicated laws.

If we have the interests of the consumers at the center of these rules, we must ensure there is no scope for ambiguity in the laws, as it is ultimately the end-users who end up paying a heavy price for no fault of theirs.



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*As per the study published in Mycoses Journal, April 2002
+ As per IMS prescription data MAT March 2016 | **Related to fungal infections

glenmark

Message from the Editor-in-Chief

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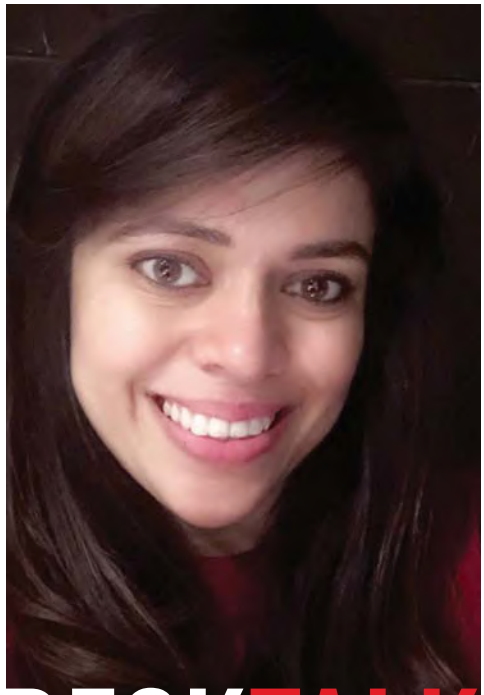

DESKTALK

Need To Work Collaboratively To Ensure Quality

THE UNION HEALTH Ministry through a gazette notification recently released the Medical Devices Amendment Rules, 2020, for mandatory registration of medical devices. The new rules are aimed at ensuring that all medical devices meet certain standards of quality and efficacy, the notification will also make medical device companies accountable for quality and safety of their products.

Medical devices are critical for correct diagnosis and treatment. Hence, there can be no compromise on the quality of these equipment as their accuracy is vital for medical practitioners to correctly diagnose a disease. The line of treatment depends on how accurate the vital data they provide are. Even the smallest error can have serious implications for the patient.

In this scenario, mandatory registration of medical devices makes good sense as it can help curb the counterfeit medical equipment market. It is important that all medical equipment have traceability embedded so that each can be traced back to manufacturers. In a market flooded by spurious products, it will help establish the credibility of the manufacturer whose product has been copied, innovation or technology stolen. Manufacturers being liable to penalties for any quality compromise would also ensure that they do not cut corners and ensure validity is maintained.

It is important that medical devices comply with stringent laws and the enforcement agencies should ensure that there is no laxity in compliance by ensuring exemplary action against those who flout the norms. However, laws alone will not help the industry manufacture high-quality medical products. The government and the industry must collaborate on establishing programs that can help local manufacturers meet the quality and compliance parameters.

Apart from promoting quality design and manufacturing practices, there is also a need to provide options on demonstrating compliance. The industry, government and other stakeholders must also work collaboratively to identify barriers to medical device quality and develop innovative methods to remove the identified barriers. It requires concerted efforts by all parties to ensure patients get access to high-quality medical devices at affordable prices.

INSIDE

THE AWARE CONSUMER APRIL 2020

REGULARS

The medical devices industry has the potential to make India one of the top manufacturing hubs in the world, provided the government takes some determined reforms to overhaul the sector.

The demand for medical devices and equipment is slated to grow as India steps up its growth. It is time to take all steps to ensure that this happens.

Shri Rajiv Nath
Forum Coordinator of Association of Indian Medical Device Industry (AIMED)

The medical device industry has unique challenges in validation of products and needs to be nurtured properly to help address these issues.

Make in India initiative of the government has the potential to make India a leading exporter of medical devices.

Technology is rapidly changing the healthcare landscape and how! Here are few technologies that are finding increasing application in the field.

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UNLOCKING CONSUMER POTENTIAL
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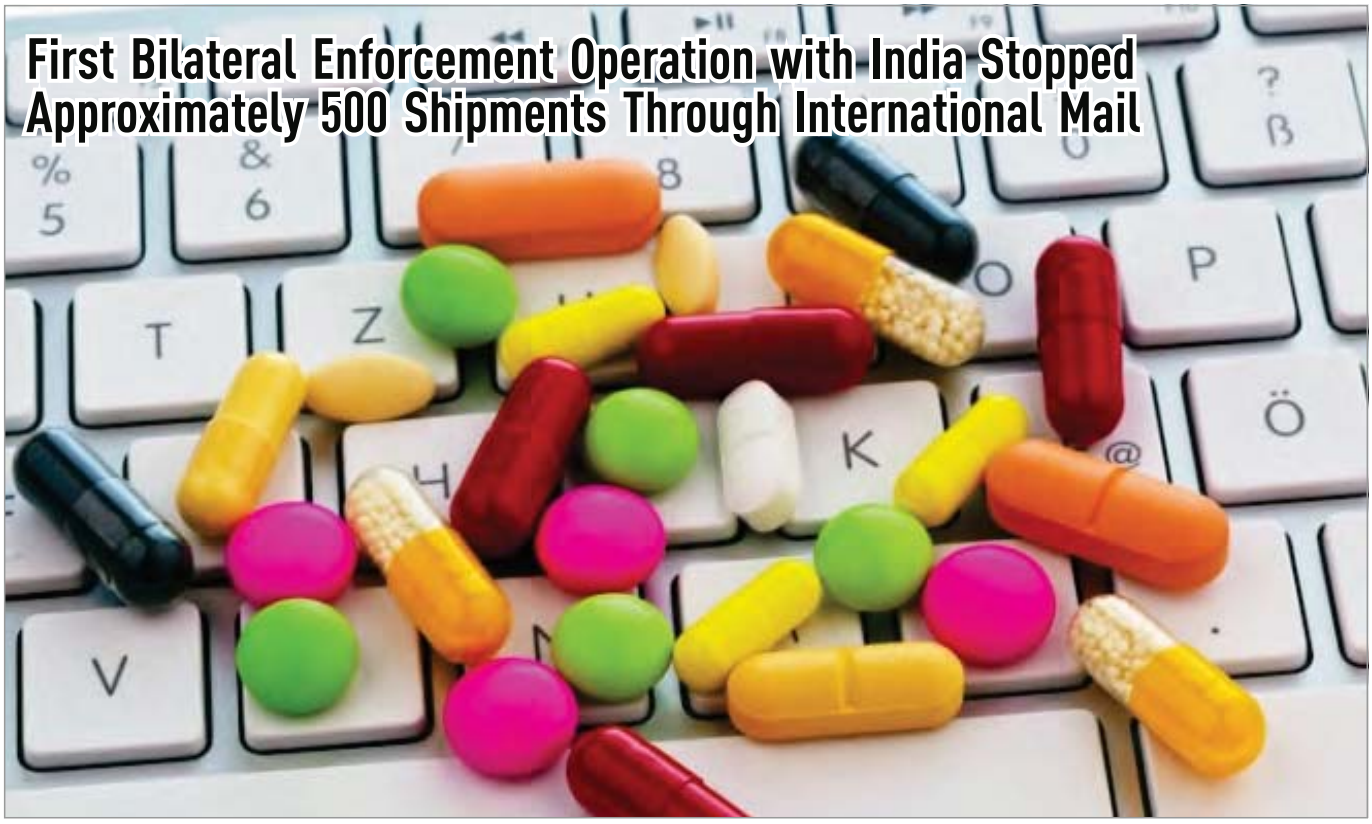
NIRMALA SITHARAMAN

MINISTER OF FINANCE AND CORPORATE AFFAIRS, GOVERNMENT OF INDIA

"To achieve the twin objectives of giving impetus to the domestic industry and also to generate resource for health services, I propose to impose a nominal health cess, by way of a duty of customs, on the imports of medical equipment keeping in view that these goods are now made significantly in India"

ROUNDUP



First Bilateral Enforcement Operation with India Stopped Approximately 500 Shipments Through International Mail

FDA Takes Action with Indian Government to Protect Consumers from Illicit Medical Products

DATA BRIEFING

80-90% –

India imports 80-90 per cent of medical devices and has an ever increasing import bill of over Rs 38,837 crore.

IMAGE: PIXABAY

IN A RECENT press release, the U.S. Food and Drug Administration said that in its first bilateral enforcement operation with the Government of India, it stopped approximately 500 shipments of illicit, and potentially dangerous, unapproved prescription drugs and combination medical devices from reaching American consumers over the course of an operation that took place in January.

"With standards and regulations varying in each country, U.S. consumers face hazards when they order drugs and other FDA-regulated products from unauthorized foreign sources and receive them through the international mail system. Consumers and physicians purchasing medicines cannot be assured the products they are receiving are legitimate, safe or effective if they are obtained from outside of the FDA-regulated pharmaceutical supply chain," said FDA Commissioner Stephen M. Hahn, M.D. "The FDA is committed to empowering patients and providing them choice, but also protecting them through collaboration with our international regulatory and law enforcement partners. It is vital that we aggressively stop illicit products from entering the country that may place patients' health at risk, and we are pleased to call the Government of India a partner in this effort," the release said.

Operation Broadsword targeted packages entering the U.S. through an International Mail Facility (IMF) from Jan. 28 through Jan. 30. The operation was a collaboration between the FDA's Office of Regulatory Affairs, Office of

Criminal Investigations, Forensic Chemistry Center and Division of Northern Border Imports along with the Government of India's Central Board of Indirect Taxes and Customs and Directorate of Revenue Intelligence and U.S. Customs and Border Protection.

During Operation Broadsword, investigators from both governments examined more than 800 shipments, which identified approximately 50 different FDA-regulated products, including medications intended to treat and or mitigate serious diseases, such as various forms of cancer and HIV. Many of the shipments, which included opioid drugs products, had been transshipped through

third-party countries to conceal their point of origin and avoid detection. Health risks are further compounded when products are sent through such third-party countries, which undermines protections afforded via regulated pharmaceutical supply chains.

The FDA believes international law enforcement cooperation is essential in the age of interconnected regulatory frameworks and systems of distribution. In September 2019, a senior-level FDA delegation traveled to India for the purpose of strengthening bilateral engagement. A series of stakeholder meetings—coordinated and facilitated by the India Office of the FDA's Office of Global Policy and Strategy—were held at the U.S. Embassy in New Delhi as well as with the government of India's Central Board of Indirect Taxes and Customs, the Directorate of Revenue Intelligence, and the Central Drug Standard Control Organization in support of an ongoing bilateral initiative to combat public health and safety-based crime.

"A bilateral enforcement exercise like Operation Broadsword allows us to closely work with our U.S. counterparts so as to share best practices, develop intelligence, better target suspect consignments, consignors and other bad actors at both ends," said Balesh Kumar, director general, Directorate of Revenue Intelligence for the Government of India. "Such an exercise also has potential for long term capacity building. The Directorate of Revenue Intelligence is committed to fighting the menace of drugs and narcotics and international cooperation with agencies like the U.S. FDA can help us in our efforts towards this cause."

In fiscal year 2019, the FDA screened approximately 25,200 parcels, containing more than 41,000 products combined at all of its IMF facilities. The FDA detained more than 38,000 of those products and expects to ultimately destroy more than 17,000 of those products as drugs subject to the FDA's administrative destruction authority.

Patients who buy prescription medicines from illegal online pharmacies may be putting their health at risk because the products, while being passed off as authentic, may be counterfeit, contaminated, expired, or otherwise unsafe. In addition to health risks posed by these products, illegal online pharmacies can pose other risks to consumers. These include the risk of credit card fraud, identity theft and computer viruses.

The FDA provides consumers with information to identify an illegal online pharmacy and information on how to buy medicine safely online through BeSafeRx: Know Your Online Pharmacy. Consumers are encouraged to report any unlawful sale of medical products online to FDA.

NEW INNINGS FOR MEDICAL DEVICES SECTOR IN INDIA

The trends for 2020 point to a medical equipment industry high on innovation and technology.

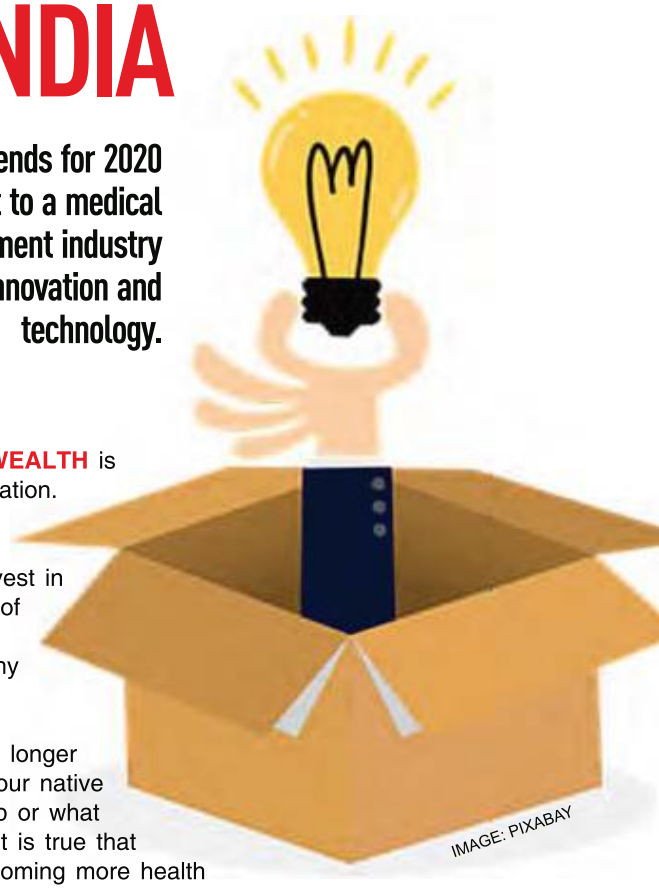


IMAGE: PIXABAY

A NATION'S WEALTH is finally its population. Hence, it is pertinent for countries to invest in the healthcare of its people and ensure a healthy and thriving population.

Health is no longer dependent on our native genetic makeup or what we eat. While it is true that people are becoming more health conscious and are working on fitness, taking care of the food they eat and in general creating healthy lifestyles, healthcare sector players, especially manufacturers and distributors of medical devices, are also stepping up their offerings using latest technology and innovation to make quality and affordable products.

A KPMG report on the global medical devices industry says that the global annual sales of medical devices which is at $483 billion in 2020 is projected to grow by over five per cent annually to reach around $800 billion in 2030. For the industry,

The trends for medical devices for 2020 promise a new dawn on the foundation of innovation and technology.

India and China are the most important emerging markets with huge growth potential.

Some of the top trends to watch out for in the medical devices industry in 2020 are as follows:

- **Technology and innovation to drive the sector:** The advent of smart devices like wearable integrated smart devices and smart online data services on healthcare are ensuring that people spend less time in the hospital as they can monitor their own health statistics. Technology in the personal healthcare space means that people will be working on the prevention of major, unexpected illness and health scares. This would mean they would require tospend less on expensive treatments and the hospital visits will be minimized. It is expected that the market will see the launch of various innovative, non-intrusive, wireless portable monitoring medical devices including watches, skin patches, etc.
- **Daily use devices will be launched:** Medical devices that are used daily will infiltrate the market as lifestyle diseases become increasingly prevalent. Another reason for development of such devices would be an increasing population of elderly with chronic complications. Non-communicable diseases (NCDs) are also rising and have led to a growing demand for daily-use medical equipment including blood pressure monitors, nebulizers, digital thermometers and glucometers as the trend to self-monitor vital stats daily rises.
- **New bacteria detection methods will be developed:** A welcome trend would be the emphasis by manufacturers on developing new ways to detect and identify microorganisms or bacteria fast. The increasing dependence on antibiotics has led to rising resistance to it and it has made it difficult for medical practitioners to treat various illnesses. The industry is working on developing innovative devices that could detect different types of bacteria in the shortest possible time and thus enable physicians to provide targeted antibiotic treatment for say only a specific part of the body. This is hoped to bring down resistance to antibiotics. Such devices will ensure patient safety as there will be no room for.
- **Devices will become more affordable:** Accessibility and affordability are the twin targets of the Indian medical devices industry as a larger part of the population in the country belongs to the lower and middle classes and cannot afford expensive, generally imported, healthcare and medical devices. The startup segment in the sector is working with this social target on various innovative products that while not compromising on the quality will be available and affordable for mass use. Once medical devices are affordable, it will make healthcare as a whole much cheaper and more people will feel encouraged to come for treatment.
- **Innovation and R&D will be the buzzwords:** When innovation meets digitization, some revolutionary products can be expected from the manufacturers' stables. Fresh and exciting medical products will be manufactured driven by the demands of the modern-day consumers and an expanding market. The big commercial manufacturers will also be seen investing heavily into partnerships with academic research institutes or will invest in R&D by setting up company owned research and development centers to ensure that they remain on the cutting edge of innovation and technology.
- **IoMT will change the landscape:** IoT has enabled billions of devices around the world to be connected to the internet. The connection with each other and to the internet allows these devices to collect and share data, among people as well as each other. IoT adds a layer of digital intelligence and transforms an ordinary device into a "smart" machine. IoMT will be a big trend as its application in the medical sector can covert medical devices into intelligent machines and allow the medical fraternity to glean insights and provide a smart healthcare to patients. The devices used by a patient at his home can transmit vital data to the hospital staff, enabling real-time monitoring of the patient's health.

India's medical devices industry is poised for significant growth in the next five years: The market size is expected to reach $ 50 bn by 2025.

Conclusion

The year 2000 promises to be an exciting one for the Indian medical devices sector. With supportive regulations and government's push, it can scale the heights and position itself as a top leader in the global industry.

Source: Secondary research & media reports

Consumers, Beware

AWARENESS & ENFORCEMENT

Key To Curbing Fakes

The laws are there, and the penalty is also tough. But counterfeit medical device makers are exploiting the loopholes. There's an urgent need to make enforcement stricter and work with different agencies to plug the gaps. Also, there must be programs to make end users aware of how to detect counterfeits.

IMAGE: PIXABAY

YOU WOULD BE surprised to know that globally 8-10 per cent of all medical devices are of fake origin. Not many are aware that manufacturers need to have a Unique Device Identification (UDI). The purpose of this identification is to ensure that the devices are traceable. Obviously, with low awareness regarding the above not many healthcare providers would know that identification and clinical examinations of medical products before procuring them is mandatory.

Lack of awareness

The lack of awareness among the medical fraternity is a leading cause of fake devices ending up in the market.

Needless to say, counterfeit medical devices are an infringement of consumer rights besides damaging brand equity leading to losses to original equipment manufacturers.

Another reason that counterfeit medical devices flourish is the fact that only 20 per cent of countries in the world have regulations to counter this menace. One of the major fallouts of counterfeit medical devices in the market is erosion of public trust in the healthcare system. The practice for medical devices is that they must undergo stringent clinical investigations to establish their safety before they can be launched in the market. Counterfeit medical devices obviously forgo such safety tests.

Prevalence of counterfeit medical devices in the market is one of the main reasons for indigenous manufacturers of India not being able to find a market for their products, as consumers are unable to repose trust in a local company and go for big brands, mostly imported.

