

Cabinet approves the Policy for the Medical Devices Sector

Six Strategies planned to tap the potential of the Sector, with the Implementation Action Plan

Policy is expected to help the Medical Devices Sector, grow from present \$11 Bn to \$50 Bn in next five years

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The Union Cabinet, chaired by the Hon'ble Prime Minister Shri Narendra Modi, today approved the National Medical Devices Policy, 2023.

The medical devices sector in India is an essential and integral constituent of the Indian healthcare sector. The Indian medical devices sector's contribution has become even more prominent as India supported the domestic and global battle against COVID-19 pandemic through the large scale production of medical devices & diagnostic kits, such as Ventilators, Rapid Antigen Test kits, Real-Time Reverse Transcription Polymerase Chain Reaction (RT-PCR) kits, Infrared (IR) Thermometers, Personal Protective Equipment(PPE) Kits & N-95 masks.

The medical devices sector in India is a sunrise sector which is growing at a fast pace. The market size of the medical devices sector in India is estimated to be \$11 billion (approximately, 90,000 Cr) in 2020 and its share in the global medical device market is estimated to be 1.5%. The Indian medical devices sector is on a growth track and has an enormous potential to become self-reliant and to contribute towards the goal of universal health care. The Government of India has already initiated implementation of PLI Scheme for medical devices and support for setting up of 4 Medical devices Parks in the States of Himachal Pradesh, Madhya Pradesh, Tamil Nadu and Uttar Pradesh. Under the PLI scheme for Medical Devices, till now, a total of 26 projects have been approved, with a committed investment of Rs.1206 Cr and out of this, so far, an investment of Rs.714 Cr has been achieved. Under the PLI scheme, total of 14 projects producing 37 products have been commissioned and domestic manufacturing of high-end medical devices has started which include Linear Accelerator, MRI Scan, CT-Scan, Mammogram, C-Arm, MRI Coils, high end X-ray tubes, etc. Remaining 12 products will be commissioned in near future. Five projects out of total 26 projects have been approved recently, under Category B, for domestic manufacturing of 87 products / product components.

Building upon these measures, a holistic policy framework to accelerate this growth and fulfil the potential of the sector is the need of the hour. While various Departments of the Government have undertaken programmatic interventions to encourage the sector, the current policy aims to put in place a comprehensive set of focus areas for growth of the sector in a coordinated manner. Secondly, in view of the diversity and multi-disciplinary nature of the sector, the regulations, skilling trade promotion of medical device industry are spread over several departments in the Government

both at the Centre and State levels. There is a need to bring together the range of interventions in a coherent manner that would facilitate focused and efficient support and facilitation for the sector by the respective agencies.

The National Medical Devices Policy, 2023 is expected to facilitate an orderly growth of the medical device sector to meet the public health objectives of access, affordability, quality and innovation. This sector is expected to realize its full potential, with the strategies viz, 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. Encouraging domestic investments and production of medical devices complements the Government's 'Atmanirbhar Bharat' and 'Make in India' programs.

Salient Features of National Medical Devices Policy, 2023:

Vision: Accelerated growth path with a patient-centric approach and to emerge as the global leader in the manufacturing and innovation of medical devices by achieving 10-12% share in the expanding global market over the next 25 years. Policy is expected to help the Medical Devices Sector grow from present \$11 Bn to \$50 Bn by 2030.

Mission: Policy lays down a roadmap for accelerated growth of the medical devices sector to achieve the following missions viz, Access & Universality, Affordability, Quality, Patient Centred & Quality Care, Preventive & Promotive Health, Security, Research and Innovation and Skilled manpower.

Strategies to Promote Medical Device Sector:

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

- **Regulatory Streamlining:** In order to enhance ease of doing research and business and further to balance patient safety with product innovation measures such as creation of a 'Single Window Clearance System' for Licensing of Medical Devices coopting all the stakeholder departments / organizations such as AERB, MeitY, DAHD, etc, enhancing the Role of Indian Standards like BIS and designing a coherent pricing regulation, will be followed.
- **Enabling Infrastructure:** The establishment and strengthening of large medical device parks, clusters equipped with world class common infrastructure facilities in proximity to economic zones with requisite logistics connectivity as envisioned under the National Industrial Corridor Program and the proposed National Logistics Policy 2021 under the ambit of PM Gati Shakti, would be pursued with the State Governments and Industry for better convergence and backward integration with medical device Industry
- **Facilitating R&D and Innovation:** The policy envisages to promote Research & Development in India and complement the Department's proposed National Policy on R&D and Innovation in the Pharma-MedTech Sector in India. It also aims at establishing Centres of Excellence in academic and research institutions, innovation hubs, 'plug and play' infrastructures and support to start-ups.
- **Attracting Investments in the Sector:** Along with recent schemes and interventions like Make in India, Ayushman Bharat program, Heal-in-India, Start-up mission, the policy encourages private investments, series of funding from Venture Capitalists, and also Public-Private Partnership (PPP).
- **Human Resources Development:** In order to have a steady supply of skilled work force across the value chain such as scientists, regulators, health experts, managers, technicians, etc., the policy envisages:
 - For skilling, reskilling and upskilling of professionals in the medical device sector, we can leverage the available resources in Ministry of Skill Development and Entrepreneurship
 - The policy will support dedicated multidisciplinary courses for medical devices in existing institutions to

ensure availability of skilled manpower for futuristic medical technologies, high-end manufacturing and research, to produce future-ready MedTech human resources and to meet the evolving needs of the Sector

- To develop partnerships with foreign academic/industry organizations to develop medical technologies in order to be in equal pace with the world market.
- **Brand Positioning and Awareness Creation:** The policy envisages the creation of a dedicated Export Promotion Council for the sector under the Department which will be an enabler to deal with various market access issues:
- Initiate studies and projects for learning from best global practices of manufacturing and skilling system so as to explore the feasibility of adapting such successful models in India.
- Promote more forums to bring together various stakeholders for sharing knowledge and build strong networks across the sector.

The policy is expected to provide the required support and directions to strengthen the medical devices industry into a competitive, self-reliant, resilient and innovative industry that caters to the healthcare needs of not only India but also of the world. The National Medical Devices Policy, 2023 aims to place the medical devices sector on an accelerated path of growth with a patient-centric approach to meet the evolving healthcare needs of patients.

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