BioSpectrum
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

Regulatory trends & challenges in store for medtech industry in 2024

23 December 2023 | Views | By Chandra Ganjoo, Group Chief Executive Officer, Trivitron Healthcare

Striking a balance between fostering innovation and ensuring patient safety emerges as a key challenge for both regulators and industry stakeholders



In 2023, India underwent a significant transformation in its medical technology landscape through a series of regulatory changes. These changes, geared towards fostering innovation, ensuring patient safety, and facilitating market access, have set the stage for a dynamic 2024 in the med-tech sector.

One crucial development is the National Medical Devices Policy, 2023, designed to reduce import dependence and boost domestic production. Aligned with 'Atmanirbhar Bharat' and 'Make in India' initiatives, the policy aims to position India as a global manufacturing hub, targeting a 10-12% share in the global medical devices market over the next 25 years. It specifically addresses the manufacturing of advanced medical devices, laying out missions for access, affordability, quality, patient-centered care, health promotion, security, research, innovation, and skilled manpower.

Another game-changing initiative is the National Policy on Research and Development (R&D) and Innovation in the Pharma-MedTech Sector, introduced alongside the Scheme for Promotion of Research and Innovation in the Pharma-MedTech Sector (PRIP).

With a substantial budget of Rs 5,000 crore over five years, PRIP focuses on establishing Centers of Excellence, fortifying research infrastructure, and tackling healthcare challenges through interdisciplinary collaborations. Precision medicine, new entities, medical devices, and antimicrobial resistance are key areas of emphasis. The scheme aims to strengthen the regulatory framework, incentivise innovation, and foster a conducive ecosystem, with a vision to reach Rs 4.02 lakh crore ($50 billion) by 2030, transforming India's MedTech industry through R&D, indigenous manufacturing, affordable healthcare, skill development, and job creation.

These regulatory shifts have ignited a surge in investments and collaborations within the Indian med-tech landscape. Startups concentrating on innovative, low-risk devices are attracting venture capital, while established players are diversifying their portfolios to align with evolving regulations. Increased funds are expected to fuel R&D, giving rise to cutting-edge medical technologies tailored to India's unique healthcare challenges.

The industry is also witnessing a growing demand for regulatory compliance expertise, prompting companies to invest in robust quality management systems and regulatory affairs teams to navigate the evolving regulatory requirements effectively.

As 2024 approaches, the implications of these regulatory changes are multifaceted. The med-tech sector is positioned for continued growth, driven by innovation, expanded market access, and a heightened focus on quality. However, challenges persist, especially for companies dealing with high-risk devices navigating increased regulatory scrutiny. Striking a balance between fostering innovation and ensuring patient safety emerges as a key challenge for both regulators and industry stakeholders.

The regulatory changes in India's med-tech landscape in 2023 have ushered in a new era of opportunities and challenges. The sector is experiencing a wave of innovation and investments. As the industry adapts to these changes, 2024 promises to be a pivotal year, shaping the future of medical technology in India.

Chandra Ganjoo, Group Chief Executive Officer, Trivitron Healthcare