



## National Medical Device Policy 2023

**For Prelims:** [India's Medical Device Sector](#), [National Logistics Policy 2021](#), [PM Gati Shakti](#), [PPP](#), [PLI](#).

**For Mains:** National Medical Device Policy 2023, Scenario of India's Medical Device Sector.

### Why in News?

Recently, the Union Cabinet has approved the **National Medical Devices (NMD) Policy, 2023**.

- 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.



- Cabinet approves the Policy for the Medical Devices Sector.
- **Six Strategies planned** to tap the potential of the Sector, with the **Implementation Action Plan**.
- Medical Devices Sector is expected to grow from present **\$11 Bn to \$50 Bn in next five years**.
- The policy is expected to meet the **public health objectives of access, affordability, quality and innovation**.

### What are the Key Features of NMD Policy 2023?

- **Regulatory Streamlining:** To make it easier to do research and business while balancing patient safety and product innovation, a "**Single Window Clearance System**" for licensing medical devices will be created.
  - This system will involve all relevant departments and organizations, such as MeitY (Ministry of Electronics and Information Technology), and DAHD (Department of Animal Husbandry &

Dairying).

- **Enabling Infrastructure:** Large medical device parks with world-class infrastructure facilities will be established, near economic zones.
  - It will be done as envisioned under the **National Industrial Corridor Program** and the proposed **National Logistics Policy 2021** under the ambit of **PM Gati Shakti**, and in collaboration with state governments and the industry, to improve convergence and integration with the medical device industry.
- **Facilitating R&D and Innovation:** The policy aims to promote Research & Development in India, complementing the proposed **National Policy on R&D and Innovation in the Pharma-MedTech sector**.
  - 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:** The policy encourages private investment and **Public-Private Partnerships (PPP)** to complement existing schemes such as **Make in India, Ayushman Bharat program**, Heal-in-India, and Start-up mission.
  - This includes funding from **venture capitalists** to support the growth of the medical device industry.
- **Human Resources Development:** The policy aims to ensure a **skilled workforce in the medical device sector** by providing skilling, reskilling and upskilling programs through the Ministry of Skill Development and Entrepreneurship.
  - It will also support dedicated courses for medical devices in existing institutions to produce skilled manpower for futuristic technologies, manufacturing and research.
- **Brand Positioning and Awareness Creation:** The policy envisages the creation of a **dedicated Export Promotion Council** for the sector which will be an enabler to deal with various market access issues.

## What is the Significance of the Policy?

- 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.
- It can place India's medical devices sector on an accelerated path of growth with a patient-centric approach to **meet the evolving healthcare needs of patients**.
- It envisions an 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.
  - With the new policy in place, the Centre aims to **reduce India's import dependence to nearly 30%** in the next couple of years; and become **one of the top five global manufacturing hubs**.
- Policy is expected to help the **Medical Devices Sector grow from present USD 11 Bn to USD 50 Bn by 2030**.

## What is the Scenario of the Indian Medical Device Sector?

- **About:**
  - The medical devices sector in India is a sunrise sector, growing at a fast pace and essential component of the healthcare industry.
  - Its importance was highlighted during the Covid-19 pandemic when India produced **medical devices and diagnostic kits like ventilators, RT-PCR kits, and PPE kits** on a large scale.
  - It is a multi-product sector, **with the following broad classifications:**
    - Electronics Equipment
    - Implants
    - Consumables and Disposables
    - In Vitro Diagnostics (IVDs) reagents
    - Surgical Instruments
  - The Sector has remained largely unregulated till 2017 when Medical Device Rules, 2017 were framed by the **Central Drugs Standard Control Organisation (CDSCO)**.
- **Status:**

- **India is the 4<sup>th</sup> largest Asian medical devices market** after **Japan, China,** and South Korea, and among the **top 20 medical devices markets globally.**
- **India's current market share** in the medical device category is **1.5% of the global space** or \$11 billion (that is ₹90,000 crore) in 2020.
  - **US dominates** the global market with a 40% market share, followed by **Europe and Japan at 25% and 15%** respectively.
- **Government Initiatives:**
  - The **Production Linked Incentive (PLI) scheme** for promoting domestic manufacturing of Medical Devices. NMDP 2023 will be in addition to the existing PLI schemes.
    - The Gol India has already initiated implementation of PLI Scheme for medical devices and support for **setting up of four medical devices parks** - one each in **Himachal Pradesh, MP, TN and UP.**
  - Promotion of Medical Devices Parks intends to encourage the domestic manufacturing of Medical Devices.
  - In June 2021, the **Quality Council of India (QCI)** and the Association of Indian Manufacturers of Medical Devices (AiMeD) launched the **Indian Certification of Medical Devices (ICMED) 13485 Plus** scheme to undertake verification of the quality, safety and efficacy of medical devices.

## What are the Issues with the Medical Device Sector in India?

- **Inconsistent Regulations:**
  - The **complex regulatory environment** is one of the most significant challenges faced by the medical device industry.
  - **Manufacturers have to navigate inconsistent regulations that use varying standards and wordings,** making it difficult to understand and comply with the requirements.
- **Research and Development Struggles:**
  - The adoption of cutting-edge technologies such as **artificial intelligence, cloud computing,** and **robotics** is still **limited in the Indian medical device sector.**
  - Embracing these technologies could help companies overcome challenges related to R&D, production, and distribution.
- **Import Dependency:**
  - India relies heavily on imports for medical devices, which leads to a high import **bill and adds to the cost of healthcare.** To reduce import dependency, India needs to increase domestic manufacturing of medical devices and encourage innovation in the sector.
- **Limited Access to Capital:**
  - Access to funding is a critical challenge for medical device startups in India, as **investors are often reluctant to invest in a sector with a long gestation period** and regulatory uncertainties.

## Way Forward

- Policy makers in India will need to set out an action **plan to reduce the country's dependency on medical devices/technology** imports.
- Medical device companies should develop India as a manufacturing hub for domestic and international markets, undertake India-based innovation in combination with indigenous manufacturing, collaborate across the Make in India and Innovate in India schemes, and produce low to medium technology products to cater to the underpenetrated domestic markets.

**Source: PIB**

