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Opportunities and Risks of Indian Medical Device Regulations

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KEYWORDS

Medical device, India, Market Share, Opportunity, Risk, Regulations.

ABSTRACT:

Objective: This short article aims to provide an overview of the current state of the medical device industry in India. It aims to highlight the drivers of its growth and the challenges and risks it faces. The abstract sets the stage for detailed discussion throughout the article.

Scope: The Indian government has launched several incentives to increase the domestic production of medical devices. Factors such as government incentives, technological advancement, and updated regulations may all be the reasons for the growth of the medical device industry. They form the basis of the medical device market. There has been a significant advancement in the industry, which paved the way for both possibilities and problems.

Results: It encounters challenges and interruptions for a variety of causes. This article highlights the growth factors and the risks faced by the medical device industry in India in the present scenario.

Abbreviations:

CAGR- Compound Annual Growth Rate
CDSCO- Central Drug Standard Control Organization
CLA- Central Licensing Authority
IVDs- In Vitro Devices
IMDRC- International Medical Device Regulatory Convergence
RPM- Remote patient monitoring
PMA- Pre-Market Approval
ISSD- Implanted String Subcutaneous Defibrillator

Introduction

There has been a huge growth in the Indian medical device industry over the last few years. Indian medical device industry is constantly growing at a Compound Annual Growth Rate (CAGR) of 15%, making India the fourth largest Asian medical device market [(1)]. The healthcare sector is at a crossroads due to rising drug prices, inadequate funding for quality treatment, and a rise in the incidence of chronic illness [(2)]. A significant change is needed to tackle this issue, which is made feasible by using cutting-edge information technology, effective networking, and biomedical and engineering concepts in healthcare services [(3)].

Modern healthcare today includes the utilization of medical devices regularly. In certain instances, the quality of treatment given to the patients has been

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enhanced by medical devices [4]. However, faulty medical equipment occasionally leads to catastrophes and serious health problems. The quality of a medical device and its safety and performance are primarily determined by the rules that a nation adheres to [5]. It is estimated that the medical device market in India is currently worth $11 billion. By 2022, it is anticipated to reach $50 billion [5].

In medical devices, notable advancements have led to the creation of improved brain surgical tools and prosthetic joints, to name a few. Despite its roots in the early 19th century, modern medical technology has only recently experienced a significant uptick. Medical devices have quickly replaced many other services provided by healthcare professionals in their attempts to identify and treat patients with medical disorders and lessen the difficulties experienced by those with functional disabilities [6].

In any emerging market with a delicate healthcare system, medical devices have become an important component [7]. These are employed in the pharmaceutical industry for various purposes, including assessment, evaluation, therapy, recovery, surveillance, etc. The market share varies amongst the devices sold in different sectors [8]. The development of Indian biomedical and pharmaceutical research and production facilities has a substantial influence on easing the availability of suitable and inexpensive medications and vaccinations for people living in developing nations [9]. However, the Medical Device Industries (MDIs) have not had the same progress, resulting in a rising imbalance in India and other emerging nations[10]

