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THE AWARE CONSUMER

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Consumers Demand Exclusive Law for Medical Devices in India

GOVERNMENT PERSPECTIVE
Evolution of The Regulatory Apparatus for Medical Devices in India

HORIZON
Medical Devices Policy 2023 – An Ambitious Vision for Make-in-India Future!

INTERVIEW

K.L. SHARMA
A civil servant of four decades standing

PLUS ROUND UP • RESEARCH FEATURE • MY MARKET

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NABL Accreditation of Medical Laboratories

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VIEW  POINT

MESSAGE FROM PUBLISHER & EDITOR

Medical Devices are Not Drugs – They Need a Separate Act!

THERE WERE TALKS of tabling the Drugs, Medical Devices and Cosmetics Bill, 2023 in this year's monsoon session of the Parliament. Every time such a draft proposal comes up in the public domain, there are vociferous demands for a recall from various quarters. Arguments start revving up calling for a separate legislation for medical devices. And it's not just medical device manufacturers alone, but healthcare institutions, patient interest groups and patients themselves have voiced the need for fresh discussions…..

It cannot be denied that medical devices are as indispensable for healthcare delivery as drugs. Every instrument, apparatus, machine, implant, software, etc. that is used for a medical purpose plays a crucial role in diagnosing, preventing, treating or monitoring diseases, illnesses and other ailments.

That these devices cannot be grouped under the same umbrella as drugs is food for thought for sure! After all, as the World Health Organisation (WHO) estimates, there are around 2 million different kinds of medical devices on the world market, categorised into more than 7000 generic devices groups.

Alas, the change that seemed to be on the cards is put on the backburner once again. And meanwhile the archaic, 83-year old regulation – circa 1940 - continues to hold sway over drugs and medical devices in more or less the same fashion. Yes, the new bill was touted as a comprehensive legislation with provisions to regulate medical devices, but it cannot hold a candle to a separate law, can it?

It should be noted here that the government think tank, NITI Aayog too criticised this flawed approach and a Parliamentary Standing Committee itself recommended having a distinct legislation and regulator for medical devices.

What the country, its consumers and the patients need is a progressive, modern and separate law that addresses patient safety concerns in toto. The right approach will be to involve all stakeholders and take their considered opinions into account. Only then can access to good quality, safe, appropriate and affordable medical devices become a reality and pave the way for universal health coverage!

Prof. Bejon Kumar Misra
Publisher & Editor
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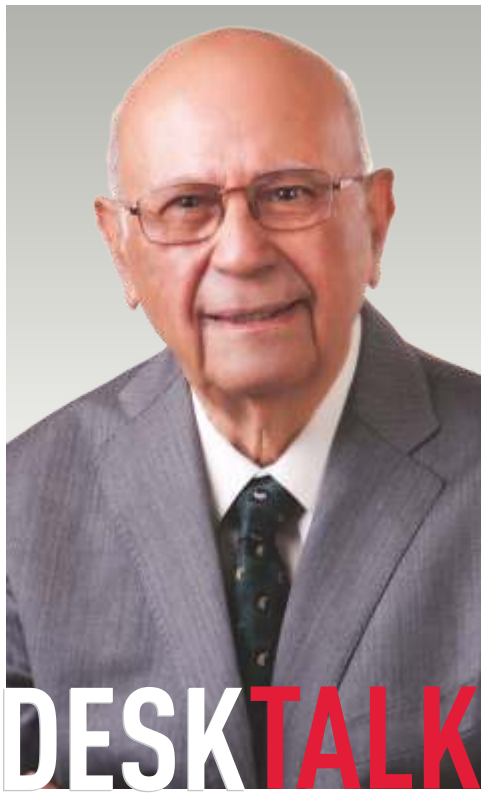


CAN WE REALLY ACHIEVE A MAKE-IN-INDIA FUTURE FOR MEDICAL DEVICES?

DESKTALK

THE PROBLEM IS not just about medical devices being subject to a regulatory framework based on drug regulations. Another pressing issue is that patient safety aspects are being overlooked!

The COVID-19 situation was a wakeup call on the severe challenges presented by shortage of priority or basic medical devices. Similarly, the infamous episode of faulty hip implants by a pharmaceutical giant laid bare the limitations of the Drugs Act and the Drugs Controller who was handicapped to discipline overseas manufacturers.

It is heartening that all medical devices have been moved into a licence regime in a phased manner. Prices of certain medical devices are also being regulated by the National Pharmaceutical Pricing Authority (NPPA). However, it boggles the mind as to why the health ministry remains unsure about bringing in a separate law even after the publication of implant files by the International Consortium of Investigative Journalists and the recent ban on pelvic mesh by the US Food and Drug Administration. For that matter, why does it neglect the medical devices sector and disregard the needs of the manufacturers?

The new Medical Devices Policy released in May finally seemed like a step in the right direction that will create an ecosystem of strategies and facilitations to promote the growth of India's medical devices sector and showcase its competence to the world.

Alas, the government quickly burst the balloon by permitting the import of second-hand high-value medical devices for re-use in the country. This comes at a time when patient safety groups are already worried about the implications of uninhibited repair and reuse of domestic medical devices.

Don't the authorities realise that this move will make India a dumping ground for outdated and risky medical devices, not to mention derail the Make-in-India initiative? There are no two ways about it – medical devices needs a separate legislation to protect and promote the industry on the one hand and safeguard the users on the other. Rather than riding on a toothless framework, the government should take a targeted approach by engaging in an effective dialogue with the stakeholders to understand the unique and complicated issues of the medical device industry before drafting a new legislation. This will pave the way for a robust and dynamic regulatory system that will ensure development of safe and efficacious medical devices in India, that will be globally reliable as well as lead to tremendous improvement in public health!

INSIDE

THE AWARE CONSUMER NOVEMBER 2023

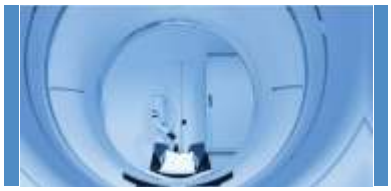
REGULARS

Medical devices, like drugs, are used worldwide. The pervasive use makes appropriate, constant and distinct regulation essential.

The medical devices industry in India is a sunrise sector - it is growing at a fast pace and has become an essential component of the healthcare industry.

K.L. SHARMA
A CIVIL SERVANT OF FOUR DECADES STANDING

The ongoing strong impetus to boost manufacturing of medical devices in the country has been derailed by a recent order to permit import of pre-owned and refurbished medical devices.



We rely on medical devices to maintain and improve our health and well-being.

Ensuring the safety and quality of any medical device is the duty of the manufacturer/distributor and the right of the consumer.

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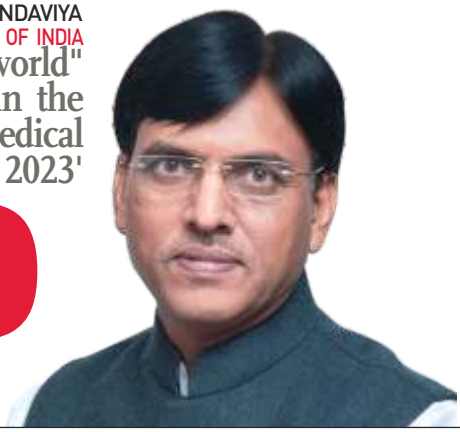
MANSUKH MANDAVIYA
MINISTER OF HEALTH AND FAMILY WELFARE, GOVERNMENT OF INDIA

India has been recognised as the "pharmacy of the world" and it is now time for India to become the leader in the manufacturing of affordable, innovative and quality medical devices" – Mansukh Mandaviya at 'India MedTech Expo 2023'



ROUNDUP

Delhi High Court Upholds Inclusion of Medical Devices as Drugs under Drugs Act

THE SURGICAL MANUFACTURERS and Traders Association (SMTA) filed writ petitions in the Delhi High Court challenging the government's notifications in 2018 and 2020 – the former declaring four specific medical devices as 'drugs' and the latter extending this classification to encompass all medical devices under the Drugs and Cosmetics Act.

The Association is a registered society representing over 400 members that manufacture and trade in surgical, medical, hospital and healthcare equipment and supplies both within India and those imported into the country.

In September this year, the Delhi High Court categorically rejected the said petitions. A bench chaired by Justice Rajiv Shakdher firmly upheld the government's stance by stating that deeming medical devices as 'drugs' falls within the realm of a policy decision. It contended that

DATA BRIEFING

While India's medical device industry has grown at a steady 14%–15% annually for most of the last decade, it only accounts for 1.5% of the global market.

there is no compelling reason for judicial interference due to the absence of arbitrariness or unreasonableness in this 'calculated policy decision'.

The bench, also comprising Justice Tara Vitasta Ganju, stated, “In its wisdom, the Ministry of Health and Family Welfare deemed it appropriate to bring all medical devices under the regulatory framework of the expression drug. The ministry had multiple reasons for this policy shift, including aligning with international regulatory norms and safeguarding patient interests.” It was also mentioned that unless there is a clear violation of fundamental rights, mere errors in a robust policy designed with patient safety in mind cannot be overturned through judicial review.

However, the court did acknowledge the need to address certain issues in the implementation of the regulatory regime for medical devices and encouraged the relevant authorities to promptly resolve any hiccups encountered during the transition.

Even as the aggrieved SMTA plans to appeal in a higher court for review of the decision, the Association of Indian Medical Device Industry (AiMeD) supports the ruling that the government has the right to define the policy. It can temporarily regulate medical devices as drugs as a policy decision to safeguard the patients.

The latter are themselves seeking regulations for medical devices in the interests of patient safety. However, rather than take legal measures - as the earlier assurances of a separate law were not implemented - AiMeD prefers to engage in a dialogue with the policymakers to communicate their concerns about medical devices being branded as drugs and seek course correction. They want the government to be progressive and use its wisdom to regulate medical devices separate from drugs!

Medical Technology Expo Charts India's Path for Becoming a Worldwide Centre for Medical Devices

INDIA'S FIRST MEDICAL technology expo, 'India MedTech Expo 2023', was organised in Gandhinagar, Gujarat from 17-19 August on the sidelines of the G-20 Health Ministers' Meeting. The three day expo - spearheaded by the government in association with the Indian medical devices industry - showcased the capabilities of the domestic industry with opportunities to network and explore collaborations both for the sector's growth in India and its potential contribution globally.

While inaugurating the event, Union Health Minister Dr Mansukh Mandaviya informed that the MedTech Expo 2023 draws inspiration from PM Modi's vision of making India Aatmanirbhar. This was an unparalleled and comprehensive platform for demonstrating the capabilities and promise of the Indian Medical Devices ecosystem.

While the health ministry was gung-ho about the forthcoming changes in the field of medical devices influenced by ongoing technological advancements, miniaturisation of devices, incorporation with the Internet of Things (IoT), 3D printing, and customised medical devices, the industry took the opportunity to air its concerns about the new Drugs, Cosmetics and Medical Devices Bill on the same forum. Mr. Rajiv Nath, Managing Director, Hindustan Syringes & Medical Devices Ltd and Forum Coordinator at AiMeD stated, “From being Atma Nirbhar in terms of medical devices, effective management of e-waste, affordability and quality, creating of direct and indirect job opportunities to completely reduce our dependence on imports – the adoption of Bill will leave behind an array of multifaceted repercussions, ultimately ensuring that Make in India campaign derails much to the delight of entrenched overseas MNCs and their aficionados in the country, only those who are seriously committed to Make in India are equally concerned as us domestic manufacturers”.

Uttar Pradesh Launches Pharmaceutical and Medical Devices Industry Policy, 2023

THE UTTAR PRADESH government released its Pharmaceutical and Medical Devices Industry Policy, 2023 in August. To promote ease of doing business, the State will have a single window clearance system, directly monitored by the Chief Minister's office. Approvals and permits will be made assured through the regulations to ensure time bound clearances, timely delivery of services and more. Additionally, it provides for pre-consultation of project plan by the regulator and a dedicated technical advisory body for guidance and support.

Under the policy, the government also envisages supporting horizontal pharma and medical devices parks, which are private parks developed over minimum of 10 acres with at least five units and 60% of which is allotted to the entrepreneurs; vertical pharma and medical device parks which are private parks developed like a tower or group of towers on minimum area of 3 acres of land, with at least three units and 60% of which is allotted to entrepreneurs.

The policy intends to identify land parcels and develop parks, for manufacturing allopathic, Ayush products, medical devices and key starting materials and drug intermediates used in bulk drug manufacturing. The impetus is to create manufacturing giants to compete global standards in the international market through mega projects with opportunities for ancillaries, downstream and SME units.

"The new policy aims to improve the state's pharmaceutical and medical device industry by encouraging local production, promoting research and development, and improving the availability of affordable medicines to citizens."

–Dr. G.N. Singh, ex-DCGI, Advisor to the Chief Minister of UP and one of the primary architects of the policy

Vizag's MedTech Zone – Saving Lives, Serving the Nation!

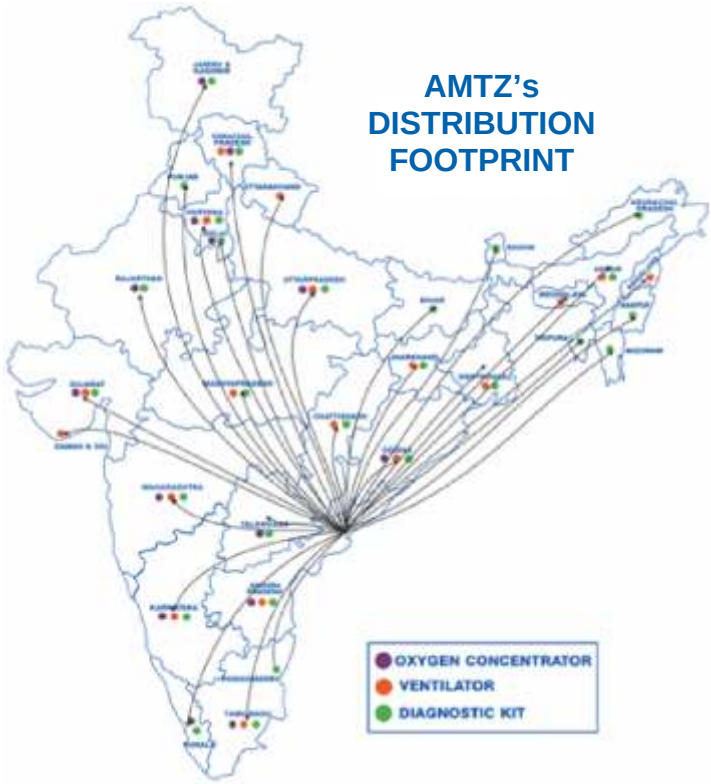
THE COVID-19 PANDEMIC had led to severe shortages of many essential goods and services - from N-95 masks and diagnostic tests to medical oxygen and ventilators. The shortage of lifesaving equipment and other essential supplies had flagged serious concerns about preventing the spread of coronavirus and assisting affected patients. While the crisis had placed these unparalleled demands, the pandemic also provided means to strengthen the healthcare industry with opportunities for innovation and cost efficiencies. There were individuals and organisations that responded with resilience, rose to the occasion and matched the needs and beyond.

To tide over the crisis, the solution was a rapid escalation of manufacturing. This was to be done at a time when prominent economies around the globe had enforced a total lockdown, disrupting global production and supply chain systems.

The Andhra Pradesh MedTech Zone (AMTZ) in Vizag, an established medical technology manufacturing ecosystem, had all that it takes to make it happen and rose to the occasion. The Common Scientific Facilities (CSFs) & Common Manufacturing Facilities (CMFs) - which include specialised laboratories, warehousing and testing centres - that were pre-existing in the campus was an added advantage for the mission AMTZ had committed to.

AMTZ

AMTZ's DISTRIBUTION FOOTPRINT



The key USP of the campus are its Common Scientific Industrial Laboratories/Centers such as the Center for Electromagnetic Compatibility and Safety Testing, Center for Biomaterial Testing, Center for 3-D Printing, Centers for Lasers, MRI Coils, Gamma Irradiation, Moulding and many other industrial service centers.

When the COVID-19 outbreak happened, there were no standard specifications for the essential products for the fight against the pandemic. India was majorly dependent on imports for ventilators, PPE kits, N-95 masks. Today, when the nation has emerged as the second-largest PPE manufacturer in the world and grew self-sufficient in ventilators and N-95 masks, the role played by AMTZ has been unique and crucial.

AMTZ contributes by producing over a million diagnostic kits every day which is a mammoth capacity. While container hospitals and mobile diagnostic labs are manufactured every week, this single campus can produce over 100 ventilators, 500 oxygen concentrators, 1 lakh N-95 masks, 5000 PPE kits and 10 lakhs RT PCR kits in just a day.

However, the real strength of AMTZ is not just products for the pandemic, but a broader ambit of the healthcare value chain. For example, AMTZ also makes superconducting magnets for MRI and multiple other medical care products. Led by the Department of Biotechnology as part of Command Strategy, AMTZ aims to produce over 10,000 crores worth of medical equipment per annum. That's almost 25% of India's import dependency. Under the DBT AMTZ Command Center, over 10 crore RT PCR kits and thousands of ventilators are produced and supplied to states across India, and also to other countries dependent on Indian supplies.

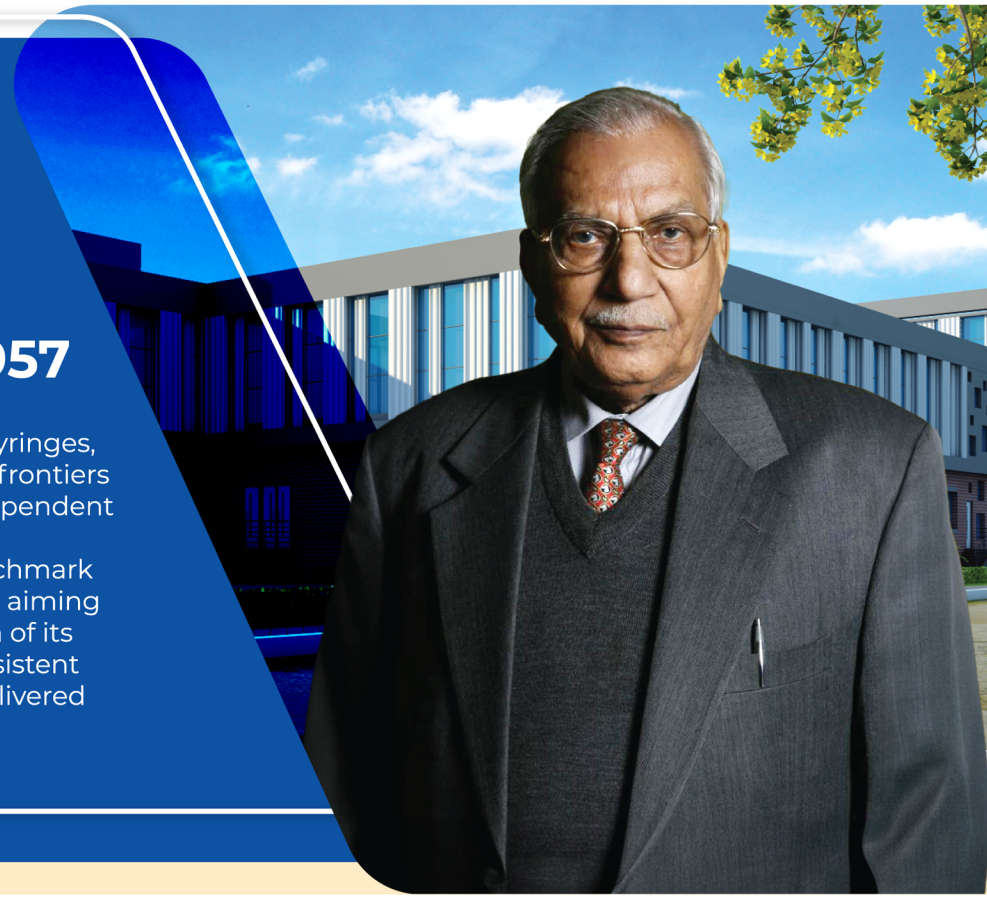
Another initiative, a mobile diagnostic unit: I-Lab (Infectious Disease Diagnostic Lab) with a biosafety facility capable of RT PCR, ELISA and 30 more tests was introduced to ensure ease of testing in rural areas. Ventilators and oxygen concentrators were manufactured round the clock in the zone to ensure the availability of these critical medical devices for treatment. Container hospitals were built in the zone to ensure the availability of beds during crucial times. Over 20 states in India use ventilators manufactured at AMTZ.

