



Regulatory Insights

5 May 2023

National Medical Devices Policy, 2023 notified – Key highlights

In brief

With an objective to establish a comprehensive framework supported by guiding strategies for ensuring sustained growth and development of the medical devices sector, the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, released the National Medical Devices Policy, 2023¹ (Policy) in line with the press release² issued last month. The government believes that the sector needs to be supported to realise its full potential by building an enabling ecosystem for manufacturing along with a focus on innovation, creating a robust and streamlined regulatory framework, providing support for training and capacity building programs and promoting higher education to foster talent and skilled resources in line with industry requirements.

In detail

Key highlights of the Policy are explained below.

- **Vision** – The Policy envisions placing the Indian medical devices sector on an accelerated growth path with a patient-centric approach, by building an innovative and globally competitive industry in India.
- **Mission** – The Policy will facilitate the growth of the medical devices sector, which meets the requirements of both the Indian as well as the global market. Laying down a roadmap for accelerated growth of the sector, the Policy aims at achieving the multidimensional mission of access and universality, affordability, quality, patient-centred and quality care, preventive and promotive health, security, research and innovation, and future-ready skilled manpower.
- **Strategies to promote medical device sector** – The government has formulated a set of strategies to meet its mission for the sector. The strategy would cover six broad areas of interventions. Each of the strategies will be further developed in consultation with all relevant stakeholders within the industry, academia and government.

Area	Strategy
Regulatory streamlining	The following interventions are envisaged under this area: <ul style="list-style-type: none"> • A 'Single Window Clearance System' for licensing of medical devices.

¹ F. No. 31026/91/2015-PI-II dated 2 May 2023

² [PIB Press Release dated 26 April 2023](#)

Area	Strategy
	<ul style="list-style-type: none"> • Expansion of standards in terms of processes, products, technologies, etc. by Indian standards setting bodies, such as the Bureau of Indian Standards to enhance the level of standardisation and quality and enable the indigenous industry to gain global competitiveness. • Development of a framework for a coherent pricing regulation to make available quality and effective medical devices at affordable prices. • Guidance framework for researchers, innovators and entrepreneurs is proposed to be designed to facilitate regulatory compliance. • Alignment of the National Medical Commission Regulations, Code of Ethics followed by industry associations, etc. to ensure ethical marketing.
Enabling infrastructure	<p>The Policy envisages the following:</p> <ul style="list-style-type: none"> • Establishment and strengthening of large medical device parks and medium-sized medical devices clusters, equipped with world-class common infrastructure facilities. • Establishment and strengthening of required number of testing laboratories. • Support is envisaged for the phased manufacturing of critical components to ensure continuous access and availability of medical devices.
Facilitating R&D and innovation	<p>The Policy envisages promoting innovation and R&D through the following:</p> <ul style="list-style-type: none"> • Structured interaction of academic institutions with the medical devices industry. • Establishment of Centres of Excellence in premier academic and research institutions towards building world-class institutions and attracting global faculties. • Innovation hubs housing a network of academic institutions, start-ups, clinical settings, funding agencies, etc. to create a health technology ecosystem, by providing 'plug and play' infrastructure. • Convergence of the available resources under various institutions such as Biotechnology Industry Research Assistance Council and Start-up Mission to maximise the utilisation of government-funded inventions.
Attracting investments in the sector	<p>The Policy envisages following additional measures to promote indigenous manufacturing, building competitiveness and promote an ecosystem for manufacturing:</p> <ul style="list-style-type: none"> • Encourage private investments in the sector by creating an ecosystem for risk-based and risk-adjusted financing. • Encourage new financing models such as a mix of public and private funds. • Engage, leverage and systematically build upon the various initiatives to encourage start-ups in the medical devices sector. • Leverage initiatives such as Public Procurement (Make in India) Policy, Ayushman Bharat program, etc. to promote domestic manufacturing.
Human resource development	<p>To develop a skilling ecosystem, the Policy envisages the following:</p>

Area	Strategy
	<ul style="list-style-type: none"> • Leverage the available resources in the Ministry of Skill Development and Entrepreneurship Skill ecosystem. • The Policy will support dedicated multidisciplinary courses for medical devices in existing institutions to produce future ready MedTech human resources. • In consultation with the industry, a national database of various skills required with respect to the latest manufacturing technologies being used in the MedTech sector and the skills required to adopt those specific technologies will be formulated and updated on a regular basis. • A framework is also envisaged to enable the academic institutions working in the medical devices sector to develop partnerships with foreign academic and industry organisations to develop medical technologies.
Brand positioning and awareness creation	<p>To strengthen the channels of stakeholder engagement, the Policy envisages the following:</p> <ul style="list-style-type: none"> • Initiate studies and projects for learning from the best global practices of manufacturing and skilling system to explore the feasibility of adapting such successful models in India. • Promote awareness on medical devices safety and standards and ensure proactive communication and outreach on the value proposition with the public. • Promote more forums to bring together various stakeholders for sharing knowledge and building strong networks across the sector.

- **Monitoring and evaluation** – The proposed strategies under the Policy would help catalyse innovation and accelerate the growth of the medical devices sector.

To measure the impact of the strategy proposed under the Policy, quantitative output or outcome metrics are proposed to be developed to measure equity in access and affordability of safe medical devices, self-reliance in manufacturing, improvement of overall healthcare index and creation of high-value jobs in R&D and innovation, in due consultation with NITI Aayog. Moreover, the set of economic indicators such as market size, exports and foreign direct investments are also proposed to be tracked by regular monitoring.

The takeaways

The Policy has been released by the government post multiple deliberations with the objective of giving an impetus to the medical devices industry. As next steps, implementation guidelines would be developed and formulated by the government to implement the policy and to equip the medical devices industry as a competitive, self-reliant, resilient and innovative industry, catering to both the Indian as well as the global market.

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