



“Latest medical technology bill opens a suitable channel for adopting new technologies”

In an exclusive interaction, Ms. Chandra Ganjoo, Group Chief Executive Officer, Triviron Healthcare shared her views on the regulatory bottlenecks for the medical technology sector, policy initiatives by the government, growth opportunities and much more.

BY RAHUL KOUL

Why hasn't the Indian medical technology industry been able to create a long-lasting impact globally? Why do we lag despite huge growth opportunities and skilled manpower?

With the majority of healthcare components, including the medical device industry, achieving outstanding outcomes in recent years, India has become one of the world's healthcare marketplaces with the quickest rate of growth. The Indian market for medical devices is ranked among the top 20 markets worldwide and is the fourth largest in Asia. Even while the healthcare industry has grown significantly in income and employment, imports still account for approximately 80% of the country's MedTech sector sales. In addition, the lack of adequate auxiliary manufacturing, supportive supply chain networks, and pertinent infrastructure prevents the production of high-quality medical devices in India.

The industry is highly competitive and fragmented, with domestic firms primarily producing low-technology products such as disposables and medical supplies and multinational corporations primarily importing high-end medical equipment. In recent years, however, some domestic companies have established extended local manufacturing operations to produce cost-effective medical devices. Most multinational corporations are involved in distributing medical technology products, while a few have established manufacturing

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operations in India. Joint ventures with local manufacturers, the establishment of subsidiaries, and the employment of local agents are typical strategies that multinational corporations seek to enter a new market. Still, many of these businesses are abandoning importing through local agents in favor of establishing subsidiaries.

India is primarily an importer of advanced medical technology products. Imports account for approximately 75% of the Indian medical technology market. Imaging equipment, pacemakers, orthopedic and prosthetic appliances, breathing and respiration apparatus, and dental equipment are the principal import categories into India. It is fascinating that although India's medical technology industry relies primarily on imports, nearly 60 percent of what is manufactured is exported. Exports account for up to 75 percent of some companies' revenue.

Though the number of STEM graduates in India are highest, there is a glaring misalignment between biomedical education and engineering disciplines. Unfortunately, only 217 biomedical engineering institutions in the nation provide

full-fledged courses in a country that is the fourth-largest medical device producer in Asia. Therefore, a streamlined approach is required where we have to align from the grass root level (education institutes) to policies that can address the manufacturing concerns to capture even the high-end medical device market at the global level.

What are your views on the Make in India initiative and PLI scheme for the medical technology sector? Has it benefited the industry, and how can it be made better?

The Indian government has designated the manufacturing ecosystem for medical devices as a priority area for its flagship "Make in India" initiative. The Production Linked Incentive Scheme (PLI) Promoting Domestic Manufacturing of Medical Devices and the Production Linked Incentive Scheme for Pharmaceuticals (PLI 2.0) has been created to support India's goal of becoming a centre for medical device manufacturing on a global scale.

The PLI program will reduce import costs, increase local manufacturing, and encourage foreign investment. The "Make in

India" program will gradually lessen India's reliance on exports and turn it into a global manufacturing centre. The path toward improvement is visible, and continuous focus will show results in the coming years. We cannot deny that these initiatives reflect India's dedication to Aatmanirbharta in Medical Devices and will improve India's manufacturing capabilities and stimulate R&D in the industry. The change data may not reflect the impact as of now, but the final results will be much better in the form of establishing India's dominance.

What do you think of the union government's move to promote medical device zones and parks in various parts of India?

The construction of world-class

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common infrastructure facilities will make it simple to access standard testing and infrastructure facilities, significantly lowering the cost of producing medical devices and improving availability and affordability on the domestic market. The move should be seen

as a part of the larger plan to enhance presence at the global level.

How do you view the regulatory scenario for Medtech in India? Is a level playing field possible for both MNCs and domestic players?

The Drugs, Medical Devices, and Cosmetics Bill, 2022, was released by the Ministry of Health and Family Welfare in August to revise the Drugs and Cosmetics Act of 1940 (D&CA), passed by the Central Legislative Assembly before independence. While there are legally enforceable criteria for medications, there are none for medical devices, and there is no way to bring charges against medical device manufacturers. The Bill corrects this deficiency by proposing abolishing D&CA to open a suitable channel for adopting new technologies. It will keep up with the pace of change in society, technology, and legal requirements. The scope relating to medical device quality is another key modification made by the Bill. This is especially crucial for produced, imported medical equipment that does not meet the required requirements or is fake, mislabeled, illegal, or contaminated. However, a topic of discussion is that the Bill does not differentiate between in-vitro diagnostic tools and medical tools for safety and efficacy studies.

There will be a level playing field for MNCs, and domestic competitors as the Bill proposes to establish independent authorities and boards for the regulation of medical devices.



Additionally, the Bill proposes the creation of the Medical Devices Technical Advisory Board (MDTAB), which will be composed of individuals with technical expertise in medical devices, members of the business community, and specialists in the field of biomedical technology, among others, who the Central Government will choose. Additionally, the Bill calls for the establishment of central and state testing facilities for medical devices. India is definitely on the path to ensuring that medical products are sold safely and effectively while they conform to the prescribed quality standards.

There have been demands for a separate department for medical devices under the health ministry. Do you justify it?

Many Indian Manufacturer Associations have been emphasizing the urgent need for a separate department for medical devices and to rename the Department of Pharmaceuticals (DoP) as the Department of Pharmaceuticals & Medical Devices or create a separate Department of Medical Devices. The goal is to make India one of the top five global hubs for medical device manufacturing and serve as the industry's point of contact with all central government departments to spur the development of the Make in India. A separate department will also help combat priority diseases as it would specify priority devices.

What are the major initiatives

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and achievements of Trivitron Healthcare in the last year?

With many opportunities in healthcare, we are impactful in bringing a change to society with our healthcare solutions. Innovating with new products is at our core. With the integration of our advanced research and innovations by our engineers and scientists, we are on the path to delivering top-quality healthcare solutions.

We are committed to deliver affordable, accessible, and quality healthcare. With various diseases emerging as prevalent diseases for the masses, our special facilities, combined with science, data, research, and technology, will continue to work on better diagnosis and prognosis with next-generation sequencing (NGS), proteomics, genomics, and advanced diagnostic solutions to transform the healthcare ecosystem. New products are coming up in our Medical Imaging, Newborn Screening, Critical Care, Renal Care, and Radiation Protection range for enhancing medical care.

What are your key focus areas at the moment? How do you address the demand for quality as well as affordable medical devices at the same time?

Trivitron Healthcare's key focus is providing the best quality and affordable solutions to many healthcare providers and medical professionals. Our team of leading scientists has solid research and development expertise; we spearhead innovation in In-Vitro Diagnostics, Imaging & Radiology, Radiation Protection, Newborn Screening, Critical Care & Operating Room Solutions and Renal Care.

Trivitron products are made after implementing rigorous product development and manufacturing processes to offer a reduction in laboratory and diagnostics errors by ensuring the best possible safety and efficacy of results.

What is your future outlook for the company and the medical technology sector in India?

There are many possibilities in the healthcare sector, and we are aligning ourselves quickly to deliver the best to create an impact with positive changes in our healthcare solutions. The motto of New India is Atmanirbhar Bharat, and we, as an indigenous healthcare organization, are implementing new strategies and plans that will enable the company to accelerate its core business globally and capitalize on new growth prospects. ■

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