Consumers lose both ways – if they have ended up with counterfeits or if they go for brands that are exorbitantly priced. There have been incidents where non-compliant and counterfeit medical devices have ended up injuring patients' health seriously and can even be life threatening. A serious implication of the use of fake medical devices is that it can lead to wrong diagnosis of a patient's condition and the line of treatment adopted dependent on it could lead to complications. Counterfeit devices also can be a setback for the device's original registration holder, as they can lose their market and all their efforts will come to naught. As is obvious, fake and substandard medical equipment can totally defeat the purpose of treatment.

As we can see, counterfeit medical devices are a clinical threat and present considerable health risk to the patient. They can lead to injury, permanent disability, or even death. They also pose an economic threat to the country as by capturing a segment of OEM's market it has a cascading effect down the value chain. The reputation of the country also suffers if the counterfeit has originated from it.

International problem

While counterfeits are an international problem with industry experts, governments and regulators of these countries facing immense challenges in tackling this menace;in India it has led to reputational loss. The world views Indian medical equipment with ambivalence and also its war against counterfeits.

India has already earned international disrepute in the pharma sector and the Office of the United States' Trade Representative, holds China and India as the leading sources of counterfeit medicines distributed globally.

Medical devices industry body AIMED refutes the claims that India suffers from counterfeit medical devices problem. It however says that licensed manufacturers of orthopedic implants have to compete with unlicensed lower priced products that look like branded products but lack the quality of those. Indian manufacturers also face counterfeiting from China.

A damaging international reputation makes investors wary and affects the country as a potential investment destination.

Counterfeit medical equipment is not the only problem facing the world. Illicit diversion of medical products is also a major issue whereby goods are redirected from the intended region of sale to a different country or destination. This is generally done to take advantage of price differential among other reasons. There is a thriving secondary market also called parallel trade or gray market.

Tackle counterfeits

It is important that we control counterfeiting of medical products as also their diversion. It calls for stringent checks at the point of use and raising the awareness of healthcare fraternity. Manufacturers must also take strong steps to improve track and trace mechanisms as well as ensure secure packaging and supply chain.

While India's regulatory framework is exhaustive and penalties are strict, it needs to strengthen its enforcement mechanism. There are many challenges ranging from detection of counterfeit medical devices to prosecution of those responsible for such counterfeits. The pharma and medical devices supply chain is complex and this makes the job tough.

Conclusion

Tackling the menace of counterfeits is an urgent issue and requires efforts from all agencies including the government, industry and the medical professionals and end users. It is hoped that it will be possible with tougher laws, stricter enforcement and inter agency coordination.

Source: Secondary research & media reports

In Need Of Deep Reforms

The medical devices industry has the potential to make India one of the top manufacturing hubs in the world, provided the government takes some determined reforms to overhaul the sector.

The medical devices sector can achieve its potential provided the government brings in some much-needed reforms.

IMAGE: PIXABAY

INDIA'S MEDICAL DEVICES industry is poised for significant growth in the next five years with the market size expected to reach 50 billion by 2025 growing at a CAGR of 28% per annum. Among the diverse segments in the sector, orthopedic prosthetics and patient aids are forecast to be the two fastest-growing verticals by 2020 and will grow at a CAGR of 9.6% and 8.8%, respectively. Diagnostic imaging, dental products, and consumables are expected to grow at a CAGR of 7.1%, 7.4% & 7.1%, respectively during 2015-20.

The industry comprises six major segments, of which equipment and instruments (surgical and non-surgical) are the largest at 53% of the pie. There are 750–800 plus (other estimates put the number at 1000) domestic medical devices manufacturers with average investment of $2.3–2.7 million and an average turnover of $6.2–6.9 million. Sixty-five percent of the manufacturers operating in the consumables segment and catering to local consumption with limited exports are domestic manufacturers.

Diagnosis and prognosis

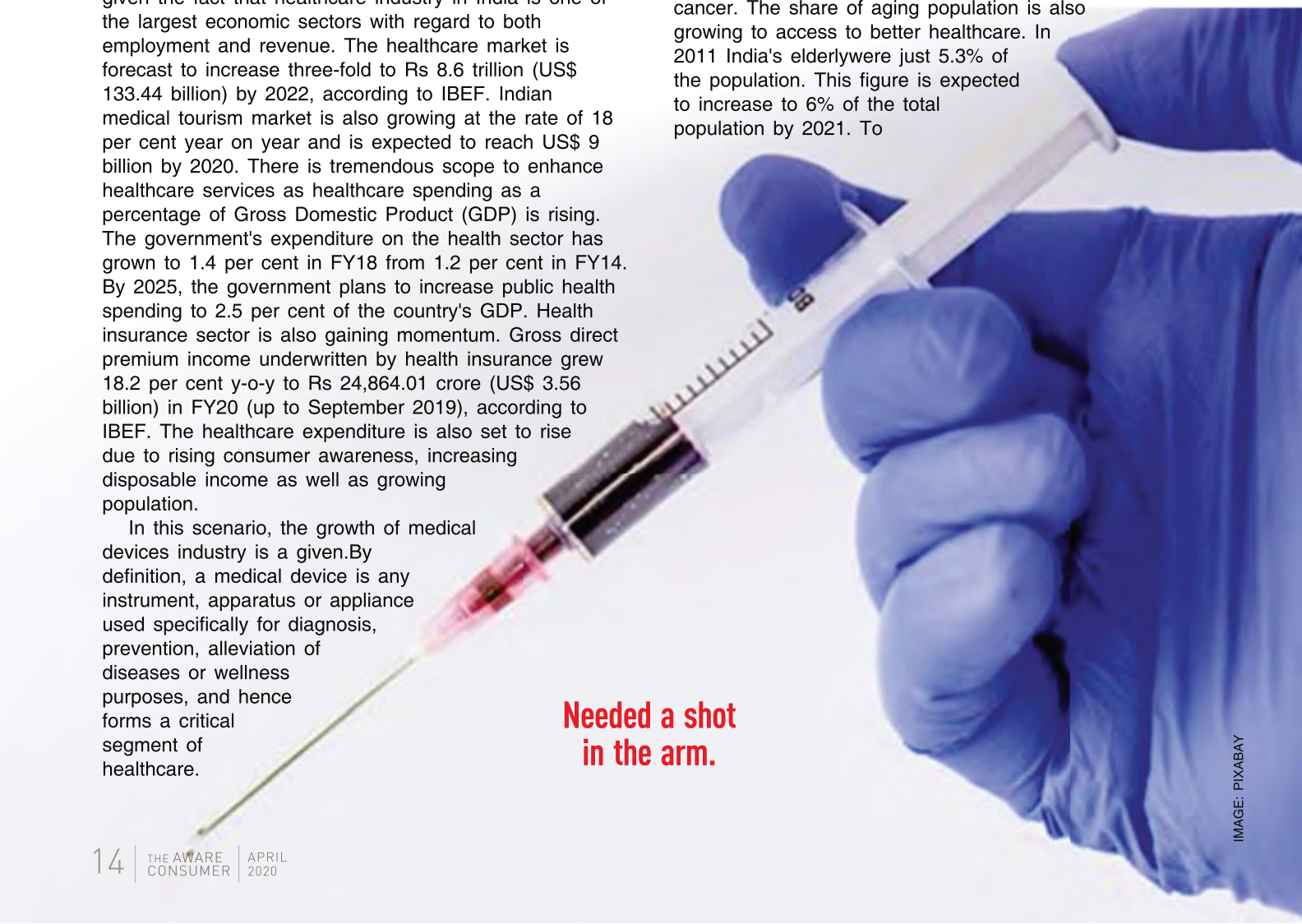
The prospects of the medical device industry are bright given the fact that healthcare industry in India is one of the largest economic sectors with regard to both employment and revenue. The healthcare market is forecast to increase three-fold to Rs 8.6 trillion (US$ 133.44 billion) by 2022, according to IBEF. Indian medical tourism market is also growing at the rate of 18 per cent year on year and is expected to reach US$ 9 billion by 2020. There is tremendous scope to enhance healthcare services as healthcare spending as a percentage of Gross Domestic Product (GDP) is rising. The government's expenditure on the health sector has grown to 1.4 per cent in FY18 from 1.2 per cent in FY14. By 2025, the government plans to increase public health spending to 2.5 per cent of the country's GDP. Health insurance sector is also gaining momentum. Gross direct premium income underwritten by health insurance grew 18.2 per cent y-o-y to Rs 24,864.01 crore (US$ 3.56 billion) in FY20 (up to September 2019), according to IBEF. The healthcare expenditure is also set to rise due to rising consumer awareness, increasing disposable income as well as growing population.

In this scenario, the growth of medical devices industry is a given.By definition, a medical device is any instrument, apparatus or appliance used specifically for diagnosis, prevention, alleviation of diseases or wellness purposes, and hence forms a critical segment of healthcare.

Further, 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 the emerging opportunities, more and more MNCs are setting up manufacturing bases in India.

The government has been keen to promote India as a hub for the manufacture of medical devices. Several, medical device clusters have come up supported by the policies of respective state government as well as the availability of skilled labor in the state. Several Medical Device Parks across India, including Andhra Pradesh MedTech Zone Limited (AMTZ), a park in Sultanpur village (Telangana) and HLL Lifecare Mediparks in Tamil Nadu, Maharashtra and Gujarat, are also coming up.

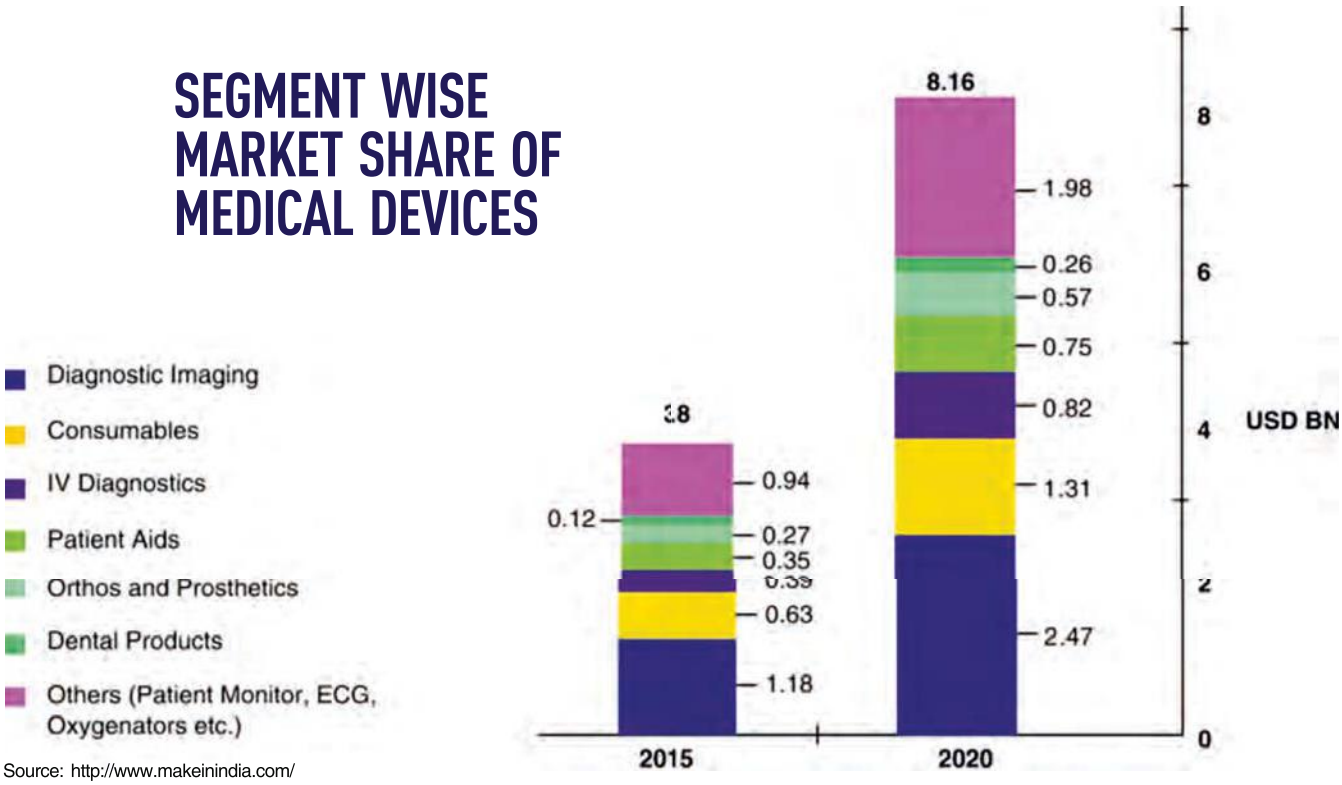
As healthcare demands rise, the demand for medical devices is also set to grow to meet the requirements of a growing population. India's population is set to touch 1.45 billion by 2028, as per the United Nations, making it the world's most populous nation. The country's development will lead to various socio-economic changes such as rapid urbanization and demographic and lifestyle changes, making the society more vulnerable to lifestyle-related ailments, including diabetes, obesity, stroke and cancer. The share of aging population is also growing to access to better healthcare. In 2011 India's elderlywere just 5.3% of the population. This figure is expected to increase to 6% of the total population by 2021. To



Needed a shot in the arm.

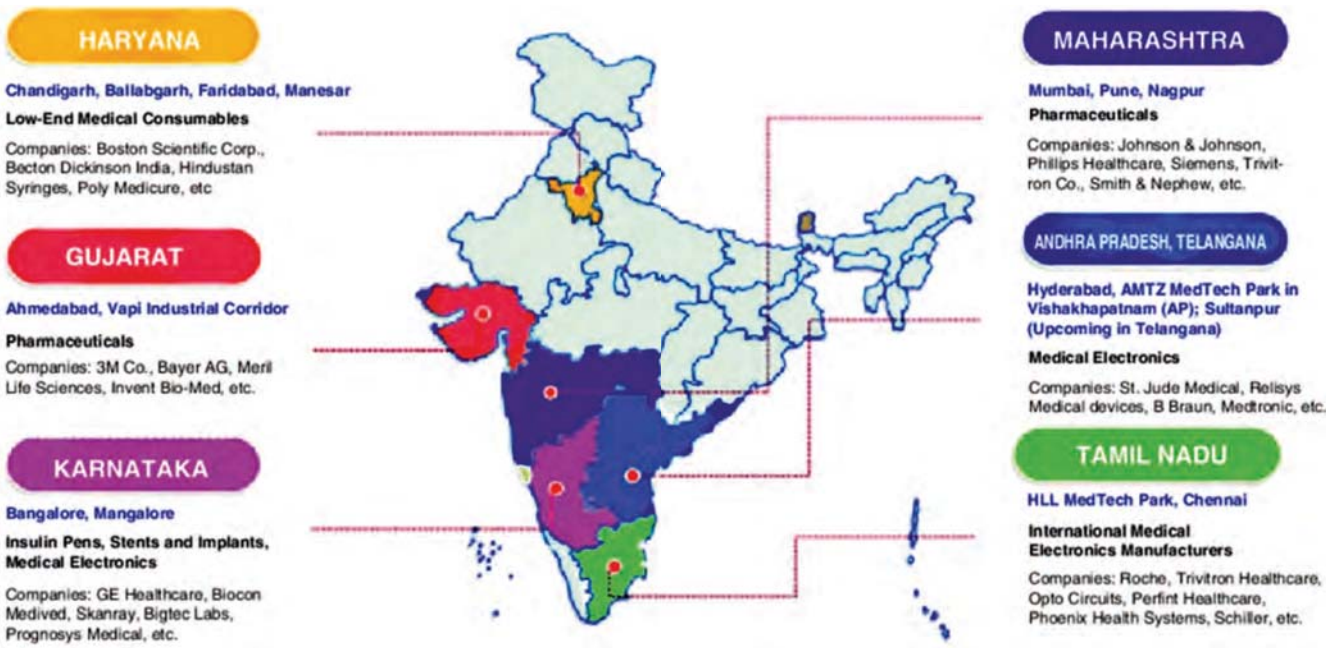
IMAGE: PIXABAY

SEGMENT WISE MARKET SHARE OF MEDICAL DEVICES



Source: http://www.makeinindia.com/

A medical device is an instrument, apparatus, implant, in vitro reagent, or similar or related article that is used to diagnose, prevent, or treat disease or other conditions, and does not achieve its purposes through chemical action within or on the body.



Source: http://www.makeinindia.com/

meet the needs of a growing aging population, there will be a greater demand for better healthcare facilities and medical devices.

Further, as the country's healthcare sector expands, more private players will be entering the fray boosting the demand for medical devices as they go about setting up hospitals, diagnostic centers and specialized facilities.

Government initiatives

The medical devices industry has undergone rapid transformation in the past two decades transitioning from being an industry dominated by domestic players prior to 1991 to import-dependent one post the liberalization; converting to non-regulated sector prior to 2006 to regulation of 24 notified devices to the new Medical Device Rules announced in 2017 and currently awaiting a massive disruption with the government notifying medical devices at par with drugs.

However, this sector is highly fragmented which calls for strong regulatory restructuring by the government. The regulatory environment is in the nascent stages. In September 2019, reports said that the Bureau of Indian Standards (BIS) will frame guidelines but these would be regulated by MDA. The government plans to stop using norms borrowed from the American regulator, the Food and Drugs Administration (FDA), for procurement by state and central governments once MDA is put in place. According to reports, the arrangement would be on the lines of food items, where BIS designs the standards, but those will be enforced by the Food Safety and Standards Authority of India. This is because BIS itself doesn't have implementing powers. The regulatory body would comprise representatives from the industry, policy makers and active medical practitioners and its role, powers and objectives would come from a Medical Devices Act, whose provisions are reportedly being framed.

Apart from the lack of regulatory framework, some other challenges that the sector faces include low penetration, accessibility and affordability and lack of awareness.

In 2014, the government took a major decision and capped the price of knee implants. This brought down average surgery costs by almost 65 per cent. The other major development in this year was the NPPA, which is the governing body for price control of pharmaceutical drugs in India, bringing down the cost of stents by almost 85 per cent.

In 2019, the government came up with a proposal to regulate pricing of over 6,000 medical devices including glucometers, blood pressure monitors, hearing aids and pacemakers. The general sentiment was that such a move would not only allow control over imported implants and devices but also make many medical procedures more affordable for the common man.

In the absence of a label for maximum retail price, MNCs sell medical devices to hospitals at exorbitant rates. The government aims to plug these loopholes in the healthcare system to curtail the practice of hospitals presenting patients with exorbitant bills for procedures in the name of imported parts.

IMAGE: PIXABAY

India manufacturers just one-sixth of the 6,000 medical devices produced worldwide. Certainly, this is a huge opportunity for the indigenous players.

Notably, more than 6,000 types of medical devices are in use worldwide, but India manufactures just one-sixth of these. The government's move to bring more devices under the notification of the Drugs and Cosmetics Act of 1940 ensured that only safe and tested equipment reaches consumers and also gave a boost to the fledgling Indian startups in the medical devices sector. The idea was to support innovation and development of revolutionary technologies required in the industry.

The highly fragmented medical devices industry in the country is dominated by multinationals that control about 75-80 per cent of the Indian market. There are just four domestic manufacturers that boast of over Rs 500 crore revenues per annum. Further, more than 80 per cent of domestic manufacturers are in the small-scale sector and have a turnover of less than Rs 10 crore.

Recent policy changes by the government have brought some imported medical devices under the price capping. While currently only 24 items including cardiac stents, knee implants and condoms are regulated, inclusion of more devices would allow the National Pharmaceutical Pricing Authority (NPPA) to notify them as drugs, thereby bringing them under the price capping system.

