May 2023

National Medical Device Policy, 2023

On May 2, 2023, the Government of India notified the National Medical Device Policy, 2023 (the "**Policy**"), to ensure that the medical device sector (a) contributes to the objectives of public health by making quality products; (b) facilitates an orderly growth to meet the public health objectives of access, affordability, quality and innovation; and (c) achieves sustained growth and development in a holistic and coordinated manner.

The Policy envisages to place the Indian medical devices sector on an accelerated growth path with a patient-centric approach to meet the evolving healthcare needs by building an innovative and globally competitive industry in India. This industry will be supported by - the world class infrastructure, an enabling ecosystem, streamlined regulatory framework and skilled manpower.

The Policy lays down a roadmap to achieve the following missions:

- Universal access to good medical devices for ensuring quality healthcare services to all.
- Enhance the domestic manufacturing capacity and capability for newer technologies, to make medical devices affordable.
- Ensure the quality of products manufactured in India boosts the global positioning, acceptability and competitiveness.
- Better quality of care by improving clinical outcomes through early diagnosis of diseases and increased accuracy in treatment.
- Offer a healthier lifestyle through extensive application of medical devices in early screening and diagnosis for detection / prevention and management of diseases.
- Create an eco-system in line with evolving times, that encourages and sustains the innovation in the medical devices sector. These could include technology driven medical devices with miniaturization /nanotechnology / telecommunication technologies / IoTs & AI and precision and Individualized care for preventive, promotive, diagnostic, curative, rehabilitative, geriatric and palliative healthcare.
- Develop strong local manufacturing capabilities including for components and ancillary industry and build resilient supply chain for inputs or raw materials.

The Policy sets out strategies for certain areas to facilitate the development of the medical devices sector. The following areas have been identified based on the current challenges and future opportunities:

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1. Regulatory Streamlining

The Policy aims to set up a Single Window Clearance System for licensing of medical devices and frame protocols for quality control. It is proposed to develop pricing regulations to offer affordable healthcare. Further to ease the research and innovation, regulatory compliance assistance is offered for development of market-ready products and align regulations to ensure ethics marketing of medical devices.

2. Enabling Infrastructure

The Policy calls for the establishment of new and strengthening of existing medical device marks and clusters and equipping them with world class common infrastructure facilities. These will be close to economic zones to ensure easy and requisite logistics connectivity. It is also proposed to establish new and strengthen existing testing laboratories to ensure quality, safety and efficacy of the medical devices market in India. Lastly, the Policy requires phased manufacturing of critical components to ensure that there is no supply chain disruption and that there is continuous access and availability of medical devices.

3. Facilitating R&D and Innovation

The Policy encourages the collaboration of industry and academia for the promotion of R&D and innovation. Additionally, it calls for the setting of Centers of Excellence for building world class institutions, as well as offering 'plug and play' infrastructure and 5G use case labs to set up a health technology ecosystem. Further it aims to identify resources to encash the government funded inventions to promote innovation commercialization and innovation.

4. Attracting investments in the medical devices sector

The Policy encourages private investments through active outreach to venture capitalists for promotion of seed capital and funding and screening of start-ups to incubate. the Policy intoduces new financing models with a mix of public and private funds. Leveraging the existing Government initiatives to promote domestic manufacturing and encouraging start-ups.

5. Human Resources Development

Development of human resources and skilled labour must be through the leveraging of existing resources; supporting dedicated multidisciplinary courses for medical devices; formulating a national database of various skills required for the medical device sector; and enabling academic institutions to develop partnerships with foreign academic institutions and industry to develop medical technologies.

6. Brand positioning and Awareness Creation

The Policy aims to adapt best global manufacturing practices and skilling systems for India whilst also raising awareness for the safety requirements of medical devices. The Policy encourages the participation in different fora of various stakeholders for sharing knowledge and building strong networks.

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JSA also has substantial experience in matters relating to regulation of foods, drugs, medical devices, cosmetics, product packaging, and dangerous chemicals. Our attorneys advise manufacturers on Indian labelling questions, national rules for testing and review of new products, reporting of safety information, and proceedings relating to product withdrawals. We regularly advise clients on regulatory standards governing advertising, the distinction between advertising and labelling and the differing regulatory standards that apply to each, and the roles of the states and self-regulatory mechanisms. JSA has been actively involved in advising clients with respect to regulation of nutrition and health claims in food advertising.

We also have extensive experience in litigating cases in courts and administrative agencies in the healthcare sector.

This Prism has been prepared by:

Sidharrth Shankar
Partner

Arjun Krishnamoorthy
Principal Associate

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