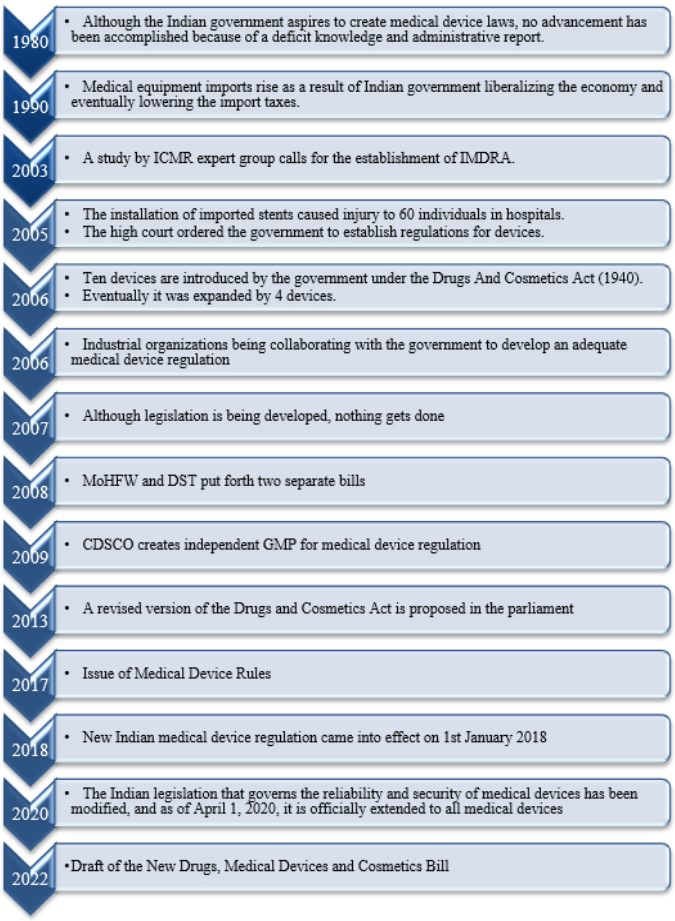

Figure 1: History of Indian Medical Device Regulations

DEFINITION:

According to CDSCO, Medical Devices means

- Substances used for invitro diagnosis and surgical dressings, bandages, staples, surgical sutures, ligatures, blood, and blood component collection bags

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with or without anticoagulant are covered under sub-clause.

- Substances, including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants, and insecticides notified under sub-clause.
- Devices notified from time to time under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 [(11)].

CLASSIFICATION OF MEDICAL DEVICES:

The Central Licensing Authority (CLA) of India divides medical devices and In Vitro Devices(IVDs) into four groups based on the intended use of the device, the risk associated with the device, and other characteristics mentioned in the International Medical Device Regulatory Convergence(IMDR).

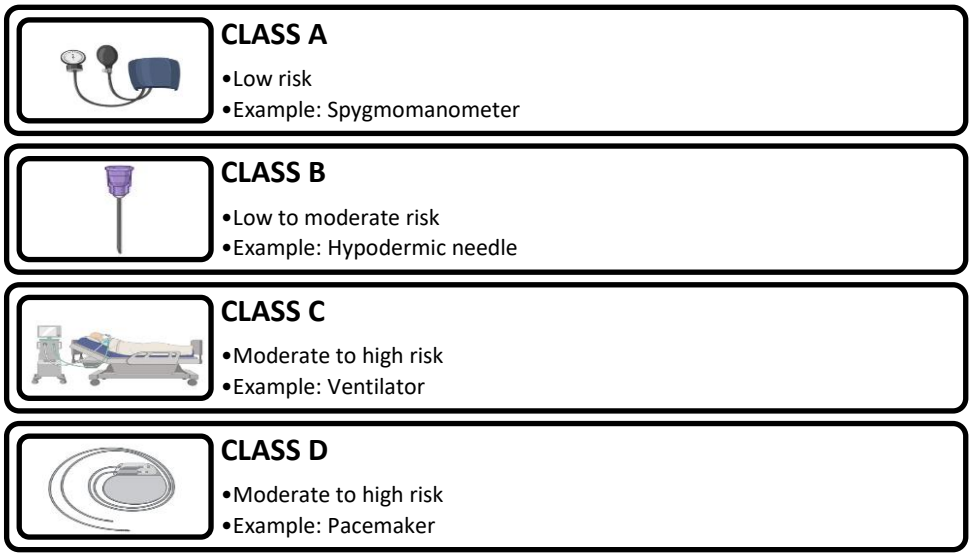

Figure 2 Classification of Medical Devices

The enlisted principles serve as a foundation for the classification of medical devices

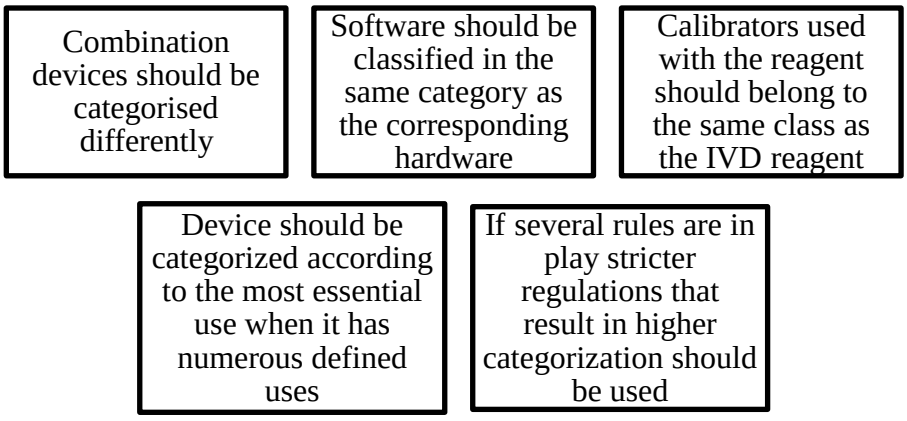

Figure 3: Essential principles for the classification of Medical Devices [(8)]