The government has been taking crucial steps to ensure that the medical devices sector is becomes a significant one. It constituted a task force to implement a range of recommendations, including the segregation of medical devices from drugs. Only 15 categories of

medical devices are being regulated as drugs. (However, in February this year, the government notified all medical devices – syringes to PET scanners to dialysis machines – as drugs for quality certification and monitoring purposes).

The government's regulatory practices are aimed at removing hurdles in the way of the sector's growth and to enable the country to meet the medical device sector's requirements. It is expected that regulatory changes will improve ease of doing business and ensure availability of quality medical devices. The rules also did away with the need for periodic renewal of licenses. This means import licenses will be valid until suspended or cancelled. The aim of the rules is also to promote a culture of self-compliance by manufacturers of medical devices.

Impact of policies

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.

According to estimates while India boasts of an estimated 900-1000 domestic medical device manufacturers, just 15 of these companies have a turnover of more than Rs 200 crore. What is the reason for companies not breaking into the big league?

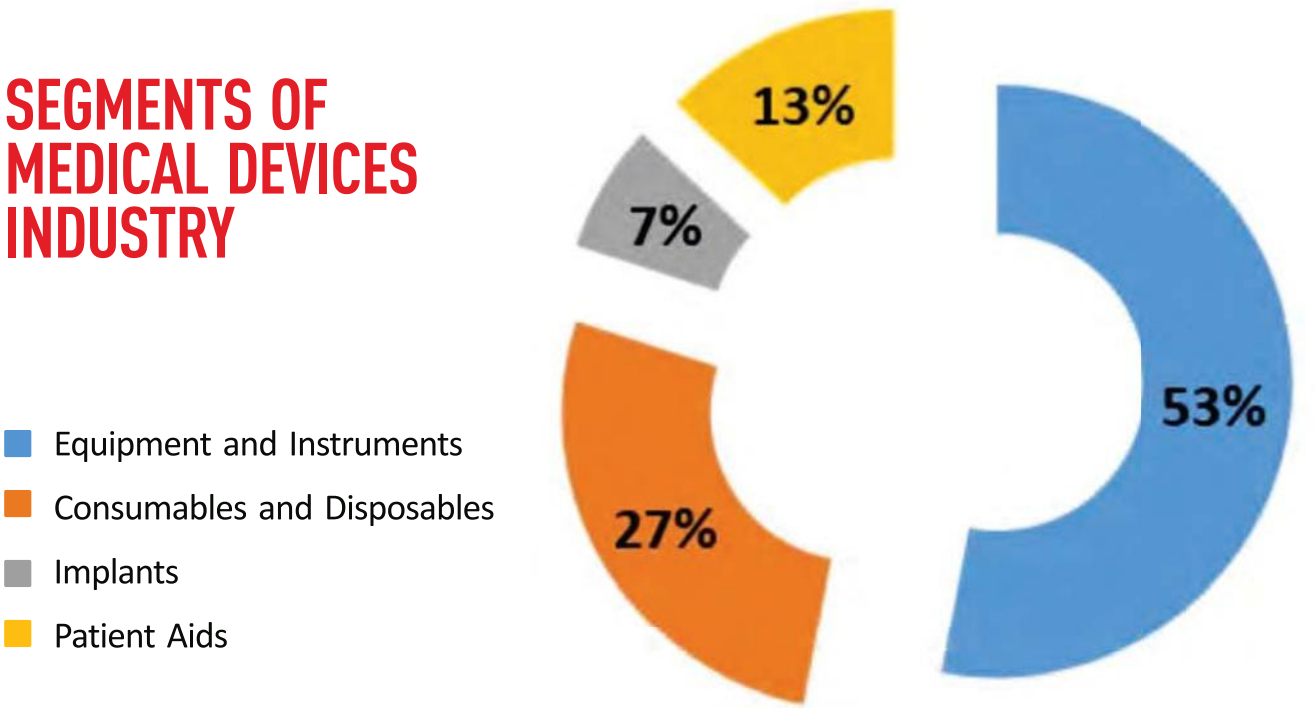
According to reports, the Government of India's Make in India initiative was a flop in medical devices and many firms were shutting shop to import. Experts blamed failed policies for pushing the domestic manufactures to start importing medical devices. A setback for the government's plan to make India among the top five medical devices manufacturing hubs in the world under its 'Make in India' initiative.

The initiative had been publicized widely and it was seen as a major boost to the medical devices sector with hopes that India would be exporting under the 'Make in India' initiative. The reports said that most of the domestic manufacturers were either closing manufacturing facilities or idling manufacturing capacities moving over to import and trade of medical devices. The medical devices industry is estimated to be worth Rs 1,05,000-crore industry (at patient level selling price).

The low tariff structure prevalent since 2010 is blamed for many manufacturers adopting a new business strategy of importing rather than making in India, given it is cheaper and more convenient to import than manufacture.

Not surprisingly, even multinational companies despite the option of 100 per cent foreign direct investment in India through the automatic route, have not bothered to establish new factories and are concentrating on creating trading arms. Apparently, the 'Make in India' scheme and incentives under it have failed whereas free market access with negligible customs duties have made importing easier for MNCs.

SEGMENTS OF MEDICAL DEVICES INDUSTRY



In 2018-19, data shows that imports rose by 24 per cent to Rs 38,837 crore from Rs 31,386 crore in 2017-18, Rs 28,067 crore in 2016-17, Rs 26,203 crore in 2015-16 and Rs 23,170 crore in 2014-15. The Indian market on the other hand has been growing at 10-12 percent per annum for the past five years.

In 2018-19, medical devices worth Rs 38,837 crore were imported and of these 66 per cent or Rs 25,624 crore worth of medical devices were in the category of electronics and equipment. The major share of these imports belonged to multinational companies. Other devices imported included consumables comprising 9 per cent of imports and worth Rs 3,378 crore, IVD Reagents (8 per cent) worth Rs 3,159 crore, implants (7 per cent) worth Rs 2,683 crore, disposables (7 per cent) worth Rs 2,666 crore and surgical equipment (3 per cent) worth Rs 1,328 crore.

The implementation of Goods and Services Tax (GST) further aggravated the situation for domestic manufacturers as cost of imports decreased by 11 per cent. Most manufacturers now import different types of medical devices from countries like China and Vietnam and after labelling it as their own brand, sell it in the market,

It is really unfortunate that thriving manufacturing hubs have all but vanished. Reports say that India had around 25-30 thermometer manufacturing units just a few years ago, but now they have shut down. There were thriving surgical equipment manufacturing hubs in Jalandhar in Punjab, and in Barampur in West Bengal as well. But now there are none.

There are 750–800 plus (other estimates put the number at 1000) domestic medical devices manufacturers with average investment of $2.3–2.7 million and an average turnover of $6.2–6.9 million.

The gravity of the situation had led to rising demands from the domestic industry for a level playing field. The domestic manufacturers contend that they are competing with multinational corporations that have deep pockets, can invest in expensive technology with long gestation periods and have lobbying power. Hence, incentives alone will not help. What the industry requires is entry barriers, reforms, and supportive legislations. Then only can India become a global medical device manufacturing hub.

Despite these constraints, India is among the top 20 global medical devices markets and is the fourth largest in Asia after Japan, China, and South Korea. Further, the market is forecast to grow to $50 billion by 2025. Yet, despite the huge size of the industry in the country, the government has yet to set up a proper regulatory body for it.

The industry has hence been demanding global regulatory norms and quality standards as also a dedicated regulator. There is also a demand to bring in a medical devices price control order like that of the Drugs Prices Control Order. It is urgently required that the draft Medical Devices Policy in the making since 2016 moved forward. Other measures in the pipeline include setting up a National Medical Devices Development Council and a medical devices export promotion council and a National Medical Devices Design Centre. The government had also planned to set up a number of medical devices parks in India.

Way forward

Industry players hence have been demanding that the government accelerate the pace of reforms and introduce measures that support the domestic players. They had been demanding to increase the custom duty on medical devices to 15-20 per cent to promote indigenous manufactures.

The medical devices manufacturers welcomed the Budget 2020 which imposed a health cess on imported medical devices. However, they were disappointed with the quantum of it, as the government announced cess of just 0.25 per cent. The effective import duty thus becomes 5.25 per cent. Yet, the industry players are optimistic that the move will trigger growth in the sector and would help bring India among the top five medical devices manufacturing hubs in the world by ending the import dependence.

Industry experts opine that the health cess will add to pricing pressures on foreign manufacturers. With 100 per cent FDI in medical devices manufacturing open for some time now, it is hoped that the imports of significant parts of medical devices requirements will come down as the new scheme for electronics' manufacturing plays out. However, the government needs to customize the scheme to encourage medical devices manufacturers to make in India.

The other demands of the industry remain unattended though, likethe demand for a regulatory framework for all medical devices, curbing MRP and trade margins over imports, restricting imports of pre-owned medical equipment in absence of regulations and preferential pricing for quality products in public healthcare.

As of now, the U.S. is the largest exporter of medical devices, accounting for 15% of the export trade. Singapore, Germany, and China are the other leading exporters, accounting for 7%, 6.7%, and 6.4% respectively. The European Union constitutes 27.1% of the total export trade. The U.S., Germany, China, Japan, and Singapore constitute the five largest exporters of high technology medical equipment to India.

Source: Secondary research & media reports

MEDICAL ELECTRONICS

The Time Is NOW

IMAGE: PIXABAY

Medical electronics find a wide range of application, from research to diagnostics, treatment to care.

For India's medical electronics sector, the time is now. Emerging technologies and innovations are providing it the right impetus and the outlook is indeed bright. The industry must take advantage of the abundant opportunities and leverage the tech developments to keep innovating. This will help it maintain its competitive edge.

TECHNOLOGICAL ADVANCES INCLUDING digital technology have led to the development of an array of new applications in healthcare. This has pushed the demand for electronic components, devices and products used for medical purposes. The breakthroughs in medical electronics technology have strengthened the existing healthcare infrastructure, with digitized medical testing, advanced diagnostics and therapeutic procedures and wider reach and deeper penetration of healthcare through telemedicine. India has become more relevant in the medical devices market as it continues to be relevant in the global medical technologies space, not just from a market standpoint, but also as a global hub for innovation and manufacturing.

Medical electronics at a glance

What are medical electronics exactly? The designing, implementation and use of electronic components, devices and equipment for medical or healthcare purposes, comes under the field of medical electronics. Some of the important applications of medical electronics are research, examination, diagnosis, treatment, assistance and care. In the past some years, the rapid developments in the technology field have helped evolve medical electronics and the use of electronic equipment in the medical field for clinical and research purposes has increased tremendously.

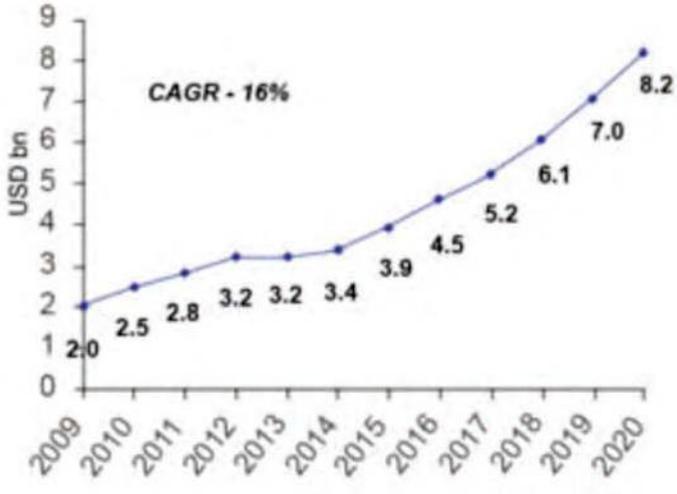
Medical electronics work to decipher the numerous signals generated by our body that are vital for diagnosis and therapy. Medical practitioners collect these signals from the body surface or from within, through electrodes of different sizes, shapes and types. There are also important non-electrical body parameters like temperature, blood flow, blood pressure and respiratory functions that must be monitored for health. These health parameters are converted into corresponding electric signals by various transducers, with the help of electronics medical devices. Usage of computers and microprocessors has become extensive in medical devices that are used for routine clinical measurements, especially if data computing and processing are being used for measurement and diagnostic procedures.

Market size

The global medical electronics market size in 2018 was US$ 73.3 billion and is set to exceed US$ 169 billion by 2020 growing at an expected CAGR of 13 per cent from 2019 to 2025, as per estimates by Global Market Insights. Further, the report indicates that the market will get a boost from peoples' preference for minimally invasive surgeries. This is because in invasive surgeries patient monitoring equipment and other diagnostic devices are in high demand.

The rapid advancements in technology will bring disruptive changes in the medical electronics market and the industry will grow on the back of these developments. Industry leaders in medical electronics industry are focusing on integrating advanced technology into the devices they manufacture to improve the accuracy of diagnosis as well as treatment.

The Indian medical devices market



(Source: WHO)

As regards India, it is expected that adoption of medical electronic devices will boost the industry's growth significantly. While the cost of medical electronic devices is pretty high, the government has introduced various initiatives and the favorable FDI policy are expected to lead to larger numbers of healthcare professionals adopting these devices.

A joint report published jointly by the World Health Organization (WHO) and the Government of India, expects Indian medical devices market to grow to US$ 8.16 billion in 2020 at a CAGR of 16 per cent. However, experts fear that strict regulations enforced on manufacturers may restrain the growth of the industry.

Market segments

The medical electronics market ecosystem is diversified and includes various components that are essential for the industry including institutions engaged in R&D, manufacturers of components, systems integrators, software service providers, distributors, marketing and sales firms, end-consumers, and sales services providers.

There are two categories of medical electronics products – invasive and non-invasive devices. The range of products includes diagnostics devices, monitoring and treatment of various diseases and chronic health conditions. The market can be divided on the basis of components into sensors, batteries, microcontrollers, microprocessors and displays. The segmentation on the basis of product types in the medical electronics market includes: a) Invasive or therapeutic products like pacemakers, implantable cardioverter – defibrillators (ICDs), implantable loop recorders (ILRs), spinal cord stimulators, gastric electrical stimulators, endoscopes; b)

Non-invasive products like imaging devices, patient monitoring devices/systems, and handheld/portable home-care products. On the basis of applications, the medical electronics market segments include diagnosis, monitoring, treatment; while on the basis of component type, the segments are sensors, batteries, memory devices, displays and microprocessors/microcontrollers.

Diagnostic imaging is the leading segment and the largest segment in the Indian medical devices market and is expected to earn revenues of US$ 2.47 billion in 2020. Patient monitors, ECG machines, defibrillators, etc., are mainly electrical and electronic devices. It is estimated that the electrical and electronic devices segments will jointly clock a turnover of US$ 1.98 billion in 2020; while the IV diagnostics market will reach US$ 0.82 billion (Rs 53.56 billion) in 2020.

Market opportunities

As regards the global medical electronics industry, it has been growing in double-digit, and it is estimated that this growth trajectory will continue as the incidence of chronic diseases rises, rapid urbanization takes place, and the elderly population continues to grow. Apart from these, the growing awareness among end-consumers about the latest technology solutions that can save or augment lives and rehabilitate patients, will push this market.

Semiconductors have an important role to play in how the medical electronic devices market shapes up.For manufacturers, this is a significant market with opportunity for growth. The semiconductor market is a key one as the performance of medical electronics devices is dependent on innovations in the semiconductor sector that can be instrumental in creating highlyintegrated microchip designs. Semiconductors play a critical role across the industry, from power supplies to displays in medical equipment. It is an integral part of most medical equipment, whether high-end imaging systems or small handheld devices. With advancements in the industry where newer innovations are creating more portable and smaller medical equipment, the role of semiconductor suppliers becomes even more critical.

As regards India, there is a growing demand for low cost systems, as most sophisticated hospital equipment available in the country are exorbitantly priced and unaffordable for rural markets or smaller hospitals. Hence, this has led to a significant growth in low cost wearable medical systems capable of wirelessly transmitting a patient's vital signs to doctors via cell phones or the internet. Fitness monitors packed with capabilities to track activities and vital statistics of users are becoming a lifestyle statement and this has further led to an increase in demand for smarter and more efficient semiconductors.

In the medical imaging product segment, some of the widely used semiconductor components in the medical electronics industry are micro controllers, microprocessors, amplifiers, data converters, digital signal processors, application specific standard products and application specific integrated circuits. In the patient monitoring systems, some of the widely used components are micro controllers, sensors, application specific integrated circuits, amplifiers, controllers, etc. In the digital hearing aid segment, some of the components that are used include amplifies, micro controllers, audio processor integrated circuits, etc. Micro controllers, regulators, transistors, etc., find use in infusion pumps segment.

IIPME — a policy boost

The Ministry of Electronics and Information Technology (MeitY) and the Biotechnology Industry Research Assistance Council (BIRAC), Department of Biotechnology, Ministry of Science and Technology, Government of India, have launched a collaborative project – the Industry Innovation Programme on Medical Electronics (IIPME). The project is aimed at funding a portfolio of projects targeting innovations in multi-disciplinary areas, from electronics, engineering, medical devices, healthcare, software, algorithms to information technology. The goal is to help the medical electronics sector and promote fast-paced research and development in the sector. This project provides funding support to innovators to test their revolutionary ideas, mentorship from experts, networking platforms and opportunity to scale up the technology.

Portable homecare products are a part of medical electronics.

Conclusion

The medical electronics sector is promising and with the right support and regulations it is poised to take a leap.

Source: Secondary research & media reports

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Need To Nurture Medical Tech

The demand for medical devices and equipment is slated to grow as India steps up its growth. It is time to take all steps to ensure that this happens.

IMAGE: PIXABAY

A technology-driven sector, medical devices industry is constantly evolving.

IMAGE: PIXABAY

Medical tourism is a driver of growth for India's medical devices sector.

MEDICAL DEVICES INDUSTRY is a technology-backed sector and the recent technological advancements have meant the Indian medical industry has made much progress. It is important that industry players plan strategically their entry into the market keeping factors as location and targeted audience in the forefront, in order to carve a niche in this highly competitive and fragmented sector.

Hospital and medical devices account for 91% of the total healthcare market which is the 4th largest sector in the country. Though the Indian medical industry is dominated by large multinationals with their extensive service networks; many small to medium enterprises are also making their presence felt on the back of innovation and strategic plan. Medical technology in India is a sunrise sector and the government is focused on its development. It is forecast that the sector would likely touch USD 9.6 billion in the year 2022.

Technology is disruptive and the advances in the medical technology domain have meant that the device industry is continuously changing its trends. Such is the opportunity in this sector that digital companies like Google, Amazon, IBM-Watson have also jumped into the fray and are investing huge sums in the R&D of medical devices and trying to predict the usage trends in the future. Latest technologies like artificial intelligence and machine learning are being employed in the manufacturing of medical devices to improve their efficacy in treatment outcomes. Manufacturers are increasingly using big data and cloud computing to design focused and better treatment solutions and intuitive devices and aids for customers.

The usage of medical devices is no longer confined to the commercial sector like hospitals as easy-to-use devices make inroads into people's homes. In India too portable devices like diabetes or BP apparatus or wearables are being actively used by consumers to keep track of their health metrics and data.

Globalization and internet penetration have meant rising levels of awareness regarding healthcare among the citizens and this paired with the growing per capita income has led to rising demand for quality healthcare services. Lifestyles have undergone sea changes and preferences become diverse, as the working-class population grows from 34% in 2011 to an assumed 40% in 2026. Progress has brought with it changing lifestyles and a host of lifestyle related diseases. Better medical facilities have also made longevity and the elderly population in the country is expected to double by the year 2026.