In the recent past, when access to oxygen was one of the key challenges this country was facing, AMTZ introduced the pan-India affordable oxygen concentrator rental program called O2Home. An app available on Android and iOS platforms enables its users to rent oxygen concentrators on a per-day basis. AMTZ partnered with Uber to ensure the last mile delivery of oxygen concentrators. Uber's extensive mobility network ensures oxygen support is delivered to every home swiftly and efficiently. The service is now available in 25 cities across India.

"Medical Technology has become a sector that has survived the uncertainties of economic turbulence as well as showcased its lifesaving capacity for social good. AMTZ stands tall today by virtue of its servitude to the country in protecting the health of people by supplying affordable, accessible and good quality products across multiple states, hospitals and geographies. We remain committed to deliver independence from import dependency and make India a proud leader in medical technology development and production."

- Dr Jitendra Sharma, MD & CEO, AMTZ

Late Mr. Narindra Nath,
Founder, Hindustan Syringes and Medical Devices Ltd.



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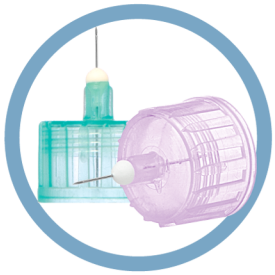

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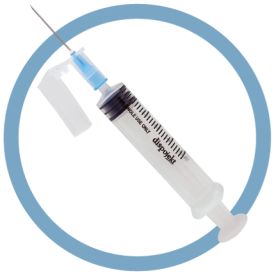

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Consumers, Beware

New Drug Bill Not Suitable for MEDICAL DEVICES

The government has proposed a new and more comprehensive legislation for drugs, cosmetics and medical devices. However, ensuring quality, safety, reliability and efficiency of medical devices for the consumers still calls for a separate Act. A distinct comprehensive regulatory framework can bring about a medical device revolution in the country!

Medical devices are a far cry from drugs; they cannot be governed by the same regulations! Food is considered different from drugs and has its own dedicated regulator...so why not have a separate body for medical devices too?

THE MANUFACTURE, IMPORT and distribution of all medicinal drugs and cosmetics in India is governed by the Drugs and Cosmetics Act, 1940. Medical devices do not have a separate legislative framework and are regulated as one of the four categories of 'drugs' under the same Act.

However, this pre-independence law has long outlived its utility. The 83-year old legislation is riddled with loopholes, drawbacks and obsolete protocols that keep us out of sync with modern developments to the extent of impinging on consumer health and safety. Moreover, the usage and complexity of medical devices has changed drastically, which is not reflected in the said regulation. The government is finally attempting to review and modernise the archaic Act.

A Medical Device Technical Advisory Group (MDTAG) was constituted in September 2021 - under the aegis of the union health ministry and led by the DCGI - to bring in medical devices regulations. However, the ministry, instead of using MDTAG, reconstituted a new committee of regulators to draft a new Drugs, Cosmetics and Medical Devices bill. The draft bill was posted on the Ministry's website in July of last year and received around 900 comments and suggestions.

"The bill seeks to regulate the import, manufacture, distribution and sale of drugs, medical devices and cosmetics; and ensure their quality, safety, efficacy, performance and clinical trial of new drugs and clinical investigation of investigational medical devices and clinical performance evaluation of new in vitro diagnostic medical device including AUSSH drugs, medical devices and cosmetics with the objective of highest possible regulatory standards and a transparent regulatory regime and to repeal the Drugs and Cosmetics Act, 1940."

Some of the pertinent proposals – apart from new provisions for clinical trials, online pharmacies and Ayush sector – are:

- Separate Medical Devices Technical Advisory Board (MDTAB) - consisting of medical professionals and specialists from various associations with technical knowledge of the devices - to advise the central and state governments on technical matters related to medical devices
- Drugs, Medical Devices and Cosmetics Consultative Committee (DMDCCC) to advise the concerned authorities on matters tending to secure uniformity in administration of the proposed Act
- Separate medical devices testing laboratories and medical devices testing officers (on the lines of the network of drug testing laboratories)

Medical devices get a more comprehensive definition - bringing under its ambit diagnostic equipment and their software, implants, devices for assistance with disabilities, life support systems, instruments used for disinfection, and any reagents or kits. In other words, medical devices will be regulated as a distinct category, placing them outside the purview of 'drugs'.

Medical devices are currently regulated by a byzantine system of regulations. The nodal agency is the Ministry of Health, but the Ministry of Chemicals and Fertilizers is also involved in certain aspects. In case a device has electronics or batteries, the Ministry of Electronics and Information Technology comes into the picture while any radioactive element will require approval from the Atomic Energy Regulatory Board. In some cases, the Department of Animal Husbandry and Dairy may need to provide approval.

Chapter VI of the new bill is dedicated to import, manufacture, sale, distribution and clinical investigation of medical devices.

Rationale for Seeking Recall and Fresh Deliberations

The New Drugs, Medical Devices and Cosmetics Bill, 2023 was scheduled to be tabled in this year's monsoon session of the Parliament.

However, domestic medical device manufacturers, patient interest groups, users and hospitals made a joint plea to the Union Health Minister, Dr Mansukh Mandaviya articulating their concerns and seeking a recall of the Bill. They submitted a letter calling for a consultation meeting with a fresh committee under the chairmanship of Indian Council of Medical

GEARING UP FOR THE CHANGE

Drugs and Cosmetics Act, 1940

- Director General of Health Services (DGHS)
- Drugs Controller General of India (DCGI)
- Joint Drugs Controller India (JDCI)
- Deputy Drugs Controller (DDC)
- Assistant Drugs Controller (ADC)
- Drugs Inspector

Drugs, Medical Devices and Cosmetics Bill, 2023

- Director General of Health Services (DGHS)
- Drugs and Medical Devices Controller General

Controller General Drugs	Controller General Medical Devices
Joint Controller Drugs	Joint Controller Medical Devices
Deputy Controller Drugs	Deputy Controller Medical Devices
Assistant Drugs Controller	Assistant Medical Devices Controller
Drugs Control Officer	Medical Devices Control Officer

WHAT THE MOVES MEANS

- Medical devices will be dealt with in a manner distinct from drugs
- Specific provision for recall of drugs and medical devices
- Creation of quasi judicial authorities to adjudicate certain minor offences
- Provisions related to powers to prohibit, restrict sale of drugs, cosmetics, med devices through online route

Research/Department of Science and Technology/Department of Biotechnology and key stakeholders for discussing their feedback and suggestions before finalising the draft bill and submitting to the Parliament.

They argued that the revised definition of manufacturer .will allow a marketing company to get a manufacturing licence and, thus, inadvertently legalise pseudo manufacturing of low-quality cheaper imports that may affect patient safety. The proposal of a central medical device testing laboratory was questioned as one laboratory in a single location to do bio-compatibility testing, animal studies and testing, mechanical and chemical testing or electronic component and product testing for over 6,000 types of medical devices may not be practical.

Additionally, it is presumed that the proposed bill will operate in conjunction with the Medical Devices Rules (MDR), 2017. However, there is no mention of updating the latter in tune with the provisions of the draft bill. Passing the bill without appropriate transitory provisions that offer clarity on the alignment with the MDR can create still more uncertainty!

Call for Separate Legislation

Above all, the medical devices industry was disappointed that the bill does not propose an independent regulatory regime for medical devices (as promised earlier) and continues the current practice of treating devices as drugs. It has reiterated its long-standing demand for a separate 'Medical Devices Act', different from the one meant for drug regulations along with a separate statutory body for regulating medical devices.

"Medical devices are not drugs and in the past a few of them were incorrectly regulated as drugs until the introduction of Medical Devices Rules in 2017. But even then, medical devices rules came under the Drugs and Cosmetics Act 1940, which will now be replaced by the proposed Bill. We strongly call for separate, simple and implementable regulations for medical devices. The law needs to be 'civil' in nature, as in the case of FSSAI (Food Safety and Standards Authority) regulations or as international Medical Device regulations like the one followed by Canada, EU, Brazil, Saudi Arabia, Japan, etc.," says **RAJIV NATH,** forum coordinator, Association of Indian Medical Device Industry (AiMeD), one of the signatories to the letter.

Indeed, Mr. Rajiv Nath has repeatedly reinforced that medical devices are very different from drugs and cannot be regulated by the same law, "We need to understand that devices are not drugs. Devices are engineering items and not medicines - an X-ray machine by no stretch of the imagination can be called a drug and, so, continued attempts to regulate devices as drugs is illogical and incorrect unless assured that it is a temporary measure."

In his words, "Given the distinct differences between medical devices and drugs, regulatory authorities need to take a unique approach to the regulation of devices, one that focuses on balancing the evaluation of safety and efficacy with innovation, rather than adopting the models of rigorous assessment that are used for drugs."

He also reiterates, "The parking of MDR 17 under Drugs Act as a drug

was a known temporary makeshift measure and what's needed in the long term is medical devices specific regulations (as was assured to us) as well as a separate regulatory framework as stated in National Health Policy 2017."

Even the Vidhi Centre for Legal Policy (an independent think-tank doing legal research to make better laws and improve governance for the public good) makes valid arguments in its submission to the MoHFW regarding the new bill, "This is a serious missed opportunity to create a dedicated regime for the regulation of medical devices, which are wholly different in nature from drugs and require specialised expertise. Although medical devices have traditionally been regulated as an afterthought to drugs, they present very different regulatory challenges. Unlike drugs, they do not have active ingredients (although there are devices like pain control pumps that might deliver agents that have pharmacological action). While many devices might require complex surgery before they can be implanted, the standards that apply to surgical procedures are not meaningful in regulating the manufacture of the devices themselves. With the increasing use of artificial intelligence in the prediction and prognosis of medical conditions, solely medical expertise is no longer relevant in judging the effectiveness of medical devices. Again, unlike drugs, they do not disappear when they are used, instead, an important aspect of their safety depends on the manner in which they are maintained and serviced."

Medical Devices Rules – A Stop-Gap Arrangement

With all medical devices now being brought into the fold of regulation, it should pave a new path in the field of medical devices. However, does defining them as drugs and extending the same laws make sense? For that matter, is it prudent to create a regulatory framework out of notifications and rules? The Medical Devices Rules ultimately have to be in conformity with the principal drug

AiMeD had earlier written to the Prime Minister requesting him to change the name of the Department of Pharmaceuticals (DoP) to Department of Pharmaceuticals & Medical Devices or to have a separate Department of Medical Devices.

legislation. This has made them just a piecemeal reform that has only partially improved the situation.

For instance, the Medical Device Rules lack penal provisions as the ministry only has the authority to create rules and not new offences or penalties through its rule-making authority. Even though the Drugs and Cosmetics Act contains a penal provision for the manufacture of sub-standard drugs, it cannot be extended to manufacturers of poor-quality medical devices because the Second Schedule to the Act covers only pharmacopeia for drugs.

Sans any penalties or prosecution for poor-quality medical devices, the manufacturers can never be prosecuted for their negligent/ intentional wrongdoings. All that the regulatory authority can do is prohibit the manufacture and sale of certain medical devices or cancel a license. But how will they be held accountable for the harm already inflicted on patients? The infamous Johnson & Johnson hip implant debacle is a sore case in point where the international behemoth could easily exploit our regulatory deficits. The looming regulatory vacuum essentially handicapped the authorities while letting the offender get away scot-free!

Moreover, owing to the poor surveillance and lack of political will, defective products will be recalled from foreign markets while continuing to be marketed in India. Come to think of it, will the Indian industry ever be able to cater to and compete in the global markets?

Finally, can we deny that patient safety is a far more complex issue with medical devices where the same are a shared responsibility of the manufacturer, medical practitioner, product user and the regulator?

Final Words

The new bill is a welcome step forward in revamping the antiquated regulations for drugs and cosmetics that definitely needed a major overhaul. However, whether the new legislation is suitable for medical devices is another question altogether!

Many pharmaceutical associations are of the view that the medical device industry has been repeatedly blocking attempts to update the drugs bill since the past two decades which is hurting the pharma sector. The irony here is that the medical industry itself is asking for more regulations, but the government seems to be refusing to listen. Why does it insist on tagging medical devices with drugs when the former are clearly a misfit for the Bill? **Can we expect the policymakers to be progressive and use their wisdom to regulate medical devices separate from drugs as done by other advanced countries?**

Unique International Regulations for Medical Devices Ensure Effective Healthcare!

Medical devices, like drugs, are used worldwide. The pervasive use makes appropriate, constant and distinct regulation essential. Many developed countries have stringent and well-respected regulatory processes. However, proper health technology assessments are rare in developing countries. Most of them have hardly any regulatory controls to prevent the import or use of substandard devices. The lack of legislation also impacts their access to high-quality devices and equipment that are appropriate for their specific epidemiological needs.

MEDICAL DEVICES ARE both ubiquitous and indispensable for the delivery of healthcare. They are used in everything from common medical interventions to complicated surgical procedures – be it bandaging a sprained ankle, detecting cancer, performing heart surgery or implanting an artificial hip. In fact, resolving debilitating and life-threatening health conditions would not be possible without the use of medical devices.

A medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose. It covers diagnostics and equipment.

Medical devices are defined as 'devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals'.

Therefore, everything from simple or low-risk items like band aids, thermometers, syringes, tongue depressors, bed pans and catheters to complex, high-risk devices like stents, pacemakers and prosthetics to sophisticated diagnostic apparatus like MRI machines and CT scanners come under the umbrella of medical devices. Even walking sticks, contact lenses and breast implants are considered as medical devices.

It is medical devices like masks, gloves, personal protective equipment and diagnostic tests that enabled the world to control the unprecedented COVID-19 pandemic to a great extent!

The use also varies a lot – from preventing, screening, diagnosing and treating a disease or illness to monitoring the treatment, facilitating rehabilitation and even serving as patient aids.

Even the settings of use are pretty diverse - by paramedical staff and doctors in clinics, inpatient/outpatient facilities and intensive care units in hospitals to specialised opticians and dentists to palliative care to even by laypersons in our homes.

Need for Regulation

It follows that anything that is used for a medical purpose has a potential risk for patient safety as well. In fact, the more complicated the device, more significant will be the health hazard. This is why they must have reasonable assurance of safety and effectiveness before being marketed or used by anyone.

The mind-boggling advances in medical technology and material science has completely transformed the landscape of medical devices over the past few decades. It has become much more complex and crucial as well!

This sets the stage for regulation by the government for good manufacturing practices, registration, device listing, labelling requirements, classification, certification, pre-market notifications, reporting of adverse effects, etc. Everything from quality assurance in manufacturing to marketing and post market surveillance is crucial here.

With the rising use of artificial intelligence and IoT in medical devices that can be controlled remotely and even transmit health information from the patient's body to the healthcare professionals, security and privacy issues are also coming to the fore.

The WHO Angle

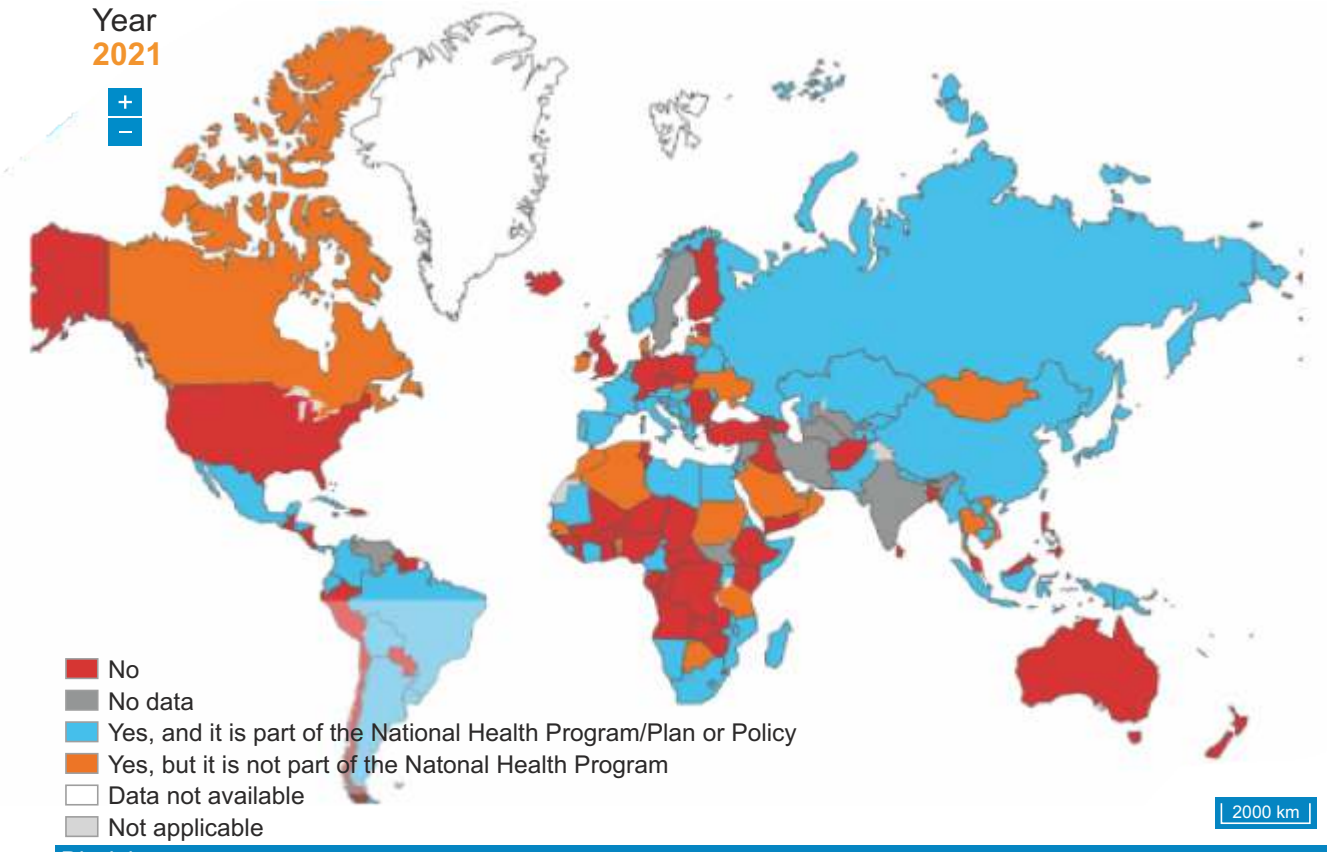
Recognising the important role of health technologies for a well-functioning health system, the World Health Assembly adopted a resolution in 2007 to support member states in achieving WHO's strategic objective, "to ensure improved access, quality and use of medical products and technologies". It states that medical devices in particular are crucial in the prevention, diagnosis and treatment of disease as well as patient monitoring. For this, the WHO Medical Devices and In Vitro Diagnostics Team devised the WHO Medical Devices Technical Series - a series of publications intended to increase access to medical devices.

Another 2014 resolution recognised that medical devices are indispensable for healthcare delivery, but that their selection, regulation and use present enormous challenges, especially for low- and middle-income countries. To increase access to appropriate, safe, affordable and effective medical devices of quality for all, the WHO formed the WHO Global Fora on Medical Devices. It provides member states with WHO resources related to policy, regulation, nomenclature, selection and management of medical devices.

WHO also publishes global lists of Priority Medical Devices to help improve access to suitable medical devices, increase safety, support quality of care and strengthen healthcare systems.

WHO has a mandate "to encourage member states to draw up national or regional guidelines for good manufacturing and regulatory practices, to establish surveillance systems and other measures to ensure the quality, safety and efficacy of medical devices and, where appropriate, to participate in international harmonisation". It upholds that regulation will enable patient access to high quality, safe and effective medical devices, while curtailing the use of unsafe products. The WHO 'Global Model Regulatory Framework for Medical Devices Including In Vitro Diagnostic Medical

Health Technology (Medical Device) National Policy



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Devices' was developed in 2017 to support member states in developing and implementing regulatory controls and regional guidelines for good manufacturing to ensure robust safety, quality and efficacy of medical devices. This will ensure public health benefit and the safety of patients, healthcare workers and the community.

Regulations Around the World

Almost all the countries that have a medical device industry, have also established appropriate policies and regulatory mechanisms.

USA – The public health agency, Food and Drug Administration (FDA) is the nodal agency that maintains constant oversight over food products, drugs, cosmetics and medical devices in the USA. The Center for Devices and Radiological Health (CDRH) under the FDA is charged with regulating medical devices and radiation-emitting products. It is supported by a massive infrastructure of scientists and other personnel to implement evaluation, certification and regulatory procedures for medical devices, apart from acting as an interface with manufacturers. It is also responsible for formulating guidelines for post-market surveillance and monitoring of the approved devices, wherever applicable.