IMPORTANCE OF MEDICAL DEVICES

Quality of life has greatly improved because of the development of medical equipment as it has increased the doctor's capacity to detect and cure illness. Adopting a comprehensive regulatory system can be highly resource-intensive, particularly for an emerging country [(12).] Setting a broad national strategy or framework for medical device regulation is an excellent way to provide

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all stakeholders with a clear vision [13]. Registration enables the government to,

- Own a listing or record of the supplier
- Place a focus on commitments following the sale
- Execute judgments against the defaulters, such as by suspending the license
- Have a renewal process to keep data current

The employment of the most recent tools and technology is essential for an improved society [14].

There are several advantages that medical devices offer to both patients and physicians. Medical devices provide patients with trustworthiness, less requirement for support, enhanced comfort, and a feeling of security [15]. For healthcare professionals, medical devices offer effectiveness, predictability, a decrease in operator error, and convenience of use [16].

Even though medical device producers often focus on enhancing the treatment and lifespan, we also need to increase the availability of devices to significantly influence these technologies in our lives [17].

Figure 4 Significance of Medical Devices [17]

Testing and Diagnosis

Diagnostic tools are employed to find and identify medical issues. They are also employed to determine the degree of injury or sickness and identify and monitor the illness. The diagnostic technique aims to classify a patient's condition into discrete categories that enable medical practitioners to decide on a course of treatment and outlook. Identification of a medical issue is the initial stage in medical diagnosis. This knowledge can enhance the course of treatment, clarify the prediction, or stop the illness or disorder from recurring [18].

Example: Stethoscope, ECG, X-ray

Remote monitoring

Equipment for remote patient monitoring (RPM) lets medical professionals track and assess a patient's acute or ongoing symptoms outside a healthcare facility. Patient engagement and a greater understanding of their health are made possible through RPM. Patients are more inclined to have long-lasting, beneficial health results when they regularly engage with their health using RPM devices [19].

Example: Glucometer, Sphygmomanometer

Treatment and care

The advancement of surgical devices has enabled physicians to manage extremely challenging and critical patients and shorten extended clinical stays. Performing difficult and elective medical treatments like knee replacement has become more possible.

Example: The techniques used in laparoscopic surgery reduce the cost of treatment and the time of hospitalization in medical centers [17].

Restoration

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For the benefit of patients, medical rehabilitation makes extensive use of modern techniques and devices for treating brain injuries. Everybody has a distinct injury. Thus, each patient's recovery strategy is unique. In other words, various technologies and tools are needed for different people.

Example: Specialized treadmills track the number of footsteps walked per minute and the pressure placed on each foot when walking [20].

Cost-Effective

A freely accessible database includes reported financial information for around one-fourth of the main Pre-Market Approval(PMA) medical device categories. According to the currently available proof, gadgets often provide acceptable value when recognizing cost-effectiveness criteria [21].

MARKET STATUS:

According to estimates, India's medical equipment business is worth $11 billion. When comparing emerging economies, India's medical equipment market is expanding quickly. Large global corporations and small and medium-sized businesses are present in India's medical equipment market, which is expanding at an astonishing rate. The predicted CAGR for the medical device sector is 15%, 2.5 times that of the worldwide industry. The market for medical equipment in India is anticipated to develop significantly during the next several years, reaching $50 billion by 2030. Over the past five years, the Indian government has taken numerous measures to support the development of a thriving ecosystem to manufacture medical equipment in India.

It was reported that India imported $8.5 billion in medical devices in the fiscal year 2021-2022. Medical devices are imported into India from nations including the United States, Germany, Japan, China, and France. China is India's main supplier of imports.

According to reports, India exported medical devices worth $2.9 billion in the fiscal year 2021-2022. India exports medical equipment to Singapore, the United States, Europe, Japan, Australia, and the United Kingdom. The majority of India's medical equipment exports go to the USA.