Another important growth driver is the growing medical tourism sector which attracts patients from foreign countries as India gains prominence for serving their needs with educated, English-speaking medical staff and caregivers and world-class private hospitals. The medical tourism market

was valued at US$ 3.0 billion in size in 2017 and is expected to reach 7.3 billion EUR by the year 2020, at a growth rate of 22%. Rising healthcare awareness has meant medical insurance penetration is also rising and is forecast to grow from 18.7% in 2015 to 22% in the year 2020.

One of the most important consumer segments currently, the millennials, are further changing the dynamics of every industry. The medical devices industry too is facing their rising demand for quality healthcare.

Other important growth drivers include India's rapidly aging population with huge disposable incomes. In fact, the Economic Survey last year indicated that the country's demographic dividend could soon shift, with a young population giving way to an aging one. What this means for the medical devices industry is that there will rising demand for aids and appliances as the burden of non-communicable diseases increases and the demand for home healthcare rises.

This data is attracting major healthcare giants to invest in the Indian medical device and equipment sector. Looking at the demand profile, many domestic private healthcare players are also entering the market with tie-ups with multi-specialty hospitals, diagnostic centers and healthcare facilities.

Opportunities also exist in Tier II and Tier III cities as population grows in them. According to estimates, 96% of India's population lives in non-metro regions, out of which 70% live in rural areas. The demand for medical services is also increasing in these areas and looking at the opportunities, many regional and national hospital chains are expanding their footprints in these underserved cities.

The healthcare industry is expanding and growing at a high pace as expenditure on healthcare increases by public and private players, supportive regulations, etc. Reports say, the number of hospitals in India is projected to grow at a CAGR of 13% by the year 2020. Hospitals are the largest segment with a 64% share in the overall healthcare market. The growth in private hospitals and the northern zone are said to be the main drivers of this growth. The healthcare industry as a whole is expected to grow by a CAGR of 18% until the year 2020.

Looking at the scenario, the government allowed 100% FDI via automatic route in the hospital and medical device sector. This made the market even more attractive and global private equity players and leading healthcare providers are exploring the Indian market.

Portable medical devices have changed the face of healthcare industry.

Medical devices are crucial in improving healthcare practices, for example, in screening, diagnosis and treatment of disease. Technologies such as minimally invasive surgeries have been a breakthrough in medical procedures.

Thus, the advancement in surgical equipment has meant doctors are better equipped to perform highly complicated surgeries and treat critical cases. Medical technology has led to the development of portable devices that have helped improve diagnostics and point-of-care services at primary healthcare centers. Quality healthcare delivery is today possible in underserved parts of the country and hence accessibility to healthcare has improved. It is due to the advanced medical devices technology that procedures such as knee replacement, bariatric surgeries, vision correction and cataract surgeries have become widespread. Assistive monitoring devices have made it possible to take patient care outside the hospital and into their homes.

Even as quality of care and patient outcomes is improving, medical devices have remained largely expensive. It is to fill this gap that many startups have stepped into the market designing low-cost technology-led medical devices, for example, handheld ECG monitors, one-touch blood pressure monitoring devices and more; with the aim to make healthcare affordable and accessible to all.

The future

According to estimates, India is projected to become a $100-billion strong bioeconomy by 2025. It would be made possible by health tech startups who are working together to build a stable network across the country. Some key trends that will dictate the growth of the sector are convergence of medical devices with channels such as telemedicine, digitization and electronic patient records maintenance; unification of wearable technologies with cloud storage and AI to transform patient experience and impact on clinical research in a big way. The growth of the home-based care segment would also be positively impacted.

The medical devices industry is on a strong growth path with more than $3 billion invested in the sector and the government too pushing it with initiatives and reforms. Research and development should be boosted as players work on next-generation technologies, including wearable devices indigenously. There is also a need to make these world-class devices affordable to the rural masses.

Source: Secondary research & media reports

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Government Takes Charge

The Government of India is taking various measures to ensure the medical devices industry gets a boost and that domestic manufacturing picks up pace.

THE GOVERNMENT OF India has been pushing the medical device industry under its Make in India agenda, as it feels the sector has the potential to play a significant role in the economy. The industry meanwhile strongly feels the need for a specific law regulating all the medical devices – imported, manufactured and sold in India – to ensure minimum standard quality of the medical equipment.

Looking at this need, the government notified the Medical Devices Rules, 2017 (MD Rules) under the Drugs and Cosmetics Act, 1940 (DC Act) and it came into effect from 1 January 2018. However, there remained a gap as only a limited number of medical devices were notified and regulated by the MD Rules. Only 24 notified medical devices are regulated by the MD Rules and the DC Act and it is proposed to regulate another 13 medical devices from a specified date under the MD Rules (Notified Devices).

IMAGE: PIXABAY

Looking at the opportunities in the medical devices industry, the Government of India is keen to help it achieve its potential.

A new chapter: Amendment to the MD Rules

On 11 February 2020, the government added a new chapter to the existing rules as the Ministry of Health and Family Welfare notified an amendment to the MD Rules (Amendment Notification). Chapter IIIA is now part of the MD Rules under which all devices notified under Section 3(b)(iv) of the DC Act, except the Notified Devices, are to be registered under the provisions of Chapter IIIA of the MD Rules.

The ministry also notified an all-encompassing definition of medical devices. Medical devices are now defined as:

All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
- diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
- investigation, replacement or modification or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- disinfection of medical devices; and
- control of conception

IMAGE: PIXABAY

New rules to support the local industry.

The new definition will come into effect from 1 April 2020. Under the Amendment Notification all importers and manufacturers of medical devices are required to be registered on a voluntary basis. They will be able to register through an identified "Online System for Medical Devices" established by the Central Drugs Standard Control Organization. The new rules require that the manufacturer display the registration number generated upon completion of the registration process on the label of the medical device.

Further, a manufacturer or importer of medical devices also need to upload a list of information on the online portal at the time of registration. This information must also include a certificate of compliance with respect to the ISO 13485 standard accredited by the National Accreditation Board for Certification Bodies or International Accreditation Forum with regard to medical devices. An importer is also required to upload a free sale certificate from the country of origin of the medical

device. The class of the medical device needs to be mentioned by both the categories.

Under the Amendment Notification, it is being estimated that approximately 1700 medical devices would become regulated in India. However, experts feel that the definition for medical devices is very wide and subjective as it aims to bring all the medical devices being sold in the Indian market under its purview. The current approach is in stark contrast to the earlier approach of the government under which only a minimal number of notified medical devices were regulated, and the remaining were unregulated.

The ambiguity in the definition and the absence of a specific list of medical devices, it would seem that the definition would apply to all sorts of medical devices. It could even stretch to stretch spectacles, wheelchairs or physiotherapy equipment. Whether the intention is to include all such devices within the definition is not clear. Manufacturers and importers would need to clarify whether their products come under the ambit of the MD Rules.

While the notification provides 18 months voluntary registration period, it is mandatory because all the medical devices would need to comply with MD Rules from 1 April 2020 itself if they are not registered.

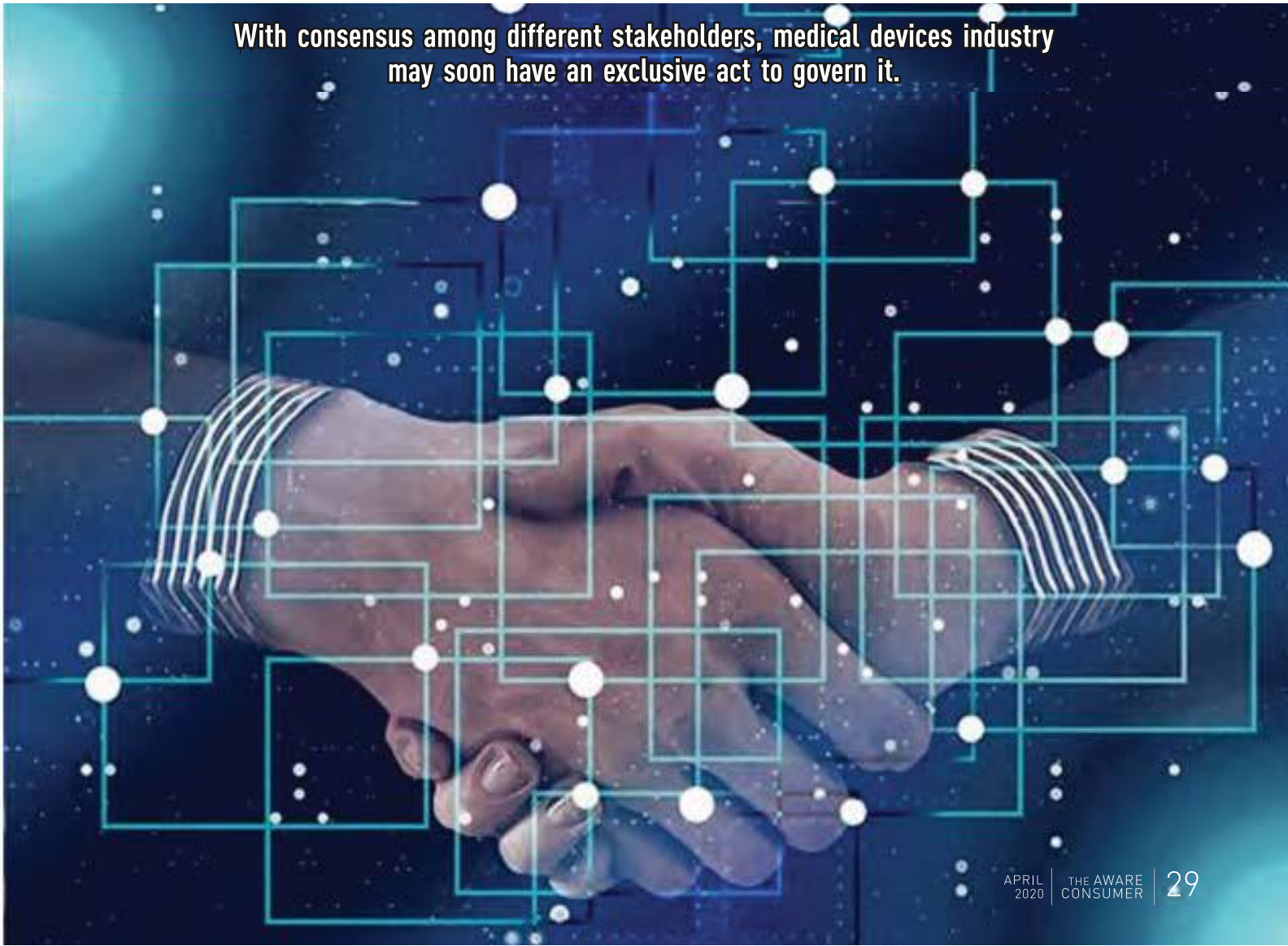
This changes in the MD Rules are expected to make substantial impact on the medical device industry. Businesses will now have to adhere to compliance requirements and calculate the costs of such compliances under the MD Rules. The regulation of medical devices sector and making them comply with internationally recognized standards under the MD Rules is expected to aid export of made in India medical devices.

Experts expect a huge change in the manner in which the medical devices industry currently operates, and market players should be prepared for it.

Consensus on Medical Devices Bill?

According to media reports, the final draft of the Medical Devices (Safety, Effectiveness and Innovation) Bill, 2019, proposes that medical devices should be regulated by a separate division under the Central Drugs Standard Control Organization (CDSCO)

Reports stated that the government and Niti Aayog and the health ministry have arrived at a consensus on


With consensus among different stakeholders, medical devices industry may soon have an exclusive act to govern it.

the Medical Devices Bill. If this is correct, then it would put an end to months of impasse over several issues that had defied a consensus.

According to reports, looking at the urgency to push local manufacturing of medical devices and also to bring down costs and reduce imports, the PMO had to intervene to break the deadlock.

Additionally, the division to monitor medical devices will be headed by a technical expert, and there will be no separate regulator, say the reports.

Some decisions are however pending like the one on using IIT labs for certification of medical devices and ensuring that certification is of global standards and there is no need for dual certification. This matter will be taken up later stage after the Bill is passed by Parliament.

It is expected that the ministry will soon move a cabinet note on this. Post approval, the Bill will be tabled in Parliament.

5% Health Cess on Import of Medical Devices

A second important development took place during the Union Budget aimed at discouraging imports and promoting local manufacturing under Make in India. The government announced a Health Cess on Medical Devices falling under Heading 9018-9022 are in the Budget 2020. The Health Cess @ rate of 5% shall be levied with effect from 2 February 2020, it was announced. The aim is to provide impetus to domestic industry and generate funds for health services.

“India is now making world-class goods and exporting such products. We have made considerable progress in medical equipment, too. Till a few years back, we were dependent on imports for medical equipment. Now, not only we are manufacturing medical equipment but also exporting them in large quantities. This sector deserves further fillip,” Sitharaman said in her second Union Budget presentation in Parliament.

“To achieve the twin objectives of giving impetus to the domestic industry and also to generate resource for health services, I propose to impose a nominal health cess, by way of a duty of customs, on the imports of medical equipment keeping in view that these goods are now being made significantly in India,” she added.

In other words, the government wants to achieve the twin objectives of supporting local manufacturers and generating funds to create health infrastructure.

But questions were raised on the efficacy of the cess to achieve these objectives. It was being feared that it could become a double-edged sword and end up not only increasing the end-cost on devices for patients, but also discourage large med-tech companies from importing high-end products into the country.

The health cess is expected to generate about Rs 2000 crore for the government which it can invest in healthcare infrastructure. In 2019, imports stood at Rs 38,000 core and is expected to record at least Rs 40,000 crore this year.

For long, indigenous manufacturers of medical devices and been trying to draw the attention of the government to the fact that Make in India initiative could be a flop if it was easier to import products rather than manufacture them domestically.

The importance of the medical devices industry can be gauged from the fact that Finance Minister Nirmala Sitharaman's mentioned it several times in her speech.

The proceeds from the 5 per cent health cess would go towards creating infrastructure in aspiration districts, the Finance Minister had said, adding that products that had a basic Customs duty exemption and input materials would not attract the cess.

Till recently, 0-7.5 per cent Customs duty was imposed on medical devices and components attracted up to 2.5 per cent duty. The industry has urged the government to gradually increase the tax on components over the years to deter indigenous manufacturers from becoming pseudo-manufacturers, merely assembling products in India or making a component like a syringe, the other component of which, say needle in this case, is to be imported. However, they do not want raw materials, that are further processed to make a product locally, to be taxed.

Some experts feel that the health cess would increase the import cost of high-end products in the short term. These products include cardiac stents to implants, radiation equipment, robotic arms used in surgeries, high-end scanners, etc. What would be worse is that this increase would most likely be passed on to patients, as importers would try to recoup any losses. However, it is hoped that in the long term, the cess would encourage domestic producers and create an ecosystem conducive to the development of medical technology.

It is felt that the government should bring in price caps on products. Currently, they reflect a maximum retail price that is six times the import landed cost. The cess may help with this.

Some sections however fear that the health cess could lead to unintended consequences, say for example, it may limit patient access to appropriate medical technology treatments in other countries, and eventually increase healthcare costs.

A stable and predictable market environment needs to be created to drive future investments in R&D, manufacturing, and other services that will lead to the growth of the medical technology industry in India and enable it to meet the current and future needs of the people.

Some experts find the health cess contrary to the idea of affordable healthcare. Further, it would also impact the ability of medical device companies to continue bringing innovative medical implants to India. It would also hurt the sector that is already feeling the effects, and this may eventually impact investments in research and innovation by the global medical devices companies in India.

Source: Secondary research & media reports

"Medical Devices Are Engineering Items And Not Drugs. It's Imperative To Have A Separate Law"

Rajiv Nath

Forum Coordinator of Association of Indian Medical Device Industry (AIMED), spoke at length to The Aware Consumer on prospects, issues and challenges of the medical devices industry

Q Tell us about the medical devices industry in India. How does it compare with the global industry and what are its future prospects?

I feel extremely aggrieved when I see that India is ranked 145 among 190 nations, lower than even Bangladesh, Sudan and Equatorial Guinea by the 2018 Global Healthcare Access and Quality Index and that even after our excellent success in engineering and scientific fields we are 75-80% import dependent in medical devices. It's time that we change this landscape completely by ensuring affordable access to reasonably priced medical devices. There have been enough reports in newspapers of unaffordable hospital bills and exorbitantly priced medical devices used in treatment which has created distrust in healthcare industry.

In the absence of fair competition to drive down pricing and options of choice of brand to consumers as is usually the case in a free market space, reasonable price controls are desired and one possible solution is keeping trade margin at a rational level along the supply chain. The marketplace is unfortunately skewed where suppliers induce hospitals to buy and push their brands based on profit margins to be made on excessively high MRPs and not on basis of cost savings to be made on the procurement cost by a hospital. The main aim of rationalization of trade margins in medical devices should be not only to help consumers, but also allow rationalized profits for traders, importers, distributors, and wholesalers and retailers and create a level playing field for domestic industry vis-à-vis foreign manufacturers. There should be clear objectives for any policy intervention so as to avoid distress (to consumers), distrust (in industry) and disruption (to market).

The Indian medical device industry is very hopeful the proposed Medical Devices Regulations Bill by Niti Aayog will be designed to make quality healthcare accessible and affordable for common masses, enable placing India among the top 5 medical devices manufacturing hubs worldwide and help end the 75-80% import dependence forced upon us and an ever increasing import bill of over Rs 38,837 crore and replicate success achieved as the enviable status of Pharmacy of the World. A proactive policy formulation to regulate medical devices differently than drugs should permit free market dynamics to succeed and keep regulations simple, protecting consumers and incentivizing Make in India.

Q 100% FDI is allowed under the automatic route in medical devices. Has this brought about any changes, especially in terms of innovation and technological knowhow?

Imports are welcome as long as they motivate and inspire indigenous manufacturers to compete fairly on quality, performance and affordable access and go up the value added tree; but when it comes to the instances of imports undermining Indian products by far lower price and not necessarily better quality then the government needs to step in.

Most overseas manufacturers on getting freedom to set up 100% FDI medical devices manufacturing plants misused that permission and instead preferred to set up warehouses, distribution and sales infrastructure and undermined existing manufacturing by lobbying for import friendly policies via associations sponsored by them. The result is that even domestic manufacturers slowly discontinued manufacturing and became importers or pseudo manufacturers for even basic items like thermometers, hot water bottles, examination gloves, masks, etc., so that now when corona virus has disrupted the supply chains from China the healthcare security in even accessing these consumables have been exposed.

Recently on February 11, the central government notified all medical devices – syringes to PET scanners to dialysis machines – like drugs for quality certification and monitoring purposes. Why was this felt necessary? Can medical devices be treated at par with drugs?

We at AIMED since long have been emphasizing the need to regulate all medical devices under a patients' safety medical devices law to protect patients and aid responsible manufacturing.

While we welcome the steps being taken by MOH&FW to bring all medical devices under single regulatory framework, however what's missing in covering note of Under Secretary is a stated policy or an assured roadmap to a separate medical devices law with a defined transition period and in a phased manner in addition to the voluntary registration as a temporary measure under the current Drugs Act to meet the final objective of patient safety. In absence of this written assurance, how can Indian manufacturers accept to be regulated under Drugs Act under above notice w.e.f. Dec 2019 and cut their hands?

