

A STRATEGIC ASSESSMENT OF INDIA'S MEDICAL DEVICE SECTOR

Dissertation Submitted to



The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree of

Master of Business Administration (MBA)

in

Pharmaceutical Management

by

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Under the Supervision and Guidance of

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2025



B – BLACK BELT BRAND BUILDERS

CERTIFICATE

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This is to certify that dissertation titled “**A Strategic Assessment of India’s Medical Device Sector**” is a record of the research work undertaken by **Shantanu Sanjay Shende** in partial fulfilment of the requirements for the award of the degree of MBA in Pharmaceutical Management from the IIHMR University, Jaipur under my guidance and supervision and her approach to the research study has been sincere, scientific, and analytical.

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled “**A Strategic Assessment of India’s Medical Device Sector**” is the Bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.



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Shantanu Shende.

Date

ABSTRACT

By utilizing secondary data, this report delves into the complexities and evolving nature of India's medical device sector. It presents an in-depth evaluation of the country's medical device market, shedding light on the underlying mechanisms that drive the sector's growth and transformation. The study incorporates key functional areas necessary for interpreting the expanding landscape of medical technology and emphasizes the role played by Indian companies in shaping it. Segment-wise analysis of the medical device market reveals substantial scope and emerging possibilities, encouraging further exploration of its current dynamics and long-term development. The report gives particular attention to the impact of the COVID-19 pandemic, demonstrating how the industry has adapted, the hurdles faced by businesses, and the new opportunities that emerged as a result. This shift has further emphasized the vital importance of strengthening access to healthcare services. To chart the potential future of the medical device sector in India, the study analyzes prevailing industry trends and outlines prospective trajectories. The findings suggest that the medical device sector is growing swiftly, often outpacing traditional pharmaceuticals in terms of investment and technological advancement. Rising healthcare costs and population growth are two significant factors that are likely to shape this trend going forward. Additionally, the report examines how investment behaviors, technological progress, and evolving regulatory systems are reshaping the Indian medical device landscape. The ecosystem is influenced heavily by the coordination between governmental strategies and private enterprise efforts that aim to improve affordability and foster innovation. Overall, the study underscores the transformative potential of medical devices in enhancing patient care and outcomes across India. By identifying key enablers and constraints within the market, this analysis offers valuable strategic insights for stakeholders, including business leaders, healthcare providers, and policymakers, who are looking to harness the opportunities presented by this rapidly growing sector.

Keywords: medical device sector, secondary research, market segmentation, healthcare accessibility, industry growth trends, innovation, affordability.

ACKNOWLEDGEMENT

Embarking on a project is akin to setting sail on a vast and boundless ocean—one cannot navigate it alone. It is through the encouragement, guidance, and contributions of many that one uncovers the true value of such an undertaking. This major project is the result of the collective efforts of several individuals, and I am deeply grateful to everyone who supported me throughout this enriching journey.

Above all, I express my sincere gratitude to the Almighty for granting me the wisdom, strength, and perseverance required during this training and throughout my life. As the scripture says, “I can do everything through Him who gives me strength.”

I would like to extend my heartfelt thanks to my esteemed mentor, Prof. Akshay Mishra, for his continuous support, insightful guidance, and for being readily available to assist me at every stage of this project. His expertise and encouragement were invaluable in helping me resolve doubts and gain clarity.

I am equally thankful to Mr. Vivek Hattangadi, my organizational mentor, whose mentorship played a crucial role in shaping my practical understanding. His support created an environment conducive to learning and growth, for which I am truly grateful.

Finally, I wish to express my deepest appreciation to my parents for their unwavering belief in me. Their constant support, encouragement, and silent strength have been the foundation of my success throughout this training period

