



Draft National Medical Devices Policy 2022

For Prelims: NIMERs, CDSCO, PLI Scheme, Quality Council of India.

For Mains: Challenges and Issues with respect to the medical device industry of India.

Why in News?

- Recently, the **Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers** has released an Approach Paper for the **Draft National Policy for the Medical Devices, 2022**.

What are the Salient Features of the Draft Policy?

- **Regulatory streamlining** in order to optimize regulatory processes and multiplicity of agencies for enhanced [ease of doing business](#), along with **harmonization with global standards** to ensure standardization (ensuring **safety of devices**).
- **Building Competitiveness** through fiscal and financial support for stimulating the development of the local manufacturing ecosystem with private sector investments.
- **Infrastructure Development** to provide best-in-class physical foundation, including [medical devices parks](#) with common facilities such as testing centres, to improve cost competitiveness and enhance attraction of domestic manufacturers.
- **Facilitating R&D and Innovation** with a focus on enhanced collaboration in innovation and R&D projects, global partnerships, and joint ventures among key stakeholders to bridge the gap between academic curriculum and industry requirements.
- **Human Resource Development** to ensure relevant curriculum at higher education level, skilling of various stakeholders, creation of future-ready HR with required skill sets across the innovation value chain.
- **Awareness Creation and Brand Positioning** in creating awareness and positioning India as a hub for manufacturing of medical devices as part of the **“Make in India, Make for the World” initiative**.

What is the Objective of the Policy?

- This policy **addresses the core objectives of accessibility, affordability, safety and quality** and **focuses on self-sustainability and innovation**.
- This Policy **envisions that by 2047**, India
 - Will be having few [National Institutes of Medical Devices Education and Research \(NIMERs\)](#) on the lines of National Institute of Pharmaceutical Education & Research (NIPERs).
 - Will be home & originator to 25 high-end futuristic technologies in MedTech (Medical Technology).
 - Will have a MedTech Industry of USD100-300 Bn size with 10-12% of Global Market Share.

What is the State of the Medical Device Industry in India?

▪ About:

- The medical devices sector in India is an **essential and integral constituent of the Indian healthcare sector**, particularly for the prevention, diagnosis, treatment and management of all medical conditions, diseases, illnesses, and disabilities.
- It is a **multi-product sector**, with the following broad classifications: (a) Electronics Equipment, (b) Implants, (c) Consumables and Disposables, (d) In Vitro Diagnostics (IVDs) reagents, and (e) Surgical Instruments.
- The Sector has remained largely **unregulated till 2017** when **Medical Device Rules, 2017** were framed by the [Central Drugs Standard Control Organisation \(CDSCO\)](#).
 - The rules were framed for **comprehensive regulation of MDs** in a phased manner, especially on the quality, safety, and efficacy aspects, under the **Drugs and Cosmetic Act, 1940**.

▪ Scope of the Sector:

- The **Indian medical device market** has a **significant presence of multinational companies** with about 80% of the sales by value generated from imported medical devices.
 - The Indian medical devices sector's contribution has become even more prominent as India supported the global battle against **Covid-19 pandemic** through the production of medical devices & diagnostic kits, e.g., Ventilators, **RT-PCR kits**, Infrared thermometers, **Personal Protective Equipment (PPE) Kits & N-95 masks**.
- The **Medical Devices industry in India** is valued at **USD 5.2 billion**, contributing about 4-5% to the USD 96.7 billion Indian healthcare Industry.
- Medical devices sector in India is very small in size as compared to the rest of the manufacturing industry, though India is one of the top twenty markets for medical devices in the world and is the **4th largest market in Asia after Japan, China, and South Korea**.
- **India currently imports 80-90%** of medical devices of the USD15 billion market.
 - The **US, Germany, China, Japan, and Singapore** constitute the **five largest exporters of high technology medical equipment to India**.

▪ Initiatives taken for the Sector:

- The [Production Linked Incentive \(PLI\) scheme](#) for promoting domestic manufacturing of Medical Devices.
- **Promotion of Medical Devices Parks** intends to encourage the domestic manufacturing of Medical Devices.
- Medical devices has been recognised as a **sunrise sector** under the **'Make in India' campaign** in 2014.
- 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 Devices Sector of India?

- The key challenges in manufacturing medical devices in India include **lack of adequate infrastructure and logistics, concentrated supply chains and high cost of finance**.
 - While the government is trying to **simplify regulations and paperwork**, the landscape is still complex, marked by the presence of many high-level government bodies at the state and central levels.
- Also, **India's per capita expenditure on health (1.35%)** is among the lowest in the world.

Way Forward

- The sector requires **special coordination and communication among Industry and Stakeholders** because of its diversified nature, continuous innovation & variation.
- 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.
- The focus should be on **enhancing competency of the Indian medical devices sector** through skilling, upskilling and reskilling, in alignment with the medical and technological advancements.
- The target should also be to **expand access and opportunities through collaborative policy support** for both demand and supply side of the medical devices industry.

[Source: PIB](#)

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