We are okay to be regulated under a risk proportionate Medical Devices Rules, 2017, we are highly uncomfortable to be regulated under the very rigid and prescriptive the Drugs Act as any non-conformity can be treated as a criminal offence by any drug inspector at his discretion and hauled before a court and there is no risk proportionate penalties. We have been seeking assurance from the health ministry that this is a temporary measure until a NITI Aayog-drafted bill to regulate devices separately from drugs becomes a separate law. But no meeting has been called to address these apprehensions.

Medical devices are engineering items and not drugs. It's imperative to have a separate law as devices are engineering items and not medicines — an MRI or a CT Scan machine, by no stretch of the imagination, can be called drugs, and, so, continued attempts to regulate devices as drugs is illogical and incorrect unless assured that it is a temporary measure. A beginning was made to correct the anomalous situation with the introduction of the Medical Device Rules in 2018. These Rules have risk proportionate controls correlating to the risk classification of devices. Similarly, the law and penal provisions need to be riskproportional as you can't have the same penalty

Rajiv Nath

"An Army General does not graduate from a Police Academy so Medical devices can't flourish under a Drug Regime – 30 years is too long to be a stop gap short-term measure for the first devices to be regulated as drugs"

for a manufacturing failure of a pair of spectacles as for a contact lens or for an intra-ocular lens. Patient safety is more complex with devices, where the same are a shared responsibility of the manufacturer, medical practitioners, product user and the regulator. The Drugs Act itself needs reforms as it does not uniformly and equitably regulate quality from state-to-state in the absence of a national singular regulatory authority and there is no point of replicating this limitation for devices too. The recent J&J episode showed the limitations of the Drugs Act and the Drugs Controller was initially seen to be handicapped to discipline overseas manufacturers.

Q How would this impact the industry though the change is not going to be sudden and would be implemented in a staggered manner?

The change, though, will not be sudden; the new rule which comes into force from April 1, will be applicable to a large set of manufacturers in a staggered manner. The compliance requirements for low risk (Class A) and low moderate risk (Class B) devices will be enforced only after 30 months from the date of notification.

Similarly, the quality compliance requirements under the new rule will be effective for moderate high risk (Class C) and high risk (Class D) products after 42 months. The health ministry has also notified an online registration requirement for these products from April 1, 2020, onwards. The registration will remain voluntary for 18 months.

The Act has risk proportionate control – meaning more regulatory control for higher risk drugs – there is no proportionate penalty. Drug controllers can initiate criminal action for a malfunctioning intraocular lens the same as spectacles. Also, devices are engineering products and must be regulated by scientists and engineers and not pharmacists.

Q Even small manufacturers will have to comply with Medical Device and Diagnostic Rules (MDR) Schedule 5. Why is this being perceived as an issue?

This decision is going to have a major impact on the small and marginal players, largely unorganized, in low-value high volume segment of medical devices industry. One can't expect a tiny manufacturer in Bhagirath making masks or neck bracing collars or belts to hire a qualified QMS manager with biomedical engineering. It is not needed worldwide – these require simple basic precautions like labels for traceability and consumer protection.

Almost all low-risk Class A category products like orthopedic collars and pillows, spectacles and wheelchairs and stretchers, etc., are made by MSMEs. Most small manufacturers can't comply with and have qualified regulatory staff to meet the Medical Device and Diagnostic Rules (MDR) Schedule 5. The Ministry of Health had been unwilling to amend this, though NITI Aayog is supportive and has assured to make a provision in its draft bill. Internationally, in Europe manufacturers of Class A devices that are not sterile or those that do not have an accurate measuring function need not get audited by a notified certification body and demonstrate a full quality management system, a simple self-defined specification and drawing and declaration to meet these self-defined specifications consistently is treated as adequate.

Q India's Commerce Minister Piyush Goel recently said that his government will continue to implement price control measures on drugs and devices in India, as the country looks to balance needs of its economically weak population. How does this impact the industry?

Mr. Piyush Goel's statements came a week before US President, Donald J. Trump's scheduled visit to India, where among several discussions the issue of price cuts of medical devices and intellectual property were on the agenda.

We are pleased and grateful that Government of India did not relent to MNC lobbying pressure to protect their profiteering and decided to protect healthcare interest of common masses to ensure continued affordable access to Indian consumers and allow Indian manufacturers to continue to further gain credibility that their lower price is NOT lower quality or less safer and less innovative, as some lobbyists would like us to believe and seek to safeguard our Ayushman Bharat Modicare program by not rolling back price caps on stents.

The domestic manufacturers have been seeking capping of trade margins on import landed price for overseas manufacturers and over ex-factory price for domestic manufacturers to a rational level with an over-rider provision of price caps for those odd cases where huge price disparity is noticed for products with identical specifications even after capping their trade margins.

Q The industry has been hopeful of some reforms in 2020 that would boost the industry and help it transition into a global device making hub? Please elaborate on your expectations from the government and how far they have been met.

Medical Devices need a Competent Regulatory Body.Policymakers while beginning to view devices and drugs differently, need to ensure these are of high quality and are safe, must consider regulating devices under the ministry of health as done for food. Food is not regulated under the Drugs Act or under DCGI, or the CDSCO, but has a FSSAI with a Secretary level chairman and CEO. While many of the manufacturers of the 24 categories of already notified devices are okay to be regulated under a familiar CDSCO, they wish it to revamped with a medical devices specific division and appropriately needed competent staffing by engineers and scientists, a vast majority of the manufacturers of devices that are currently not regulated prefer to seek a separate national regulatory body which will not view devices from the prism of drugs, as reportedly envisioned in the NITI Aayog's draft Bill.

When it comes to the instances of imports undermining Indian products by far lower price and not necessarily better quality then the government needs to step in.

The government should stick to earlier assurance given to the industry by the MOH&FW in 2016 of four steps—starting with the Medical Devices Rules (MDR), initially experimenting with a few electronic devices under the MDR, the MDR to be amended as per experience gained after six months of introduction and the simultaneous drafting of a Medical Device Bill to be reviewed by us and other stakeholders and passed by Parliament and the MDR to accordingly be tweaked in order for it to migrate to an eventual Medical Devices Law.

The National Accreditation Board of Certification Bodies is already accrediting certification bodies for voluntary quality assurance (the Indian Certification for Medical Devices (ICMED) scheme) under the QCI (Quality Council of India). Incentivizing ICMED certification by the QCI will help Indian manufacturers in capacity building for voluntary compliance to quality standards, thereby ensuring global competitiveness and enabling the smooth transition to mandatory compliance under the proposed draft Medical Devices Bill from Niti Aayog. A strong and fair regulatory environment will help the Make in India campaign by encouraging the growth of this industry. Right from trade margin rationalization to ensuring a separate set of legislations and regulatory frameworks to govern the medical device sector and everything in between needs to be looked at afresh to galvanize domestic manufacturing.

There is a growing realization that India needs to have standards and technical regulations for different products categories under various line ministries and healthcare and medical device is a priority need. The fresh look at regulating medical devices independent of drugs by NITI Aayog will allow the Government to experiment with reforms of risk proportionate penal system and empowers the regulators to penalize the manufacturer instead of through lengthy overly burdened judicial processes. Later, the lessons gained for regulating devices and food can be carried forward to regulatory reforms also in drugs as there is a need for harmonized controls of drug quality.

Q The industry has been demanding some kind of curb on imports of medical devices. Please explain your concerns, challenges and suggestions.

There is an urgent need for the Government to move towards ending over 80-90% import dependence forced upon us and an ever increasing import bill of over Rs 38,837 crore, expedite steps for patients' protection, stronger quality standards, safety regulations, judicious price controls to make medical devices and quality treatment accessible and affordable and promote indigenous manufacturing.

GoI should not allow themselves to be misled by USTR officers and lobbyists of US MNCs incorrectly using US trade talks as an opportunity to dictate and attempt to interfere in Indian domestic healthcare policymaking.

Government must ensure importers of medical devices are not kept out of the move to cap trade margins. Are MNC importers not traders? How can we have importers having irrational 200% margin as was indicated in NPPA report analyzing trade margins on catheters and guide wires which is used to finance doctors overseas trips/sponsoring medical conferences/unethical marketing practices, while the rest of supply chain have only 30% trade margin as incorrectly defining on price to stockists as first point of sale.

Based on evidence of successful price caps of stents, the government must proactively make cohesive, industry-friendly policy giving at least a level playing field, if not a strategic advantage to domestic manufacturers while safeguarding consumers. Devices are not drugs though both are medical products but differ in approach in marketing – any move to bring in trade margin rationalization that's based on PTS (price to stockist) instead of first point of sales (when goods enter India), may not meet objectives to boost domestic manufacturing, end exploitative MRP and unethical marketing.

Q With even multinational medical devices company defaulting on quality and compensation when it comes to emerging nations' consumers, are their mechanisms in the domestic industry to ensure that the Indian consumer is not short-changed?

No, not in Drugs Act or Medical Devices Rules but we are informed that the draft Bill by Niti Aayog has provisions for compensation to patients After J&J implant row, govt plans to hire 750 officers to regulate medical devices.

Healthcare Public Policy Should Not Be Part of Trade Discussions

Price control must to protect indigenous medical equipment industry.

By Rajiv Nath

THE UNITED STATES has reportedly asked India to do away with price controls on high-end and premium medical devices. The American medical devices industry has been asking India to do away with price caps on all medical devices and instead consider TMR over price to stockists.

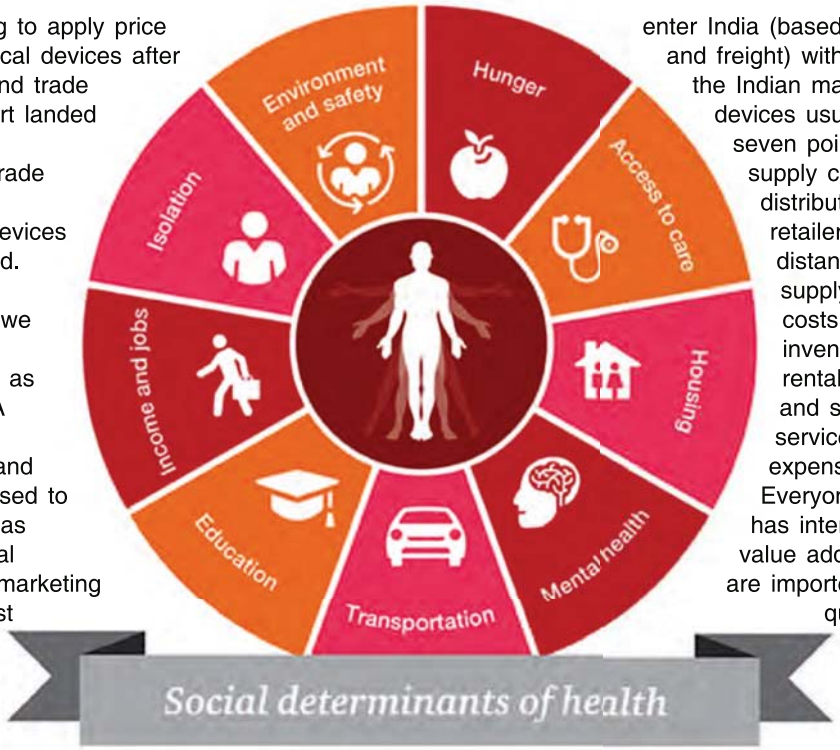
The trade margin is the difference between the price at which overseas or Indian manufacturers sell to trade (price to trade) and the price to patients (maximum retail price), and TMR (Trade Margin Rationalization) entails a cap on the profit.

Before US President Donald J Trump's scheduled visit to India, whenever among several discussions, the issue of price cuts of medical devices and intellectual property was on the agenda, we are thankful that India's Commerce Minister Piyush Goel said that his government will continue to implement price control measures of drugs and devices in India, as the country looks to balance needs of its economically weak population.

While we are pleased and grateful that Government of India did not relent to MNC lobbying pressure for rolling back price caps when PM Modi visited US as part of trade negotiations and even now during US President Donald J Trump's visit to India to protect the MNCs' profiteering and market share; however the government now needs to be more bold and pursue policy making by evidence by extending the advantages gained in fostering Make in India and protection to the consumers in stents

by similarly considering to apply price controls on other medical devices after studying their MRPs and trade margins over the import landed price.

When it comes to trade margin rationalization, importers of medical devices should also be included. Aren't MNC importers traders too? How can we have importers having irrational 200% margin as was indicated in NPPA report analyzing trade margins on catheters and guide wires which is used to finance doctors overseas trips/sponsoring medical conferences/unethical marketing practices, while the rest of supply chain have only 30% trade margin as incorrectly defining on price to stockist, as first point of sale.



Importers in order to avoid customs duty, argue that intermediate costs like R&D and clinical evaluation are not part of the import landed transfer price. However, they also induce hospitals with higher MRP and higher trade margins. This tactical marketing warfare is highly unethical and has cost the consumers dearly as well as adversely impacted domestic manufacturers.

The main aim of rationalization of trade margins in medical devices should be not only to help consumers, but also allow rationalized and reasonable profits for traders, importers, distributors, and wholesalers andretailers and create a level playing field for domestic industry vis-à-vis foreign manufacturers. There should be clear objectives for any policy intervention to provide quality and affordability and avoid distress (to consumers), distrust (in industry) and disruption (to market). The marketplace is, unfortunately, skewed where suppliers induce hospitals to buy and push their brands based on profit margins to be made and not on basis of cost savings to be made on the procurement cost by a hospital, thus spiraling prices of medical devices leading to an artificial inflation.

In order to accord a levelplaying field, the policy needs to equate an overseas manufacturer's first point of sale on which GST is charged first time at which their goods enter India (based on cost, insurance and freight) with the ex-factory price of the Indian manufacturers. Medical devices usually go through four to seven points of sale along the supply chain — from a distributor to a wholesaler to a retailer to a consumer in a distant village. Each point in supply chain incurs various costs, such as freight, inventory carrying costs, rental, salaries, marketing and sales overheads and service and statutory expenses of compliance. Everyone in a supply chain has intermediate costs and value addition, so what value are importers doing and the question is what's a rational margin for them?

Price caps are needed as an over rider on an initial consumer protection safety net of trade margins capping when for identical product specifications there continues to be blatant price disparity. Businesses need profits to grow and serve their clients adequately, but profiteering is a No-No in healthcare delivery.

We are thankful that India's Commerce Minister Piyush Goel said that his government will continue to implement price control measures of drugs and devices in India, as the country looks to balance needs of its economically weak population.

Based on evidence of successful price caps of stents, the government must proactively make cohesive, industry-friendly policy giving at least a level playing field, if not a strategic advantage to domestic manufacturers while safeguarding consumers. Devices are not drugs though both are medical products but differ in approach in marketing – any move to bring in trade margin rationalization that's based on PTS (Price to Stockist) instead of first point of sales (when goods enter India), may not meet objectives “to boost domestic manufacturing, end exploitative MRP and unethical marketing”

Also, there is a need to counter attempts to spread misinformation vis-à-vis any kind of government policy to control prices of medical devices.When MRP prices or trade margins are capped, the manufacturers' margins are not impacted so fear mongering regarding detrimental impact on quality and innovations in medical devices on account of price control policy stipulations will not be in the interest of consumers or domestic manufacturers. Such misinformation by any particular lobby should be discouraged and countered effectively.

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Pyush Misra
Director,
Consumer Online Foundation

High On Innovation And Dedication

Medical device startups are filling a niche space that promises not just high profits but also to fill the gaps in the existing healthcare in India.

India's medical devices startup segment is a space to watch.

INDIA'S MEDICAL DEVICES industry is hailed as the sunrise sector and despite being plagued by various challenges it stands at the brink of exponential growth.The medical device industry in the country is focused on multiple segments like consumables and disposables, implants, stents, artificial joints, surgical equipment, medical consumable products, and the entire gamut of products that comprise the industry. Some of the major segments Indian medical devices manufacturers are focusing on includes:

- Consumables and disposables: staples, needles, gowns, adhesive, masks, tubing, syringes, catheters, sutures, medical gloves, etc.
- Diagnostic imaging: including MRI scan, X-rays, CT scans, ultrasound.
- Orthopedic products: artificial devices such as splints and braces, and artificial limbs
- Dental products: floss, waxes, excavators, operative burs and more.
- Equipment and instruments: centrifuge, aspiration/suction pump, patient monitors, ECG, oxygenators etc.

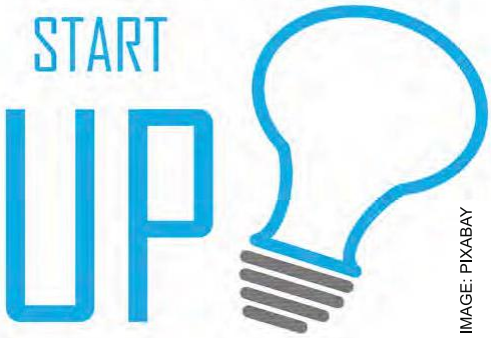


IMAGE: PIXABAY

Startups are coming up with novel solutions for India's unique problems.

- I-V Diagnostic medical device: usually used for in-vitro examination of specimens.

Since the Indian medical devices industry is in nascent stages, more than 90% of sophisticated devices are imported. This indicates the enormous scope for R&D development in the countryand the opportunities galore. It has not only attracted big private players and government sector spending on the healthcare sector but also startups.

Businesses face several challenges in the sector, for example, they are required to ensure product quality and regulatory compliance, contend with the high cost of product development, and unavailability of resources. Medical device industry has to adhere to strict regulatory compliance to ensure safety standards and norms that are mandatory. From thermometer to imaging machines are required to comply with defined standards of the country where it is being exported. Yet, despite the constraints, medical device manufacturers, including the small and mid-sized manufacturers, are proactively investing in product development projects, with the aim to deliver quality products and avoid product recalls as it directly impacts the brand and the bottom line negatively.

A major challenge for small manufacturers is getting the support of the government for expeditious approvals, tax rebates, financial support and subsidized research, etc. The increasing cost of product development is also a huge challenge that start-ups face in India.

Other big issues include the unavailability of skilled resources, uncertain regulations, and irregular pricing environment. Further, innovation is low and customization in the products is extensive, which complicates things.

India's medical devices industry is poised for significant growth in the next five years. The market size is expected to reach $ 50 bn by 2025.

IMAGE: PIXABAY

Carving a space of their own and exploring untapped markets.

The medical device industry works in a Central Drugs Standard Control Organization (CDSCO) regulated environment where higher visibility, real-world benefits, and tangible ROI make growth a possibility. CDSCO regulated compliance standards are detailed and should be followed with utmost accuracy – this directly connects with the reputation of the company.

According to media reports, medical devices startups have reached niche but potentially lucrative markets and are catering to highly niche but important problems overlooked by global giants.

Startups are actively looking to understand specific pain points in the healthcare ecosystem and develop products to answer unmet needs of consumers.

From building fecal management kits to provide solution to the hitherto neglected area of incontinence to addressing other highly niche but important issues that have been overlooked by MNCs; Indian startups are following tough paths in order to tap the huge market for unaddressed needs.

There is an increasing number of medical technology startups that are finally making breakthroughs in the difficult and long cycle of research, development, trials and securing regulatory approvals before going to the market with their products.

The key differentiator for these startups is making products accessible both in terms of innovation as well as affordability in a country like India where healthcare is expensive and mostly unavailable in its small towns and villages.