Manufacturers, importers and sellers of medical devices are subject to a range of regulatory requirements – like pre-market review, labelling, establishment registration and device listing, and quality system regulation - to ensure that devices are not adulterated or misbranded and to otherwise assure their safety and effectiveness for their intended use.

The FDA has the authority to impose regulatory actions for irregularities and violations related to medical devices - like initiating recall, issuing warning letters, citation, prosecution, seizure and even monetary penalties.

Additionally, there is the Safe Medical Devices Act (SMDA) and Quality System Regulations for

medical devices. MedWatch is the FDA Safety Information and Adverse Event Reporting Program that allows manufacturers, healthcare professionals and consumers to report serious problems related to the use of medical devices.

European Union – To resolve the issue of differing medical device regulatory requirements throughout Europe, the European Union established three EC Medical Device Directives governing the clinical investigation, production and distribution of medical devices in Europe. The directives specified the essential (general and mandatory) requirements for medical devices, while the member countries can elaborate the detailed technical specifications for demonstrating conformity with the essential requirements in voluntary harmonised standards.

Products that comply with the directives carry the CE Mark of conformity – based on mandatory third-party conformity assessment (including calibration, testing, certification and inspection) by an EU Notified Body.

Only the medical devices that carry a valid CE Mark can be placed on the EU market.

The directives were replaced by the European Union Medical Device Regulation (EU MDR) in 2021 that make notified bodies, competent authorities and the European Commission more responsible than ever before for the safety of medical devices. They have tightened the rules for clinical testing of medical devices on patients and laid out stricter requirements for manufacturers in terms of follow-up on quality, performance and safety of devices. Following this, all medical devices need to be reassessed for compliance and certification.

The MDR also provide for the establishment of a central European database on medical devices, EUDAMED that will list information about manufacturers, notified bodies, clinical investigations, certificates, medical devices as well as serious deterioration in health caused by medical devices and/or medical device malfunction or failure.

United Kingdom – The Medicines and Healthcare Products Regulatory Agency (MHRA) regulates the medical devices (including in vitro diagnostic medical devices, custom-made devices and systems or procedure packs) in the UK. Manufacturers of medical devices need to be registered with the MHRA and comply with relevant product marking and conformity assessment requirements. The MHRA performs inspections and market surveillance apart from governing the marketing and supply of devices in the UK.

A medical device cannot be put on the market in Great Britain unless it has a UKCA or a CE marking. The UKCA (UK Conformity Assessed) marking is a UK product marking provided after third-party assessment by MHRA-designated UK approved bodies. It is not recognised in EU.

Manufacturers must ensure their devices meet appropriate standards of safety and performance for as long as they are in use. They are required to take appropriate safety action when required and submit vigilance reports to the MHRA when certain incidents occur in the UK. Since 2021, a number of changes have been introduced (through secondary legislation) on how medical devices are placed on the market.

Canada – The Medical Devices Directorate (MDD) is the national authority that monitors and evaluates the safety, effectiveness and quality of diagnostic and therapeutic medical devices in Canada. It enforces pre-market review, post-approval surveillance and quality systems in the manufacturing process.

Most medical devices require a license before they can be sold in Canada. The low-risk devices that do not require a license are monitored through the establishment licensing process.

Even though Canada has one of the best regulatory systems for medical devices in the world - with some of the most stringent requirements - it is constantly working on further strengthening the approval, monitoring and follow-up, to better ensure optimal health outcomes.

Brazil – Medical devices in Brazil are regulated by the National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária - ANVISA). A dynamic and complex regulatory approval system is in place that requires registration at ANVISA, product testing, INMETRO certification for certain devices, BGMP inspections, etc.

New medical device regulations were introduced in 2021 with changes in risk classification, notification, registration, labelling requirements and more. All devices now require a Medical Device Technical Dossier (following the IMDRF's Table of Contents structure). A Documentary Repository of Medical Devices is being launched for storing and making available documents related to both notified and registered medical devices.

China – The National Medical Products Administration (NMPA) – formerly named China Food and Drug Administration (CFDA) - regulates pharmaceuticals and medical devices in China. Manufacturers are required to register their devices with the NMPA before

Every medical device should have a Unique Device Identification (UDI) so that it can be traced throughout the supply chain from manufacturer to patient. UDI is a medical device requirement in most countries, but every country is at a different stage of implementing UDI requirements.

selling or distributing in China. It has strict requirements for submission documentation, testing and clinical data.

Apart from the above, countries like Malaysia, Singapore and even Saudi Arabia have full-fledged and impactful regulations for medical devices.

Uniformity in Regulation

Almost all countries classify the medical devices into different categories based on the potential risk that the use of the device presents or could potentially present. The regulation primarily follows a risk-based approach with the reviews, approvals and other rules being based on the categories. However, they tend to vary from country to country.

With the rapid growth in the global market for medical devices, there is a need to harmonise these national standards so as to minimise regulatory barriers, facilitate trade and improve access to new technologies. Harmonisation will also reduce the cost of implementing regulations for the industry and government.

The Global Harmonization Task Force (GHTF) was constituted in 1992 by the EU, USA, Canada, Australia and Japan as an international initiative to harmonise the medical device regulations of different countries. The forum drafted a number of regulatory initiatives to achieve mutual recognition of regulatory processes among the participating countries and encourage convergence in standards. It even proposed several harmonised definitions for medical device nomenclature.

"A standardised classification and nomenclature of medical devices will serve as a common language for recording and reporting medical devices across the whole health system, at all levels of healthcare, and for a whole range of uses." – WHO

GHTF was replaced by the International Medical Device Regulators Forum (IMDRF) in 2012. Constituting of EU, USA, UK, Australia, Canada, Japan, China, Russia, Brazil, Singapore and South Korea, it is developing internationally agreed upon documents related to a wide variety of topics affecting medical devices.

USA, Canada, Australia, Brazil, and Japan have also established the Medical Device Single Audit Program (MDSAP) - an auditing methodology based on the requirements of both ISO 13485 and regional regulations.

Where Does India Stand?

It is clear that India is lagging far behind other countries as it continues to regulate medical devices on par with drugs. Regulation and monitoring appears to be almost non-existent. It may sound harsh, but the reality is that the stepmotherly treatment from the common regulator has reduced the industry to a headless sector!

We need to pull up our socks and bring in a modern and separate medical device regulatory paradigm in tune with the international forces and rapid development of technology. Who will take the onus to drive clear and comprehensive regulations is looming question for our country!

The medical device industry in India is brimming with potential that lies untapped due to the lack of proper regulations and supportive policy interventions by the authorities!

SUPERCHARGING GROWTH OF INDIA'S MEDICAL DEVICE INDUSTRY

A recent GTRI report has identified six policy interventions for the government for accelerating growth of the medical device industry. This includes banning import of used and refurbished devices into the country to check dumping.

A REPORT BY think tank Global Trade Research Initiative (GTRI) on 'Supercharging India's Medical Device Industry Growth' released in August this year unequivocally states that the Indian medical devices market can expand from $12 billion today to $50 billion by 2030. This high growth can even outpace the recent expansion seen in the smartphone industry!

GTRI aims to create high-quality and jargon-free outputs for governments and industry on issues related to trade, technology and investment from the perspective of development and poverty reduction.

The projected exponential growth in the medical devices sector will come from the rapid expansion in India's health sector, which is anticipated to grow from $200 billion annually to $600 billion by 2030, as more Indians opt for formal healthcare services. This will not only reduce our dependence on imports of medical devices to 35%, but also increase our exports to $18 billion by 2030.

It should be noted that India produces around $7.6 billion worth of medical devices – of this $4.2 billion are used domestically which meets only 34.6% of the $12 billion needs of the Indian market, while imports total to $7.6 billion (2022-23). Meanwhile, our exports stand at just $3.4 billion currently. The expected shift can generate over 1.5 million jobs in medical device manufacturing and healthcare services like hospitals and laboratories.

The report suggests that the domestic medical device sector is primed for a turnaround powered by factors like strong local production setup, capability to produce quality products and the rapidly expanding local market.

Indeed, India has 1200 local companies and multinational corporations that manufacture a wide range of medical devices, except for advanced high-tech ones. The sector has already showcased its capabilities during the COVID-19 pandemic by swiftly scaling up the production of essential items like ventilators, Rapid Antigen Test kits, RT-PCR kits, infrared thermometers, PPE kits and N-95 masks for both domestic and global use.

The medical device market is underpenetrated in India. Globally, people spend about $75 per person on medical devices, but in India, it's only $8.6. This is projected to increase to $35 by 2030.

The GTRI proposes six action points for the government which will basically replicate the strategy followed for smartphones. They include:

- Adjust Customs Duty
- Restrict Input Tax Credit (ITC)
- Ban Imports of Used/Refurbished Devices
- Introduce Performance Linked Incentive (PLI) Plus Scheme
- Combat Foreign Influence
- Promote Local Sourcing

Indian Health and Medical Device Sector Estimates

	2022	2030	CAGR (%)
Healthcare Sector			
India Market Size – US$ billion	200	600	14.7
Medical Device Sector			
India Market Size – US$ billion	12	50	19.5
Imports – US$ billion	7.6	17.5	10.9
Import dependence – %	64.6	35	-7.4
Domestic Production – US$ billion	7.6	50.5	26.7
Domestic Supply – US$ billion	4.2	32.5	29.1
Exports – US$ billion	3.4	18	23.2
Per capita use – US$	8.6	35	19.2

©-GTRI

Indeed, the report upholds that the government should stop import of used/refurbished discarded medical devices as it has the potential to kill all policy initiatives and will throw the domestic sector out of production. Meanwhile, it should also ensure that Indian manufacturers can compete effectively with foreign imports for vital supplies.

"Achieving the full potential of the sector will require further support as the sector faces 15% cost disability due to high cost of power, supply chain inefficiencies."
– Ajay Srivastava, founder, GTRI

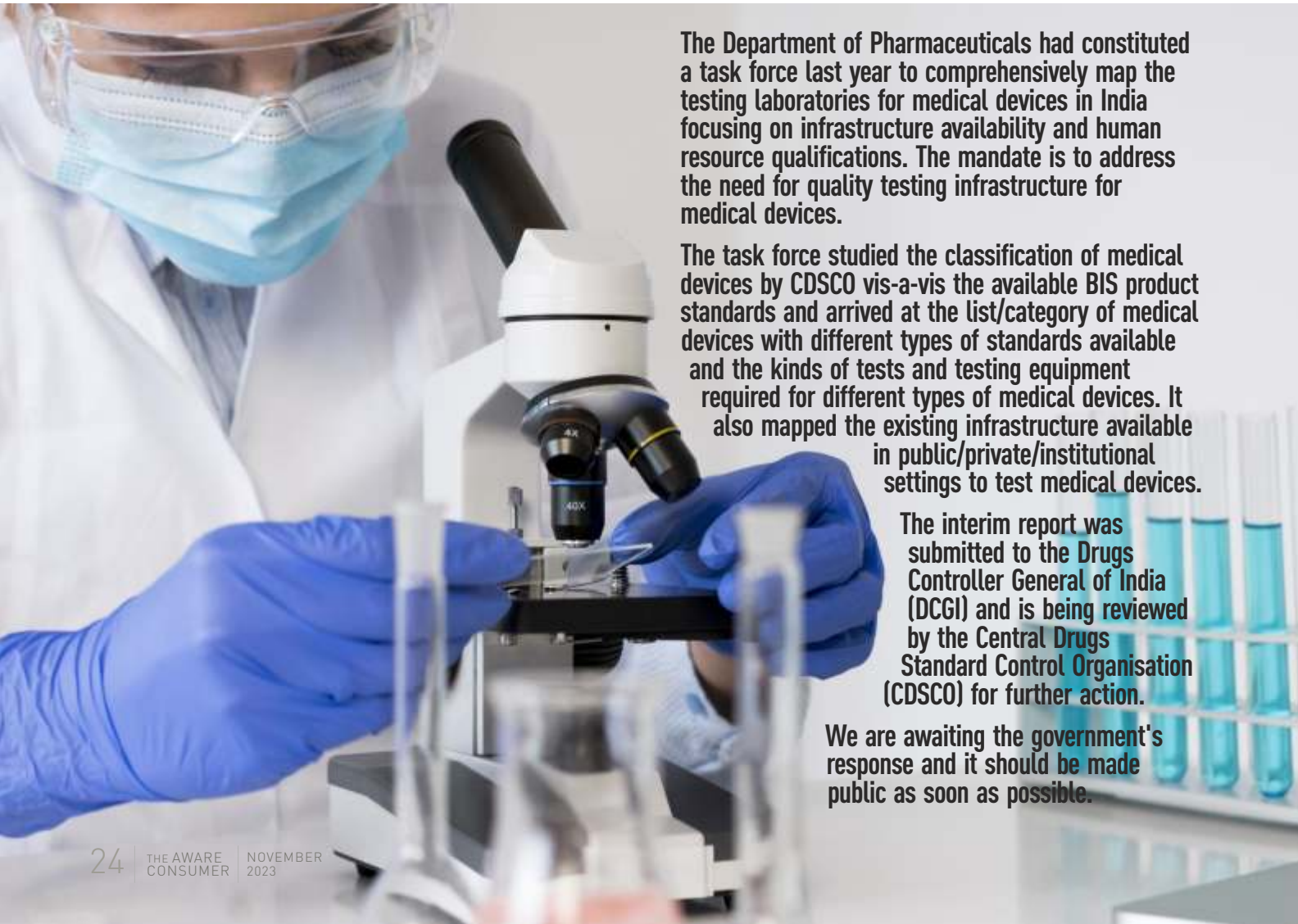
GTRI also sounds a warning note by stating that the government should identify industry and research bodies influenced by foreign lobbies and persevere to guard against foreign interests dictating policy outcomes reports of such bodies.

Supporting its suggestion that the basic customs duty should be raised from the current 0-7.5% to 15-20% for devices not covered under WTO's Information Technology Agreement–1, the report states that this approach is WTO (World Trade Organization) compatible, as bound duties stand at 40%. Global import duties for medical devices vary a lot - in Brazil it is 14%, Russia is 0-15%, China is 3.3-17%, South Africa is 0-20% and India is 0-7.5%.

Richa Chauhan, Senior Consultant (Oncologist), Mahavir Cancer Sansthan opines that, "With only a few manufacturers across the world for radiotherapy machines, there is an urgent need for indigenous production of these machines". She further adds, "With no dearth of talent in our country, I am sure we can utilise this opportunity and become a leading manufacturer and importer of medical devices!"

The Way Forward

The future of India's medical devices industry is at a pivotal juncture. The sector holds immense promise to not only reduce reliance on imports but also create a robust job market, accelerate technological advancement and ensure India's self-reliance in critical healthcare supplies! Is the government listening?



The Department of Pharmaceuticals had constituted a task force last year to comprehensively map the testing laboratories for medical devices in India focusing on infrastructure availability and human resource qualifications. The mandate is to address the need for quality testing infrastructure for medical devices.

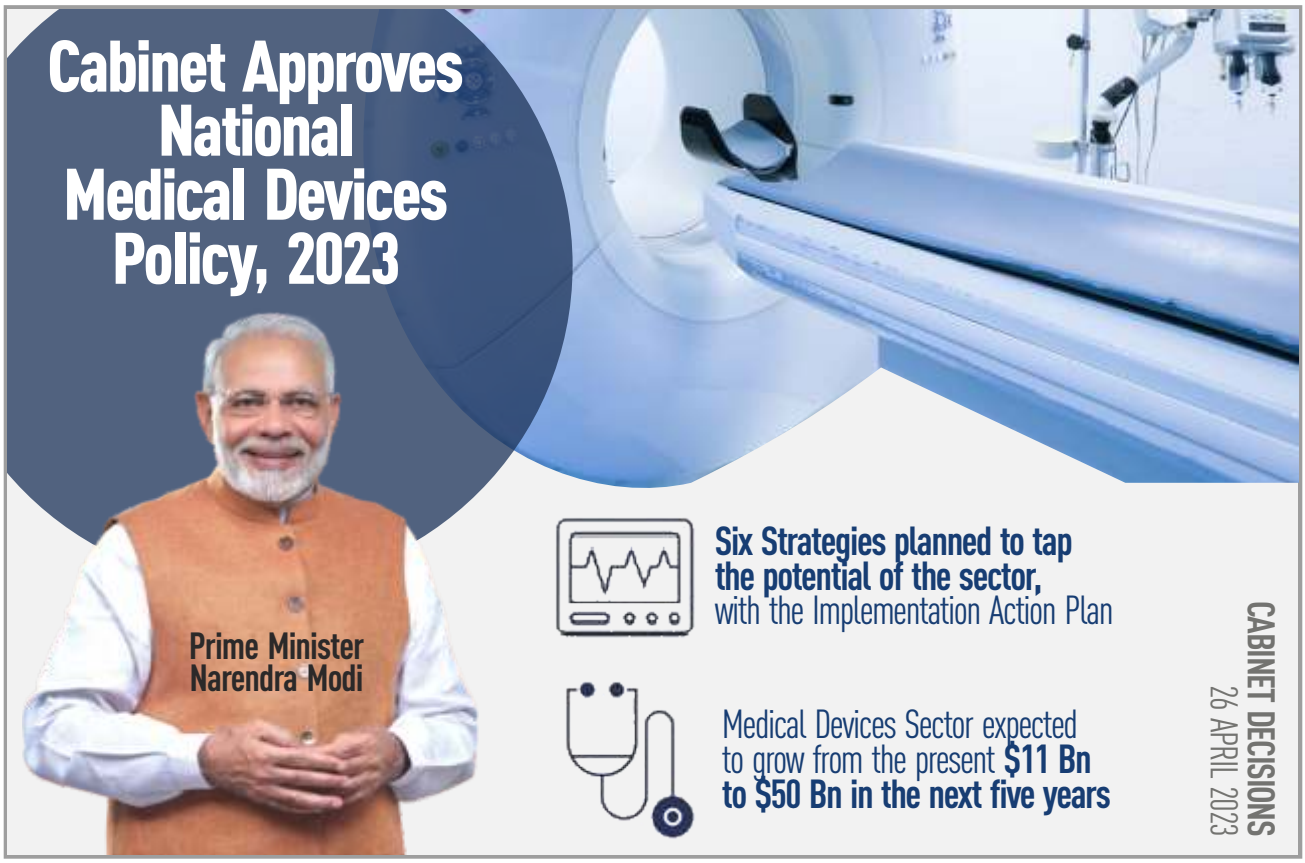
The task force studied the classification of medical devices by CDSCO vis-a-vis the available BIS product standards and arrived at the list/category of medical devices with different types of standards available and the kinds of tests and testing equipment required for different types of medical devices. It also mapped the existing infrastructure available in public/private/institutional settings to test medical devices.

The interim report was submitted to the Drugs Controller General of India (DCGI) and is being reviewed by the Central Drugs Standard Control Organisation (CDSCO) for further action.

We are awaiting the government's response and it should be made public as soon as possible.

Medical Devices Policy 2023 – An Ambitious Vision for Make-in-India Future!

The medical devices industry in India is a sunrise sector - it is growing at a fast pace and has become an essential component of the healthcare industry. The government recently launched a new policy focused on establishing India as a global leader in manufacturing and innovation of medical devices.



The forward-thinking National Medical Devices Policy, 2023 aims to reduce import dependency and establish India as a global manufacturing hub for medical devices while promoting safety and quality!

AN INDIAN BRAND Equity Foundation (IBEF) report states that India is the fourth largest Asian medical market after Japan, China and South Korea and is among the top 20 globally. However, the share of Indian medical devices sector in the global medical device market is estimated to be only 1.5% with a market size estimated at $11 billion (Rs. 90,000 crores) in 2020.

It should be noted that approximately 75% of the medical devices currently sold in India - including high-end and sophisticated devices like imaging equipment (X-ray, CT and MRI machines), cardiac stents, orthopaedic implants and critical care equipment - are imported into the country. Indigenous manufacturing remains extremely low with small and medium enterprises focussing on low-cost, low-tech and high volume products, like consumables and disposables. In fact, we are among the major global manufacturers of syringes, needles, surgical blades, surgical gloves, condoms, PPE kits, masks, etc. Other basic consumables like examination gloves, hot water bottles and home care products like blood pressure instruments, diabetes sugar monitors and thermometers are still being imported.

