

Draft National Policy for the Medical Devices, 2022

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In news– Recently, the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers has released an Approach Paper for the Draft National Policy for the Medical Devices, 2022.

About the Draft National Policy-

This Policy envisions that by 2047, India

- will be having few National Institutes of Medical Devices Education and Research (NIMERs) on the lines of NIPERs.
- will be home & originator to 25 high-end futuristic technologies in MedTech.
- will have a MedTech Industry of \$100-300 Bn size with 10-12% of Global Market Share.

The Draft Policy addresses the core objectives of accessibility, affordability, safety and quality, focusing on self-sustainability and innovation.

The salient features are as follows-

- **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.
- **Quality Standards and Safety of the Devices** in order to provide safe devices to the consumers, in harmony with the global standards.
- **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 centers, 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.

Medical devices sector in India-

- **The medical device is a multi-product sector, with the following broad classifications:** (a) Electronics Equipment; (b) Implants; (c) Consumables and Disposables; (d) IVD reagents; and (e) Surgical Instruments.
- It has remained largely unregulated till **2017 when Medical Device Rules, 2017 were framed by the Central Drugs Standard Control Organization (CDSCO) for comprehensive regulation of MDs** in a phased manner, especially on the quality, safety, and efficacy aspects, under the Drugs and Cosmetic Act, 1940
- 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.
- This 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, IR Thermometers, PPE Kits & N-95 masks.

- **The Sector is expected to grow in market size from the present 11 Bn USD to 50 Bn USD by 2025.**