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ASIA EDITION

Policy Reforms Give India’s MedTech Sector a Global Edge

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Since medical technology (MedTech) is a sunrise industry, the government is giving it priority to support patient-centric growth, while also concentrating on lowering reliance on imports and aligning regulations with international norms. With a focus on capital, incubation, talent development, and market access, the Indian government has started a broad range of programmes to support MedTech firms. This article examines governmental and regulatory efforts, emphasizing how policy-driven assistance is helping MedTech businesses become more globally competitive.

The MedTech sector in India represents a dynamic intersection of healthcare, engineering, and digital innovation, encompassing devices, diagnostics, and software solutions aimed at improving patient outcomes, reducing costs, and enhancing accessibility. From wearable health monitors to AI-driven diagnostic tools, MedTech startups are pivotal in addressing India's vast healthcare challenges, including a burgeoning population of over 1.4 billion, rising chronic diseases, and unequal access to medical services in rural areas.

The sector, valued at approximately Rs 1,02,660 crore ($12 billion) in fiscal year 2024, is projected to reach Rs 4,27,750 crore ($50 billion) by 2050, growing at a compound annual growth rate (CAGR) of around 15 per cent. This growth is fueled not only by market demand but also by robust government and regulatory support, which has transformed India from a net importer of medical devices to an aspiring global hub.

Historically, India's MedTech landscape was dominated by multinational corporations, with domestic firms contributing less than 20 per cent to the market. However, post-2014, initiatives like ‘Make in India’ and ‘Aatmanirbhar Bharat’ have shifted the focus toward indigenous innovation. The government recognises MedTech as a sunrise sector, prioritising it to enable patient-centric growth, while focusing on regulatory alignment with global standards, and reducing import dependency. The Indian

government has launched a multifaceted ecosystem of initiatives to nurture MedTech startups, focusing on funding, incubation, skill development, and market access.

Government and Regulatory Initiatives Supporting MedTech Startups

MedTech Mitra

A landmark programme is MedTech Mitra, introduced in December 2023 by the Indian Council of Medical Research (ICMR) in collaboration with the Central Drugs Standard Control Organisation (CDSCO) under the guidance of NITI Aayog. This initiative acts as a one-stop platform for innovators, providing end-to-end support from ideation to commercialisation. It includes clinical validation, regulatory guidance, and funding linkages, aiming to boost the success rate of MedTech products.

MedTech Mitra addresses a critical pain point: many innovators successfully demonstrate proof-of-concept in the lab but face tremendous hurdles in regulatory approval, clinical trials, and manufacturing readiness. The portal coordinates support across multiple agencies—ICMR, Atal Innovation Mission (AIM), CDSCO, Kalam Institute of Health Technology, and Department of Health Research-Health Technology assessment (HTAIn), to ensure smoother commercialisation pathways. In 2024, MedTech Mitra supported over 360 innovators, focusing on areas like diagnostics and therapies. Some of these pioneering innovators such as Logy.AI, Marche Healthcare and Neuranics Labs have been supported by MedTech Mitra and AIM-associated incubation centres to facilitate prototype development and for other product development activities. Furthermore, startups such as Pune-based Kozhnosys have leveraged Medtech Mitra's strategic handholding support to seek better guidance regarding the clinical investigations and regulatory pathways required for their CanScan device, non-invasive solution for breast cancer screening using patients' exhaled breath samples. This support has played a pivotal role in facilitating the adoption of devices among healthcare providers such as Sahyadri Hospitals and Onco-Life Cancer Centre.

National Medical Devices Policy 2023

Approved in April 2023, the National Medical Devices Policy marks a watershed moment for India's MedTech industry. The policy envisions scaling the market share of India in the global medical device market from 1.5 per cent in 2020 to 10-12 per cent over the next 25 years. The focus is on facilitating orderly growth of the medical device sector to meet the public health objectives of access, affordability, quality and innovation.

Key pillars include:

- Creation of Centers of Excellence, innovation hubs, and plug-and-play infrastructure.
- Establishment of a single-window clearance system merging licensing from agencies such as Atomic Energy Regulatory Board (AERB), the Ministry of Electronics and Information Technology (MeitY), Bureau of Indian Standards (BIS), and Department of Animal Husbandry & Dairying (DAHD).
- Human resource development through specialist multidisciplinary courses integrated with the Ministry of Skill Development and Entrepreneurship
- Formation of a dedicated Export Promotion Council to lower barriers to global markets

Production Linked Incentive (PLI) Scheme

The PLI scheme for medical devices, with an outlay of Rs 3,420 crore ($400 million), incentivises domestic manufacturing by offering 5 per cent rebates on incremental sales. Launched in 2020 with production tenure from FY 2022-23 to FY 2026-27, it targets high-value segments like implants, and imaging devices aimed at reducing India's 80 per cent import reliance. Under the scheme as of December 2024, 19 green-field projects have been commissioned, and production of 44 products including linear accelerator, MRI machines, CT-Scans, ultrasounds and mammograms have been started in the country. The cumulative sales made by the applicants under the scheme up to September 2024 is Rs 8,039 crore ($959 million), which includes exports worth Rs 3,844 crore ($458 million). The success of the PLI scheme has not only helped in reducing India's dependence on imported high end medical devices but also allowed the country to emerge as a major exporter of these products.