Startups are building such innovative solutions like detection of hearing impairment in infants which has far reaching impact. Hearing loss in infants mostly goes undetected and by the time it is caught, it is already too late. With 26 million babies born every year in India, this is a much-needed intervention.

They are building foot-operated resuscitation system that can function without electricity and is a simple device that can be handled by caregivers even in villages.

As is obvious, developing such products requires a lot of time and effort. Stringent processes have to be adopted and the products go through years of testing and research. Then depending on securing regulatory clearances from relevant authorities they are launched in markets.

Such scientific research requires huge funding that comes mostly from grants as few investors are willing to take the high risk and long gestation periods.

Fortunately, supporting ecosystem has evolved over the years and is giving these innovative startups a huge push.

The pricing decisions also require a lot of thought in the sector, as medical device startups must ensure profitability for their company while keeping the prices affordable for the large majority.

It is not that only startups can develop such innovative solutions. While they do have the advantage of lean structure and competitive pricing, they lack the resources of the big companies. Meanwhile the big MNCs too want to be part of the evolving ecosystem of innovation and startups, which is poised for big changes.

There is thus a need to nurture this ecosystem by providing the startups with the right kind of infrastructural support enabling geographic expansion, clinical and technology support, access to labs, supply chain or regulatory inputs. This would go a long way in building the sustainability of the startups on a basis of commercial scalability of their enterprise.

Efforts are being made and an important development is the various programs aimed at supporting more such startups that are stepping into untapped market plugging the gaps in the value chain.

Source: Secondary research & media reports

CORONAVIRUS

COVID-19

Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus.

Most people infected with the COVID-19 virus will experience mild to moderate respiratory illness and recover without requiring special treatment. Older people, and those with underlying medical problems like cardiovascular disease, diabetes, chronic respiratory disease, and cancer are more likely to develop serious illness.

The best way to prevent and slow down transmission is be well informed about the COVID-19 virus, the disease it causes and how it spreads. Protect yourself and others from infection by washing your hands or using an alcohol based rub frequently and not touching your face.

The COVID-19 virus spreads primarily through droplets of saliva or discharge from the nose when an infected person coughs or sneezes, so it's important that you also practice respiratory etiquette (for example, by coughing into a flexed elbow).

At this time, there are no specific vaccines or treatments for COVID-19. However, there are many ongoing clinical trials evaluating potential treatments.

SYMPTOMS

COMMON SYMPTOMS INCLUDE:

- fever
- tiredness
- dry cough.

OTHER SYMPTOMS INCLUDE:

- shortness of breath
- aches and pains
- sore throat
- and very few people will report diarrhoea, nausea or a runny nose.

People with mild symptoms who are otherwise healthy should self-isolate and contact their medical provider or a COVID-19 information line for advice on testing and referral.

People with fever, cough or difficulty breathing should call their doctor and seek medical attention.

PREVENTION

To prevent infection and to slow transmission of COVID-19, do the following:

- Wash your hands regularly with soap and water, or clean them with alcohol-based hand rub.
- Maintain at least 1 metre distance between you and people coughing or sneezing.
- Avoid touching your face.
- Cover your mouth and nose when coughing or sneezing.
- Stay home if you feel unwell.
- Refrain from smoking and other activities that weaken the lungs.
- Practice physical distancing by avoiding unnecessary travel and staying away from large groups of people.

Helpline Number Toll free: 1075
+91-11-23978046

Email : ncov2019@gov.in • ncov2019@gmail.com

VALIDATION Required

The medical device industry has unique challenges in validation of products and needs to be nurtured properly to help address these issues.

IMAGE: PIXABAY

Validation of medical device is integral to product lifecycle.

KEEPING IN MIND the steady growth of the medical devices industry and in line with the Make in India initiative of the Government of India, the Central Drugs Standard Control Organization (CDSCO), published the new Medical Device Rules, 2017, and it came into force on 2018.

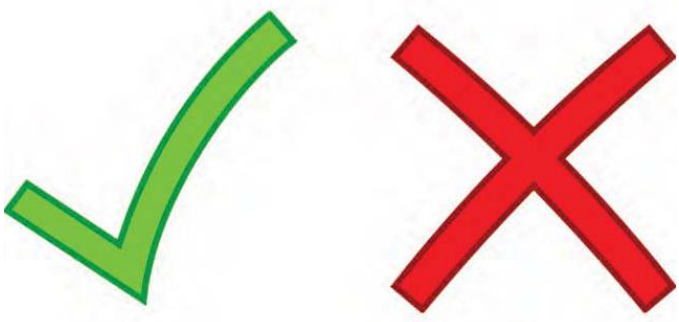
The new rules were aimed at promoting domestic manufacturing and regulate import and manufacturing in line with the GHTF (Global Harmonization Task Force) guidelines. The rules are in consonance with these rules' risk-based classification.

These rules allow Indian manufactures to export the high-quality products to the world. For an Original Equipment Manufacturer (OEM), it is important that the products comply stringent global quality standards and that there are no incidents that happen to the patient or to the operator of the equipment that could lead to a recall. It is imperative that manufacturers all the appropriate verification and validation protocols in place that ensure total safety, precision, accuracy and functionality once the product is launched in the market. These quality parameters ensure that there are no recalls that lead to considerable financial and repetitional damage for the company.

Validation, a tough call

Since validation of medical devices is integral to the complete product development lifecycle, it is imperative that the manufacturer undertakes validation throughout the production cycle of the product from design, manufacturing to release. A precisely planned validation program needs to be in place that ensures that the final product is without any risks of non-conformity.

Verification and validation are parts of the complete assurance process and ensure that the product meets the parameters and specifications and can fulfill its intended purpose. Verification ensures that the product meets a set of design specifications and is undertaken at every output stage of the product development lifecycle to ensure that each output is verified as conforming to its input. The process of validation must take place on two levels – design and process validation. Design validation requires establishing by objective evidence that a device's specifications conform to user needs and intended use(s), while process validation means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.



Validation is expensive and challenging.

With technological advances, medical devices are becoming more complex while getting smaller and more advanced. This makes ensuring a strict device validation routine even more important.

Manufacturers need to establish documented evidence for high quality manufacturing process employed which assurance the end user that the product meets pre-determined quality requirements. As several companies come up with new technologies and devices to meet the unmet needs in the healthcare ecosystem, regulatory authorities are putting greater focus on risk analysis in order to ensure that solutions are not just innovative but also safe solutions for patient use. All these critical requirements have led companies to appoint a highly qualified mix of regulatory experts, biomedical engineers, usability engineers, requirement engineers and electrical engineers to bring in their understanding to the entire process of validating medical devices.

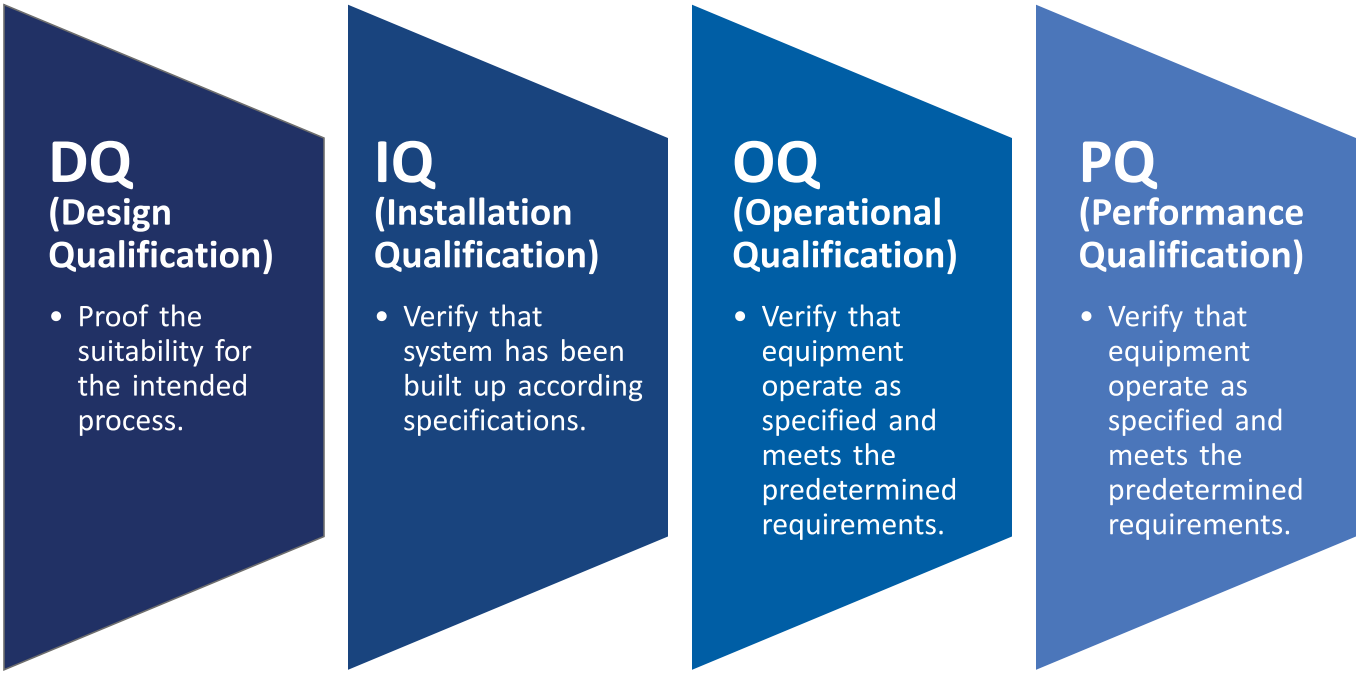
Imported medical devices that form the bulk of the products sold in India account for around 80% of the total medical device sales. However, these devices are meant for developed countries with higher per capita income. India has unique challenges of accessibility and affordability, and it is important that indigenous manufactures developed targeted products to cater to these needs.

India needs affordable healthcare, and if the medical devices industry can enhance reach of diagnosis with affordable and user-friendly medical devices that proliferate the healthcare delivery systems; it could change the face of healthcare forever. Hence, for innovators and entrepreneurs, this presents immense opportunities and fortunately there is a rising tribe of enthusiastic and socially oriented startups who are building products that could revolutionize healthcare.

Challenges galore

Despite the opportunities in the sector and though we see a deluge of point-of-care devices and diagnostics proliferating the healthcare space in India, few of the indigenously developed ones actually reach the market. The reason for this is the clinical validation requirement that is a persistent challenge for manufacturers. Innovations have longer gestation period and the time-to-market is invariably convoluted due to these clinical and product validation requirements and eventually the twin objectives of affordability and efficiency in health systems remain unfulfilled. For innovators it is constant struggle to design protocol-based studies that are statistically significant and tested in real-world clinical settings. A crucial step to generating objective evidence remains elusive and hence the large-scale adoption of these

Medical Device Design validation focuses on the device itself and involves creating evidence that it meets the user's needs and their intended uses.



breakthrough innovations by healthcare establishments remains a pipedream.

The result is that the imported devices with existing technologies of the West remain popular with medical practitioners. The medical devices sector needs a dependable and supportive regulatory framework and it must be ensured that innovators have access to an environmental where compliance requirements to not hamstring innovation.

As of now, the sector is squeezed of funds, as investors are unwilling to get involved in the sector where the risk is high, gestation periods long and domain knowledge low.

A WAY FORWARD

There is an urgent need to create an effective ecosystem for medical devices innovation to thrive. The government and the industry must work together to establish a platform that can identify, enable and accelerate the most-promising healthcare innovations and enable their entry into the market, adoption and scale. Innovators and startups need handholding to survive the obstacle-ridden path to market their products and investors need vital domain knowledge to be able to accurately assess risks and rewards. There must also be a body to manage the capital with the understanding that medical devices have long product development cycles and numerous risks associated with them.

Once this kind of supportive ecosystem for innovators and entrepreneurs has been established it would become possible for them to access the resources they need and work towards creating a deep and meaningful social impact by improving the quality of life of the people, especially of the unserved, A platform that does all this would need the ability to firstly assess manufacturing readiness for early validation of designs. This would help reduce risks and enable lower manufacturing costs. Secondly, it would need adequate expertise in designing of clinical studies for validation and be able to facilitate access to clinical testing hospitals/PHCs for innovators.Thirdly, the platform must have the ability to offer customized mentoring to startups to advise them on refining their business model, wading through the regulatory compliance landscape successfully, and also a good understanding of domestic and global market dynamics. Fourthly, the platform must build a foundation of grants and other capital sources and enable access to working capital.

Provided that we succeed in establishing a supportive ecosystem to support medical devices manufacturers and innovators, India has a good chance at becoming a global hub of innovation and manufacturing of medical devices. It would not be surprising then if India begins supplying to the world next generation of cutting-edge medical devices.

Source: Secondary research and media reports

MAKE IN INDIA

BOOST TO MEDICAL DEVICES INDUSTRY

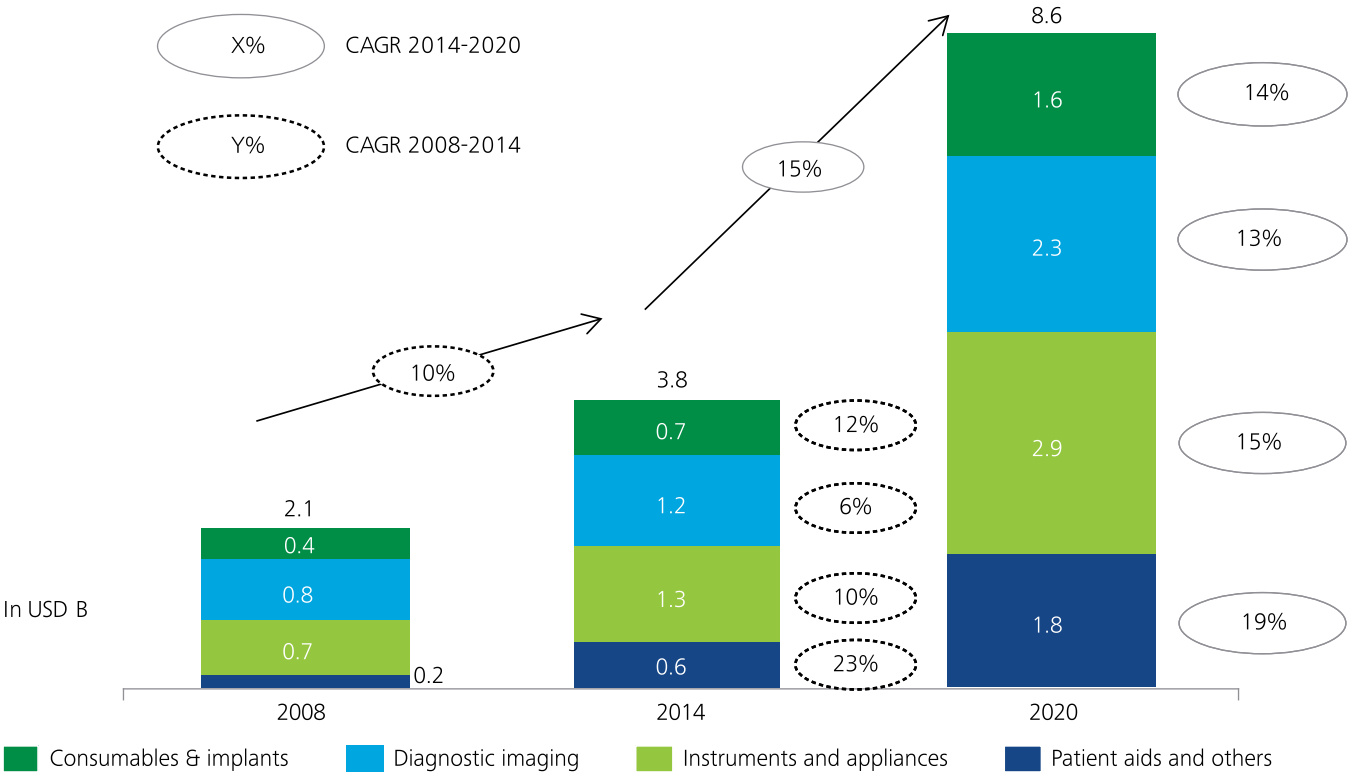
Make in India initiative of the government has the potential to make India a leading exporter of medical devices.

IMAGE: RAZORPAY (GOOGLE IMAGES)

Make in India has the power to unleash the potential of the medical devices sector.

Historical and Expected Performance of Medical devices industry

Scenario 1: Organic growth at 15%



SOURCE: DELOITTE

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.

The India medical devices industry is still in its infancy with a disproportionate reliance on imports further complicated by a complex regulatory environment. A 2018 PwC report says the per capita spend on medical devices in India is one of the lowest, much lower than the global average of USD 66.3; which suggests huge potential for growth. In 2016, a Deloitte report had estimated it to be the lowest among BRIC countries at USD 3. Meanwhile the per capita spend in China was USD 7, USD 21 in Brazil and USD 42 in Russia. While developed economies like the USA spend much higher on medical devices. In the USA it was USD 340 in 2016.

This shows the under penetration of medical devices in India and points to the huge opportunities existing in the sector.

Regulatory environment

The medical devices sector was ambiguous, complex and lacking in transparency. However, much of this changed with the implementation of the Medical Device Rules in 2018, and with it the medical technology industry could be seen to be ready for the next phase of evolution.

The government recognizes the medical technology industry as a sunrise sector and allows 100 per cent foreign direct investment (FDI) investment through the automatic route. Though the industry continues to be import dependent to a large extent, the government is promoting the sector under supportive policy initiatives like Make in India in a bid to boost domestic manufacturing and export competitiveness. The government is playing a collaborative role with the industry to promote standardization through various initiatives.

Medical devices have been subsumed under the larger pharmaceutical structure and the policy applicable to it has been that of the pharmaceutical industry There has been a demand for the government to institute unambiguous and transparent policy for the sector to enable investments and growth.

Dependence on imports

The sector continues to be is largely dependent on imports and most local manufacturers produce products in the lower end of the technology value chain. The

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 specic 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

SOURCE: DELOITTE

reasons for this are the limited availability of technology and funds for indigenous manufacturing.

Imports constitute more than 80% of the medical devices industry sales in India as the barriers to import are low. There are several reasons for the high percentage share of imports. India has an inverted duty structure historically skewed in favor of import of finished goods rather than raw materials/components for medical devices manufacturing. In the Budget 2020, the government took a concrete step towards discouraging imports and promoting domestic manufacturing so as to accelerate medical devices manufacturing under Make in India. A Health Cess on medical devices was announced in the Budget 2020. The Health Cess @ rate of 5% is applicable with effect from 2 February 2020. Industry, however, feels that the cess is low and may not prove to be a detriment to imports.

Another important reason for the large volume of imports is the absence of a concrete regulatory framework specific to medical devices industry. This constrains investments into the industry. Additionally, India has not been able to establish a component manufacturing ecosystem or develop skills base that can support domestic manufacturing. Multinational firms with deep pockets and global capacities are also boosting imports.

Imports are the mainstay of the medical devices industry in India and many types of medical devices are imported, particularly higher end products like cancer diagnostics, medical imaging, ultrasonic scans, and PCR technologies. As world-class hospitals grow in India backed by powerful industrial groups, the demand for high-end infrastructure is further growing.

