



# PULSE

## a healthcare update

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### Perspective



## The Medtech Landscape of India: Challenges and Opportunities

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India is one of the fastest-growing markets for healthcare services, globally. The country's demographics, a rapidly aging population, growing middle class, and increasing prevalence of lifestyle-related diseases have created a surge in demand for advanced healthcare solutions.

Currently, India's healthcare system is undergoing a transformation, and the medical technology (Medtech) sector is emerging as a critical player in this evolution. However, despite its growth potential, the sector faces significant challenges, particularly in terms of import dependency, domestic manufacturing, and regulatory hurdles such as price capping.

### Underlining the need for MedTech Solutions

India's healthcare challenges are deeply tied to its demographic trends. Today, India has surpassed China to become the world's most populous country. By 2050, the proportion of individuals over the age of 60 will almost double, reaching approximately 320 million. This aging population will require increasing access to medical devices to address chronic diseases.

However, India's MedTech landscape remains underdeveloped compared to global standards. This gap is partly a result of heavy reliance on imported medical devices, impacting domestic manufacturing and innovation. The dependency on imports of medical devices, components and raw materials particularly on China raises concerns about the availability and affordability of medical technologies.

Recognizing the need to reduce import dependency, fostering a self-reliant MedTech industry for universal healthcare in the country, the government has taken steps like providing Production Linked Incentive (PLI) scheme to promote domestic manufacturing, medical device Parks to create supply chain ecosystem, and has initiated rolling out of scheme for Promotion of R&D and Innovation in Pharma MedTech (PRIP) and HRD scheme for skill development. In addition, simplifying regulatory processes to expedite approval timelines will encourage companies to scale operations and launch new products in India.

### Responsible Manufacturing

Domestic MedTech companies also have a crucial responsibility to invest in high-quality manufacturing. It enhances the safety and efficacy of products, in turn making our products more globally competitive. Moreover, strong clinical validation builds trust, improves patient outcomes, and drives long-term success. Homegrown companies like Translumina, manufacturing devices and implants for heart diseases have demonstrated good manufacturing practices with strong focus on delivering quality products backed by solid clinical data adhering to long term clinical trials of international standards. This approach has helped the company expand the reach of its world class medical devices to over 50 countries while meeting the demands of Indian patients.

### Learning from Global Best Practices

Many countries have successfully fostered the growth of their Medtech industries through targeted policies and investments. Germany's success as a Medtech leader is rooted in its strong public-private partnerships and significant investment in R&D. German MedTech companies work closely with academic institutions and government agencies, benefiting from government-funded research that drives innovation.

Similarly, the United States has a robust innovation ecosystem, including start-ups, venture capital funding, and cutting-edge research institutions. The U.S. Food and Drug Administration (FDA) has streamlined the regulatory process for medical devices, encouraging rapid approval of life-saving technologies through initiatives like Breakthrough Devices Program, allowing high-priority devices to reach the market more quickly. India can learn from these global best practices by enhancing collaboration between academia, industry, and the government, while also ensuring a more business-friendly regulatory environment.

### Price Capping of Medical Devices: Balancing Affordability and Innovation

In recent years, India has implemented price controls on several high-demand medical devices. These price caps were introduced with the goal of making life-saving medical devices more affordable for the general population. On the surface, it seems like a positive step, especially in India where lack access to affordable healthcare is still a challenge.

However, price capping presents several unintended consequences. For one, manufacturers may be discouraged from investing in R&D or launching new, innovative products in India due to the low-profit margins imposed by price controls. This could ultimately limit the availability of high-quality devices in the market. Furthermore, price caps may lead to a reduction in the variety of devices available, as companies may choose to withdraw premium products from the market rather than sell them at reduced prices. This creates a scenario where patients are left with fewer options, which could compromise the quality of care.

While affordability is a legitimate concern, it should not come at the expense of innovation and quality. Policymakers should explore alternative mechanisms, such as offering subsidies to domestic manufacturers or incentivizing cost-effective production methods, to keep prices low without discouraging industry growth.

If India is to realize its potential as a global hub for medical devices, a concerted effort is needed to foster innovation, support local manufacturers, and strike a balance between affordability and quality. With the right policies and investments, India's Medtech sector can become a cornerstone of the country's healthcare system.



### Impact

## Price Control and healthcare Access- A Future Forward Approach

**By Chaitanya Sarawate**

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The 2030 Sustainable Development Goals (SDGs) underline the Universal Health Coverage (UHC) as the cornerstone to accessible and affordable healthcare. India, home to the world's largest population, with a fragmented healthcare system and restricted access to healthcare must address some of the biggest healthcare challenges to achieve the goal of UHC. Affordable access to quality healthcare is the core of achieving universal health coverage. However, every year, millions of people are pushed into poverty due to high out-of-pocket expenditure on healthcare. With the rising burden of communicable and non-communicable diseases, pricing and reimbursement decisions are becoming critical for the government to manage the rising healthcare costs.

Empirical and theoretical economic analysis show that price control leads to short term savings that are outweighed in the long term by becoming barrier to advance technologies leading to poor healthcare outcomes and shorter life expectancy. There is a fine balance to ensure timely and continued patient access to new ground breaking technologies, while safeguarding affordability concerns. The other fall outs are patients and physicians' opting for cheaper compounds with lower therapeutic value, distortion of competition in the market, reduction in incentives to innovate and monopoly of certain products leading to price increase.

### So, what is the way forward?

Globally, medical device pricing is driven by competition irrespective of public or private healthcare provider through reference pricing or value-based pricing using Health Technology Assessment (HTA). Some countries like Thailand and Russia have introduced price control limited to only top National List of Essential Medical Devices.

Most of the medical devices/equipment industry, follow the B2B transaction mechanism which has an in-built market driven price monitoring and self-regulation mechanism. Medical devices & equipment including their accessories, spares, software and components that are not sold to the patients directly and are used for the purpose of diagnosis, therapy, surgical intervention at health care providers' site are currently exempted from any kind of price control. This practice must continue as arriving at a fixed MRP (Maximum Retail Price) for these products is challenging and impractical. Pricing for such devices is determined based on customization in terms of hardware, accessories, components, software, business model, service contract and/or extended warranties. The patient is billed for the service and not the product as these are neither sold to patients nor used by them.

Currently, NPPA (National Pharmaceutical Pricing Authority) monitors MRPs under Para 20 of the DPCO, 2013 to ensure that no manufacturer/importers can increase the price more than ten percent in preceding twelve months. In absence of a public health emergency or urgent public health need, the government may continue its current practice of price monitoring.

As per World Health Organizations guidelines and international best practices, under extraordinary circumstances, governments have the discretionary power to put any device under price control. Our suggestion is to implement this through the process of Trade Margin Rationalisation (TMR), as done during COVID for six medical devices namely, oxygen concentrators, blood glucose monitors, blood pressure monitors, pulse oximeters, nebulizers, and digital thermometers instead of price capping on MRP which does not differentiate prices of advanced technologies. The implementation of trade margin up to 42% (Mark-up of 75%) brought substantial reduction in price of these medical devices to the tune of 54% to 70% and was positively accepted by the industry.

Medical devices due to its complexity, diversity and rapid innovation, needs a well-differentiated policy on pricing, to make healthcare accessible and affordable keeping patients at the centre of decision making. Eventually, with maturing of the healthcare ecosystem, India can discover its own evidence-based pricing framework, which is scientific, rewards innovation, addresses patient's unmet needs, is cost effective and has ease of implementation and universal applicability across public and private healthcare reimbursement packages.

