

National Medical Devices Policy- 2023

April 28, 2023

In news— The Union Cabinet has approved the National Medical Devices Policy, 2023.

Salient Features of the Policy-

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 be 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:
- **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.

The medical devices sector in India-

- It 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.