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India: Trends and Developments

Manisha Singh and Pankaj Musyuni
LexOrbis

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Contributed by:
Manisha Singh and Pankaj Musyuni
LexOrbis

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Authors

Manisha Singh is the founding partner of LexOrbis. Manisha is known and respected for her deep expertise in prosecution and enforcement of all forms of IP rights and for strategising and managing the global patents, trade marks, and design portfolios of large global and domestic companies. She is also known for her sharp litigation and negotiation skills in both IP and non-IP litigations and dispute resolution. She has been involved in IP litigation, with a focus on patent litigation covering all technical fields – particularly pharmaceuticals, telecommunications, and mechanics. She is an active member of many associations, including INTA, APAA, AIPLA, AIPPI, LES, FICPI, and regularly authors articles and commentaries for some of the top IP publications.

Pankaj Musyuni is an advocate registered with the Bar Council of India, as well as a patent agent. He has a master's in pharmaceutical science and management. He regularly advises clients on IP strategy and portfolio management. Pankaj has in-depth knowledge of patent law and the healthcare regulatory framework in India, as well as extensive experience in patent filing, drafting, prosecution, and advisory matters, especially in the chemical, pharmaceutical, and start-up fields. He has written several articles and delivered talks at various forums on patent law practice, the regulatory landscape, and clinical research.

LexOrbis

709-710, Tolstoy House
15-17 Tolstoy Marg
New Delhi-110001
India

Tel: +91 11 2371 6565
Fax: +91 11 2371 6556
Email: mail@lexorbis.com
Web: www.lexorbis.com

Expanding Growth Prospects for Medical Devices and Consumer Healthcare Products in India

Introduction

In terms of output and employment, India's healthcare industry is one of the most important in the country. The rapid growth of India's medical business has resulted in the creation of 4.5 million new jobs and the development of its economy. Healthcare delivery at all levels, including pre and post-operative care, tests, and operations, is heavily reliant on the use of various medical devices.

The demand for medical products and services in India has increased significantly during the last decade. The growth of the healthcare industry can be attributed to a number of causes, including the developing economy, rising middle-class incomes, and the growing presence of medical insurance companies. Furthermore, the recent shift away from chronic diseases and toward lifestyle-related ailments has had a significant impact on the Indian medical industry.

Market trends

The pharmaceutical, biotechnology, and healthcare industries in India are attracting a significant amount of investment interest given the current condition of the market. A significant increase in total deal value was seen in 2022: approximately USD6.14 billion, compared to the USD3.69 billion in 2021. In 2023, it is anticipated that the healthcare industry will expand by more than 8–10%. Almost 75% of the medical device industry's revenue in India is generated by exports and imports of medical apparatus. This high percentage of imported electronic devices in India can be attributed to a variety of factors.

Several multinational corporations are concentrating their efforts on establishing a presence in India to cover the market gap between medium and high-priced, technologically advanced products. Virtually every one of the top 40 global medical device manufacturers has established a presence in the country. The proportion of businesses owned by multinational corporations varies between 40% and 50% in the consumables, instruments, and medical appliances subsegment and between 80% and 90% in the remaining subsegments. The overwhelming majority of multinational corporations operate their primary manufacturing facilities outside of India and sell their products within the nation.

The market for medical devices in India is expected to increase at a compound annual

growth rate (CAGR) of 41.93% between fiscal years 2023 and 2027, resulting in a market value of INR4.4 trillion by 2027. The rapidly rising prevalence of lifestyle diseases is anticipated to generate opportunities for proactive point-of-care diagnostics, preventive drug therapies, and over-the-counter medications. The digitalisation of the health industry is anticipated to be a notable feature of the sector in 2023, with global solutions that can be adapted for local use. This is due to the entry and expansion of the e-pharmacy model in the Indian market. It is anticipated that opportunities for non-traditional healthcare will further increase due to ongoing shifts in the preferences of patients and providers as well as improvements in the accessibility and affordability of technological resources.

Current regulations and initiatives by the government

In India, the Central Drugs Standard Control Organisation (CDSCO), which is authorised by the Directorate General of Health Services within the Ministry of Health and Family Welfare, regulates the medical device industry. The Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945 govern the medical device industry in India, along with the Medical Devices Rules of 2017 and the Medical Devices (Amendment) Rules of 2020. Both the Central Licensing Authority (CLA) and the State Licensing Authority (SLA) are responsible for issuing licences to import, manufacture products for sale or distribution, as well as sell, stock, exhibit, or offer for sale. The CLA is responsible for procuring licences for all imported medical devices, including Class C and Class D medical devices, as well as licences for wholesale sales and financing. The SLA oversees the issuance of licences for the manufacture, loan, and wholesale distribution of Class A and Class B medical devices.