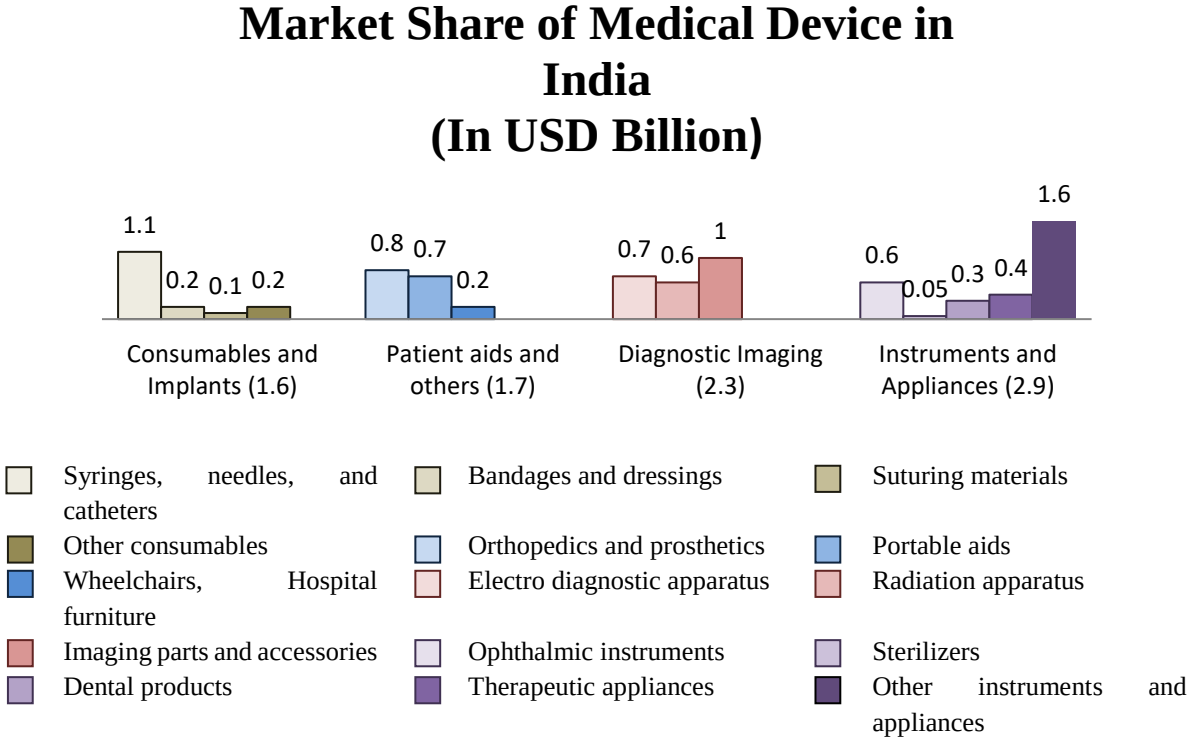

Figure 5: Market Share of Medical Devices in India

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OPPORTUNITIES AND RISKS OF MEDICAL DEVICES:

A. Orthopaedic Devices

- Price Restraint: It can be anticipated that manufacturers would be encouraged to lower the price of orthopedic devices and increase the accessibility of such devices to the majority of customers who require them by encouraging investment in compliance and cost-effective designs.
- Improvements in technology: According to experts, minimally invasive operations are becoming more popular since they result in less discomfort, bruising, and hospitalization. Orthopedic surgery constantly needs equipment that may be used to lessen the impact and increase precision while cutting into bones, no matter how big or tiny it is.
- 3D printing: The rate of 3D printing adoption in the healthcare system is remarkable. Despite ethical and scientific advancements, leading manufacturers implement 3D printing in sophisticated procedures.
- Product Innovations: Shortened process time appears to be among the top demands from both patients and healthcare providers. Innovative and precise goods are necessary due to the aging population's increasing need for orthopedic operations. The most challenging aspect is creating equipment with all these functions that can be purchased at reasonable pricing [22].

B. Cardiovascular Devices

- Implantable Defibrillators: An implanted String Subcutaneous Defibrillator (ISSD) can avoid unexpected cardiac mortality. It might use a solitary, malleable, string-like device outside the heart.
- Robotic Sleeve: A soft robot that surrounds the heart and stimulates its beating. The robot concurs with the heart using a thin silicone sleeve with supple pneumatic actuators that resemble the external muscle layers of the heart. It accomplishes this without coming into direct contact with the blood. As a result, possibly harmful blood thinners are no longer necessary [23].

C. Ophthalmic Devices

- Point of Care Testing: Patient care choices can be made instantly from the emergency department to the doctor's office, providing enhanced protection, therapeutic results, and general satisfaction.
- Bionic Eye Implants: Bionic eyes are intended to meet practical rather than purely aesthetic vision goals. Because of this, they are distinct from artificial or prosthetic eyes.
- Artificial Corneal Implants: It may be a solution for individuals who are blind in the future. Patients can currently have corneal transplants if their corneas are unhealthy or damaged. A synthetic alternative, however, will undoubtedly be welcome news given the scarcity of corneas [24].