Apart from this huge import dependency and trade imbalance, the medical devices sector is also struggling under inconsistent regulations, limited access to capital and insufficient research and development.

India will need medical devices worth $50 billion by 2030. If the domestic industry does not expand due to technology or policy constraints, the space will be occupied by large-scale imports.

Government Interventions

To tap the enormous potential of the Indian medical devices industry to become self-reliant and contribute towards the goal of universal healthcare, the central government had earlier initiated a PLI Scheme for medical devices (26 projects have been approved) and assured support for setting up of 4 Medical Devices Parks.

In May 2023, the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India notified the National Medical Devices Policy, 2023 as a roadmap for accelerated growth of the medical devices sector to achieve the public health objectives of access and universality; affordability; quality and patient-centred care; preventive and promotive health; security; research and innovation; and skilled manpower. It is focused on:

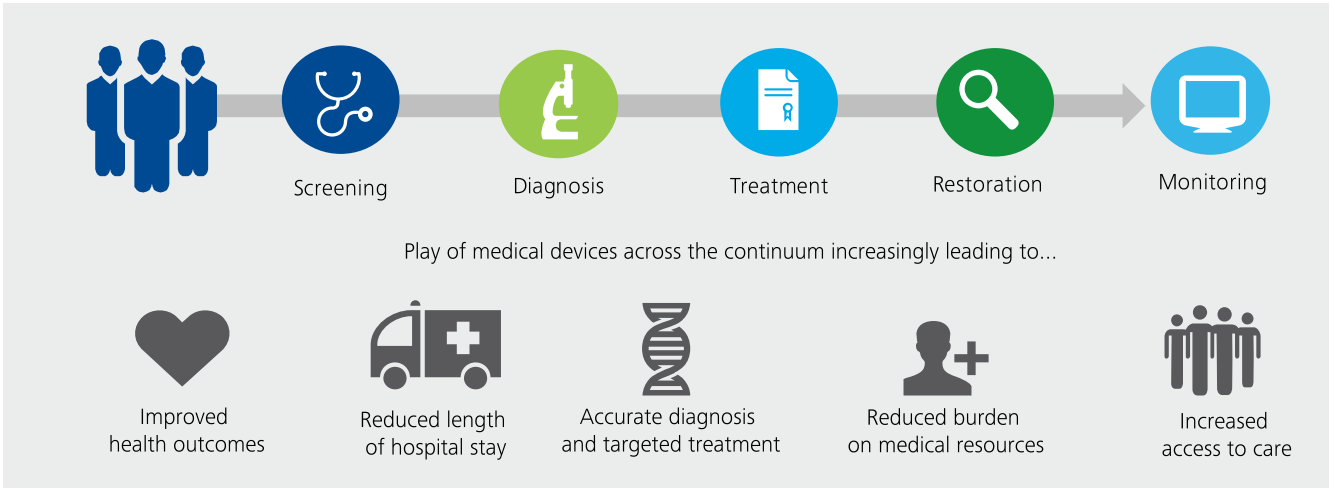
- Building an enabling ecosystem for manufacturing along with a focus on innovation
- Creating a robust and streamlined regulatory framework
- Providing support in training and capacity building programs and promoting higher education to foster talent and skilled resources in line with the industry requirements

The medical devices sector will be facilitated and guided through a set of strategies that will cover six broad areas of policy interventions:

- Regulatory Streamlining
- Enabling Infrastructure
- Facilitating R&D and Innovation
- Attracting Investments in the Sector
- Human Resources Development
- Brand Positioning and Awareness Creation

National Medical Devices Policy, 2023 is expected to help the medical devices sector grow from the present $11 billion to $50 billion by 2030. It aims to reduce India's import dependence to nearly 30% in the next couple of years as well as become one of the top five global manufacturing hubs by achieving 10-12% share in the expanding global market over the next 25 years.

Role of Medical Devices Across the Healthcare Continuum



In effect, the policy outlines a regulatory mechanism, protocol for setting up standards for medical devices, price control, research and development (R&D), and a code of ethics for industry associations to ensure the ethical marketing of medical devices. It will also establish and strengthen common infrastructure facilities in the medical devices clusters and fortify testing facilities for medical devices. The overall goal is to guarantee access to patent-centric, innovative and affordable healthcare products of exceptional quality for improved healthcare outcomes.

The most significant measures are the enhanced role of the Bureau of Indian Standards (BIS) and the Single Window Clearance System for licensing medical devices that will make it easier to do research and business while balancing patient safety and product innovation.

Encouraging domestic investments and production of medical devices complements the government's 'Atmanirbhar Bharat' and 'Make in India' programs.

Mr. Rajiv Nath, Forum Coordinator at the Association of Indian Medical Devices Manufacturers (AiMeD) lauded the proposed designing of a coherent pricing regulation stating that, "Some private hospitals give higher priced products instead of available low-cost options. Because of this, the manufacturer or importer of India is tied up in a system of market operating with artificially inflated MRP labelled on the device. He added separately that, "We have been seeking MRP of imports be monitored and compared with imports' landed prices and steps taken to control when found irrationally excessive."

Final Words

This forward-thinking policy provides a holistic policy framework to accelerate growth in a coordinated manner and fulfil the potential of the sector by making it competitive, self-reliant, resilient and innovative. It also has a patient-centric approach to meet the evolving healthcare needs of patients. However, the success of these planned measures is entirely dependent on their quick and effective implementation and enforcement. It remains to be seen how this will unfold.

Evolution of The Regulatory Apparatus for Medical Devices in India

Medical devices play a critical role in ensuring a holistic and properly functioning healthcare system. It follows that their quality and efficacy should be regulated at all levels of the supply chain to ensure safety to the patients. Over the years, the Government of India has inculcated a series of rules and regulations that have streamlined and integrated the manufacture, sale, distribution and import of medical devices (including diagnostics), albeit under the umbrella of drugs.

The medical devices sector is an essential and integral constituent of healthcare!

MODERN HEALTHCARE CANNOT deliver results without the use of a variety of medical devices. The range of medical devices in not only very broad, but also constantly evolving as new devices emerge. While they enhance the quality of care, the devices can also lead to unintended safety issues. Therefore, it is imperative to ensure that all medical devices sold in India are safe, effective and conform to quality standards, and this calls for government regulation!

Historically, medical devices have mostly been unregulated in our country. Even now, they are regulated as drugs. We did not have any specific medical device regulations until 2017.

Circa 1982, the definition of 'drugs' under the Drugs and Cosmetics Act, 1940 was amended to include such medical devices as may be notified by the Government from time-to-time. Disposable syringes, needles and perfusion sets were the first to be notified in 1989 under the Act followed by a few more through periodic notifications.

The import, manufacture, sale and distribution of medical devices in India is regulated under the provisions of the Drugs & Cosmetic Act 1940. The regulatory authority is the Drugs Controller General of India (DCGI) of the Central Drugs Standard Control Organisation (CDSCO) under the Directorate General of Health Services, Ministry of Health & Family Welfare (MoHFW), Government of India.

Yet, no clear regulations existed prior to 2005 when the Health Ministry notified the requirements and guidelines to be followed for obtaining permission to import or manufacture new drugs (including medical devices) and for conducting clinical trials. Notified medical devices were placed under the purview of the DCGI.

This was in the aftermath of the JJ Hospital controversy, where unapproved and untested stents were used on 60 patients. Subsequently, the Mashelkar Committee had recommended the creation of a specific medical devices division to address the management, approval, certification and quality assurance of medical devices.

Again, following the embarrassing Johnson & Johnson debacle, the MoHFW notified the Medical Device Rules, 2017 under the Drugs & Cosmetics Act, 1940. This marked a new era in the regulation of medical devices as the rules were framed in alignment with WHO Global Model Regulatory Framework for Medical Devices (including IVDs) and adhere to the stepwise approach to regulating medical devices based on guidance documents developed by the Global Harmonization Task Force (GHTF) and the International Medical Device Regulators Forum (IMDRF). They lay out comprehensive quality requirements and other special regulations to be followed by manufacturers, marketers, sellers and importers of notified medical devices.

The medical devices were classified based on their intended use, risk profile and other parameters:

Device Class	Risk	Examples
Class A	Low Risk	Tongue, Wheelchair, Spectacles, Alcohol Swab
Class B	Low to Moderate Risk	Hearing Aids, Thermometer
Class C	Moderate to High Risk	Ventilators, Infusion Pumps
Class D	High Risk	Pacemakers, Defibrillators, Implanted Prosthetics, Breast Implants

Regulatory requirements and the appropriate licensing authorities are based on the risk class of the device

This classification system dictates how the device is regulated - Class C and D devices are subject to more stringent regulations than Class A and B devices. This gave manufacturers some much-needed clarity on the design and material-related risk assessment and management.

"The Medical Device rules are harmonised with the international regulatory practices and provide comprehensive legislation for the regulation of medical devices, which will foster 'Make in India' also. Any medical device which is being marketed in India should comply with the Bureau of Indian Standards (BIS) or as notified by the central government. If both of them are unavailable, then International Organization for Standardization (ISO), International Electrotechnical Commission (IEC) and ASTM International are there for standardisation of medical devices."

- O S Sadhwani,
Former Joint Commissioner & Drugs Controller, FDA – Maharashtra

The scope of the regulation was restricted only to the specific medical devices which are notified by the Government as 'drugs' (commonly referred to as 'notified medical devices'). Till 2020, only 37 categories of the almost 6000 medical devices available in the country were notified and regulated by the authority. The rest were sold in the market without any particular quality/safety standards or regulations.

Amidst rising concerns about the safety, quality and performance of the majority of medical devices that were largely unregulated and outside the purview of the law, various stakeholders kept pushing for regulating all non-notified medical devices.

The Quality Council of India (QCI) introduced a voluntary certification scheme - Indian Certification for Medical Devices (ICMED) - in 2016 to fill the regulatory gap by providing functional quality assurance through the product certification system. This is the first indigenously developed international class certification scheme for medical devices in India. It aimed to bring credibility for domestic medical devices manufacturers to reduce time and cost-run for obtaining globally accepted certification.

Later, QCI and AiMeD (Association of Indian Medical Industry) added some more features and brought in the ICMED 13485 PLUS so as to ensure product quality and safety while limiting the threat of counterfeit products and fake certification. These mechanisms should be further refined so that the medical devices industry is able to demonstrate compliance with various international product standards to enter the global market.

Historic Move

On 11th February, 2020, the Drugs Technical Advisory Board (DTAB) - India's highest advisory body on drugs – finally decided to bring all medical devices under the fold of quality and safety regulation. The Ministry released two notifications:

- A new comprehensive and all-inclusive definition of medical devices which brings all medical devices (including both imported and locally manufactured implantable and diagnostic devices) under the ambit of the regulatory framework for quality control and price monitoring.
- The Medical Devices (Amendment) Rules, 2020 requiring the initial registration (and subsequent licensing) of the medical devices.

The Amendment introduced two changes in the Medical Device Rules:

- A new chapter for registration of newly notified medical devices by their respective manufacturers and importers.
- Exemption for the 37 categories that are already regulated/notified medical devices from the requirement of registration introduced by the new chapter. They can carry on business based on the license issued by the appropriate licensing authority.

Accordingly, the definition of 'drugs' was expanded to include all devices intended for diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder; diagnosis, monitoring, treatment, alleviation or assistance for any injury or disability; investigation, replacement, modification or support of the anatomy or of a physiological process; supporting or sustaining life; disinfection of medical devices; and control of conception. This includes software and accessories covering all wearables boasting health features.

Everything from hypodermic syringes, sutures, staplers, catheters, digital thermometers and condoms to cardiac stents, knee implants, prosthetic replacements and sophisticated machinery for CT scans, MRIs and dialysis are now placed within the framework of the Medical Device Rules, 2017 and will be regulated as drugs.

These rules provide detailed regulations for classification, registration, manufacturing, import, labelling, sales and post-market requirements for medical devices - supervised by the Medical Devices and Diagnostics Division of the CDSCO - thus ensuring that they are safe and conform to quality standards.

The primary feature is the mandatory registration and licensing requirement (from the appropriate licensing authority) before undertaking any business in notified medical devices. This kind of double verification – registration followed by license - creates a robust verification regime while incentivising new players.

The registration number has to be mentioned on the label of every medical device. Registered importers and manufacturers have to strictly conform to their documented quality management system. Licensees are mandated to maintain detailed records of the sale-

A dedicated online registration portal - Online System for Medical Devices – has been established by the CDSCO while license application is streamlined through another online electronic platform.

An ISO 13485 certificate of compliance (Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes) accredited by the National Accreditation Board for Certification Bodies (NABCB) or International Accreditation Forum (IAF) is mandatory for registration.

https://cdscomdonline.gov.in/NewMedDev/Homepage

purchase of notified medical devices and ensure traceability in the event of a quality/safety-related failure or complaint.

The CDSCO is the nodal authority to investigate complaints related to the quality and safety aspects of medical devices. It can suspend the defaulting manufacturer's registration or even cancel the license.

Registration of newly notified medical devices was kept voluntary for an 18 month period (till 1st October, 2021). Post registration, manufacturers and importers had a window of 36 months for Class A and B devices and 42 months for Class C & D devices for acquiring the requisite license (after this, all compliance provisions of the Medical Devices Rules 2017 are applicable).

"Regulations are aimed at quality control and to create a facilitating environment."
– Rajeev Singh Raghuvanshi DCGI

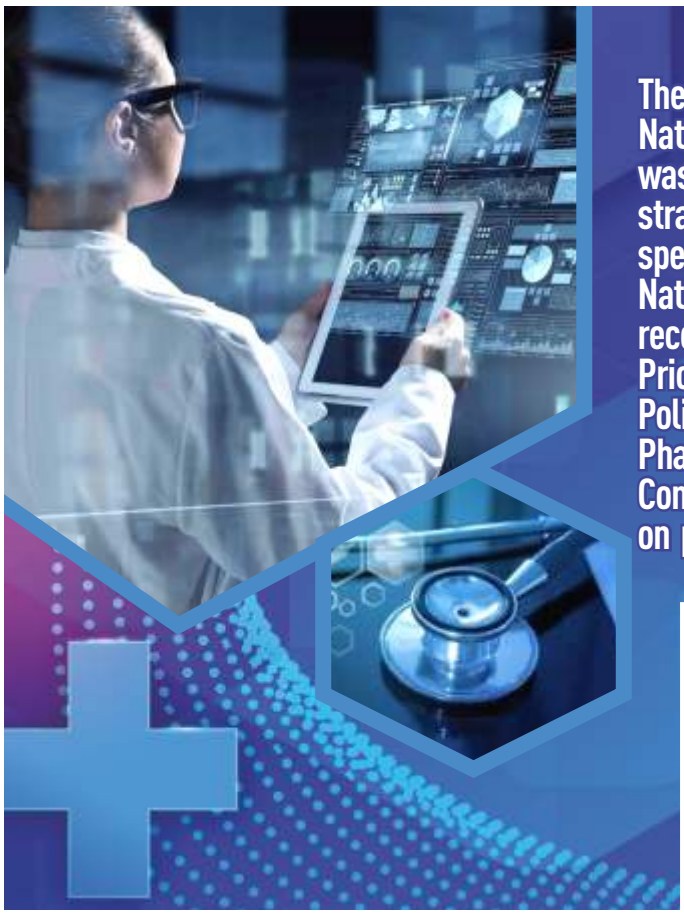
The CDSCO released a new classification of non-notified medical devices and in-vitro diagnostic devices (IVDs) on 3rd September, 2020 which provides new risk-based classification lists to manage India's clear regulatory pathways and requirements.

Classifying almost 1866 medical devices and 80 IVDs, the CDSCO has established 24 categories of medical devices and 3 categories of non-notified IVDs based on sub-divisions applied at internationally acceptable classification and on the First Schedule of Medical Device Rules, 2017.

Software has been included as a category for the first time in the regulation encompassing 60 device types such as data analysis software, secondary displays for glucose monitoring, insulin pump and other devices, and orthodontic and dental software.

Class of Medical Device	Licensing Authority	Stipulated Timeline for Processing Application	Deadline for Obtaining License
Class A and B (import)	DCGI	Up to 9 months from the date of application	August 11, 2022
Class C and D (import)	DCGI	Up to 9 months from the date of application	August 11, 2023
Class A (manufacture)	State-level Licensing Authority	Up to 45 days from the date of application	August 11, 2022
Class B (manufacture)	State-level Licensing Authority	Up to 140 days from the date of application	August 11, 2022
Class C and D (manufacture)	DCGI	120 – 180 days (estimated)	August 11, 2023

It is not mandatory to have a registration number in order to obtain a license



The Healthcare Technology division at National Health Systems Resource Centre (NHSRC) was established to support the MoHFW on policies, strategies and action plans for health technologies, specifically for medical devices under the National Health Mission. This division has been recognised as a 'WHO Collaborating Centre for Priority Medical Devices and Health Technology Policy'. It also supports Department of Pharmaceuticals, Indian Pharmacopoeia Commission, Bureau of Indian Standards, etc. on proposals related to medical devices.

Recent Developments

- CDSCO has registered 12 notified bodies for the audit of Class A and Class B medical devices
- MoHFW has notified 6 central medical device testing laboratories
- CDSCO has registered 28 laboratories for the testing of medical devices on the behalf of manufacturers.

Final Thoughts

No doubt, the government wants patients to have access to quality and safe medical products. It has devised various measures to support the manufacture and use of medical devices. The regulation has also moved from a bit-by-bit approach to a systematic and pre-planned arena.

All medical devices – whether manufactured in India or imported –will have quality assurance and be subject to oversight from the regulator. Regulating all medical devices and ensuring they meet certain standards of quality has made the companies accountable for quality and safety of their products.Yet, we remain miles away from a quality-driven, safety-led, performance-oriented, transparency-focused and self-sufficient medical devices sector!

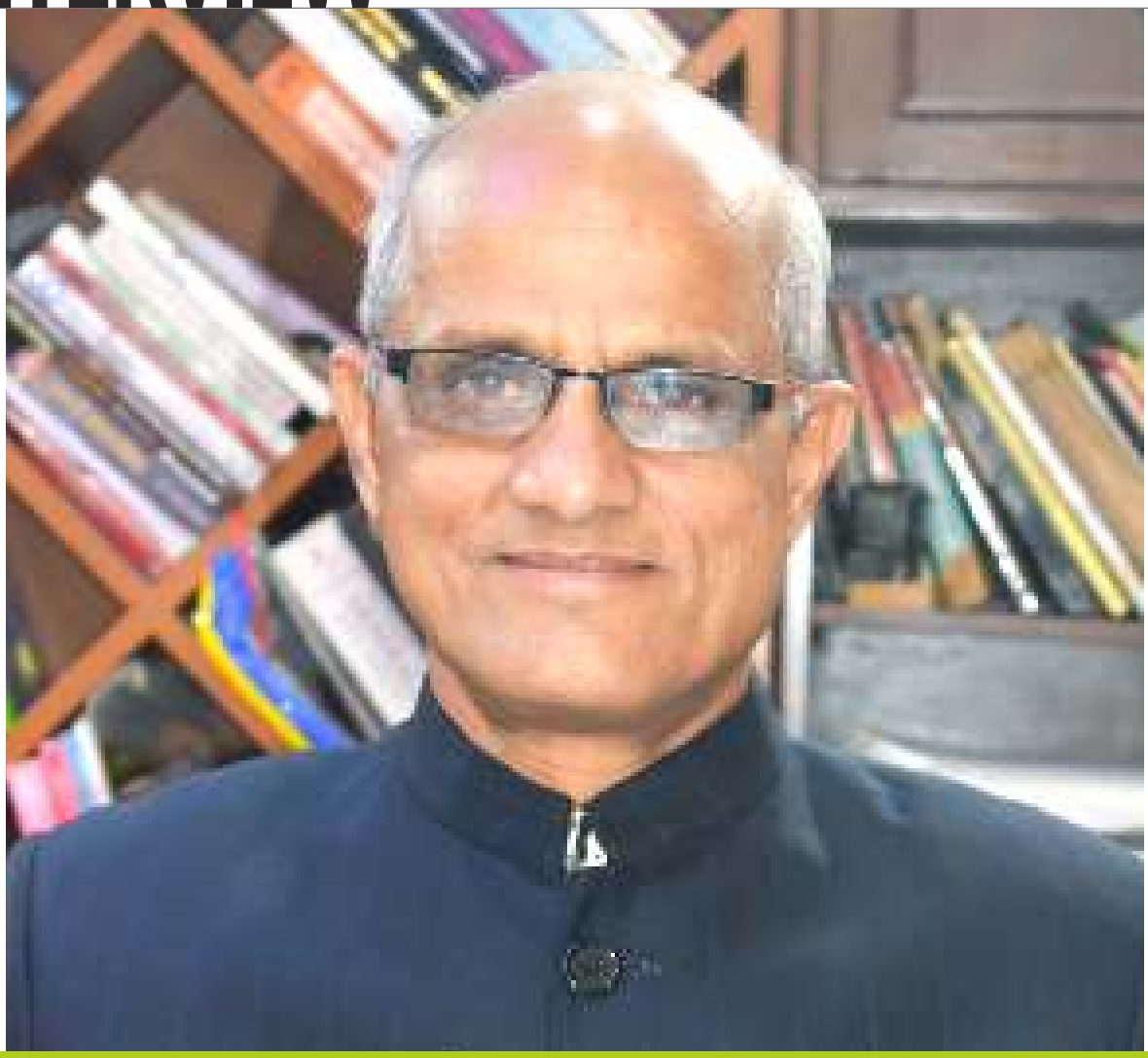
1st October, 2023 was the deadline for bringing Class C and D medical devices under CDSCO regulation. Following this, it has become mandatory for all imported and locally manufactured medical devices sold in the country to be certified by the drug regulator before they enter the market to ensure quality.