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Shantanu Sanjay Shende

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Chapter 1

INTRODUCTION

1.1 Introduction

- 1) India's healthcare sector has undergone a significant transformation over the last two decades, driven by rising incomes, increasing health awareness, growing incidence of lifestyle diseases, and public and private investments in health infrastructure. Within this expanding landscape, the medical device sector stands out as a critical pillar supporting the delivery of quality healthcare. From basic diagnostic tools to complex surgical instruments and advanced imaging systems, medical devices are instrumental in prevention, diagnosis, treatment, and rehabilitation. As the country aspires to achieve Universal Health Coverage (UHC) and align with the Sustainable Development Goals (SDGs), a strong and self-reliant medical device ecosystem becomes indispensable.
- 2) The Indian medical device industry has seen steady growth, estimated to be valued at over USD 11 billion (approximately INR 91,000 crore) in 2023, and projected to reach USD 50 billion (around INR 4.15 lakh crore) by 2030. However, this growth comes with unique challenges and opportunities. The sector is currently import-dependent, with nearly 70–80% of medical devices being sourced from countries such as the United States, Germany, China, and Japan. This reliance on imports has raised concerns about affordability, accessibility, and the country's resilience during health emergencies like the COVID-19 pandemic, where global supply chain disruptions exposed the vulnerabilities of an import-heavy system.
- 3) Despite its criticality, the medical device sector in India remained relatively under-regulated and fragmented until recent years. For decades, devices were treated as ancillary to pharmaceuticals, with regulatory oversight limited to a narrow list of notified devices. This lack of comprehensive regulation hampered quality control, innovation, and foreign investment. Recognizing this gap, the Indian government has initiated multiple policy reforms aimed at establishing a robust regulatory framework, fostering domestic manufacturing, and encouraging research and development (R&D). Key initiatives such as the Medical Devices Rules (2017), the Production Linked Incentive (PLI) Scheme, and the Promotion of Medical Device Parks have been instrumental in laying the foundation for a more strategic and self-sustaining ecosystem. Furthermore, the Uniform Code for Pharmaceutical Marketing Practices (UCPMP), while originally aimed at pharmaceuticals, is now being seen as influencing the medical devices industry as well. It emphasizes ethical marketing practices, impacting the way devices are promoted to healthcare professionals.
- 4) India's position as a global hub for affordable healthcare services, often referred to as the "Pharmacy of the World" due to its strong pharmaceutical manufacturing capabilities, offers a unique opportunity to replicate a similar success story in the medical devices space.

However, this requires a cohesive and well-executed strategic approach that aligns various stakeholders including policymakers, manufacturers, healthcare providers, regulators, and academia. The sector's heterogeneity—spanning consumables, implants, diagnostic equipment, digital health tools, and advanced imaging systems—calls for nuanced and sector-specific strategies rather than a one-size-fits-all model.

- 5) The Make in India initiative, launched in 2014, serves as a powerful catalyst in this regard, aiming to transform India into a global manufacturing hub. Medical devices have been identified as a priority sector under this initiative. The recent establishment of the National Medical Devices Policy (2023) further underscores the government's commitment to creating a streamlined, innovation-driven, and globally competitive industry. This policy outlines several strategic pillars including regulatory streamlining, fostering innovation and research, human resource development, quality assurance, brand positioning, and infrastructure development. These pillars are aimed at reducing import dependency, promoting exports, and building a resilient supply chain ecosystem.
- 6) India also has the potential to emerge as a global leader in frugal innovation—designing cost-effective yet high-quality medical devices that can cater not only to domestic needs but also to other low- and middle-income countries (LMICs). This is particularly relevant given the global focus on equitable access to healthcare technologies. Several Indian startups and MedTech companies have already begun to make their mark in this space, with innovations in portable diagnostic tools, affordable prosthetics, and AI-powered screening solutions. However, scalability remains a challenge, often hindered by limited funding, regulatory uncertainties, and a fragmented procurement system.
- 7) To realize the full potential of India's medical device sector, a comprehensive strategic assessment is essential. This includes analysing the current market landscape, evaluating the regulatory and policy environment, identifying key domestic and global players, mapping the value chain, and examining the barriers to innovation and scale. Equally important is understanding the role of public-private partnerships (PPPs), academic institutions, and incubation hubs in fostering a culture of innovation. The global competitive landscape also needs to be studied to benchmark India's progress and identify areas of strategic investment.
- 8) A strategic assessment must also consider regional disparities in access to medical devices and related services. While metropolitan cities have better access to advanced medical technologies, rural and underserved areas continue to face significant gaps in availability and affordability. Bridging this divide requires not only better infrastructure but also the promotion of telemedicine, remote diagnostics, and low-cost portable devices tailored for such

environments. Therefore, the alignment of medical device innovation with India's public health priorities is crucial for achieving inclusive health outcomes.