There is also a ready market for refurbished medical laboratory instruments to be used as back-up machines in top hospitals. For the mid-range hospitals and hospitals in districts, it makes financial sense to imports refurbished medical laboratory instruments. The government imposes several restrictions on the import of used equipment in India under the import-export policy. It allows imports of second-hand capital goods with a minimum residual life of five years by actual users themselves without a license. However, the importer has to furnish a self-declaration to the customs department specifying the residual life of the second-hand capital goods in a prescribed format. Further, the refurbished equipment cannot be transferred, sold or otherwise disposed of within a period of five years from the date of import, except with prior permission of the Director General of Foreign Trade (DGFT). As India is a high-cost economy for capital equipment, and manufacturers and investors in the country seek to reduce capital costs; the demand for refurbished and reconditioned equipment is high across a range of industry sectors.

Make in India, strategic step forward

With Indian medical technology industry at a critical juncture, the government stepped in with the 'Make in India' initiative to provide opportunity to indigenous

Build context

1. Context of 'Make in India' initiative

Establish context of 'Make in India' program – innovation, IP, best-in-class manufacturing, skill development

2. Significance of Medical devices industry

Establish significance of medical devices in overall healthcare continuum and provide market overview of medical devices industry in India covering the sub-segments: instruments and appliances, diagnostic imaging, consumables and patient aids

3. Manufacturing landscape of medical devices in India

Manufacturing landscape of medical devices in India – level and nature of imports/exports, degree of manufacturing; learnings from allied industries and global manufacturing destinations

Obtain stakeholder inputs

4. Personal interactions

Personal interactions with key stakeholders (providers, medical devices, central & state government) to get required inputs

5. Online Questionnaire-based survey

Questionnaire based survey to capture the sentiments of NATHEALTH executives around key themes of the initiative

6. Industry viewpoint along thematic areas

Understand and synthesize the industry viewpoint around ease of doing business, infrastructural support requirement, medical devices ecosystem, viability of manufacturing in India and enablers required for the shift

Develop suggestions

7. Articulation of measures to achieve objectives of 'Make in India'

Initiatives to be taken across multiple areas: policy measures, regulatory framework, development of manufacturing clusters, strengthening of ecosystem for innovation and manufacturing

8. Visibility and communication of the study to all stakeholders

Ensuring visibility and communication of the study to all stakeholders

Note: List of participants for primary interactions and survey in the annexure

SOURCE: DELOITTE

industry players to step up manufacture of medical devices locally. The immense potential of the medical devices sector made its inclusion in the 'Make in India' initiative pertinent and timely, as it could provide the essential leverage to kickstart local manufacturing and achieve the twin objectives of accessibility and affordability.

It has been estimated that an enabling policy framework and ecosystem support could help the industry grow at ~28% to USD 50 billion by 2025. This growth is expected to be driven by indigenous manufacturing and exports and, sales from local innovation.

According to a report by Deloitte, 'Medical Devices – Making in India - A Leap for Indian Healthcare', at the estimated rate of growth, India can be expected to contribute significantly to the incremental share of the global market. The contribution of Indian medical devices market to the incremental growth of the global market for 2020-2025 is expected to be around 30% (USD 33.6 billion in the overall global contribution of USD 108.6 billion), which is significant for global trade.

Deloitte notes that factors relating to the policy framework and tax structure lead to high dependence on imports these include historical presence of inverted duty structure favoring imports of finished goods over raw materials, limited access to technology, IP protection and, size and scale of indigenous manufacturers. The fragmented nature of indigenous manufacturing is also of concern.

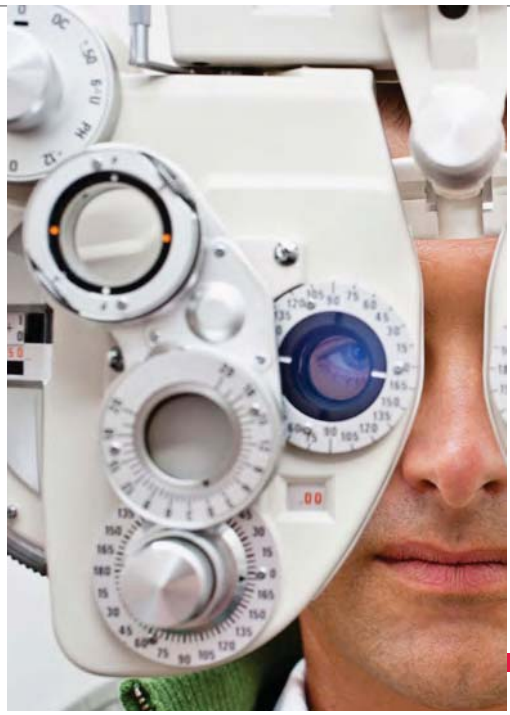
Local manufacture is limited to products in the lower end of technology value chain, and mostly producing

consumables and implants segment. Multinational companies present in India either manufacture complex medical devices in a limited quantity or they are imported.

The R&D efforts of indigenous manufacturers are mainly focused on developing affordable medical devices to cater to the lower-and-middle-income segments of the country's market. Hence, the local manufacturers are mainly operating in the low-priced, high volume market segments.

In these efforts to scale up indigenous manufacturing, some states like Maharashtra and Tamil Nadu are setting good examples developing a holistic ecosystem to boost the indigenous medical devices industry. Further startups in the country are driving the culture of local innovation and MNCs too are working on it and together their efforts could give a boost to indigenous manufacturing. It is expected that this could lead to rapid growth of exports market.

Export of medical devices is estimated at around USD 4.9 billion. The market is no doubt small but is growing at an unprecedented rate developing at a CAGR of 17% over the past few years. It is expected that the sector would witness double-digit growth at CAGR of 15% in the coming decade with the demand and supply-side dynamics providing an unprecedented opportunity for manufacture of medical devices in India.



The 'MAKE IN INDIA' initiative provides an opportunity to create a 'step change' in Indian healthcare, especially in the medical devices industry.

Demand Side

The Indian medical devices market was valued at Rs 338.62 billion in 2017 and is expected to reach Rs 794.29 billion by the end of 2023, expanding at a compound annual growth rate of ~15.27% during the 2018-2023 period. This growth will be fueled by government's plans to achieve universal health insurance cover, initiatives like Make in India, and expansion by private healthcare firms.

Despite the double-digit growth rate of the market, the per capita consumption of medical devices remains low. The primary cause of this is lack of affordability for high-end technology devices among masses. To overcome this challenge, the local manufacturing industry, especially the startup segment, is taking the path of frugal engineering to develop India-specific low-cost products. This could unlock the demand as per capita consumption increases.

The innovations in low-cost medical devices could lead to newer market access as the products being produced areon par with global medical devices in terms of quality with highly complex technical products and have found a niche market in many countries globally.

Supply Side

As domestic demand becomes stronger combined with other supporting factors, India can emerge as a medical devices manufacturing hub especially for global companies that are looking to align their global manufacturing footprint with shifting consumption patterns. Further, a shorter lead-time as well as the opportunity to significantly enhance service levels will all work in India's favor. For MNC players, India is a prominent de-risking option from regional/global risks and as it becomes a major consumption location, with high potential to become an export-oriented country, it could be a win-win.

Conclusion

All these factors can help India can move up the technology ladder and concentrate its efforts on manufacturing of low and mid-tech products in the near term.

India's continued innovation and development of new technologies, global demand and potential in the near-and-medium term offer India with an opportunity to become a major participant in the global supply chain of medical devices.

The government must adopt a phased approach to indigenization and develop supportive manufacturing ecosystem. Once this ecosystem matures, indigenous manufacturing of comparable global quality products will take off. Further, orientation of the industry towards quality would make the products globally competitive.

Source: Secondary research & media reports

Technology Trends To Watch For

Technology is rapidly changing the healthcare landscape and how! Here are few technologies that are finding increasing application in the field.

Telemedicine is making healthcare available in remote areas in India.

IMAGE: PIXABAY

TRADITIONALLY SLOW TO adopt technology, the healthcare industry is on the brink of disruptive changes over the next decade. Leading companies have already embarked on their digital transformation journey are applying it to their main functional areas to redefine themselves.

Businesses in the medical devices industry are also adopting the latest technologies in a bid to boost performance and productivity. They share the same security concerns with other industries that are tech-driven and are undertaking extensive research on new ways to make their companies customer-centric. Here are some of the top tech trends transforming the industry.

TREND #1: TELEMEDICINE

Evolution in telemedicine is not just changing the US healthcare system rapidly, in India too it is making rapid inroads backed by the government. In a country of India's size where access to healthcare providers is limited, telemedicine provides a transformative impact. Telemedicine is the roadmap for improved medical care in rural areas. According to NITI Aayog, the National Health Stack (NHS) is a virtual digital platform for healthcare in the country. The aim of the NHS study is to create digital health records of all citizens by 2022. This would make telemedicine and e-health easier. Ayushman Bharat scheme as the biggest health financing scheme in the country shows how ICT (Information and Communication Technology) can transform health sector in the country. The scheme is underlined by tele-health development ideology that looks at providing long distance medical care and establish a safe, effective, efficient, patient-centered and timely health management environment.

According to reports, India's telemedicine market is growing rapidly. It has expanded in the country in the past few years and is being touted as the next frontier in healthcare. The importance of health data cannot be overemphasized and with technologies like artificial intelligence and machine learning, this data is proving to be a veritable goldmine for research and development in the healthcare field.

Telemedicine also helps serve underserved communities in urban centers;wait time at the doctors or hospitals can be checked; and by providing access to specialists, it improves diagnosing and treatment. Electronic records make it easier to forward documents to specialists and in rural areas this could make a huge difference by allowing expert input into a case.

These data exchange platforms are transforming telemedicine as never before. The video chat platforms serve immense purposes, but telehealth services are set to evolve beyond that. Hospitals can reduce readmission rates if they can do real-time monitoring of patients at their homes. Wearable devices have added another dimension to telehealth. It has made possible for remote monitoring systems to now be included in post-discharge plans for patients.

TREND #2: THE INTERNET OF MEDICAL THINGS (IOMT)

Great strides are being made in the telehealth sector with devices and mobile apps playing a critical role in the tracking and prevention of chronic illnesses. This breakthrough is being achieved by combining IoT development with telemedicine and telehealth technologies, giving rise to what experts call a new Internet of Medical Things (IoMT). Care teams and patients are being connected to each other using IoMT to achieve more connected healthcare delivery.

Such is the trend, that the number of devices connected to IoT, and with each other, is growing sharply. This trend is growing rapidly in the healthcare industry and from around 4.5 billion medical devices in 2015 that were connected to the Internet of Medical Things (IoMT), the number is IoMT devices is forecast to grow to 20-30 billion devices by 2020.

One of the biggest boons of IoT in healthcare is that it enables remote patient monitoring and medical device and asset management. A number of wearables, including ECG and EKG monitors are used in this approach. Other medical measurements such as skin temperature, glucose level, and blood pressure readings can also be monitored via IoMT.

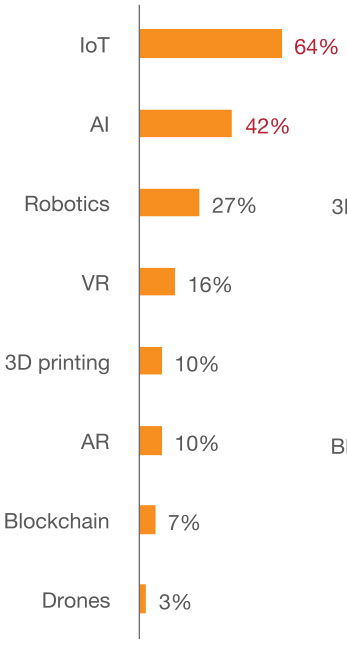
In India investments are happening in AI and IoTM.

One of the biggest challenges faced in using IoT in healthcare is ensuring continuous and effective communication with numerous medical IoT devices. Manufacturers also use proprietary protocols for talking to devices and this complicates the issue, especially in collecting large amounts of data by servers. The other challenge stems from connectivity issues, as this can disrupt collection of data by micro controllers and smartphones. Use of technology also brings with it security concerns, as data breaches can prove costly when you are dealing with the personal data of hapless consumers.

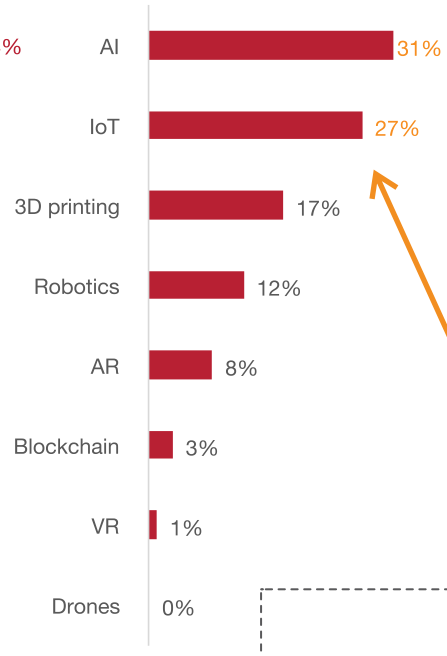
TREND #3: CLOUD COMPUTING

The rapid growth of the healthcare cloud computing market globally is indicative of its rising importance. According to reports, the global healthcare cloud computing market is expected to grow at a compound annual growth rate of 20%, exceeding USD 15.5 billion by 2024. Cloud can transform the healthcare scenario by redefining systems, processes, and informatics. It can be the route to innovation, and allow the medical fraternity, governments and concerned health organizations to draw insights from huge data sets. Usage of cloud also leads to lowered costs, enhanced efficiency and personalization. It also allows organizations to abide by high standards of security, privacy, and compliance.

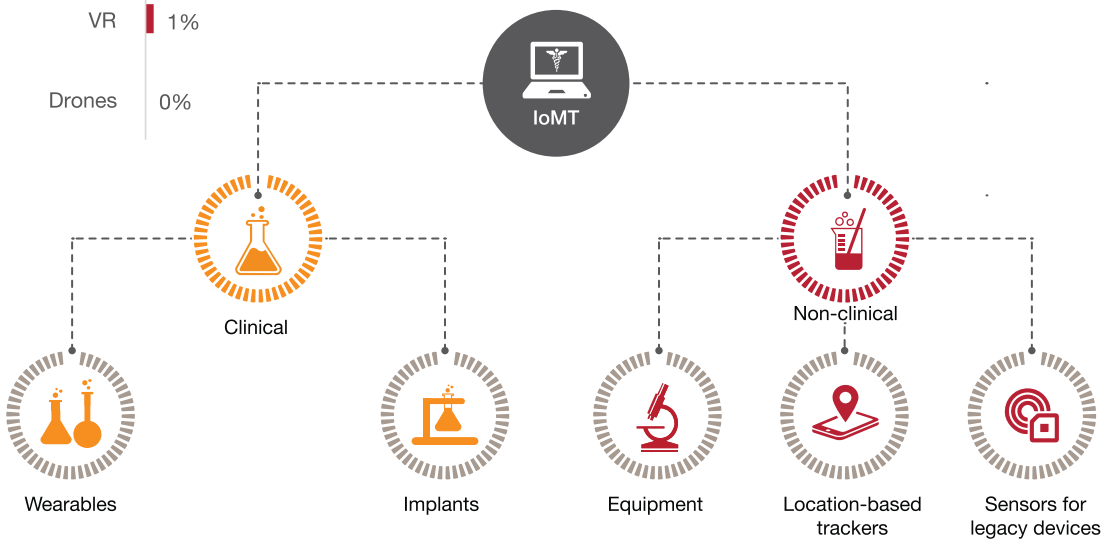
In India, investments are happening in IoT and AI



Globally, healthcare executives rate AI as most disruptive tech in the industry, followed by IoT

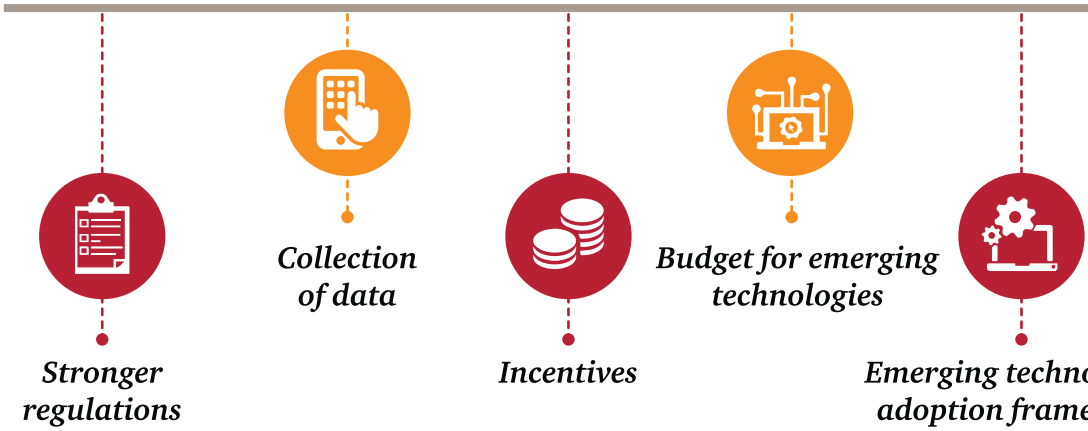


- AI is assisting with predictive medical diagnosis
- AI is drastically expediting clinical trials.
- **PwC's Bodylogical™** uses machine learning algorithms to digitally represent the physiology of the human body.
- AI is assisting with confirmation on medicine ingestion.



SOURCE: PwC

Changes expected to drive adoption of AI and IoMT amongst healthcare providers in India



SOURCE: PwC

IMAGE: PIXABAY

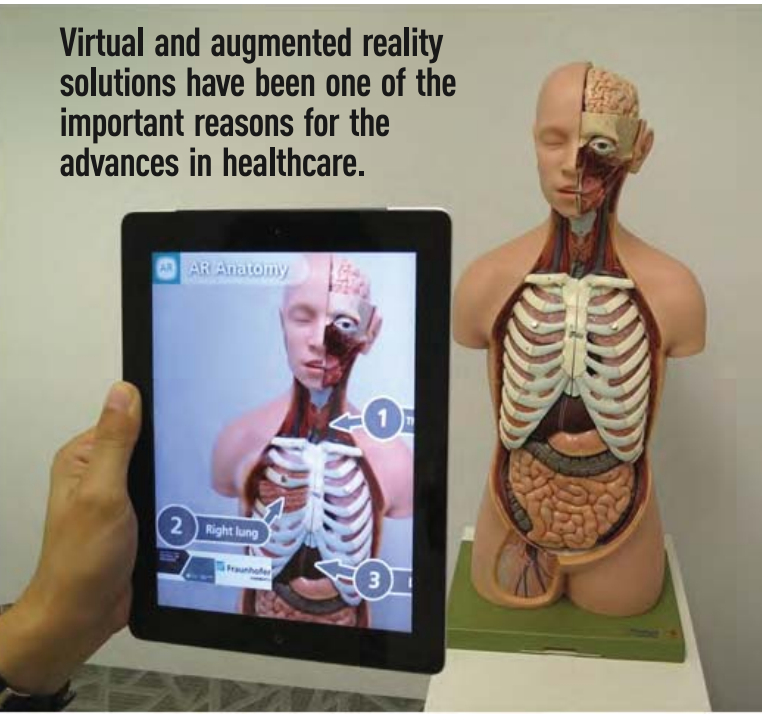
Healthcare cloud computing market is growing rapidly as it finds huge application in healthcare.

From tracking a patient's compliance with medication, dietary instructions to ensuring that they do not miss the doctor's appointments, cloud technology allows reporting of real-time activity and enables health providers to monitor patient behavior remotely.