Complementing the PLI is the Promotion of Research and Innovation in Pharma-MedTech Sector (PRIP) scheme, allocating Rs 5,000 crore ($600 million) for R&D infrastructure, including establishing seven Centres of Excellence at the National Institutes of Pharmaceutical Education & Research (NIPERs). These centres foster collaborations between academia, industry, and startups.

Pfizer INDovation programme

In September 2025, the India's Department for Promotion of Industry and Internal Trade (DPIIT) signed a memorandum of understanding (MoU) with Pfizer Limited to mentor MedTech startups through the Pfizer INDovation programme. The collaboration aims to accelerate the lab-to-market journey of innovative healthcare products by extending both financial and

non-financial support to startups. Under the partnership, the Pfizer INDovation programme will empower DPIIT-recognised startups with grants of up to Rs 60 lakh ($68,000) each, along with a tailored 18-month incubation programme delivered by Social Alpha. The programme is supporting pioneering 14 MedTech startups in screening, diagnostics, health monitoring, and treatment, with a particular focus on non-communicable diseases, oncology, brain health, maternal and child health, and immunisation.

Promotion of Medical Device Parks

In August 2022, the Department of Pharmaceuticals greenlit the promotion of medical device parks programme from FY21-25 with a total financial investment of Rs 400 crore ($48.9 million), with maximum support under the programme of Rs 100 crore ($12.2 million) for each medical device park. The financial assistance to a selected medical device park would be 70 per cent of the project cost of common infrastructure facilities. In case of North-eastern and hilly states, financial assistance would be 90 per cent of the project cost. Till date, the scheme has sanctioned Rs 100 crore ($12.2 million) each to Himachal Pradesh, Uttar Pradesh, Madhya Pradesh and Tamil Nadu. For instance, as of July 2025 the medical device park at Yamuna Expressway Industrial Development Authority based in Greater Noida, Uttar Pradesh and spread across 350 acres has attracted strong interest from 89 companies such TI Medical, Avience Medical and Syon Med Tech for developing medical devices. In August 2025, OIC International, Medi Mold and AddUp entered into collaboration to establish an advanced orthopaedic implant manufacturing facility powered by 3D printing and precision engineering at Andhra Pradesh Medtech Zone (AMTZ), a medical device manufacturing park at Visakhapatnam. The AMTZ is among the world's largest medical technology manufacturing parks with over 100 companies working on research, development and production of life saving medical devices. The park in August 2022 received grant-in-aid of Rs 25 crore ($2.9 million) for establishment of a super conducting magnetic coil testing and research facility.

Startup India Initiative

Launched in January 2016, the Startup India initiative provides tax exemptions for the first three years, simplified compliance, and access to dedicated funds. Under this umbrella, the Startup India Seed Fund Scheme (SISFS) offers up to Rs 20 lakh - Rs 50 lakh ($22,000- $56,000) for proof-of-concept, prototype development, product trials, market entry, and commercialisation, specifically benefiting early-stage MedTech ventures. As of June 2022, some of the startups that have received funding to the tune of Rs 10 lakh – Rs 50 lakh ($11,000- $56,000) under the initiative include Ismo Bio-Photonics, Oxy Neuron India and Biovantis Healthcare related to development of prototype, product testing, and market launch.

Regulatory Framework: Enabling Compliance and Innovation

India's regulatory landscape for MedTech has evolved significantly since 2017, shifting from a drug-centric approach to a dedicated framework for devices. The Medical Devices Rules (MDR) 2017, under the Drugs and Cosmetics Act 1940, classify devices into four risk-based categories (A to D), with CDSCO overseeing approvals. This aligns with international standards like those from the International Medical Device Regulators Forum (IMDRF), facilitating exports.

For startups, MDR simplifies registration: low-risk Class A/B devices require self-certification or state-level approvals, while higher-risk ones need central licensing. Amendments in 2020 introduced a unique device identification (UDI) system and post-market surveillance, enhancing safety. The National Medical Devices Policy 2023 builds on this, promoting harmonised standards and a single-window clearance portal.

Concluding Thoughts

India's MedTech sector stands at an inflection point, propelled by a compelling convergence of innovation, scale, and purposeful policy support. What once was a market dominated by imports and multinational firms has gradually transformed into a vibrant ecosystem where over 1,000 startups are now applying advanced medical technologies to bridge healthcare gaps across the country. Key government-led interventions have not merely provided enabling infrastructure but have also sent a clarion call for self-reliance, regulatory confidence, and global competitiveness. As India's medical device sector leaps from a $12 billion industry towards a projected $50 billion horizon by 2050, sustained focus will be vital. Continued execution on single-window regulatory reforms, talent development, financing access, and commercialisation support, particularly in Tier-2 and Tier-3 regions, can ensure that India doesn't just participate in the global MedTech narrative but truly leads it.

In essence, India's MedTech journey is more than technological progress, it is a blueprint for inclusive, innovation-led transformation in global healthcare.

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