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STRATEGIC ANALYSIS OF MARKET POTENTIAL OF MEDICAL DEVICE IN INDIA

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Abstract

The medical device industry is one of the most important sectors in the world. A medical device can be any instrument, apparatus, implement, machine, or software intended by the manufacturer to be used alone or in combinations for medical purposes. The real risk-based classification of a medical device depends on its intended usage and purpose. There are so many opportunities in the field of medical devices due to the huge population and healthcare conditions. Medical devices are approved by various government bodies to ensure quality and safety. Some rules and regulations are required for monitoring the entry of devices into the market. The quality and safety of devices mainly depend on the regulatory guidelines. India is a huge market for medical devices and it increasing constantly from last few years. There are 750–800 domestic Medical Devices manufacturers in India, with an average investment of $2.3–2.7 mn and an average turnover of $6.2-6.9 mn. Segment wise market share of medical devices in 2015 average range was 3.8 USD bn which raised to 8.16 USD bn in 2020. The registration certificate and import licence are mandatory for an Indian manufacturer. Currently, the regulatory body CDSCO governs device regulation in India. This review gives an overview of prevailing medical device regulations in India along with the growth in market share.

Keywords: CDSCO. GHTF. Medical Device. COPD, Regulatory Framework, Indian Market.

Introduction

Any substance, software, appliance, instrument, or apparatus that is used alone or in combination that is intended for use in diagnosis and therapy in order to prevent, support, and cure disease is considered a medical device. Numerous conditions, including diabetes, arthritis, obstetrics & gynecology, COPD, and others, are treated with medical devices. An essential component of patient care is the use of medical equipment. There are many different types of medical devices, including monitoring, diagnostic, and therapeutic devices. To encourage regulatory standards and practices with respect to quality, safety and effectiveness of medical devices, the Global Harmonization Task Force (GHTF) was founded in 1993 with the help of governments of five countries Canada, Australia, European Union, Japan & United States.(1)

Medical technology plays a vital role in the delivery of healthcare services in a country. When it is the question of India, the world‘s most populous democracy, which is fast becoming the hub for medical device design and medical tourism where people from other countries flock to get good quality, affordable medical treatment, medical technology is in a nascent state.(2)

Significance - The healthcare sector has significant transformation as a result of the development of medical devices. Medical devices offer an excellent platform for illness diagnosis and treatment. It helps patients by cost reduction of treatment as well as physicians by increasing their capacity to analyze and treat the ailment. Medical devices have associated with quality and different problems according to different cases. Medical devices affect both people and animals, quality is a crucial component of the medical device sector.

Medical device Classification

Medical devices are categorized according to their technological model, manufacture location, or medical applications. However, regulatory bodies have categorized medical devices based on their safety, effectiveness, and quality requirements that are defined globally. Risk, impacted bodily system, effectiveness, and other local and systemic consequences are determined using several criteria. Medical equipments are classified differently in each nation.

CLASS A- These medical devices are subjected to general controls and referred as low risk devices. Class 1 is subjected to regulatory control. In this category mainly it contains the banned devices, replacement, refund, good manufacturing practices, repair, and notification. Class 1 devices are not used in preventing any impairment to the human health. These are mainly exempt from pre-market notification. These articles are basically simpler approach than other one. Examples- surgical instrument, toothbrush, examination gloves, elastic bandages.

CLASS B- This class mainly includes the general control and specific controls. It requires more regulatory control than class 1. These are referred as the low medium risk devices. These need certification by the notified body. These are performed as indicated without causing harm to patient or user. These include special requirements, post marketing surveillance. Examples- sterile items surgical gloves, urinary catheters, stomach tubes, needles, tracheal tubes etc.

CLASS C- these devices are referred as the medium high risk devices, they need certification by the notified body for the design and manufacturing of medical devices. They follow the quality management system. Examples ă blood bags, condoms, non absorbable sutures, anesthesia machine, contact lens care products.

CLASS D: General controls and specific control with premarket approval. These are referred as the high risk medical devices. These devices required premarket approval to ensure the device effectiveness and safety. These devices usually sustain human life. It is useful in preventing impairment of human health or risk of injury[3,4].