Any medical device that is not registered and licensed cannot be marketed or sold now. Failure to obtain a license can result in criminal prosecution resulting in imprisonment and fine. Any stock of medical devices that are sold without registration or license can be confiscated.

However, the CDSCO missed the 1st October deadline to issue regulatory licenses to the applicants. Several manufacturers that had filed for a licence in July are still awaiting audits, on the basis of which they will be given licences. AiMeD had written to the health ministry in September itself requesting a 6 month extension by stating that "CDSCO seemingly has resource constraints for timely inspection and issuance of manufacturing licences by the September 30, 2023, deadline, as this may lead to supply-chain disruptions for many Indian-made medical devices".

Finally, the government granted a 6 month extension to the manufacturers and importers that have already applied for a license (from the date of the government's order - which was 12th October - or until the Central Licensing Authority makes a decision on their application, whichever comes first). Those that had not applied did not get any extension and have to halt their operations.

INTERVIEW

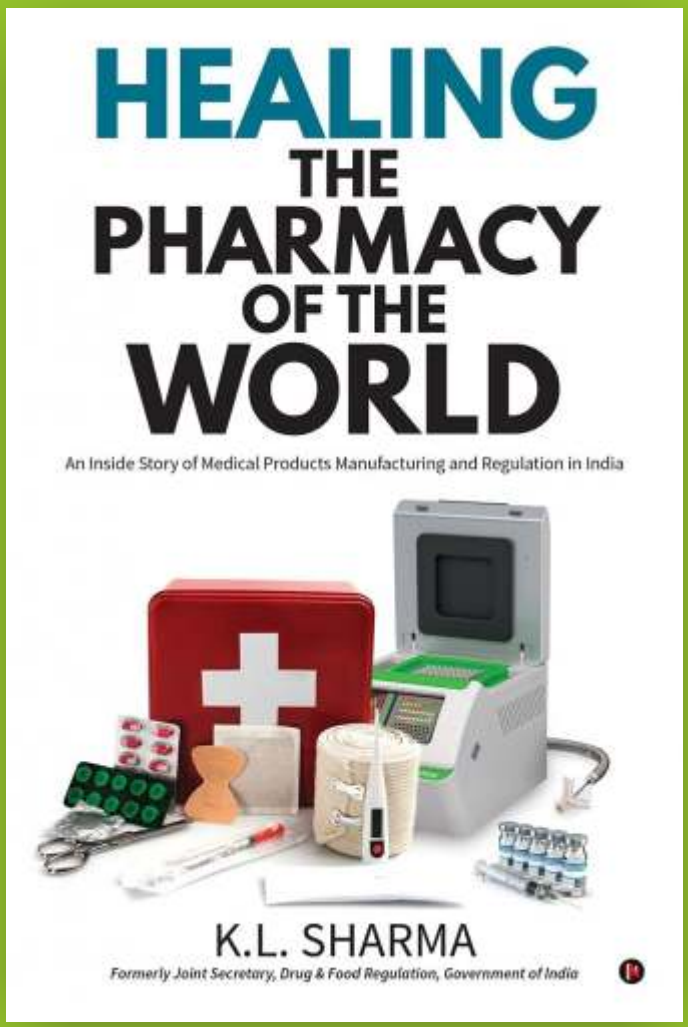


Mr. K.L. Sharma

– a civil servant of four decades standing - has a wide exposure to policy formulation at the highest levels in the government. In his post of Joint Secretary in the Ministry of Health & Family Welfare, GoI (2014-17), he coordinated the creation of Medical Devices Rules, 2017 apart from spearheading a string of key initiatives for streamlining the processes and rationalising rules for drugs, cosmetics, medical devices and clinical trials. He has also held the post of Joint Secretary in the Cabinet Secretariat.

Mr. Sharma authored a book, 'Healing the Pharmacy of the World – An Inside Story of Medical Products Manufacturing and Regulation in India'. In this interview, he shares his views on the existing medical device regulations in India and what the sector needs to move forward in a robust manner.

K.L. Sharma, Author

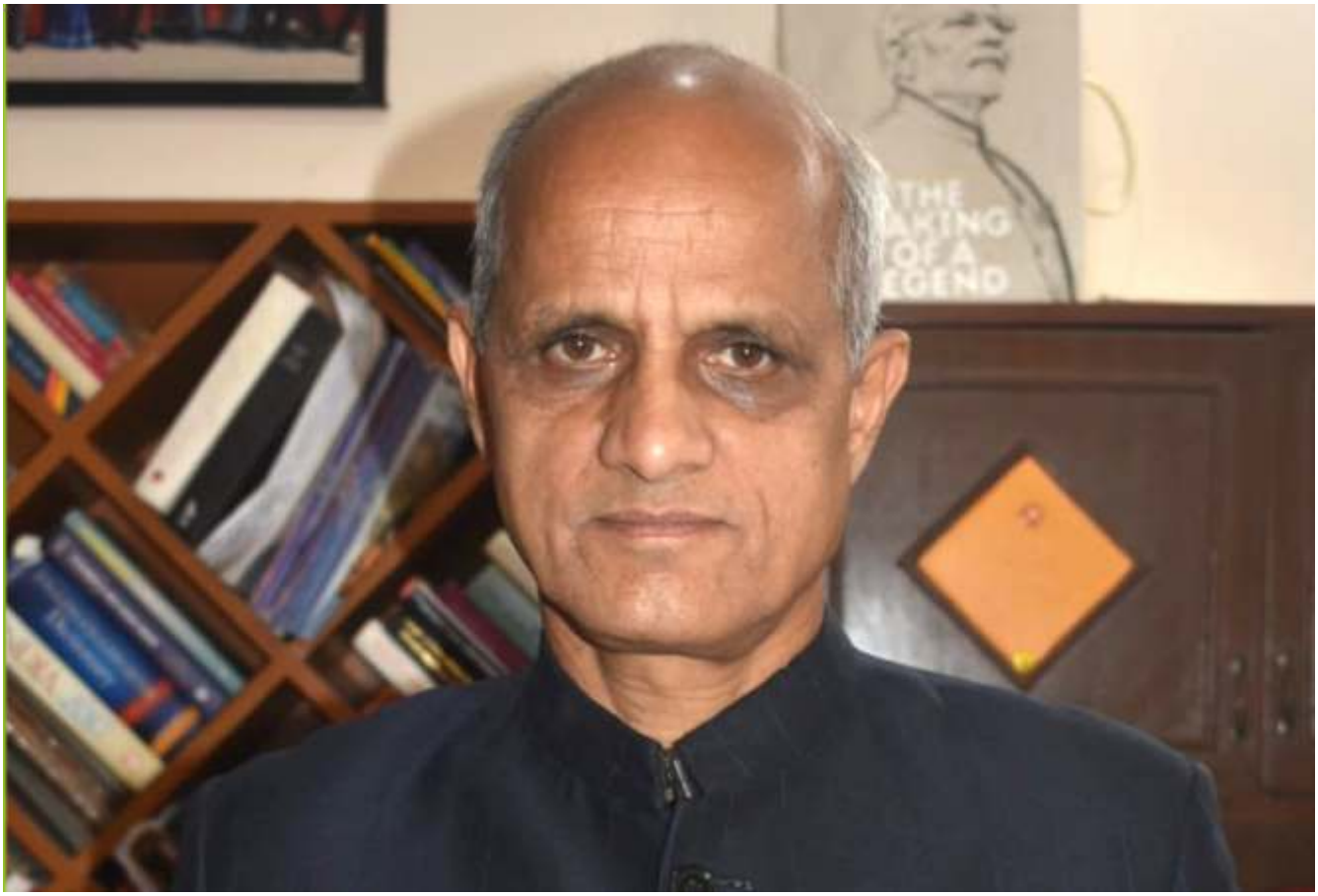


> "It would be disastrous to allow import of second hand equipment, both from the perspective of quality and nurturing of domestic industry."

Q Various stakeholders have been demanding a separate regulatory framework for medical devices for many years. What are the potential risks and consequences of not having distinct regulations for medical devices, given their unique nature and functions?

Medical devices are essentially engineering products and while having commonality in terms of their usage with drugs or medicines, these form an entirely distinct category. Keeping this in view, the regulatory regime for the two cannot be the exact replica of each other. Even within medical devices, there are vast differences and those need to be duly factored in while establishing the regulatory framework. That having been said, it needs to be acknowledged that there are certain commonalities that need to be applied universally for all medical products and, therefore, there is a need for synchronising the regulatory frameworks for medical devices and drugs.

Treating medical devices at par with drugs for regulatory purposes is fraught with danger for various reasons including the fact that such an arrangement puts unnecessary burden on medical device manufacturers in terms of compliances and leaves out more vital aspects that are crucial for ensuring the safety and effectiveness of medical devices.



Q How do you think a separate legislation will help the medical devices industry and the patients?

There could be different ways of looking at this issue. To be frank, I do not think that we essentially need to have different legislations for drugs and medical devices. In a well calibrated and thought out legislation, it will be possible to address the pertinent issues with a single legislation and clear delineation of the applicability of different chapters/sections. In such an arrangement, different chapters will deal with different medical products e.g., chemical drugs, biologicals, medical devices, etc. and common areas that apply across all medical products can be put in a separate chapter. This will facilitate removal of any haziness in law. Such an arrangement is considered imperative in the context of combination products that have features of both the drugs and medical devices. In such an arrangement, it will be necessary to clearly spell out which chapter will be applicable to which product.

Q You were involved in the framing the Medical Devices Rules as Joint Secretary in the Union Health Ministry. Do you think that the Rules have teeth without a separate regulation to back them?

Medical Devices Rules, 2017 had been framed as an interim measure in the context of the fact that, at that point of time, the Government was eager to remove the complete vacuum with regard to regulation of medical devices in the country and it would have taken a lot of time to put in place a new legislation for this. These Rules were never intended to be a replacement for a parliamentary legislation.

It needs to be clarified that the Rules framed have to be in conformity with the applicable law which in this case was the antiquated Drugs and Cosmetics Act, 1940 that was based on pre-independence and pre-constitutional governmental framework. In the absence of an updated parliamentary legislation, an effort was made to draft the rules in a manner that these conformed to the Globally Harmonised framework and could pave the way for enactment of a proper legislation for regulation of medical devices. However, these rules were subject to the provisions of the Drugs and Cosmetics Act, 1940 and, to that extent, the arrangement was not perfect.

Q How does India's approach to regulating medical devices compare with international standards?

To the extent, permissible under the Drugs and Cosmetics Act, 1940, Medical Devices Rules, 2017 are harmonised with GHTF. At the same time, the structures for regulating medical devices are yet to be updated and

Mr. K.L. Sharma

it is only now that this issue has been engaging the attention of the government and, regulators, albeit, at junior level with suitable qualifications are being recruited.

For bringing in complete harmony with international regulatory practices, it will be necessary to bring in a new legislation as well as set up a separate vertical for regulating medical devices. Further, the practices will need periodic updation in keeping with the international practices.

Q What steps can be taken to enhance the efficiency and effectiveness of medical device regulations in India, considering the dynamic nature of the industry?

It needs to be recognised that regulation of medical products is an important aspect not only from the perspective of quality, safety and effectiveness/efficacy but also for fostering innovation. The capacity of regulators at present at the state and the national level in India is limited both in quantitative and qualitative terms. It is, therefore, essential that the efficient regulatory structures that could regulate, nurture and educate industry on best global practices with specialised manpower and required domain knowledge are put in place; the legislative framework is updated periodically; and structures outside the government regulators are also roped in for facilitating the industry with certification processes.

Initiatives such as the ICMED (Indian Certification of Medical Devices) by Quality Council of India and Industry are the way forward. The existing diffused regulatory structures with 37 national and state regulators undertaking regulation of medical products is the most inefficient system and is counterproductive as very often, such multiple structures tend to work at cross purposes. There is also a need for regular updation of the knowledge of the regulators on such issues in keeping with the best global practices.

Q The government has placed a new Drugs, Medical Devices and Cosmetics Bill, 2023 in public domain. What are the drawbacks of the Bill with respect to medical devices? Do you agree that it requires further discussions?

The Bill as now prepared is old wine in new bottle as only the label is getting changed. It will be necessary to rework the entire legislative framework i.e., the Act and the rules after extensive consultations with the stakeholders. The proposed Bill has been prepared largely through consultations within the governmental structures and only limited external inputs have been taken. This makes the entire process infructuous.

Q What are your views on the new National Medical Devices Policy launched in April this year?

The Central Government has been coming out with policy prescriptions for different segments from time to time to ensure that the medical devices industry in the country flourishes. There is no doubt about the intention of the government to make India a major player in this segment. However, the policy paradigm has been changed far too frequently which creates a degree of uncertainty. The entire issue needs to be addressed comprehensively with all stakeholders including major MNCs and a package worked out for positioning India as the ultimate destination for medical devices manufacturing rather than as China plus one. Under the current scenario, even the plus one position is getting garnered by other players.

Q Do you think the government should allow the import of pre-owned medical devices from other countries? Does this not contradict the new policy which is pushing for Make in India?

It would be disastrous to allow import of second hand equipment both from the perspective of quality and nurturing of domestic industry. It is an open secret that the refurbished equipment - especially those used for diagnostic purposes - very often does not undergo proper certification/recalibration and could prove to be a health hazard.

Q Based on your path-breaking book, 'Healing the Pharmacy of the World', what would be your inputs for a separate Act for medical devices for ensuring product quality and patient safety?

It is considered that a separate legislation exclusively for medical devices or a combined one for all medical products is not material. What is material is that the legislation(s) must take into account the peculiarities of the products to be regulated and separate chapters in the same legislation could very well take care of different requirements.

What is even more important is the fact that a very good law may be poorly implemented and a not so good law may be imaginatively implemented. Therefore, more emphasis should be on the good legislation and implementation machinery rather than on whether such a legislation should be a combined or a separate one.

The law must end the multiplicity of regulators and also make it mandatory to put in place alternative mechanisms outside the government for certification of quality of products and processes to make the entire process more dynamic.

Q What do you think the medical device sector needs to focus on to improve patient safety?

The focus needs to be on the quality, availability and affordability of medical devices for better health outcomes, and it is possible only when we have the proper legislative framework and an efficient and effective implementation and facilitation machinery!

सत्यमेव जयते

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AFTERWORD

Pyush Misra
Trustee,
Consumer Online Foundation

Why Does a Regulatory Vacuum Still Persist for Medical Devices?

"It is not just the medical devices industry that has been batting for a separate regulatory mechanism for medical devices. Various government authorities itself have vocally criticised the drug law for falling severely short in effectively regulating medical devices. They have also argued that the CDSCO lacks the requisite expertise to regulate medical devices while exhorting the health ministry to implement a separate legislation!"

– Pyush Misra

Isn't it appalling that medical devices are still being regulated like drugs? A more enabling regulatory system will nurture and boost the medical devices sector.

IT IS HIGH time the Indian government stopped viewing medical devices through the lens of drugs and cosmetics!

The Government think tank, NITI Aayog itself criticised the regulation of medical devices under the Drugs and Cosmetics Act and stated that, "The National Health Policy 2017 envisages strengthening the regulation of medical devices and establishing a regulatory body for medical devices to unleash innovation and the entrepreneurial spirit for medical devices in India."

Backing up its statement, the think tank framed the Medical Devices (Safety, Effectiveness and Innovation) Bill, 2019 to 'improve quality, enhance transparency, make it easier for the sector to do business, and formalise a regulatory framework as well as a framework for compensation'. Various stakeholders including patients who have been adversely affected by unsafe medical devices were involved in the consultation phase.

"The purpose of the draft Bill is to ensure that medical devices in India are safe and effective. Further, the Bill should create an enabling ecosystem for manufacturing, research and innovation", NITI Aayog said in a statement to industry stakeholders while releasing the Bill in 2019.

The primary provisions of the bill were compensation to patients who are harmed by faulty or unsafe medical devices and maintaining a National Registry of Medical Devices. It was also primed to reduce our import dependency for medical devices.

Apart from the draft legislation, NITI Aayog recommended setting up a separate regulator for medical devices – the Medical Devices Administration (MDA) - on the lines of the Food Safety and Standards Authority of India (FSSAI). The MDA should work parallel to the Central Drugs Standard Control Organisation (CDSCO), under the Directorate General of Health Services (DGHS). One of the reasons cited by the think tank was that the CDSCO and DCGI may not have the relevant expertise to exercise oversight in this realm.

Industry experts hailed the NITI Aayog Bill as a 'visionary and well-thought out roadmap' and have been exhorting the government to pass the law, but all in vain.

Apart from this, a Department-Related Parliamentary Standing Committee (DRPSC) on Health and Family Welfare itself strongly recommended that the health ministry should appreciate the potential of the medical device industry and formulate a separate legislation accordingly. In its 138th report on 'Medical Devices: Regulation & Control' released in September 2022, the committee had proposed setting up a 'National Commission on Medical Devices' to conduct a detailed examination of all aspects of the industry and bring forth a comprehensive law supported by a holistic policy and institutional infrastructure for the purpose.

Chaired by Prof. Ram Gopal Yadav, the report made 49 recommendations, like staffing the new regulator with qualified and well-trained medical device officers, provision for risk-proportionate regulatory controls and penal system, etc. It even observed that there are only 18 certified and CDSCO-approved medical device testing laboratories in the country. The testing infrastructure has to be scaled up to encourage local manufacturers to get their products tested, which will ultimately improve the availability and affordability of medical devices for the consumers. However, only 9 of the recommendations were accepted by the ministry and incorporated in the draft drug bill.

The looming question is that does the CDSCO have the expanded personnel to ensure the requisite oversight over the broad range of medical devices that are being used today? For that matter, do the authorities even possess the necessary training to inspect and regulate these devices? Can the existing regulatory framework handle emerging products like artificial intelligence, exoskeletons or neural implants?

Again, the same DRPSC stated in its 146th report released in August this year, "Instead of bringing a combined legislation for drugs, medical devices and cosmetics, the ministry should formulate a separate legislation for medical devices and create a new department, namely the Department of Medical Devices".

The committee - under the chairmanship of Rajya Sabha member, Mr. Bhubaneswar Kalita - opined that though both drugs and devices are medical products, the medical devices are not pharmaceuticals. It is convinced that a separate law is required to create a world-class regulatory framework, boost the medical device industry and minimise the dependence on imports.

The report further said, "The committee has observed that in recent years the indigenous medical industry is growing fast and to match with the pace existing drug inspectors (medical devices) and medical device officers working under the CDSCO would not be able to cater the needs of the industry. Therefore, a separate regulatory infrastructure for medical devices with dedicated work force instead of adjoining with the CDSCO would serve the purpose better".

Alas, the ministry mulishly continues to uphold its stance of continuing with a single regulator stating that its combined draft bill for regulation of drugs, cosmetics and medical devices has a separate chapter for regulation of medical devices that will suffice. It also stated that the CDSCO is being strengthened in terms of manpower (from various engineering fields) and infrastructure which will effectively regulate the medical devices sector.

Conclusion

It does not make any sense at all for medical devices to follow a regulatory framework based on the drug regulations. **It remains to be seen whether the government will pay heed to the different voices and migrate the medical devices to a separate legislation in the near future. We really hope that the landmark Medical Devices Bill by NITI Aayog actually sees the light of day!**

Dr. Anamika Wadhera
Director
Consumer Online Foundation

Greenlighting Import of Used Medical Devices – A Big Blow for Domestic Industry

"The ongoing strong impetus to boost manufacturing of medical devices in the country has been derailed by a recent order to permit import of pre-owned and refurbished medical devices. Quality of healthcare will become a sure shot casualty of this contrarian approach!"