TREND #4: AR/VR/MR

Virtual and augmented reality solutions have been instrumental for advances in healthcare technologies, that could not have been thought possible a decade back. AR and VR find application in a wide array of situations, from educating students to planning procedures. AR solution can be very effective in improving the overall patient experience and ensuring that it is less problematic by adding pop-up information and navigating features among other things.

Stroke patients require robust environments to overcome motor deficiencies to improve. However, this presents problems. Here in AR and VR can function to provide enhanced and simulated environments that will allow diverse interactions during physical therapy. Moreover, data gathered using monitoring can assist therapists in devising customized care plans. AR & VR can also allow better communication between doctors and patient's relatives.



Virtual and augmented reality solutions have been one of the important reasons for the advances in healthcare.

IMAGE: PIXABAY

TREND #5: ARTIFICIAL INTELLIGENCE

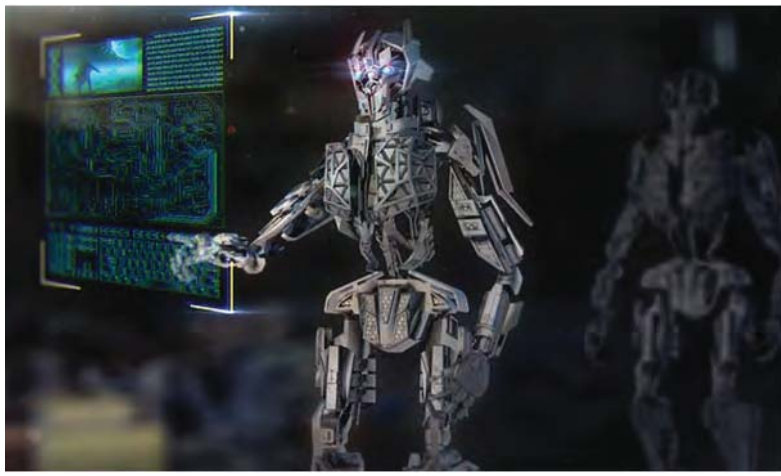
Artificial Intelligence is one of the nascent healthcare technology trends and can make tremendous difference in the field. With AI processing information and providing decision-making data in a way that is similar to what a human does—a whole new sector of innovative health technologies has been born. With AI applications, the speed and accuracy of the diagnosis process can be improved tremendously; and with analytics relevant developments can be identified and practitioners can identify the best possible approaches for early treatment.

Further, artificial intelligence and machine learning technologies can help healthcare professionals derive new insights from the huge data generated during the delivery of healthcare every day. For the medical device manufacturers, this data yields important insights that helps them innovate their products to provide healthcare providers better assistance and thus improve patient care.

TREND #6: CHATBOTS

Chatbots are becoming an integral part of healthcare services. They can be an effective tool for dealing with routine patient queries and help organizations save

IMAGE: PIXABAY



The use of artificial intelligence in the healthcare sector is still evolving.

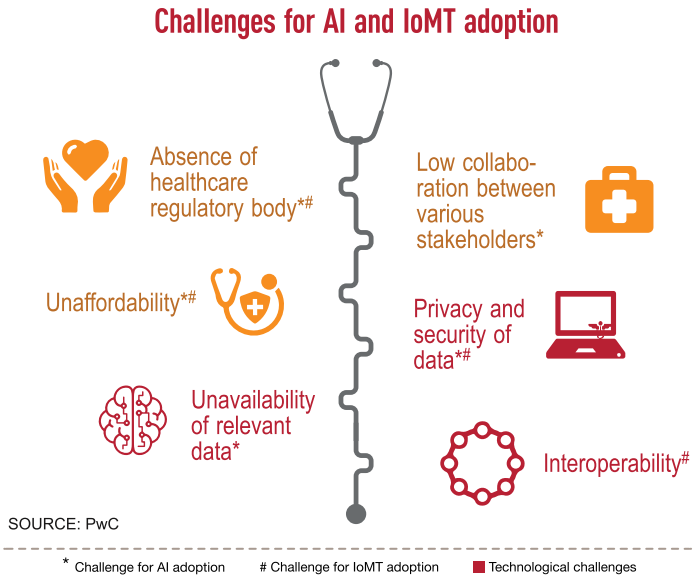


IMAGE: PIXABAY

Chatbots can help free medical practitioners from routine for more important work.

costs. Chatbots can also be an inexpensive and unique networking tool for medical institutions, pharmacies and manufacturers.With chatbots taking on the routine jobs, healthcare professionals and experts would have more time to focus on other urgent issues. Chatbots can also be used to work with elderly patients as assistants to provide reminders about medications and along with technologies, such as analytics and AI, the assistant can even warn about potential drug interactions.

TREND #7: DATA SCIENCE AND PREDICTIVE ANALYTICS

Patient care yields huge information which is a data mine. However, we also need to discover this data and then compress it into something meaningful and actionable. The revolutions in data science and predictive analytics are making these possible and medical practitioners are now getting deeper insights from data. It is now possible for doctors to just feed information from ancestry and family histories into AI-based systems to get statistically grounded profiles of patients and not just diagnose problems faster but also predict them and hence enable preventive actions.

TREND #8: BLOCKCHAIN

Blockchain allows distributing transaction records through a peer-to-peer system and with a shared digital ledger the data can be available to a large number of users while maintaining the integrity of information. The access to the common ledger is secure. In today's scenario where diseases are breaking borders, fostering a combination of security, portability and ready accessibility of data is important for technology trends in healthcare, including IoMT devices and cloud-based hosting.

Source: Secondary research & media reports

IMAGE: PIXABAY

Data science and predictive analytics help in discovery of meaningful patient data.

IMAGE: PIXABAY

Blockchain can allow integrity of information and access to it.

Access to **Safe Drinking Water** is a Human Right

KENT
Mineral RO™
Water Purifiers
HOUSE of PURITY

Make Water
100% Pure
and Protect Your Family from Waterborne Diseases

KENT® TECHNOLOGY
Removes Dissolved Impurities
Retains Essential Minerals
Miltiple Purification
RO + UV + UF + TDS Control

Kent Deta Hai
Sabse Shudh Paani

Insights India: Which Way?

India as an economy is unique. It has different needs from other countries, and it calls for tailored healthcare products for the masses.

IMAGE: PIXABAY

A growing nation has different needs from the developed ones and products must be tailored to meet its unique requirements – be affordable and accessible.

RESEARCH POINTS TO a number of factors propelling the healthcare market in the country. These include growing incidence of lifestyle diseases, demand from the masses for affordable healthcare delivery systems as healthcare costs rise, technological advancements with R&D, telemedicine becoming mainstream and increasing penetration of health insurance. Government further supports the industry through initiatives like e-health and tax benefits and incentives.

The healthcare expenditure over the coming years is expected to grow tremendously and between 2008 and 2022, the market is projected to record a Compound Annual Growth Rate (CAGR) of 16.28%. The total industry size is expected to touch $372 billion by 2022. The hospital industry in India is also expected to grow from $61.79 billion in 2017 increasing at a CAGR of 16-17% to reach $132.84 billion by 2022.

Despite the advances, there is still a significant gap between what is available and what is required in the healthcare infrastructure. This is driving considerable investment into assets like hospitals and other facilities. As healthcare becomes more readily availability and affordable, the demand for other services like diagnostics, pharmacies, equipment, etc., is also seeing a boost.

Several non-healthcare corporates and private equity firms are also infusing capital and non-capital resources into the sector looking at the opportunities there. Medical tourism is also fueling this growth as the cost of procedures in India are low. Many healthcare global companies are setting up their R&D base as India becomes a destination for conducting clinical trials.

In a report on Indian healthcare sector, KPMG has delineated the challenges that the industry faces on its way up. There is an urgent need for industry players to ensure optimal utilization of resources, minimize operational costs, maximize performance and efficiency, scale up the business by adopting latest technology and bring in global standards in healthcare delivery.

By allowing 100 percent FDI through automatic route the government gave a further leg up to the industry. The sector witnessed increase in investment and expenditure from public as well as private investors. Reputed global players began investing in the industry and Foreign Direct Investment (FDI) played a pivotal role in this growth.

According to the IBEF, the rise in investment in healthcare infrastructure will benefit both 'hard' (hospitals) and 'soft' (R&D, education) infrastructure. This will promote the growth of the hospital industry, which will grow at a CAGR of 16-17% to reach $132.84 billion by 2022. The Government of India's aim to increase healthcare spending to 3% of the Gross Domestic Product (GDP) by 2022, will act as a further boost. Estimates by the Department of Industrial Policy and Promotion (DIPP) say that hospital and diagnostic centers in the country received FDI worth $5.25 billion between April 2000 and June 2018.

According to reports, several new specialty and super-specialty hospital facilities are in the pipeline as well as modernization of existing hospitals with both the government and the private sector planning to invest. As of now, there is a huge shortage of healthcare infrastructure, especially in rural areas and smaller towns

Growth drivers

Infrastructure
$200 billion is expected to be spent on medical infrastructure by 2024

Medical tourism
Visas for international patients and attendants introduced to ease medical tourism

Rising disposable income
Growing middle-class and increased insurance penetration would lead to a steep rise in annual earnings of Indians

Demographics
Home-based care services to gain popularity as average life expectancy will cross 70 years by 2022

Health & wellness centres
150,000 centres with a budget of $1.8 billion will make the healthcare system more accessible

Robotic process automation (rpa)
RPA to improve the efficiency of healthcare workforce; reducing costs and creating value proposition

Source: National Investment Promotion and Facilitation Agency of India

Investment opportunities in healthcare

77
Projects

USD 890.39 mn
Opportunity

47
Promoters

69
Districts

6
Private projects

71
Govt. projects

Source: National Investment Promotion and Facilitation Agency of India

Source: India Health (Informa markets)

and cities. It is estimated that by 2025, India will have a projected requirement of 1.75 million new beds. Currently, the hospital services market is valued at $80 billion and accounts for 71% of the industry revenues. It is also among the most important segments of the Indian healthcare industry.

Some of the upcoming hospital projects in the country according to Invest India, the National Investment Promotion and Facilitation Agency of the country are: a $243.74 million project to set up of a 500-bed multi-speciality hospital in Dharamshala; a $139.28 medical equipment manufacturing project in West Sikkim; a $96.52 million super-speciality hospital project in Mumbai; and a $87.75 million medical center project in Guwahati.

Some of the important FDI projects in India are an investment of $ 17.2 million by Japanese venture capital firm SBI Investment, in a Bengaluru-based health-tech AI startup mfine. mfine will use the funds to expand its hospital network across the country and build its AI technology; Amway India is investing up to $4.17 million to ramp up its digital platform; the World Bank is funding 7,500 health centers in Andhra Pradesh; the Aster DM group has plans to invest $59.6 million in Chennai to launch a 500-bed multi-speciality hospital; and Metropolis Healthcare with plans to add 800 centers and ten labs.

Health insurance India's health insurance sector received a major push in September 2018 with the launch of a nationwide health reform called Ayushman Bharat. Ayushman Bharat aims to provide universal health coverage. The government has the task of ensuring that the program is sustainable and delivers high-quality care. According to reports, health insurance is gaining momentum in India. Currently, government health insurance companies cover only 15% of the population, and 2% are covered by private health insurance. There is much scope for penetration of health insurance. Health insurance will also increase the affordability of healthcare services for the masses. Private health insurance companies are tying up with hospitals to provide cashless treatment to their subscribers and this will further boost healthcare industry.

Medical tourism

India's medical tourism industry is poised to grow by 200% by 2020, hitting $9 billion. In 2015, the country ranked as the third most popular destination for medical tourism. At the time the industry was worth just $3 billion. In the same year, the number of foreign tourists coming into the country on medical visas were nearly 234,000. By 2017, the number of arrivals more than doubled to 495,056.

The growth in the medical tourism sector is being driven by the low cost of medical care in the country. India has world-class hospitals and highly skilled medical professionals and this has made it the most preferred destination for patients abroad.

As the healthcare industry proactively works on developing global standards for the medical tourism industry with, it is expected that the sector will get a further boost.

This growth in the medical tourism is encouraging hospitals and hoteliers to forge alliances.

Medical devices & equipment

An important segment of India's healthcare industry is the medical device market. Estimated at around $9 billion it is expected to exceed $14 billion by the end of 2025. While largely import oriented, it is expected that the recent policy reforms will boost indigenous manufacturers and make India an exporter of high quality medical equipment.

The increasing role of technology

Technology is disrupting healthcare sector in India in a big way as an EY report titled 'Life Sciences 4.0: transforming health care in India' highlights. We are at the cusp of the Fourth Industrial Revolution (Industry 4.0 and technological ubiquity and adoption of emerging technologies and tools by healthcare stakeholders will ensure that the industry meets the increasing demand and also improves affordability and accessibility, so that more people can avail healthcare services.

Digital technologies will be the key going forward to improve quality, affordability and accessibility of healthcare solutions. Technology will reshape healthcare delivery across the patient pathway in the country.

Signs of disruption are already visible in the healthcare industry and it is critical the life sciences companies will have to take charge of this change. Industry 4.0 journey of India has begun with some beginning to adopt digital technologies including patient engagement, physician engagement, field force effectiveness, R&D efficiency and supply chain management.

Conclusion

India with its huge population that are still denied healthcare presents a unique opportunity to healthcare players. They only need to ensure that their services are affordable and accessible to the large masses. As different sectors in the industry work on their synergies, this year could be a crucial leap year for the healthcare industry in the country.

Source: Secondary research & media reports

IMAGE: PIXABAY

Only clear regulations will give the industry an idea of what the regal requirements.

REGULATE MEDICAL DEVICES

A separate law to regulate medical devices industry is long overdue.

By Nikhilesh Tiwari

ACCORDING TO A recent survey conducted by Anna University, only one in five ventilators used in hospitals across Tamil Nadu has been certified safe for use by biomedical engineers. Further findings from the survey showed that at least 35% of the medical equipment used in hospitals did not pass calibration tests.

While we do not have concrete data on complications and deaths caused by malfunctioning equipment, it is not hard to imagine a scenario where treatments are prescribed based on faulty readings, leading to catastrophic consequences. This scenario is all too common in states across the country, and the lack of a regulatory framework for medical devices is the main reason behind this laxity.

Niti Aayog's proposal to institute a separate regulatory body for medical devices was long overdue as per many industry associations.

While the industry awaits the full draft of the 41-page document to be uploaded in the public domain, people in the medical device manufacturing industry have been expressing their desire for central regulatory provisions for quite some time now. Any regulatory provision, if implemented correctly, it will give the industry a clear idea of the legal requirements they have to follow in a centrally regulated market.

Even as Ayushman Bharat successfully completes a year, the medical devices industry is still at a nascent stage. However, the National Health Protection Scheme has led to an increase in the patient pool as well as bed capacity, and the medical devices industry is set to be one of the biggest beneficiaries, especially categories like instruments and equipment, and disposables and consumables.

The shift in disease burden also means that certain categories, like diagnostic equipment, will witness a greater growth than others. If the scheme is implemented effectively, we can expect a compound annual growth rate of at least 30% over the next three years.

At present, India imports over 80% of its medical devices and the government has stated its intention to make India one of the global hubs for medical devices manufacturing and distribution. This move will attract investors, both Indian and overseas, as the lack of predictability has been one of the biggest factors holding back investment in local manufacturing.

It will also help patients who suffer from health problems caused by faulty medical devices and implants get the compensation they deserve.

According to the Ministry of Health and Family Welfare, medical devices are regulated under the Drugs and

Cosmetics Act of 1940 and Medical Device Rules 2017. The industry is awaiting an official announcement to migrate to an independent Medical Device Act. If the government is intent on regulating medical devices under a separate regulatory body, then it has to fast track implementation. It should quickly announce so and remove the confusion in this matter.

It will be beneficial for everybody in the healthcare ecosystem to have clarity on future regulation. Manufacturers will be able to obtain licenses under a streamlined framework encouraging local manufacturing and reducing the costs incurred on imports, more hospitals will be able to procure them and improve their infrastructure, and patients will be able to benefit from better diagnoses and treatments, helping us move closer to achieving universal health coverage in line with the United Nations' Sustainable Development Goals.

It is equally important to ensure that the regulatory body has competent bio-medical engineers, technocrats, scientists, lab technicians, clinicians, and surgeons on its panel.

The range of medical devices is quite vast, and they must not be seen through the lens of Drugs & Cosmetics as medical devices do not have any systemic effect/ pharmacological actions. Improper implementation can have adverse consequences. Lack of regulation allows unscrupulous manufacturers to take advantage of the loopholes and end up manufacturing low-grade equipment, which will end up worsening the state of healthcare.

To play it safe, the government can start by experimenting with just a handful of new devices in the market and see if the transition is smooth. Meanwhile, it can go about seeking the expertise of the players in the industry to draft the bill. Once the bill is drafted and approved by the stakeholders in the ecosystem, it can be passed in parliament. This will ensure that the regulatory environment is fair and strong, encouraging positive growth in the industry bolstering the government's Make in India campaign.

(The writer is the Founder and Director ColMed)

(The article was first published in https://www.deccanherald.com/. Reprinted here with author's permission.)

सत्यमेव जयते

DEPARTMENT FOR PROMOTION OF INDUSTRY AND INTERNAL TRADE MINISTRY OF COMMERCE AND INDUSTRY GOVERNMENT OF INDIA

DPIIT has set up a control room to monitor in real time the status of transportation and delivery of goods, manufacturing, delivery of essential commodities to common man and the difficulties being faced by various stakeholders during the lockdown period from 25.3.2020 to 14.4.2020. In the event of any manufacturing, transporter, distributor, wholesaler or e-commerce companies facing ground level difficulties in transportation and distribution of goods or mobilization of resources, the same may be informed to the Department at the following telephone number/ email:-

Telephone: + 91 11 23062487
Email: controlroom-dpiit@gov.in

The telephone number will be functional from 8 AM to 6 PM. The issues reported by various stakeholders will be taken up by the Department with the concerned state government, district and police authorities, and other concerned agencies.

SOURCES / REFERENCES

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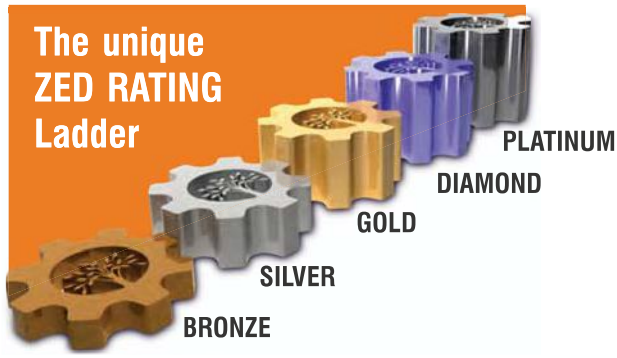

HIGHLIGHTS

- A scheme by Ministry of MSME, Govt. of India
- Certification on the systems and processes of MSMEs
- Handholding MSMEs towards world class manufacturing
- Special emphasis on MSMEs supplying to Defence Sector
- Direct subsidy to participating MSMEs
- Creating a credible database of MSMEs for OEMS/CPSUs/Foreign Investors under "Make in India initiative"
- Quality Council of India (QCI) to function as the NMIU (National Monitoring and Implementing Unit) of the scheme

"Let's think about making our product which has 'Zero Defect'; so that it does not come back (get rejected) from the world market and 'Zero Effect' so that the manufacturing does not have an adverse effect on our environment"

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