Impact of Union Budget 2023

The healthcare priorities of the Amrit Kaal Budget, also known as the Union Budget 2023, included an enhanced healthcare infrastructure, technologically assisted treatments, and the eradication of diseases via prudent public health management. Considering the COVID-19 pandemic and the need for co-ordinated public health measures, the government has given a higher priority to medical research and development by financing the expansion of Indian Council of Medical Research (ICMR) laboratories. In addition to expanding medical education and research, the Union Budget aimed to establish 157 new nursing institutions. The minister of finance advocated vehemently for an increase in Section 80D of the Income Tax Act's maximum tax deductions. This cap is primarily responsible for the rising cost of healthcare and health insurance. Families are more likely to obtain comprehensive health insurance for all members if they have more money in their wallets after paying taxes, thereby expanding access to healthcare financing.

The National Medical Devices Policy (2023)

The Indian government approved the National Medical Devices Policy (2023) (the "Policy") on 26 April 2023 and released it on 2 May 2023. The policy intends to:

- ensure that the medical device sector contributes to public health by producing high-quality products;
- facilitate orderly growth to meet public health objectives of access, affordability, quality, and innovation; and
- achieve sustained growth and development in an integrated and co-ordinated manner.

The strategy seeks to increase sales of medical equipment from USD11 billion to USD50

billion in five years. The healthcare industry in India relies on medical equipment. India produced numerous ventilators, rapid antigen test kits, real-time reverse transcription polymerase chain reaction (RT-PCR) kits, infrared (IR) thermometers, personal protective equipment (PPE) kits, and N-95 masks to combat the COVID-19 pandemic. The medical equipment industry in India is an emerging sector.

The Indian medical device sector is expected to be valued at USD11 billion (INR900 billion) in 2020, accounting for 1.5% of the worldwide market. The Indian medical device business is developing and offers considerable potential for self-sufficiency and universal health care. The Policy will be implemented concurrently with the Production-Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices (the "PLI Scheme"), which was authorised by the Indian government on 20 March 2020. The PLI Scheme offers cash incentives to selected enterprises for products manufactured in India that fall within specific categories. India also authorised the Scheme for Promotion of Medical Device Parks on 20 March 2020, to centralise testing and laboratory facilities. It reduced production costs and developed a viable medical device manufacturing environment in India.

The Policy contributes to the government's goal of creating a strong regulatory, economic, and legal environment in India for medical device manufacture. The policy prioritises the patient to create a balance between industry and consumer requirements. The strategy aims to make medical devices more accessible and affordable for hospitals to improve the quality and affordability of healthcare in India. Through the PLI Scheme, the Indian government has financed four medical device centres in Himachal Pradesh, Madhya Pradesh, Tamil Nadu, and Uttar Pradesh. The PLI medical equipment plan has approved 26 projects worth around INR12 billion. The PLI Scheme has commissioned 14 projects totalling 37 products, and local manufacturing of high-end medical devices such as linear accelerators, MRI scanners, CT scanners, mammography systems, C-arms, MRI coils, and high-end X-ray tubes, has commenced.

A comprehensive policy framework is required to encourage development and achieve the sector's potential based on these activities. The present strategy seeks to co-ordinate a wide range of sectoral development priorities among government entities. Legislation, training, and trade promotion for the medical device business are scattered among multiple federal, state, and municipal government entities due to the sector's complexity and multidisciplinary character. The range of actions must be co-ordinated so that agencies can assist and facilitate the sector more efficiently. Establishing an ecosystem conducive to manufacturing and innovation, establishing a robust and streamlined regulatory framework, supporting training and capacity-building programmes, and promoting higher education to cultivate talent and skilled resources in line with industry demands are all expected to help this sector reach its full potential. Medical device manufacturing and investment contribute to the government's "AatmaNirbhar Bharat" and "Make in India" programmes.

Salient features of the National Medical Devices Policy (2023)

The Policy defined a vision for accelerating development with a patient-centric strategy and emerging as the global leader in the manufacturing and innovation of medical devices over the next 25 years by capturing a 10–12% share of the growing global market. This goal was communicated as part of the vision. With policy sup-

port, the medical device industry is projected to grow from its current value of USD11 billion to USD50 billion by 2030. Access and universality, affordability, quality, patient-centred and quality care, preventive and promotional health care, security, research and innovation, and trained labour are among the goals of the policy, which outlines a road map for a more rapid expansion of the medical devices industry.

Regulatory simplification efforts, such as the establishment of a "Single Window Clearance System" for the licensing of medical devices, are being undertaken to make it easier to conduct both research and business, as well as to strike a better balance between patient safety and product innovation. Infrastructure facilitating convergence and reverse integration, as envisioned under the national industrial corridor programme and the proposed National Logistics Policy 2021, under the purview of PM Gati Shakti, would be pursued in collaboration with state governments and industry for the purpose of facilitating convergence and innovation.