D. Dermatology Devices

- Regeneration: Skin wounds require a very long time to recover. Work can be carried out on various technologies to hasten the healing process and speed up the body's natural reactions for more efficient skin regeneration.
- Health Sensors: The first ailments detected or treated by tiny, sensor-like materials or devices are likely to be skin-related [25].

E .Oncology Devices

- Nanotherapy: Attention may be paid to using small equipment at the micro and nanoscale to make the treatment more precise.
- Focal Therapy: Focal treatment involving heating or cooling tissue can mimic the oncological outcomes of prostate cancer patients who have had all or part of their prostate removed [26].

OPPORTUNITIES AND RISKS OF INDIAN MEDICAL DEVICE REGULATIONS

Opportunities :

Favourable government initiatives and policies

The Indian medical device sector is still in its infancy, and some prominent efforts launched by the Indian government include:

- 100% FDI to draw foreign capital to the manufacture of medical devices
- The initiative "Make in India" to increase domestic manufacturing
- Financial incentives for international businesses looking to leave China
- The Production Linked Incentive Scheme offers financial rewards for the domestic production of medical equipment [27].

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Medical Device Parks

A medical park with all the required facilities is being built in several locations as part of the Make in India program so businesses may effectively produce medical equipment there [28].

Population Growth

The World Bank estimates that India's population is expanding yearly, which may raise the need for medical equipment and medical services [28].

Medical Tourism

India draws medical tourists from all over the world due to the high caliber of healthcare services offered and affordable costs compared to other nations. The growing number of these visitors will increase the need for high-caliber medical gadgets [29].

Disease Burden

Because of dietary changes and aging, the incidence of the disease has changed from acute to long-term [30].

Awareness

With expanded media access and attention, awareness levels are rising. Diagnostic and therapeutic procedures have increased due to increased knowledge of medical technology breakthroughs by people [30].

Challenges

The expansion of the healthcare sector has been appealing. But much more work has to be done. The majority of Indians can only afford and get minimal medical care. Consequently, achieving universal healthcare is difficult. These are a few of the challenges encountered.

Low Penetration

The amount spent on medical devices per person in India is far lower at $3 compared to $5.3 in China and $16.7 in the United States.

Insufficient Accessibility

The healthcare system in India is insufficient, ineffective, and unequally dispersed. While 73% of certified consulting doctors are found in metropolitan areas, 69% of Indians live in rural regions, and the remaining 19% work in semi-rural areas [31].

Financial Charge

Medical device manufacture has substantial production costs. Without government incentives, this might financially strain producers [28].

Insufficient Regulatory Framework

- Issues that impede sector advancement include a shortage of facilities for quality product testing and noncompliance with international standards.
- Heavy capital expenses prevent the expansion of delivery infrastructure.
- A complicated tax structure and inadequate focus by policymakers are further factors in the backwardness of the industry.
- A thorough plan of action and attention to building the healthcare ecosystem is absent.
- India's lack of appeal as a location for medical equipment due to unreliable pricing and regulatory environments, lack of qualified labor, and the simplicity of running a company compared to other Asian countries with comparable economies.
- Patients have fewer alternatives due to a lack of innovation and customization.
- Weak regulations for fining pharmaceutical corporations.
- There is no mechanism for the medications or gadgets to be recalled in case of a problem or failure [27].

Conclusion:

While there are many prospects in the medical device industry, India must keep working to foster a supportive environment for domestic production if it is to take a significant place in the post-pandemic world [32]. India will need to rethink its long-term plan for advancing this industry. First and foremost, attention should be paid to improving the industry's competency through skill development, upskilling, and reskilling in line with technical and medical improvements. The second goal should be to increase possibilities and accessibility by collaborating on policy support for the supply and demand sides [28].

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Author contribution:

Venkatesh Shrikrishna Shinde & Nivetha D: The lead author and synthesis of the literature.

Bogadi Subhasri: synthesis of the literature.

Kalaivanan Ramakrishnan: Critical revision of the manuscript

Madhu Kiran Parvathaneni: Critical revision of the manuscript

Dr. Karri V V S R: Conceptual input, design, and critical revision of the manuscript

All authors read and approved the final paper.

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Declarations:

Competing interests: The authors declare that there are no conflicts of interest in this study. The authors alone are responsible for the content and writing of the paper.

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