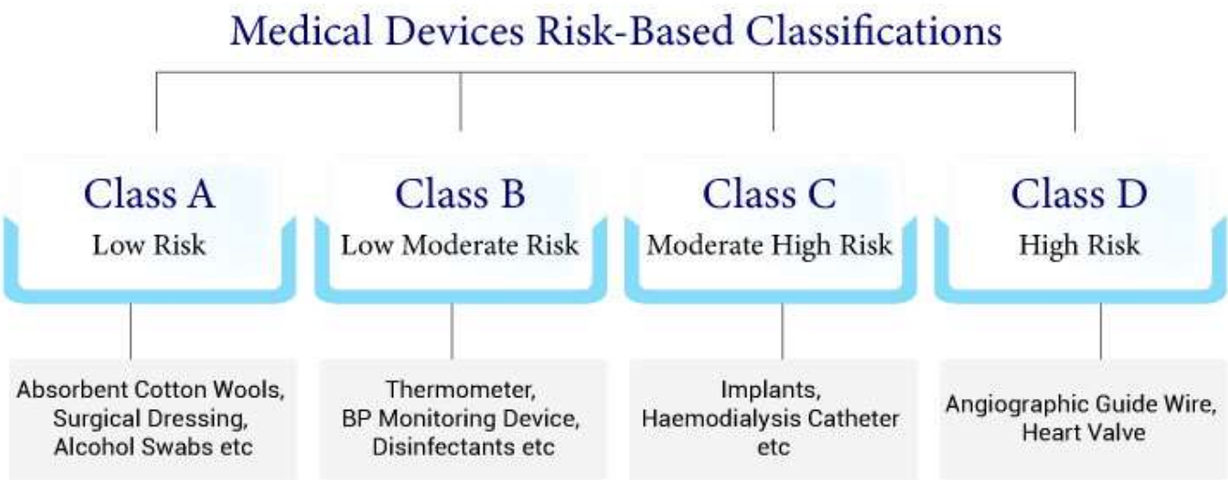

figure 1: classification of medical devices

1.1. An overview on medical device market

The dynamic medical devices market is intricately interwoven into the healthcare landscape. In order to give patients better care, several aspects of the sector are becoming more interdependent, integrating different goods and high quality care.[5] Includes India as a key growth region in the global medical device market.

As the number of people with chronic diseases continues to escalate, demand for devices for a variety of conditions will continue to escalate. Orthopedic devices come in second, but the market for cardiovascular devices is still the largest in the medical device industry. Driven by the baby boomer population and the demand for reconstructive surgery, growth rates in the orthopedic spinal and biologics segments will be significant. As reduction in healthcare costs and faster recovery times become a high priority, devices that enable minimally invasive procedures in all areas of medicine will witness strong growth, with the goal of becoming the standard of care for many treatments. According to a recent report issued jointly by the Department of State and the Department of Health and Human Services, National Institutes of Health, National Institute UK on Aging, almost 1 billion people worldwide will be 65 and older by 2030.[6] As new medical devices offer tremendous promise to the world's aging population, some global trends are directly affecting the competitive industry — particularly the increasing emphasis on medical device design.

1.2 Indian medical device market

For a long time, India was closed to many foreign markets through government protectionism and a nationalistic tariff system. Today, however, India is ripe for market entry for many industries, especially medical devices. Entering soon (or expanding one's business there) will help keep Western enterprises from being left out of India's exponential growth. The device categories that are most likely to increase in India are those connected to its changing disease profile. As Indians increasingly lead sedentary lifestyles, smoke, and eat more, lifestyle diseases such as cardiovascular disease and cancer are on the rise. Imaging, diagnostic, and surgical devices to treat these diseases are well-situated.