– Dr. Anamika Wadhera

THE CENTRAL GOVERNMENT has been arming the domestic medical devices sector with policy interventions to make it self-reliant – meet the burgeoning demand for medical devices and reduce the dependence on imports. Production Linked Incentive (PLI) scheme was announced, 100% FDI has been permitted under automatic route and medical device parks are being set up to augment and strengthen indigenous manufacturing of medical devices. The new Medical Device Policy is also focused on easing clearances for medical device manufacturers following which even some leading international companies are setting up shop in India.

The Export Promotion Council for Medical Devices was launched recently along with a scheme for Assistance for Medical Devices clusters for Common Facilities (AMD-CF) to promote infrastructure development and strengthen the testing facilities for medical devices in the country.

Amidst this, came a bolt from the blue – in June this year, the Ministry of Environment, Forest and Climate Change (MoEFCC), in consultation with the union health ministry, issued an office memorandum permitting the import of 50 pre-owned high value and non-ICU medical devices like MRI machines, CT scanners, ultrasound machines, C arms, mammography machines, blood cell count analysers, high-end X-Ray machines, PET-CT scan machines, radiotherapy devices, etc. for reuse.

The rationale behind this is that refurbished equipment costs approximately 20-25% less than new equipment based on configuration, technology and features. This will make them affordable for small hospitals and healthcare establishments, especially in tier 2 and tier 3 cities.

The Bone of Contention

Domestic device makers and industry bodies are objecting to the order by stating that it will hurt local entrepreneurs who are manufacturing medical devices and discourage new investments in the sector. As the used devices are way cheaper than the new ones, it will definitely throw the domestic sector out of gear as it will not be able to compete with the lower-priced products. This also directly contradicts the Make-in-India and Atmanirbhar Bharat approach; in fact, it is being dubbed as 'Un-make in India'!

The irony here is that Union Health Minister **Mr. MANSUKH MANDAVIYA** recently remarked that, "our goal is to become self-reliant in the medical device sector and reduce our import dependency." Will India ever be able to become self-sufficient given such skewed policies that make the industry stumble time and again?

GAURAV AGARWAL, Managing Director, of Innvolution Healthcare said that the utilisation of refurbished equipment under the guise of C-arms and advanced X-ray systems for performing catheterisation procedures is both misleading and potentially hazardous. He further emphasised that by importing refurbished equipment, India misses the opportunity to nurture a robust ecosystem of innovation, research and development in the medical technology sector.

While the authorities argue that the 50 types of used medical devices permitted for import are presently not being made in India, the reality is 40 of them are already manufactured in the country! Even a recent GTRI report upholds that India has world class production facilities for most devices in the list. So, why should be import used medical devices when we are capable of delivering our own quality machines?

What About the Safety of Patients?

Given the lack of clarity over regulating the import of these refurbished products, patient safety will definitely be at risk given the chances of faulty products entering the supply chain and giving wrong prognoses that can threaten lives. Not to mention the possibility of old devices spreading harmful contaminants - like depleted uranium – and having other undesirable effects on the environment.

Another valid argument against this retrograde policy is that developed countries can easily dump their used/outdated/third-rate devices in India and move to newer and better devices. Who is to say that some of the importers will not bring in substandard, cheap and unsafe (even radioactive) products?

This has been affirmed by a recent Global Trade Research Initiative (GTRI) report that unequivocally states that such used equipment does not have a market in their own countries. What's more, they may actually be forbidden at home due to the harmful effects – but such information will be withheld from Indian users. We will have no way of realising the harmful effects, given the lack of proper regulation and surveillance.

Come to think of it, as many as 22 countries of the world including China, Vietnam, Indonesia, Egypt and Peru (constituting 58% of the world's population) do not allow refurbished medical devices in their country?

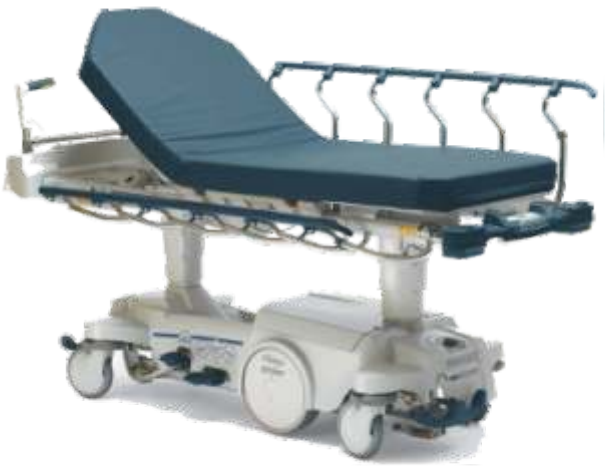
> India is not a dumping ground for obsolete technologies and Indians are not guinea pigs. If MNCs are so confident of the quality of refurbished products, why do they not use them in their own countries?
>
> *- **Rajiv Nath,** Forum Coordinator, Association of Indian Medical Industry (AiMeD)*

> If the bill is implemented, the Medical Devices manufacturing sector may face supply chain crisis and effectively lose its ability to meet domestic demand.
>
> *– **Dr, Girdhar Gyani,** Director General, Association of Healthcare Providers India, a network of private hospitals in the country*

In fact, the proposed Drugs, Cosmetics & Medical Devices Bill, 2023 is also expected to have a devastating impact on the domestic players as it is heavily tilted in favour of MNCs. If implemented, it can prove catastrophic to the survival of the local medical devices sector that has invested hugely over the years. The looming question here is that why does the Bill not incentivise local production and innovation in medical devices?

To Wrap Up

Even as the government is reviewing the import order, policymakers need to understand the unique nuances of the medical devices sector and take the industry-specific woes into consideration. The only way to make India stand on its own two feet in the medical devices realm is to support the local ecosystem, boost scale manufacturing of medical devices and also better leverage the policies as most of the MedTech companies are often not even aware of the central schemes!



Old devices used for MRI or ultrasound scanning, X rays, mammography may provide faulty prognosis and threaten lives, and many old devices are at risk of spreading harmful contaminants like depleted uranium.

The Taxation Angle

In India, medical devices attract multiple rates of GST ranging from 0% and 5% to 12% and even 18% on certain equipment. 18% is excessively high and as medical devices are by no way a luxury product, AiMeD has appealed to the government to bring down the taxation on these life-saving and wellness devices to a more reasonable 12%.

In fact, after the initial outbreak of COVID-19, the GST department of the finance ministry stated that 18% GST is applicable on hand sanitisers. It was raised from the earlier 12% by changing the category and classifying the alcohol-based sanitisers as a 'disinfectant'. This was even after the Ministry of Consumer Affairs had brought hand sanitisers under the ambit of an essential commodity. Industry associations had petitioned to the Ministry of Finance for a lower GST rate; some even requested exemption from GST on the grounds that it was declared as an essential commodity, but to no avail.

On the contrary, GST on certain devices is reduced to 0% or 5% which may sound attractive, but does not actually help the consumers - it only ends up giving an edge to importers by making imports cheap while making domestic products more expensive. Why are the authorities making Indian products non-competitive to imports as manufacturers miss out on input credit and have to raise their ex-factory prices?

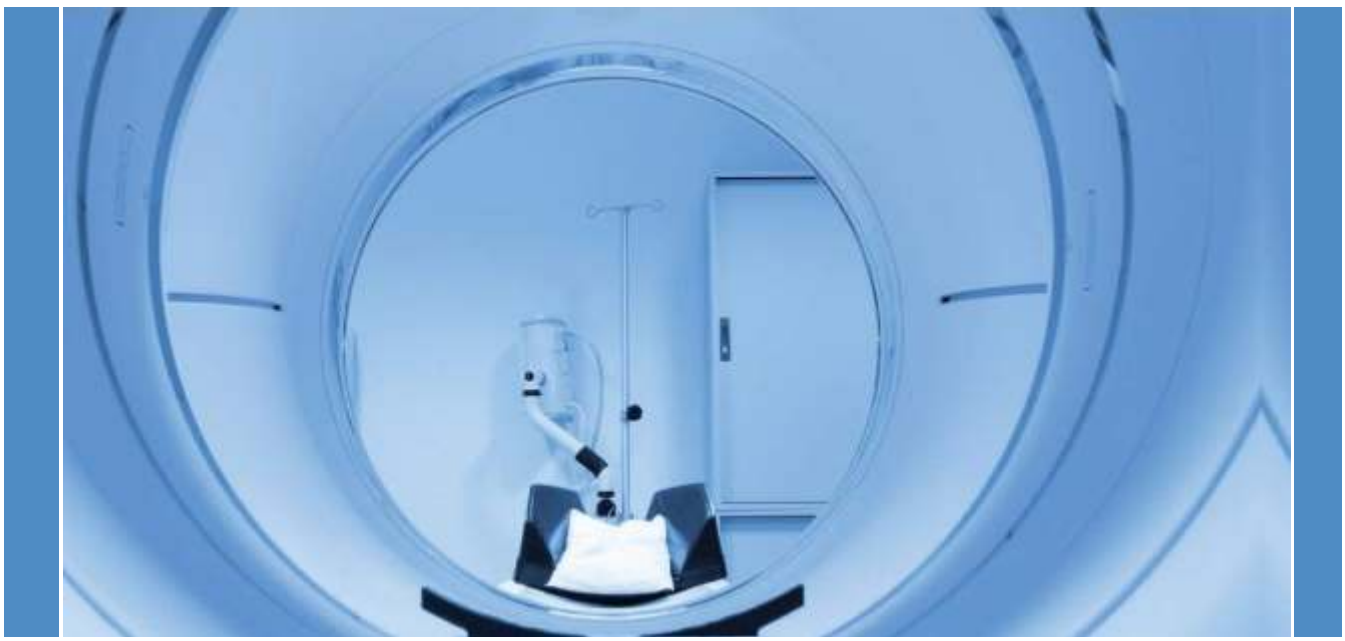
Even the government agreed, "Lower GST rates help importers by making them cheaper. This is against the nation's policy on Atmanirbhar Bharat. Consumers would also eventually not benefit from lower GST rate if domestic manufacturing suffers on account of inverted duty structure." But it still refuses to bring in a policy intervention for a more reasonable tax regime that is beneficial for everyone!

Payal Agarwal
Editorial Consultant

Grey Area of Reusing Medical Devices after Repair, Reprocessing or Refurbishment

"We rely on medical devices to maintain and improve our health and well-being. Are we willing to take the chance of reusing a used medical device if its safety, accuracy or reliability remains suspect? Is the cost-saving worth compromising on your health and life?"

– Payal Agarwal



REDUCE, REUSE, REPAIR and recycle are the mantras of a circular economy – adopting the 4Rs in all spheres of life has become crucial for preserving the environment and our planet! However, can we extend these environment-friendly practices to healthcare, especially in the case of medical devices? Indeed, while we encourage reuse and repair, will we be comfortable with a doctor or hospital using an already-used implant, catheter or other medical device?

The price difference between a brand new and reused product may be huge, but where is the assurance of quality and safety?

Unearthing the Hidden Dangers

Generally speaking, medical devices can be divided into single-use and reusable medical devices. Syringes, gloves, catheters, stents, implants, etc. are designed and validated

for use on a single patient and procedure only. As per the manufacturer's guidelines, they have to be discarded and should not be used again. Yet, keeping the costs and environmental effects in view, many healthcare institutions propagate the reprocessing and reuse of expensive single-use items like catheters that are priced around Rs. 20,000. But who will take the onus of verifying and validating the proper and safe sterilisation of these items prior to reuse under the right conditions? And what if the device were to fail due to mechanical or technical reasons?

It should be noted that some devices that have certain kinds of rubber or plastic cannot be properly washed and cleaned for reuse. Disinfecting may kill the bacteria, but other contaminants may linger, making them unsafe for the patients. Even metal instruments may have grooves and serrations that can continue to conceal contaminants despite washing and sterilisation. Therefore, the medical products should actually be designed with cleaning and reuse functionality in mind.

Then there are forceps, stethoscopes, endoscopes, etc. that can be used multiple times; however, most of them have to be cleaned and disinfected properly after every use. In fact, using these medical devices properly and performing regular preventive maintenance can increase their average life, thus lowering costs for both the healthcare providers and the patients, not to mention reducing the burden of e-waste. However, proper protocols for cleaning and sterilising them for safe reuse have to be followed – for instance, simply placing an instrument under a UV light for a couple of seconds may not render it completely free of contaminants.

Another key point here is that such reusable medical devices also have a specific lifespan. Who will determine whether they are being reused on numerous patients over long periods of time beyond their 'expiry date'? Not to mention that the utility/effects may decrease with every reuse.

What we need is scientific studies and research data to back the reuse of medical equipment after following the proper safeguards for cleaning and disinfection. There should also be clarity about how many times a device can actually be sterilised effectively making it safe for reuse before being required to be discarded.

Then again, many medical devices like diagnostic equipment can be repaired when they break down or malfunction. Who is performing the repairs is the big question here. We definitely promote the right of patients, clinicians, hospitals, etc. to choose where they wish to get their products repaired and not be overcharged for the same. While the onus is on the manufacturers to extend the 'Right to Repair' to the consumers without maintaining monopoly on repair services or spare parts, they cannot be held liable for the malfunctioning of a device that has been serviced by a third-party entity, especially when it is beyond the warranty period.

Indeed, advanced medical devices come with complex electronic components, and repairing them requires intricate knowledge, skill, tools, etc. Poor quality servicing can affect device performance and even lead to adverse events.

A refurbished medical device can be defined as a restored medical device rebuilt to meet safety and performance requirements that are comparable to its condition when new, without changing the intended use of the original device. Unlike used equipment, which is generally just cleaned up and sold as is, refurbished equipment involves replacement of worn-out parts, repair of mechanical and electrical components, reassembly, cosmetic touch, software updates, quality check, and testing and labelling updates.

The key point here is that in India, we do not have a national policy– not even a proper rulebook - on the reuse, repair or refurbishing of medical devices. The industry has been seeking clear regulations and guidelines on the quality checks, recalibrations and other safety parameters for reused/repaired/refurbished medical devices since many years. They have also asked for demarcating such devices into different categories in consultation with the manufacturers based on criteria like metal, plastic, rubber which will define their suitability for sterilisation and reuse.

Around 4 to 5 years back, an Ethics Committee at Indian Council of Medical Research (ICMR) debated this issue within medical circles and with other stakeholders as well. However, it got bogged down soon without any clear outcome. Government think tank, NITI Aayog has also initiated discussions on the same topic but to no avail. Alas, the union health ministry continues to take a loose and arbitrary approach. What we need is clear Standards of Procedure and full protocols for reuse of medical devices – however, there is not even a guidance note for the same. This has to be followed up by a proper monitoring mechanism to ensure safety and quality of the devices that are being reused.

The famous Implant Files investigations by the Investigative Consortium of Investigative Journalists (ICIJ) highlighted that a high proportion of private clinics and hospitals in India use pre-owned or second-hand equipment that has not been tested for safety or accuracy!

This is unlike the international arena where many countries like USA, UK and European Union have drafted distinct classification of single and reusable medical devices with clear policies governing the refurbishing, reconditioning, rebuilding, remarketing, remanufacturing, servicing and repairing of medical devices. The focus is on ensuring their quality, safety and continued effectiveness.

USA has a clear policy for safe reuse of reusable medical devices. It mandates safe washing, cleaning and sterilising of reusable equipment. In fact, the use of plastics is subject to a lot of regulations under the U.S. Pharmacopeia. A country like Malaysia has actually instituted Good Refurbishment Practice Of Medical Devices (GRPMD) regulations!

Ground Reality

Meanwhile, even top healthcare institutions in India - like AIIMS for example - advise patients and their families to opt for reused medical devices on many occasions. They uphold that the said device has been properly sterilised and is as good as new. While they assure that it is safe to use and nothing can go wrong, consumers are still not sure of the right move given that their health and life can also be at stake.

Indeed, the cost difference can be huge in many cases, but who is to say that a physician or hospital that uses a refurbished device will always pass on the price benefit to the consumers, or even inform them about their reuse practices? What if you are simply taking on the additional risk without any saving to show for it? Come to think of it, have you ever come across a lab offering a discounted price because it is testing using a refurbished MRI machine?

The Consortium of Accredited Healthcare Organizations (CAHO), India encourages reuse of expensive medical devices. It upholds the right to information by clearly advising its members to communicate to the consumers about the options of reused devices and get their consent for the same. It also promotes maintaining complete transparency by conveying the price difference between a new and reused device so that they can make an informed choice. Transferring the cost advantage to the patients remains imperative.

In sum, we cannot really decipher the clinical consequences of the reuse of single-use devices or the magnitude of dangers posed by third-party maintenance activities, as no data is collected in the absence of regulation. Neither is there any prior scrutiny or regulatory requirement to report problems. The only way out is regulation, including registration and reporting on refurbishing and reuse of medical devices.

Reporting of Adverse Events

Another case in point is that it is the shared responsibility of the consumers, healthcare providers and manufacturers to provide information on malfunctioning of medical devices – be it new, repaired or refurbished.

Following a WHO directive, many countries including India have established their own post marketing surveillance system of adverse events caused by medical devices.

The Ministry of Health & Family Welfare (MOHFW), Government of India launched the Materiovigilance Programme (MvPI) in 2015 with a mission to safeguard the health of the Indian population by ensuring that the benefits of use of medical devices outweigh the risks associated with its use.

Shatrunajay Shukla | Rajeev Singh Raghuvanshi

"Although refurbished medical devices save materials and resources, regulating the refurbished devices market is important to ensure the quality and safety of these products. WHO is finalising the guidelines for refurbishing processes, labelling requirements and regulations in the revised version of 'WHO Global Model Regulatory Framework for Medical Devices Including In Vitro Diagnostic Medical Devices'. If such guidelines are developed and implemented, possible harm to patients or users due to refurbished device malfunction can be reduced."

– Shatrunajay Shukla (Indian Pharmacopoeia Commission) and Rajeev Singh Raghuvanshi (current Drugs Controller General of India) in their paper on 'How to Improve Regulatory Practices for Refurbished Medical Devices' published in May 2023

The regulatory requirement mandates that all the adverse events should be notified to the National Coordination Centre (NCC) - MvPI via the designated Medical Devices Adverse Events Monitoring Centres (MDMC) which will, in turn, report and collaborate with other stakeholders.

The Indian Pharmacopoeia Commission (IPC) functions as NCC for MvPI. It is currently managing 174 MDMCs across India.

In the absence of specific guidelines for MvPI coupled with poor infrastructure and capacity building, recall action or safety signals generated by MvPI from reported adverse events remain negligible. There is low awareness about the reporting mechanism – consumers don't even know about the toll-free helpline 1800-180-3024. Even the annual performance report of MvPI and monitoring centres regarding collection and submission of data are not published at all.

Summary

It is clear that reuse of medical devices has to be done with a lot of care, which seems to be glaringly absent in India. Patient safety hangs in the balance here. It all boils down to the lack of proper regulation which again points to the need for a separate legislation for medical devices. In the absence of norms, the regulatory environment remains unpredictable, incomplete, incorrect and above all, hugely unsafe!

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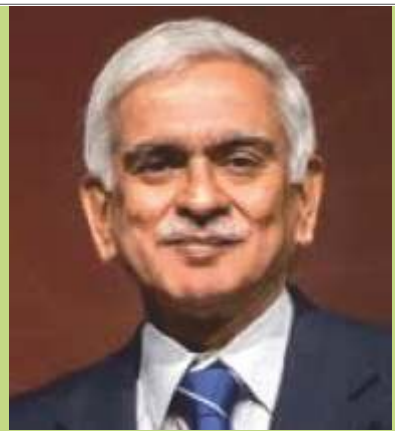


Drugs vs Devices

– The Need For A Different Regulatory Approach!

"Ensuring the safety and quality of any medical device is the duty of the manufacturer/distributor and the right of the consumer. The state is responsible for assuring the quality of every product placed on the market. Absence of clear and distinct regulations coupled with import of low-cost medical devices without internal quality control mechanisms puts the people at risk of injury and the Indian medical device industry at a huge disadvantage!"

– Dr. G.S. Bhuvaneshwar

It is clear from current international experience, that ensuring the safety of medical devices requires an entirely different approach and method of regulation from the one being applied to drugs and cosmetics!