In addition, the Policy is intended to supplement the department's proposed national policy on research and development and innovation in the pharmaceutical and medical technology sectors in India by promoting research and development in India. In addition, the government intends to establish centres of excellence in academic and research institutions, innovation centres, "plug and play" infrastructure, and start-up assistance. The strategy promotes private investments, venture capital financing, and public-private partnership (PPP), in addition to recently implemented programmes and initiatives such as the Make in India initiative, the Ayushman Bharat programme, the Heal in India initiative, and the Start-Up Mission.

The policy contemplates using the available resources of the Ministry of Skill Development and Entrepreneurship to train, retrain, and enhance medical device industry professionals. This will enable the entire value chain to maintain a steady supply of skilled employees, including scientists, regulators, health experts, managers, and technicians. The policy will support dedicated multidisciplinary courses related to medical devices in existing institutions to ensure the availability of skilled personnel for cutting-edge medical technologies, high-end manufacturing, and research, to produce future-ready employees, and to meet the evolving needs of the sector. To advance medical technology and maintain a competitive position on the global market, it is necessary to establish ties with international academic and industrial organisations.

The policy also calls for the department to establish a sector-specific export promotion council. Priority should be given to expanding the number of forums that facilitate information exchange and the formation of robust networks within the industry. It is anticipated that the policy will provide the necessary assistance and guidelines to transform India's medical device industry into a globally competitive, self-reliant, resilient, and innovative enterprise that not only meets India's healthcare requirements but also those of the rest of the world. The National Medical Devices Policy aims to place the medical devices industry on a faster growth trajectory by employing a patient-centric strategy to meet patients' constantly evolving healthcare needs.

Challenges

Adoption of cutting-edge technology and advances in product design have led to the medical device industry's extraordinary growth over the last decade. Due to the significant initial – and ongoing – investment in the neces-

sary equipment, the total cost of ownership is proportionally high. One of the most serious challenges confronting the medical device business is the complexity of its regulatory system. When rules are uneven and use a variety of standards and terminology, producers may struggle to understand the criteria and operate in a compliant manner. Research and development activities face several challenges. Artificial intelligence, cloud computing, and robots are examples of cutting-edge technology that have yet to be widely implemented in the Indian medical equipment market. Businesses may discover that by implementing these technologies, they may address research and development, manufacturing, and distribution concerns more effectively.

The high expense of medical care is worsened by India's reliance on foreign providers of medical equipment. India can lessen this dependence by increasing the domestic manufacture of medical equipment and encouraging innovation in the field. Capital is a major impediment for India's new medical device businesses. Start-ups in India's medical device market face financial challenges, in part due to a scarcity of available resources. Investors may be wary of entering a market that has a long gestation period and regulatory concerns. The difficulties can be overcome if certain factors are considered, such as ensuring that people have easy access to healthcare when they need it. Having a government-created budget makes sense by keeping a suitable level of preventative maintenance in place while focusing on improvement. Further, a continuous watch on health and medical research policy and subsequent revisions are necessary.

Comment

It is anticipated that a robust regulatory framework will provide India's medical device industry with the necessary impetus for growth; consequently, the sector's future is bright. The regulatory framework, which serves as a growth-inducing catalyst because of the current laws and regulations, supports the market conditions as they are. Recent government actions are likely to facilitate the expansion of domestic production, despite the companies' reliance on imported devices with limited technological access. This is done to ensure that multinational corporations face meaningful competition across a vast array of product categories. Numerous multinational corporations have established manufacturing operations in India, and the country's anticipated growth makes it an attractive location for investments across a broad spectrum of industries. It is anticipated that the domestic medical device industry will expand as a result of the adoption of the Policy, allowing it to better meet the healthcare requirements of patients in India and around the world. For effective performance, economic and regulatory obstacles must be overcome.

To achieve this objective, the policy establishes a system of checks and balances that is both desirable and essential. This system will quantify and measure parameters such as accessibility, affordability, disease burden reduction, employment creation in research and development, safety, and autonomy, among others. These measures will be created in collaboration with NITI Aayog. In addition, consistent monitoring of economic indicators such as market size, exports, and foreign direct investment is required by the policy. Although India's medical device industry produces a diverse array of devices and equipment, it has yet to penetrate the market for high-end and expensive products. X-ray, CT, and MRI scanners are still imported

into India as opposed to being manufactured there. The objective of this Policy is to satisfy both this criterion and the needs of the global market. It was emphasised that the effectiveness of these measures is highly dependent on how swiftly and thoroughly they are implemented and enforced; however, the current state of affairs is unknown. Many of the proposed projects would necessitate collaboration between industry, research institutes, and/or manufacturers, and obtaining their feedback at each stage would be crucial to the success of this initiative. Swift implementation of policies will enhance the chances of global development and innovation in the field of medical devices. If the policy is not implemented as soon as practicable, this window of opportunity may close. Undoubtedly, it is a step in the correct direction; however, only time will tell if it will be successful in achieving its goals.

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