Though India's business environment has improved markedly over the last 15 years, in some ways it is still a difficult country to work in. Assistance on the ground by experts with medical device experience is indispensable. India's regulatory system is complex and can be difficult to navigate.[7]Up until very recently, there were no regulations for medical devices as a class. Today, though, various devices (i.e., hypodermic syringes, cardiac stents, and orthopedic implants,

among others) are designated as needing registration as drugs under the Drugs and Cosmetics Act. A few specific devices, such as diagnostic X-ray equipment, have individual registration requirements instead. The government has drafted a medical device law, which may streamline the process but include many more medical devices (requiring registration) within a year or two. India has no comprehensive national reimbursement system.

1.3 Importance of Medical Devices

Medical devices must be able to meet the standards and should be designed in a specific way so that patient health and safety can be achieved. Population of India was a big factor for the growth rate of medical device due to the patient health care, increased awareness among people regarding healthcare facilities and health insurance policy. The Ministry of Health and Family Welfare, Government of India in 2009 notified an amendment that tends to strengthen the law against counterfeit medical devices in India.

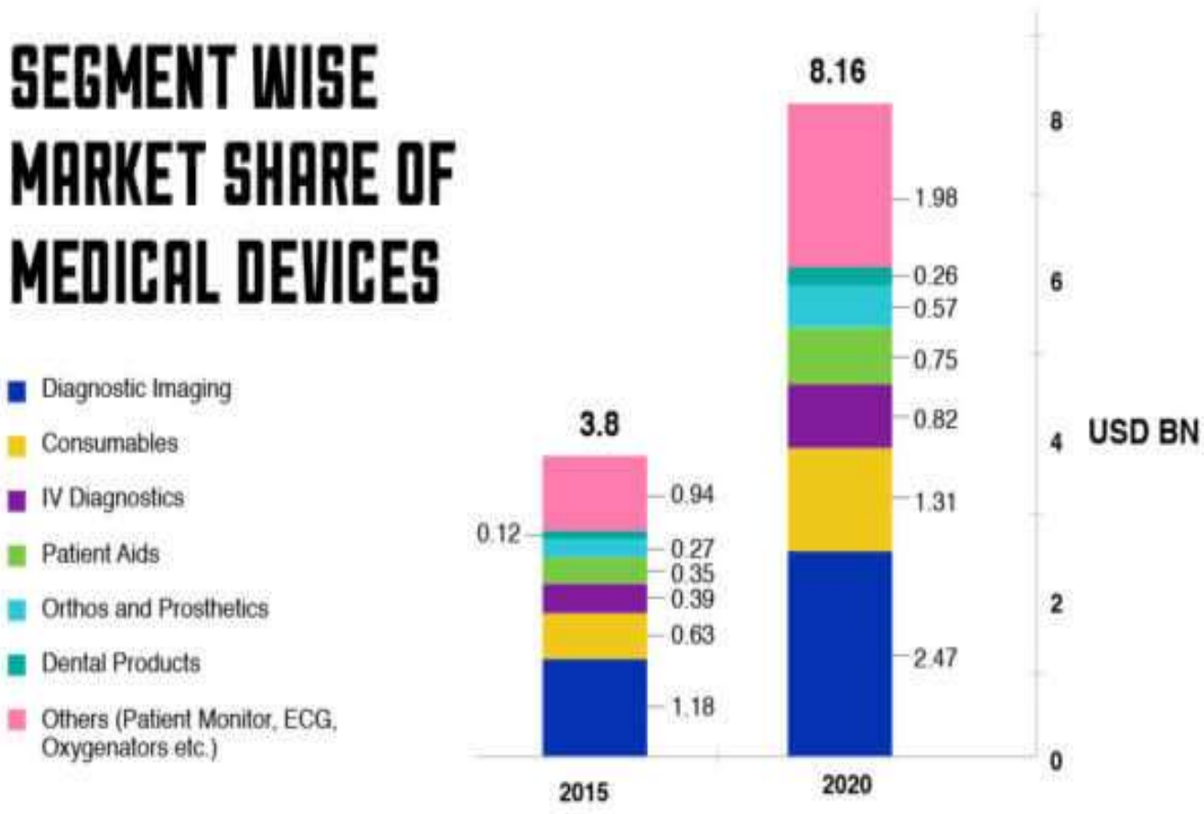

figure 2: medical device market in india[8]

Research Through Innovation

2. Opportunities and challenges for India's medical device market

India is among the top 20 global markets for medical devices and the fourth largest in Asia. An Indian Brand Equity Foundation (IBEF) analysis projects that the country's medical device market will expand at a compound annual growth rate (CAGR) of 35.4% with the overall market valued at $11 billion in 2020 and $50 billion by 2025. Imports, on the other hand, currently supply the bulk of the country's medical device market, accounting for 80% of overall sales.