ALTHOUGH MEDICAL DEVICES have been in existence for centuries, they did not become numerous or critical components in healthcare until the technological explosion following World War II. Since then, advances in implantation surgery and bio-materials technology have produced numerous critical life-saving and life-supporting devices.

It goes without saying that any foreign material that comes in contact with the human body – whether externally or internally – can have associated health risks. Moreover, the more sophisticated a device, the more complex is its operation and more serious are the consequences of its malfunctioning.

Therefore, like drugs, the entry of medical devices into the market or medical practice needs proper evaluation and approval in the form of systematic and rigorous pre-clinical and clinical studies to ensure their quality, efficacy and safety. Additionally, every implant and installed device needs to be assessed for its long-term safety and/or performance. This calls for a well-conceived regulatory agency supported by adequate legislative safeguards and resources.

Why Devices Cannot Be Regulated As Drugs?

- The wide range and huge number of medical devices that are being constantly introduced in comparison to the few drugs every year make the traditional pre-market approval approach impossible to implement.
- The duration of use of devices varies from a few minutes to long-term implantation inside the body. They can be single use disposables or reusable. Moreover, many devices have to be supplied sterile.
- Drugs generally have well-defined physiological characteristics, therapeutic effects and side effects. In contrast, medical devices can interact with the body and affect it in many different ways.
- The scientific disciplines involved in assessing new drugs are usually those of physiology, pharmacology, toxicology, medicine and biology. However, complex implantable devices can only be assessed by a multi-disciplinary team, since it may involve bio-compatibility, electronic circuits with ICs, computer programs, electrophysiology, hemodynamic effects, toxicology, etc.
- Overdose, incorrect drug administration or side effects usually lead to drug-related injuries or deaths. As devices are based on a number of advanced technologies having a great diversity in mechanism of their action, they can fail because of myriad mechanical faults, electrical component failure, software issues, biocompatibility problems or even material degradation.
- The failure of a drug is usually apparent quite soon after its administration to the patients. By contrast, an implantable device may fail after many years of use in a manner that was not predictable at the time of implantation. Therefore, clinical trials and pre-market evaluation are not as effective in predicting long-term adverse effects of devices as they are in the case of drugs.
- Then again, many device failures are attributed to user errors. Thus, the correct use has to be ensured to assure safety and performance of the device.
- Drugs have a relatively finite development period as a completely new molecule for a specific new treatment. Devices on the other hand, develop incrementally; i.e., they are evolving continually with small improvements and upgradation to existing models. Consequently, device standards have to be more complex and detailed to describe the many technical varieties of a device class. Device approvals also have to be re-assessed in line with the changes in technology.
- Some medical devices need regulatory interactions with the Atomic Energy regulatory agency. Some others may incorporate electronic instrumentation that emit or be affected by electromagnetic interferences and have electrical safety concerns. So, they need to be adequately safeguarded or regulated in all these aspects also.
- Medical devices should be so designed that they can be disposed safely, without causing environmental pollution or other hazards.

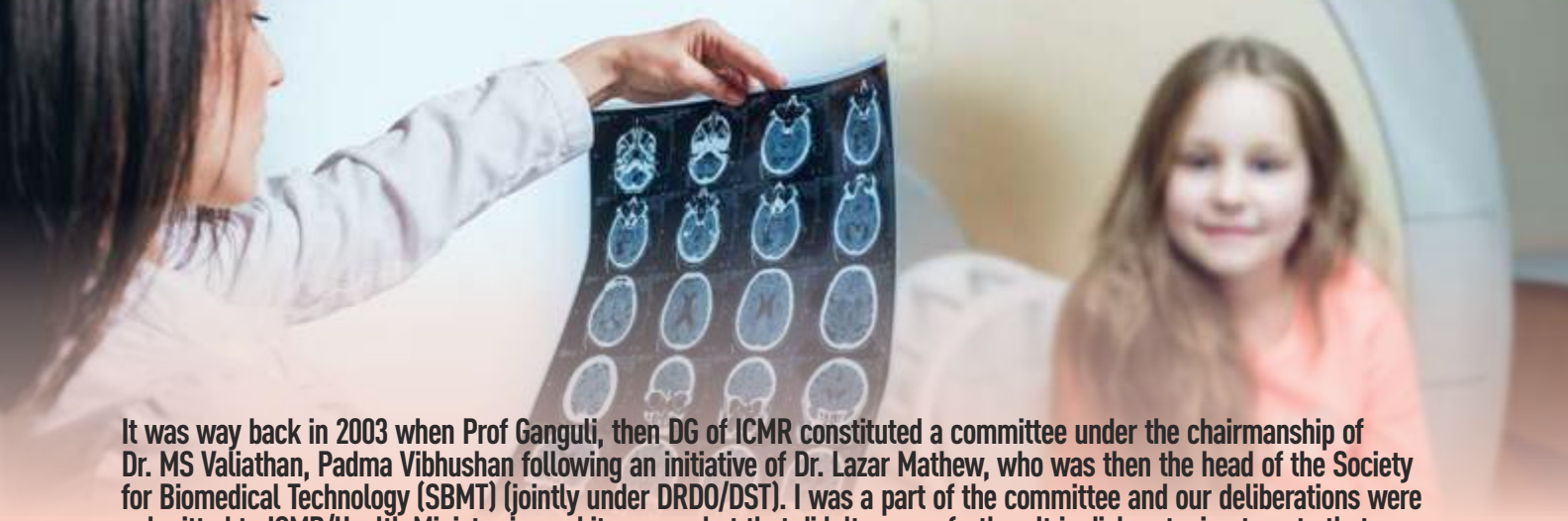
Need for an Independent Regulatory Body

The initial models for medical device regulation in the international arena were that of drugs, since the early entrants to this area have had long and well-established drug regulatory programs in their respective countries. As is well known, drug regulations rely heavily on exhaustive pre-market review of manufacturer's research data and clinical trials followed by approval and licensing of the drug by the regulatory agency.

Devices are categorised based on their risk assessment – we have simple low risk ones like stethoscopes and tongue depressors to high risk life-saving implants. The indiscriminate application of the drug model to device regulation has led to serious difficulties.

Modern medical devices are complex, are highly technology based and are not similar to drugs. The sheer complexity of modern devices makes assessment by traditional methods extremely difficult, if not impossible.

The most classic example of this failed approach is brought out by the history of device regulation in USA. Even the largest and most well-funded of regulatory agencies, Food and Drug Administration (FDA), USA could not implement the Medical Device Amendments of 1976 in its real spirit, which were based on the drug approach. Hence, the US congress had to make subsequent amendments to the original 1976 version to make the law appropriate to the needs of medical device regulations. All



It was way back in 2003 when Prof Ganguli, then DG of ICMR constituted a committee under the chairmanship of Dr. MS Valiathan, Padma Vibhushan following an initiative of Dr. Lazar Mathew, who was then the head of the Society for Biomedical Technology (SBMT) (jointly under DRDO/DST). I was a part of the committee and our deliberations were submitted to ICMR/Health Ministry in a white paper; but that didn't go any further. It is disheartening to note that many of the issues that were applicable then remain unaddressed till date. Unfortunately, India has lost a huge bank of opportunities for pushing forward MedTech manufacturing in these two decades.

It cannot be denied that we have made some good progress over the past 20 years – especially with the implementation of the Medical Devices Rules in 2017 - but a complete and effective system for regulation of medical devices is still a long way off. With the ongoing small steps, I am hoping to see a robust working regulatory system, maybe in 10 years from now!

these changes in the US system has moved them closer to the recommendations of the Global Harmonisation Task force (GHTF).

Even in India, the general tendency as of now is to insist on the same requirements as drugs for manufacturing of medical devices. Alas, the top functionaries in CDSCO have a pharmaceutical background only – hence little understanding of the technology and science involved in medical devices – and in turn fail to understand the regulatory requirements that are needed.

We do not have trained technical examiners to review the device technical files or inspect manufacturing units – particularly for high risk devices (Class C and D) – both for domestic and imported ones. Biomedical engineers were to be recruited and trained for this – some posts were proposed– but there is no information in the public domain if any progress was made on this important requirement.

Also, it is not known if CDSCO has considered and planned how these young engineers will be trained for technical examination – particularly considering the wide range of technologies involved. In my opinion, a core group should be sent to MHRA, UK for training on examining technical documentation and inspection of manufacturing facilities.

For auditing/inspecting manufacturing units of Class C and D devices, again, the personnel need training in ISO 13485 audit process as well as GMP requirements for various classes of devices. To be a good auditor, good experience in manufacturing and working under ISO 13485 QMS is need. For example, inspection of Class 10,000 clean areas – one needs experience in managing and maintaining them to understand how well a particular unit is being maintained and if it is really clean. Just paper checking of records is not enough.

I know of one European auditor, who would run his hands on working flat surfaces (table tops) to check for dust or look behind furniture to see if those difficult to reach areas are being regularly cleaned. One common spot of trouble is the back areas of Class 100 laminar flow benches!

What Can Be Done?

The GHTF recommendation, based on the European Union model, with a two-tiered system and a third party assessment seems most appropriate to us. A number of advantages can be realised by piggybacking on the EU system, including the benefits of a proven system, harmonisation with the global players, reducing the cost of regulation through international MRAs and most importantly, the possibility of fast-tracking the implementation.

Therefore, a separate medical device regulatory system in India with its own administering authority and technically qualified staff that are suitably organised to deal with the wide variety of technical challenges is very essential. It should be an independent and autonomous body. This will be advantageous to one and all, provided that it is well-implemented and administered like in Europe and many other developed and developing countries.

To sum up, without a separate regulatory framework for medical devices, India is prey to unscrupulous market influences that are putting patients' lives at risk!

The R&D efforts and the manufacturers in the field of medical devices are facing several constraints in our country. They appreciate the need for development of distinct regulatory mechanisms and formulation of appropriate legislation to implement those regulations.

Anil Jauhri
Ex-CEO, NABCB

UNDERSTANDING AUTHENTICITY OF CERTIFICATIONS IN MEDICAL DEVICES SECTOR

"As India transits from a largely unregulated regime to comprehensive regulation of medical devices under the Medical Devices Rules, 2017 wef 1 October, 2023, it must tackle another malady that afflicts the medical devices sector – the unauthentic, even fraudulent, certificates in the market!"

– Anil Jauhri, Ex-CEO, NABCB


CERTIFICATE OF COMPLIANCE

INTERNATIONAL CERTIFICATION SERVICES PVT. LTD.

QUALITY MANAGEMENT SYSTEM of

AIMTRON ELECTRONICS PVT. LTD.

Plot No. 1/A, G. I. D. C. Estate, Waghodia, Dist.- Vadodara 391 760, Gujarat, India.

ISO 13485: 2016

The Quality Management System for Medical Devices applicable to :

Scope : Provider Of Hi-Tech Electronic Assemblies And Contract Assembly Works.

Registration No. : RQMD91/9734
Registered Date : 13th January, 2018
Issue Date : 12th January, 2018
Expiry Date : 10th January 2021

Managing Director
International Certification Services Pvt. Ltd.

Accredited by National Accreditation Board For Certification Bodies, India.

Example of authentic certificate

Example of fake certificate

THE ROOT CAUSE of the problem is that anyone can set up a certification body in India – **there is no regulation which requires it to take any approval!** It can be a proprietorship, partnership or a private/public limited company; it can be a governmental or private body; it can be a trust or society; and it can be a profit or non-profit body.

How does one trust any of these certification bodies then, you may wonder.

If it is a governmental certification body - like the Bureau of Indian Standards (BIS) or STQC Directorate - you can trust it. You may trust it if it is a known brand name. Or if a friend recommends someone he had dealt with.

But is there a formal, structured way of authenticating a certification body?

Yes, fortunately there is!

It's called accreditation.

Almost every country around the world has an accreditation body – some like USA, Japan and South Korea have multiple such bodies that accredit certification bodies – be it management systems, products, processes or persons – based on applicable international standards produced by the International Organization for Standardization (ISO).

In India, the National Accreditation Board for Certification Bodies (NABCB), a constituent Board of the Quality Council of India (QCI), is the national accreditation body which accredits all types of certification bodies. This accreditation of third party bodies should not be confused with accreditation in healthcare or education, which in ISO terms is actually certification!

Certification can be of various types: The product certification that is most visible to Indian consumers since a long time is the well-recognized ISI mark or Agmark.

Since early 1990s, the management systems certification has popularized ISO like nothing else before – ISO 9001 for quality management systems, ISO 14001 for environment management systems, ISO 22000 for food safety management systems, ISO 13485 for medical devices and many more.

It has to be clearly understood that these certifications do not certify the product quality, although it is expected that the product would be good when coming out of such a system.

Then there are process certifications – like organic certification or good agricultural practice certification. There can be service certifications also – like education or healthcare. And finally, we have person or personnel certification – where individuals can be certified for their competence, like welders, electricians or yoga instructors.

How Does one Ensure that a Certification is Authentic?

If the certificate is issued by a governmental body, one can assume that the certificate is authentic. Again, if the certificate is issued by a certification body which is authorised by a regulatory body - like CDSCO in medical devices - it should be considered authentic. For example, the European Commission has a system of 'notified bodies' for medical devices and the list of notified bodies is available on the EC website. The well-known CE mark is a European regulatory mark and its presence on a product or certificate means the product complies with European regulations. If a manufacturer produces a certificate with CE mark, it must be from a 'notified body'.

Unfortunately, in India, many private certification bodies issue certificates with CE mark and there is no system of checking them in the absence of a regulation for certification bodies. Some certification bodies have even been issuing certificates of compliance to USFDA requirements for medical devices, when the USFDA does not use third party bodies at all! This is an issue for consumer organisations to agitate about and push the government!

If a certification body has been authorised by a regulator, even if without accreditation, it should be acceptable. We are all familiar with the ISI mark – both voluntary and mandatory – and trust it even though BIS is not accredited.

As regulators like FSSAI for food or CDSCO for drugs and medical devices are at the apex in the regulated sectors, in the voluntary sector, the body at the apex is called a Scheme Owner.

The scheme owner may decide to authorise certification bodies without any accreditation based on its own criteria. In such a case, the website of the scheme owner would display the names of authorised certification bodies. Certificates from such certification bodies, even if not accredited, should also be acceptable. In case of medical devices, there is the ICMED Scheme owned by the QCI jointly with the Association of Indian Medical Device Industry (AiMeD) – both management systems and product certification options being available – where certification bodies initially are approved on a provisional basis without accreditation. (website link https://qcin.org/indian-certification-for-medical-devices-icmed-scheme/)

Other than the above exceptions, it is essential that the certification bodies are accredited.

Accreditation ensures that the certification bodies adhere to international standards applicable, certify to recognised auditable standards, are impartial and competent and follow a uniform process consistently. It's important to stress 'recognised standards' because may certification bodies, in pursuit of more business, certify to standards which are not auditable. For instance, accreditation bodies are barred from accrediting certain certifications – e.g., ISO 31000 for risk management or Codex HACCP – which are guidance standards and not auditable. Therefore, one must shun any unaccredited certificates.

However, there is still a catch - The accreditation bodies can be suspect or unauthentic too!

NABCB is signatory to APAC MRAs and IAF MLAs for all its schemes where such arrangement is in place. This includes ISO 13485 for medical devices.

Who Supervises Accreditation Bodies?

If you think ISO, you are wrong. ISO is only in standards setting and has no role in certification against its standards.

Then who? Fortunately, some visionaries saw the need for an oversight and established the International Accreditation Forum (IAF) in 1993. To support the oversight, there are regional bodies like Asia Pacific Accreditation Cooperation (APAC),in case of India.

The accreditation bodies can become members of APAC and IAF and are then subject to oversight by them. The regional bodies evaluate individual accreditation bodies every four years, and if successful the first time, they can sign a multilateral mutual recognition arrangement (MRA in APAC and MLA in IAF). This means that the accreditation body is internationally equivalent and recognised so by its fellow members in other countries.

The certificate for ISO 13485 must carry the logo of the Accreditation Body (AB), NABCB or any other IAF MLA signatory AB, to be recognised as authentic. It may also carry IAF logo to further provide proof of international equivalence, but this is optional. Its absence does not mean that the certificate is not internationally equivalent.

But there is a problem.

The oversight system of IAF is entirely voluntary – there is no law which requires an AB to be member of IAF – nor is there any law which requires a Conformity Body (CB) to be accredited under IAF system.

So, there are ABs carrying addresses in Europe or USA (who are not members of IAF) accrediting CBs in India and elsewhere whose credentials are unknown. These are the certificates which need to be shunned.

Sometimes, well-known scheme owners may recognise specific accreditation bodies, not members of IAF, for their purposes – these may be considered authentic. Fortunately, such exceptions are not yet prevalent in medical devices sector and therefore, logo of an IAF MLA signatory accreditation body is the best assurance of the certificate being authentic.

In order to enable check on authenticity of certificates, IAF has taken another significant step – to create a global database of management systems certificates like ISO 9001, ISO 13485 etc. While the database is still being populated, it would serve as an excellent tool to check the genuineness of certificates (https://www.iafcertsearch.org/),

To sum up, the certificate should be issued by a:

- Government body
- Certification body authorised by any regulator or government agency
- Certification body approved by a recognised scheme owner in voluntary sector
- Certification body which is accredited by a signatory to IAF MLA for ISO 13485, with the certificate carrying the logo of the AB and preferably the IAF logo too
- Certification body which is accredited by an IAF member body, if IAF does not have a mutual recognition programme yet.

To conclude, till proper regulations are not in place, manufacturers of medical devices will show mostly show unauthentic certificates to impress the buyers who are generally ignorant. There is no quality assurance as voluntary, unauthentic and even fake certificates continue to rule the Indian market!

Mr. Rajiv Nath
- Forum Coordinator, AiMeD (Association of Indian Medical Devices Industry) and MD of Hindustan Syringes & Medical Devices Ltd

An Aspiring Nation Needs a Modern Regulatory Framework for Patient Safety

THE MOST IMPORTANT aspect of our NMD (National Medical Devices) Policy 2023 is the patient-centric approach. The Policy aims to build an innovative and globally competitive industry in India, supported by world-class infrastructure in alignment with PM Gati Shakti, Make in India and Atmanirbhar Bharat programs. The goal is to become a global leader in the manufacturing and innovation of medical devices by increasing our market share in the global market from the current 1.5% to 10-12% in the next 25 years.

This is a huge step forward considering the lack of access to home grown medical devices noticed at the onset of COVID-19 in 2020 that exposed our critical healthcare insecurity. Regretfully, a section of the government is being misled by some administrators and India recently slid back two steps from achieving these global ambitions.

First, by recently allowing the imports of preowned medical equipment by Ministry of Environment, the risk of importing sub-standard products into the country will increase. This will negatively impact the manufacturing and innovation of medical devices in India, slow down investments in the sector, and discourage domestic manufacturers. Also, the industry can in no way compete with abysmally low priced imports.

MNCs having no use for their obsolete products in their own country and dump this in India. Other countries like China, Vietnam, Indonesia, Egypt, Peru, etc. have strictly banned the imports of such equipment.

Should India be importing preowned equipment in the name of affordable access where clinics don't necessarily give a discount to patients by way of age of equipment or would patients gain more in the long term by our country seeking investments to Make in India?

Patient Safety may be hugely compromised with exposure to obsolete technology and absence of calibration and validated performance and attempts for maintenance by *jugaads.* This policy needs a review and roll back.

It's shocking that FICCI - set up as the voice of India's business and industry - permitted it's Medical Devices division to be misused for helping overseas manufacturers dangle carrots of affordable access to patients to befool the policymakers so that not only their overseas replacement market can thrive and money is made twice, but also as a clever competitive strategic move to stumble the upcoming healthy domestic competition in medical electronics devices manufacturing.

One Step Forward Two Steps Back

The second step backward - In over 30 years, till 2022, hardly 30 medical device product categories got regulated, that too incorrectly under the Drugs Act. Most industries avoid regulations. However, many aspiring medical devices manufacturers sought regulations, but as appropriate regulations. MoHFW recently listed tabling of a new bill on Drugs, Cosmetics & Devices to the Parliament this monsoon session with the intended aim of ensuring higher Patient Safety.

Regretfully a golden opportunity to provide progressive modern regulations benchmarked to latest best international regulations was being squandered away as it's a flawed bill by a flawed process – drafted by a committee of regulators to empower themselves as a huge conflict of interest, without following due democratic pre-legislative processes and that continues to seek to regulate devices alongside drugs under the garb of a separate chapter for some provisions instead of using the opportunity to bring in a progressive modern separate law for addressing Patient Safety needs and using the earlier separate visionary NITI Aayog draft Medical Devices Bill (Safety, Effectiveness &Innovation) Bill 2019 or using impactful references of the separate medical devices legislations as in Canada, UK, EU, Brazil, Japan, Saudi Arabia, etc.

