

# The National Medical Devices Policy, 2023

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## **Introduction:**

In a significant move to strengthen India's healthcare infrastructure and position the country as a global leader in medical device manufacturing and innovation, the Union Cabinet recently approved the *National Medical Devices Policy, 2023*[\[1\]](#). This policy aligns with the 'Make in India' and 'Innovate in India' initiatives, aiming to accelerate growth in the medical devices sector while promoting safety and quality. With the healthcare sector gaining paramount importance, especially during the COVID-19 pandemic, where India played a key role in producing critical medical devices and diagnostic kits, the policy envisions accelerated growth. It emphasizes a patient-centric approach and lays out a comprehensive roadmap to achieve missions related to accessibility, affordability, quality, research, and innovation.

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## Strategies:

### Regulatory Streamlining:

The National Medical Devices Policy 2023 marks a significant shift by focusing on regulatory streamlining aiming to address the complexity caused by multiple regulators overseeing various device classes. The proposed solution is a unified online clearance system. However, challenges arise in implementation, recognizing the diverse expertise needed for different device categories. To address this, the Policy suggests forming a committee with specialized backgrounds.

It also highlights affordability and quality control, entrusting the National Pharmaceutical Pricing Authority (“NPPA”) with regulating medical device pricing. The introduction of a “Single Window Clearance System” for licensing medical devices emerges as a groundbreaking development. This collaborative system, involving key departments such as **MeitY** (Ministry of Electronics and Information Technology) and **DAHD** (Department of Animal Husbandry & Dairying), is designed to elevate both research and business operations. This shift aims to simplify compliance procedures, fostering ease of doing business and aligning seamlessly with the government’s broader objective of enhancing India’s global business competitiveness.

### Enabling Infrastructure:

Recognizing the importance of infrastructure in fostering growth, the National Medical Devices Policy underscores the establishment and fortification of expansive medical device parks. These parks, equipped with world-class infrastructure facilities, will strategically be situated in economic zones. The collaboration with state governments and the industry aims to enhance convergence and integration within the medical device sector, harmonizing with the National Industrial Corridor Program and the proposed National Logistics Policy 2021 under PM Gati Shakti.

### Facilitating R&D, Intellectual Property, And Innovation:

To fuel Research & Development (R&D) in India, the policy aligns with the

proposed National Policy on R&D, Intellectual Property, and Innovation in the Pharma-MedTech sector[2]. It envisions the establishment of Centers of Excellence (“COE”), innovation hubs, and ‘plug and play’ infrastructures, creating a conducive environment for startups. The dedicated fund mentioned in the Strategy Document[3] will support R&D activities, elevating the quality of medical devices and fostering joint research initiatives among industry players, including SMEs and startups. It also proposes mechanisms to incentivize innovation, aid startups in global expansion, and support patent holders in commercializing their inventions, reflecting a commitment to fostering a dynamic and protected landscape for medical device innovation.

### **Attracting Investments:**

Acknowledging the essence of private investment, funding, and venture capital, the policy aligns with existing initiatives such as ‘Make in India,’ ‘Ayushman Bharat,’ and ‘Start-up Mission.’ Encouraging private investments, including funding from venture capitalists, is crucial for creating a robust ecosystem for manufacturing and indigenous development in the medical devices sector.

### **Human Resources Development:**

Ensuring a skilled workforce is imperative, and the policy underscores this by providing skilling, reskilling, and upskilling programs through the Ministry of Skill Development and Entrepreneurship. Dedicated courses for medical devices in existing institutions aim to produce skilled manpower for futuristic technologies, high-end manufacturing, and research.

### **Brand Positioning And Awareness Creation:**

A dedicated Export Promotion Council is envisaged to address market access issues. The memo from the Department of Pharmaceuticals[4] dated December 5, 2022, indicates that the government has already begun the process of establishing the council. Initiatives like webinars, workshops, and forums will bridge the awareness gap, fostering collaboration between academia, hospitals, industry, government, and funding institutions.

### **Significance Of The Policy:**

The National Medical Devices Policy, 2023, holds profound significance in the context of India’s healthcare landscape. It envisions an accelerated growth path with a patient-centric approach, aspiring to make India a global leader in medical device manufacturing and innovation. The policy’s holistic strategies aim to reduce import dependence, enhance affordability, and position India among the top global manufacturing hubs.

### **Scenario Of The Indian Medical Device Sector:**

The Indian medical device sector, a sunrise industry, plays a fundamental role in the healthcare ecosystem. The sector’s growth was particularly underscored during the COVID-19 pandemic when India scaled up the production of essential medical devices. Despite being the fourth-largest Asian medical

devices market, India's current market share globally is 1.5%. The new policy sets ambitious targets, intending to propel the sector's growth from \$11 billion to \$50 billion by 2030.

## **Challenges And The Way Forward:**

The Indian medical device sector faces challenges, including inconsistent regulations, limited adoption of cutting-edge technologies, import dependency, and restricted access to capital. The policy, with its multifaceted approach, seeks to address these challenges and chart a course toward self-reliance, innovation, and global competitiveness.

## **Conclusion**

The National Medical Devices Policy, 2023, emerges as a cornerstone in India's journey towards self-reliance and global leadership in the medical devices sector. With a comprehensive approach covering regulatory streamlining, infrastructure development, R&D promotion, investment attraction, human resource development, and brand positioning, the policy reflects the government's commitment to creating a thriving ecosystem. As the policy takes concrete steps towards implementation, monitoring mechanisms, including quantitative output and outcome metrics, will play a key role in evaluating its success.

## **FAQs**

### **How does the National Medical Devices Policy, 2023, address regulatory challenges in the medical device sector?**

The policy introduces a "Single Window Clearance System" for licensing medical devices, streamlining the regulatory landscape and enhancing ease of doing business.

### **What initiatives are in place to promote research and development in the medical device sector?**

The policy emphasizes the creation of Centers of Excellence, innovation hubs, and a dedicated fund to promote research and development in the medical device sector.

### **How does the policy aim to reduce India's import dependency in the medical device sector?**

The policy encourages private investment, including funding from venture capitalists, to bolster domestic manufacturing and reduce India's import dependency in the medical device sector.

[2] <https://pharmaceuticals.gov.in/sites/default/files/Draft%20Policy.pdf>.

[3]

[https://pharmaceuticals.gov.in/sites/default/files/Strategy%20Document%20on%20NMDP%202023\\_0.pdf](https://pharmaceuticals.gov.in/sites/default/files/Strategy%20Document%20on%20NMDP%202023_0.pdf).

[4]

[https://pharmaceuticals.gov.in/sites/default/files/DoP%20M%20Dated%205122022%20reg%20Establishing%20of%20EPC-MD\\_0.pdf](https://pharmaceuticals.gov.in/sites/default/files/DoP%20M%20Dated%205122022%20reg%20Establishing%20of%20EPC-MD_0.pdf).

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