The high reliance on imports presents an appealing opportunity for domestic manufacturers.[9]The 2017 Medical Devices Rules came into effect on January 1 2018, making it the most significant year in terms of regulatory changes for medical device companies.

A critical feature of India's medical device market is its heavy reliance on imports, which supply the bulk of demand. As of 2020, imports accounted for approximately 80% of total sales.[10] This dependency stems from historical underinvestment in domestic manufacturing capabilities and a preference for advanced, often imported technologies such as diagnostic imaging systems and surgical equipment. While this import dominance ensures access to cutting-edge devices, it also exposes India to vulnerabilities such as global supply chain disruptions—evident during the COVID-19 pandemic—and elevated costs due to currency fluctuations and tariffs.[11] For instance, high-end devices like MRI machines and pacemakers are predominantly sourced from multinational corporations based in the United States, Germany, and Japan, limiting price competitiveness in a cost-sensitive market like India.

A pivotal moment in this transformation came with the introduction of the *Medical Devices Rules, 2017*, which took effect on January 1, 2018. This regulatory overhaul marked 2018 as a watershed year for the industry, establishing a distinct framework for medical devices separate from pharmaceuticals.[12]Prior to this, the lack of a tailored regulatory structure hindered market entry and innovation, as devices were subject to ambiguous drug-related regulations. The 2017 rules introduced risk-based classifications (Classes A-D), streamlined approval processes, and mandatory quality certifications, aligning India's standards with global norms like those of the International Medical Device Regulators Forum (IMDRF).

For example, low-risk devices (Class A/B) now face lighter compliance requirements, encouraging small and medium enterprises (SMEs) to enter the market, while high-risk devices (Class C/D) undergo rigorous scrutiny to ensure safety.[13] This regulatory clarity has attracted foreign investment and bolstered confidence among domestic players, though challenges such as inconsistent enforcement and bureaucratic delays persist.

3. Regulatory environment

Medical devices manufacturers are interested in setting up a manufacturing facility in India due to the significant population and favourable regulatory environment. Medical device regulations were put in place in 2017, incorporating changes that are at par with global standards.[14] Licenses for the importation, production, or sale, or licencing the use of Risk-based regulation was implemented, and medical gadgets were made available. This procedure has reduced regulatory requirements, saving money and time.

The 2017 Medical Device Rules (MDR) will bring all health products under the regulatory purview of both the producers, importers, and suppliers. There are two different risk levels: low risk and medium risk.

30 months from the initial device arrival for those on the higher level, and 42 months from the date of registration for those on the lower level, or low risk. Registration will be required for the first 18 months and then optional after that. However, once the regulation is put into effect, manufacturers and importers have a strong incentive to register their products as soon as possible.

Currently, MDR covers 16 medical products, with another eight regulated by drug control and 13 by 2021.[15] Industry has been concerned about the sluggish speed of medical device regulation for some time.

4. Marketing potential of medical devices

Medical devices plays a major role in the treatment and cure of diseases. It helps in restoring patients to normal lives like physiotherapy rehabilitation centers. Because of its enormous potential in healthcare, the Indian medical device business is expanding at an incredible rate. Medical devices are used in screening, diagnosis, restoration, and monitoring, among other aspects of healthcare.