It has even revised the definition of 'manufacturer' that will now allow a marketing company to get a manufacturing licence and inadvertently proposes to legalise pseudo manufacturing of low-quality cheaper imports that may affect patient safety. Unfortunately, it discourages investments to manufacture these in India by treating domestic manufacturers as potential criminals while overseas manufacturers are not required to go through the same rigours to demonstrate conformity.

Engineers and scientists who step forward to design and develop products need to do so fearlessly following defined simple regulatory pathways. Manufacturers similarly need to be disciplined for compliance to regulatory conformity requirements and prove conformity by third party certification or testing to accredited certification bodies and laboratories. The regulators and QCI's NABCB (National Accreditation Board of Certification Bodies) need to jointly supervise the performance of these certification bodies and laboratories to ensure a competent staff with relevant expertise is auditing manufacturers and seeking continuous improvement in quality management systems and product performance. India needs to move away from Inspector Raj with inspectors empowered for search and seizure for even licensed manufacturers instead of treating them as criminals with threats of imprisonment for even minor offences.

We can't be building world class expressways and expect public to drive at a speed limit of 60 km per hour and fine and harass majority of them for breaking the law. Instead, if strong discipline is inculcated, we need to aim to for safer higher speed limits until we have the confidence to trust our drivers like in Germany and even not have an upper speed limit but a minimal speed limit on the expressways. A strong post-market surveillance is needed to monitor the medical devices marketplace to ensure the regulatory system is

A good law needs to be simple, reasonable, implementable and give direction of intent for a progressive aspiring nation. Medical electronic devices, which are an engineering product, like cars can't be manufactured or regulated like drugs and need to be stored, transported, installed and maintained and regularly calibrated to ensure patient safety for the lifecycle of the product. Users need to be trained and skilled to use medical devices safely and appropriately and have a shared responsibility in the upkeep.

performing well, and when triggered by an adverse event reporting then instead of witch-hunting, systemic preventive and corrective actions are sought by regulators to ensure patient safety.

The wise Parliamentarians in the Health & Family Welfare Committee responded to the government's action taken report that instead of drafting a combined legislation for Drugs, Medical Devices and Cosmetics, the Ministry should appreciate the huge potential of the medical device industry and formulate a separate legislation for Medical Devices.

The Committee reiterated its earlier recommendations made last year that the new legislation should set up a new set of regulators at different levels for regulating the medical devices industry. Unlike the present structure, the proposed National Regulator should license the manufacturing of medical devices (like FSSAI) and the state regulators be supervised by the National Regulatory Authority to help harmonise the regulatory process throughout the country.

The Committee believes that with industry growing by leaps and bounds, the government cannot afford regulation of medical devices by pharma experts and its time the medical device regulations are dispensed with by qualified and well-trained Medical Device Officers to give a fillip to the medical device industry in the country. Therefore, a separate regulatory infrastructure for medical devices with a dedicated workforce - instead of adjoining with the CDSCO - would serve the purpose better.

The Committee recommends the Ministry to introduce stringent standards and certification processes (particularly for Class C&D products) comparable to global standards. The Ministry, along with compulsory compliance to Quality Management System as per schedule 5 of the MDR, 2017, should also allow cognizance to third party voluntary assurance schemes like QCI's ICMED 13485.

The Parliament Health Committee rightly felt that since MoHFW was the key stakeholder in medical devices, the inter-ministry coordination for the promotion of medical devices should be done by this ministry only. CDSCO as a regulator needs to enforce regulations and not usurp the job of the policymakers.

Time will tell if the Dog wags the Tail, or the Tail will continue to wag the Dog!

Medical Devices Need Patient-Centred Regulations!

Malini Aisola
Co-Convenor of the
All India Drug Action Network
(AIDAN)

Health watchdog, All India Drug Action Network (AIDAN) is an independent network ofindividuals and non-governmental organisations working to increase access to and improve the rational use of medicines and health products.

THE DRUGS AND Cosmetics Act, 1940 and Medical Device Rules, 2017, which together constitute the current regime of regulation for medical devices, do not address primary aspects of patient safety. Unfortunately, the draft Drugs, Medical Devices and Cosmetics Bill, 2023 does little to plug gaps and lacunae in the prevailing Act, and similarly lacks a genuine consumer/patient interest grounding.

As medical device manufacturers and their associations in India have been vociferously advocating, there remains a concern about clubbing pharmaceuticals and medical devices under the same law without adequately addressing the distinct regulatory requirements that arise due to the differences between these types of health products.

Medical devices cover a huge range of products that differ in complexity, use and potential risk for the user (from thermometers to diagnostic tests and equipment, consumables, implants and many more). They are often composite products, requiring the application of skills from fields such as engineering, biotechnology, pharmaceutical science, software etc., because of which transplanting the basic regulatory framework for pharmaceuticals to medical devices is problematic.

Patient Safety Concerns

The overarching objective underlying regulation of health products by any country is to ensure access to safe, quality and efficacious products. Yet, consumer/patient safety concerns, instead of having primacy in the regulatory framework, are insufficiently addressed both in the written law as well as in implementation in India.

I touch upon several such patient concerns that should be embedded in the applicable laws and regulations across the entire lifecycle of a medical device –clinical investigations/clinical performance evaluations of devices during the pre-licensure phase, when the device has received licensure and is being marketed, and during any events of failure.

Clinical Investigations – New medical devices (not having a predicate device already present in the market) should undergo clinical investigative studies involving human participants (clinical performance evaluations are required in the case of in vitro diagnostics) as per the current rules. Yet, there are no clearly defined norms for conducting clinical investigations, particularly for high-risk devices that go into the body of a patient or have higher potential to cause harm, leading to some very poor study designsand insufficient or dubiousdata.

There is a complete lack of transparency in the way the regulatory mechanism and expert committees provide recommendations and undertake assessments of the studies, and the data which is the basis for granting approval. Medical device manufacturers, on their end, often do not share or publish the details either of the studies undertaken or their results.

Presently, in the absence of clearly defined norms for conducting investigations, some of the industry players are getting away with ridiculous study designs. Nobody knows how a medical device gets approval, how it was assessed by the experts or the data on the basis of which approval was granted!

This lack of transparency extends to cases where waivers from investigational studies have been granted by the regulator, based on the determination of equivalence with a predicate device that has been previously approved.

As medical devices, such as implants, are used over an extended period of time and years, devices which have accumulated data over many years and have an established safety profile may sometimes be clinically preferred to an upgraded version with new features but that may have limited data of just a few months/years. In the current scenario, the consumer is complete unaware of the scientific data that was considered in granting approval for the device, which could otherwise aid in health decisions.

Under current law, medical devices are granted virtually automatic approval in India if they have received licensure/certification for use in a number of developed country jurisdictions. Yet, even in high-income countries, the laws may have serious loopholes (e.g., 510(k) approvals in the US) or have sub-optimal and watered down requirements for granting approval (as under the CE certification prior to amendments in recent years). Moreover, even these regulatory agencies are not immune to undue influence by industry lobbies[1]. It bears noting that a blanket dependence on some foreign regulatory systems, if applied without regulatory scrutiny by the Indian regulator, would not be prudent.

In the process of expanding regulatory oversight to all medical devices in the country, the maximum timeframe for registration and coming into compliance with the Medical Devices Rules, 2017 has been granted to the devices with highest risk classification (classes C & D), and the deadline keeps getting extended. Two key factors have played a role – 1) CDSCO's insufficient competence and expertise in respect of medical devices coupled with a lack of capacity to clear applications by manufacturers and 2) intense pressure from the industry to delay regulation. This situation does not serve the consumer who needs to be protected in the use of the most invasive and high risk devices.

[1]https://www.icij.org/investigations/implant-files/

Marketing and promotion – The marketing and sale of medical devices in India is driven by commissions and inducements in the supply chain which is the source of deep market distortions. Particularly, large healthcare institutions (that can provide a high volume of sales for medical device marketers)are serviced with the highest commissions by companies with deep pockets to push and prefer their products.

Not only does this culminate in artificially inflated prices of the devices - the cost of which must be borne by the patient - but it also has implications for rationality and appropriateness of medical interventions. For example, patients are often pushed towards relatively more expensive or 'latest'/'advanced' model of a device even though they may not actually be associated with better clinical outcomes. The only difference is some additional superficial features. Worse, they may be advised to undergo unnecessary procedures to boost revenues of the healthcare institution.

The law should lay down clear provisions for marketing and ethical promotion with specific penalties and corrective action for flouting the rules. Mandatory disclosure requirements of company sponsorships to hospitals or medical practitioners should be put in place; this should include details about conference funding, and the terms and remuneration of any professional agreements/ contracts of doctors working for companies (e.g., company advisory boards for development of a device).

A law being envisioned to regulate safety and quality of medical devices would be the right place to address these concerns as they are linked to the safety and well-being of the patients, also keeping in mind the failure of the Department of Pharmaceuticals to bring in a statutory instrument to regulate marketing.

Though issues of pricing merit a discussion that is beyond the scope of this article, the CDSCO (under the MoHFW) also has a role in working with the NPPA and other arms of the government towards actively promoting affordability of medical devices, especially the commonly used and critical devices.

Post-marketing surveillance; adverse event reporting; procedures and penalties for quality failures – As mentioned earlier, medical devices like implants (stents, orthopaedic implants, pacemakers, etc.) are designed to function optimally inside the body for several years. Unlike pharmaceuticals, where negative effects can be picked up within a matter of hours, days or weeks, many medical devices require long term monitoring and ongoing surveillance through the expected lifespan of the device. Therefore, the follow up periods in investigational studies are inadequate to pick up safety issues that may develop over a period of time.

Registries for individual high-risk devices such as cardiac stents or orthopaedic implants have been established in many developed countries, but these are still mostly absent in India, except for an initiative to set up a National Joint Registry a few years ago, without the involvement of the government.

Adverse event reporting remains particularly critical. The Materiovigilance Programme of India (MvPI), under the Indian Pharmacopeia Commission (IPC), is the nodal program for reporting of adverse events caused by medical devices. It is meant to gather data about adverse events, including from patient reports of untoward occurrences and to identify clusters of incidents pertaining to a device, and to aid in identifying substandard, malfunctioning or faulty devices. In reality, this is a far

The Indian regulatory system lacks clear norms for post-marketing studies to be conducted in India and companies are often conducting extremely limited studies with short follow-up of only 6 months or a year.

Excerpts from 'Need for Patient-Oriented Comprehensive Regulation of Medical Devices', Statement by Hip Implant Patients Support Group (HIPS) and All India Drug Action Network (AIDAN), 5 October 2019:

Towards instituting a patient-oriented regulatory regime for medical devices, we believe there is a need to bring in urgent regulations and reforms in the following broad areas:

- **strengthen regulatory systems for ensuring product safety through adequate testing and laying down of norms for clinical trials and related investigations particularly for high-risk devices and implants**
- **approval of foreign made devices: examine critically the data submitted by the manufacturers and relied upon the foreign regulators before deciding to waive trial and testing requirements in India, and in general stop overreliance on foreign regulatory authorities for granting licenses in India**
- **statutory provisions to check unethical business practices in the marketing and promotion of medical devices that cover manufacturers, traders and institutions and greater scrutiny of conflicts of interest of doctors hired by manufacturers to promote or develop devices**
- **standard treatment protocols for common procedures involving the use of medical devices and medical audits to curb irrational treatment**
- **consistent post-marketing monitoring of performance of devices, particularly high-risk devices, including institution of patient registries**
- **urgent need for revamping regulations pertaining to reporting and collection of adverse events and instituting systems to ensure responsiveness of the regulatory agency in dealing with device failures, including public awareness, statutory recalls and cancellation of licenses**
- **provisions for compensation to victims of faulty implants**
- **affordable pricing – instituting ceiling price caps on devices regulated under the Drugs and Cosmetics Act and commonly used consumables in order to make these critical devices accessible, reduce financial burden of patients to curb corrupt practices that are driving up the costs of healthcare.**

from rigorous mechanism that operates like a blackhole because there is no public access to any aspects or analysis of the adverse events database. The patient reporting format is also extremely inaccessible for members of the public to submit. Most importantly, there is very little information about how the MvPI links to the CDSCO to enable the regulatory body to make use of the data for conducting investigations and issuing alerts or recalls.

Procedures for recalls of medical devices that have found to be substandard or faulty need to be laid out through legal provisions. Recalls, depending on the extent and severity, may not be exclusively conducted by the company, but also government-led to mitigate risks to the public and prevent further harm from use of the faulty device in question. The government also needs to bring in a mode of compensation for serious injury or death caused by the failure of a medical devices in real world settings – compensation is currently provided only during clinical investigations.

Penalties defined in the draft Bill for violations of regulatory standards are a major sticking point with the industry. One could support graded penalties depending on and proportionate to the severity of the transgression and its outcomes, including administrative action, fines or prosecution. The idea should be to instil greater accountability and facilitate corrective action for an industry that is still building its foundations in India. Still criminal provisions may be retained to penalise serious offences and as a deterrent to curbwanton malpractices.

It bears mention that infirmities in the framing of the current law have also contributed to Johnson & Johnson not being held to account for the suffering and disability of hundreds of patients across India caused by faulty metal-on-metal hip implants and evidence of non-compliance with terms of licensure. This example should be kept in mind while framing laws so that such instances never recur in the future.

In short, we have to think like a patient to protect their interests and to ensure their safety while using medical devices!

UPDATE ...

Moving a Step Ahead

Update on the September edition on

World Patient Safety Day 2023 – Initiatives by NABH

National Accreditation Board for Hospitals and Healthcare Providers (NABH) conducted a series of activities to mark World Patient Safety Day 2023

- **NABH Patient Safety Conference 2023 (NPSC 2023)** - Adopting the message and this year's theme, NABH organised a one-day conference 'NABH Patient Safety Conference 2023' on 17th September on the theme “Deep Diving Into all the Facets of Patient Safety”. It marked the congregation of global thought leaders, industry experts and healthcare practitioners sharing their experiences, best practices and new innovative approaches to patient safety. The fundamental aim of the conference was to discuss how proactive practices for patient care, streamlined systems for understanding and involving patients in the healthcare systems and decision making can improve patient safety. More than 500 delegates from all over the country actively participated,

marking this event as one of the biggest conferences in India.

- **NABH Quality Connect Grants 2023 -** This program is for the healthcare quality professionals who are keen to establish new initiatives with innovative thinking and changemaking in the field of healthcare quality and patient safety. It was proposed to award grants ranging from Rs. 25,000/- to Rs. 1,00,000/- to those selected for the program. Five innovative proposals were selected and were awarded trophies, certificates and cheques.

- **NABH Best Practices Club -** To encourage sustainable quality in healthcare and patient safety, innovative ideas and implemented practices, NABH came up with an initiative to provide a platform named "NABH Best Practices Club" where NABH accredited/ certified/applicant hospitals can present and pitch the best practices in their organisations. Five innovative and best practices were selected and awarded trophies and certificates.

- **Release of New and Revised NABH Standards -** NABH released 6 new and revised standards which will help the healthcare industry to promote quality in various aspects of healthcare.

- **NABH-NATHEALTH Patient Safety Microsite -** Taking patient safety high up on the agenda and improving health seeking behaviour for improving health outcomes by an intense mass media public education programme, NABH and NATHEALTH launched Patient Safety microsite to support government's intent to focus on quality healthcare by unpacking the key indicators for quality healthcare.

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YOUR OPINION MATTERS

We are truly humbled by the praise and acknowledgment that is flowing in from varied sources. Please feel free to send in your comments, views or feedback on The Aware Consumer magazine at bejonmisra@theawareconsumer.in – we will publish your opinions and implement your feedback while ensuring that your voice is heard on the right platforms.

letters to the editor

(September issue: World Patient Safety Day 2023 Theme: Engaging Patients for Patient Safety)

The editorial in Aware Magazine on patient safety is not just informative but also thought-provoking. It sheds light on a critical issue that affects every individual who seeks medical care. The piece effectively highlights the fundamental expectation we all have when entering a healthcare facility – to get better, not worse.

The statistics presented by the World Health Organization (WHO) are staggering and serve as a wake-up call. It is evident that patient safety is a global concern that demands immediate attention.

What makes this editorial truly commendable is its balanced perspective. It acknowledges that healthcare providers are dedicated to their patients and their wellbeing. However, it also emphasises the undeniable reality that errors can occur for various reasons. This acknowledgment is vital in fostering understanding and collaboration to address this issue.

The editorial's focus on World Patient Safety Day, declared by WHO on September 17th, underscores the urgency of the matter. It emphasises that patient safety is not just a healthcare concern but also a global health priority. This call for global solidarity and concerted action is precisely what the world needs to make progress in improving patient safety!

Furthermore, the editorial rightly highlights that patient safety is an integral part of achieving universal health coverage. Patients should be able to trust the healthcare system to provide them with safe, high-quality care, and healthcare providers bear the responsibility to make this trust a reality. The emphasis on skills, knowledge, communication and engagement as essential components of patient safety is a crucial reminder that it's not just about avoiding mistakes but also about delivering compassionate care.

In conclusion, the Aware Consumer magazine edition on patient safety is an eye-opening piece that raises awareness about a pressing issue while maintaining a constructive and empathetic tone. It calls for action and underscores the importance of patient safety as a global concern. It is a magazine that should be read by healthcare professionals and patients alike, serving as a reminder that everyone plays a role in making healthcare safer for all.

Really impressed with India's progress in patient safety!

– Deepak Talati
President,Sechrist Industries, Inc., USA
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We are extremely lucky to have sucha dedicated team which has presented the nation the 100th edition of The Aware Consumer.

The service and support provided by various editions would pave the path for all the healthcare professionals to safeguard the Safety, Rights and Well-being of consumers.

I am lucky to have association with such a wonderful team of yours. Heartfelt congratulations to each of the members for their untiring efforts. Wish a grand success to your team in future too.

*– **Dr G N Singh,** Advisor to Hon'ble CM,UP & Former DCGI*

The Aware Consumer magazine September 2023 issue focused on World Patient Safety Day. The editor's Message "Putting Patient Safety First" highlighting the pressing need to prevent and minimise harm to patients during the course of their medical treatment is of contemporary significance. Empowering for patient safety and well-being byMr. Prafull D Sheth, (Member, Editorial Board) is an eye-opener suggesting that patients also have to become equal partners with the healthcare team in our care. In the article "Reporting Medication Errors", Dr. Jai Prakash suggested using the mobile application ADR-PvPI and toll-free helpline to report the ADRs are more consumer-focused.

The article "Looming Threat of Errors in Diagnosis" by Ms. Payal Agarwal nicely narrates gaps in patient safety in laboratory medicine. "Overcoming Medication Errors to Drive Safety for Patients" by Ms. Bina Jain mentions decreased patient satisfaction and a growing lack of trust in the healthcare system.

Overall, all articles in the Magazine are highly beneficial to the public as the consumer of various commodities.

– Dr. Jayasekhar P Nair
Former Professor of Pharmacy, Government Medical College, Kozhikode • p.jayasekhar@gmail.com

The September issue of 'The Aware Consumer' is packed with valuable information. Prof. Misra's editorial, 'Putting Patient Safety First,' rightly points out that patients should trust the healthcare system. I firmly believe that patients pay for the trust that manifests itself in safe, secure and sustainable healthcare delivery when seeking the same.

Mr. Prafull D. Sheth, in his column, rightly points out that strong accreditation benchmarks will usher in a paradigm shift in healthcare delivery by sensitizing the healthcare community towards their rights and responsibilities. The article 'Need to Strengthen Oversight on Spurious Drugs with Drug Regulations' was very interesting and shed light on many contentious issues.

The article on 'Accreditation of Healthcare Providers in India' was informative. Still, the author could have taken some pain to explain how the patient safety measures and protocols are monitored, as there are alarming numbers of cases of poor patient safety even in NABH-accredited hospitals. The article 'Putting Patient Safety at the Centre of Digital Health' is a timely reminder of things to unfold in the days to come.

The selection of articles was well thought out and organized, and I liked the captivating gait of the magazine.

*– **Dr. Abhijit K Chattoraj** (PhD)*
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WATCH OUT

Watch out for the next issue in December dedicated to 'Improving Access to Safe and Quality Medical Products' on the occasion of National Consumer Day!

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