To overcome the adverse effect of low quality devices or products post marketing surveillance must be conducted for the reliability of medical device used in the healthcare.[16]

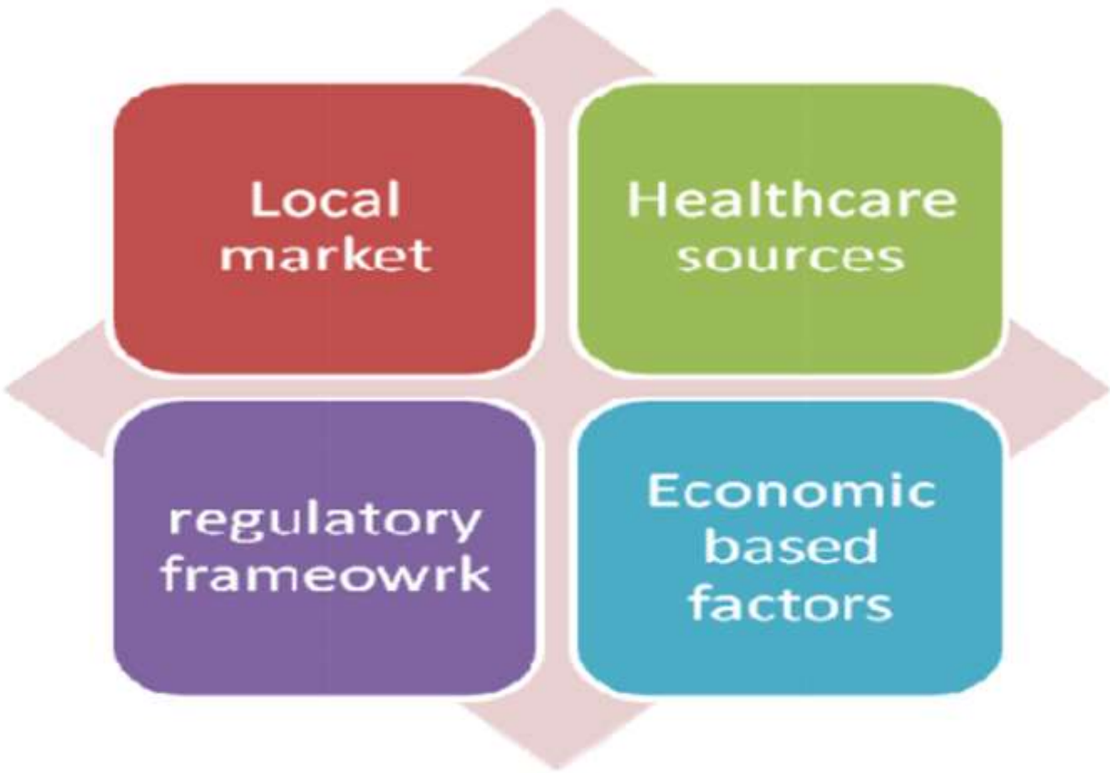

figure 3:factors affecting medical device industry

5. Market access in future

The current volatility in the global economy is expectedto continue into the near future. Moreover, pressure from governments to contain their burgeoning healthcare bills will also continue. Thus, market access is expected toassume greater significance, particularly in the emerging markets. Pharmaceutical companies need to proactively engage with the key stakeholder groups in order to keep up with their potential future needs.[17] This is critical to effective product commercialization since the future success of an organization often hinges on its ability to understand and embrace changes in a dynamic pharma- ceutical environment. These modification affect all aspect of business operations, not only the organizational structure. Pharmaceutical businesses must, above all, embrace an organizational mindset that is focused on market access. Pharmaceutical businesses have been compelled to concentrate increasingly on emerging countries, which are seen as the future growth engines, due to the developed markets.

Thus, growth for any pharmaceutical company will depend on its performance in these markets. A customized market access strategy integrated with the right processes and talent can help mitigate these challenges, allowing effective commercialization and increased drug accessibility for patients.[18]

6. Conclusion

Medical device industry becomes progressive in last five years due to their innovation and advancements in medical technologies. Stringent regulatory procedures of authorities provide quality to their customers and consumers. Medical device manufacturers are keep on enhancing their standards by overcoming the challenges of the medical device industry. This article helps the readers to find knowledge about the medical device industry including various markets e.g. US, Europe, China and India. It tells about the growth drivers and threats of this industry globally.

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