- 9) Another vital aspect is regulatory harmonization and convergence with global standards such as those set by the International Medical Device Regulators Forum (IMDRF) and ISO. Building capacity in quality assurance, certification, and testing labs will be instrumental in enhancing India's credibility as a manufacturing destination. Furthermore, strategic international collaborations and technology transfers can accelerate the learning curve and innovation cycles for Indian firms.
- 10) The availability of a skilled workforce is another cornerstone of strategic planning. While India has a vast pool of engineering and biomedical talent, specialized training in areas such as regulatory science, device engineering, and clinical evaluation is still lacking. Institutions of higher learning must be aligned with the evolving needs of the MedTech industry through curriculum reforms, joint research projects, and industry-academia collaborations.
- 11) The post-pandemic world presents a renewed sense of urgency to strengthen healthcare systems, making this a decisive moment for India's medical device sector. The COVID-19 crisis was a stress test that highlighted the need for self-sufficiency in critical healthcare technologies, prompting several Indian startups and companies to develop ventilators, PPE kits, and diagnostic kits locally within compressed timeframes. This has demonstrated the country's latent potential and agility when supported by the right policy environment and institutional mechanisms.
- 12) The medical device industry is a cornerstone of the global healthcare ecosystem. It supports healthcare professionals in delivering more effective, less invasive, and faster treatments. In India, the significance of this sector is growing rapidly, driven by increasing population demands, lifestyle changes, rising chronic disease incidence, aging demographics, and technological innovations. Additionally, as India seeks to become self-reliant through its "Make in India" initiative, the medical device sector is poised to become a critical contributor to national health infrastructure and economic growth.

Medical Device Classification

Medical devices are classified based on their intended use, level of risk to patients and users, and the regulatory controls necessary to ensure their safety and effectiveness. These classifications help with the regulation and management of medical devices by imposing standards before they can be marketed and utilised.

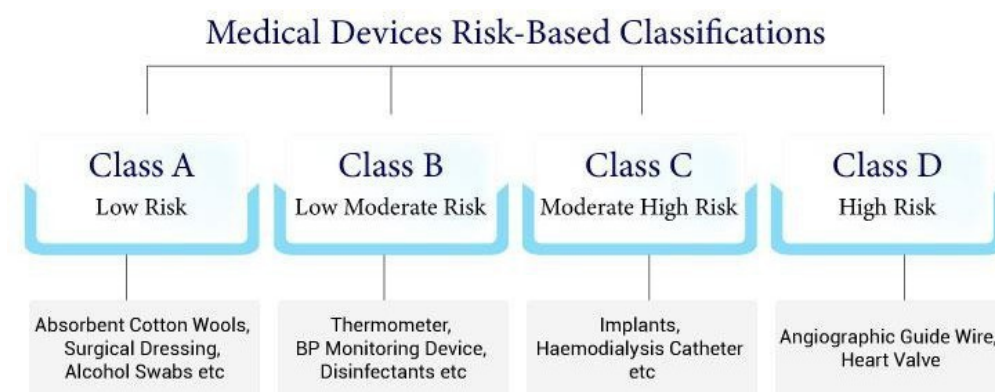


Fig 1.1: Classification of medical Devices

Market Size

Major worldwide firms and small and medium-sized enterprises make up India's medical device industry. By 2020, the medical device industry in India is expected to be worth US\$ 12 billion, growing at a compound annual growth rate (CAGR) of 15%, or 2.5 times the pace of growth observed globally. Ranking fourth in Asia behind South Korea, China, and Japan, India is among the top 20 global markets for medical equipment.

From 2020 to 2025, the diagnostic imaging market is projected to expand at a compound annual growth rate (CAGR) of 1.5%.

Medical equipment exports from India were valued at \$2.90 billion in FY22, and by 2025, they are expected to reach \$10 billion. to increase the country's medical device exports. The Central Drugs Standard Control Organization (CDSCO) and the Ministry of Health and Family Welfare (MOHFW) initiated the following initiatives:

Schedule MIII, which outlines the standards for facilities and good manufacturing processes, has to be reviewed and put back into effect.

Significance of the Study

The analysis of India's domestic medical device market holds significant importance in deciphering the underlying dynamics, market behavior, and expansion opportunities in this rapidly evolving healthcare segment. As the country experiences a surge in healthcare demand, driven by population growth, lifestyle diseases, and digital health adoption, it becomes crucial to explore how the medical device industry can contribute to meeting these emerging needs. This study, through an extensive review of secondary data, seeks to uncover patterns, gaps, and possibilities within the Indian market.

By delving into industry data, regulatory documents, and market performance reports, the research sheds light on key growth drivers, barriers to entry, and transformative developments shaping the sector. These findings are instrumental not only for healthcare professionals and manufacturers but also for policymakers, regulators, and investors aiming to make evidence-based decisions. For instance, understanding where the market is over-dependent on imports, or which product categories show domestic potential, can guide strategic investments and manufacturing policies.

One of the pivotal considerations addressed in this study is the role of **equitable access to healthcare**. In a country like India, where healthcare delivery is marked by disparities across urban and rural populations, medical devices can bridge crucial gaps by enabling remote diagnostics, affordable screening tools, and point-of-care technologies. Evaluating how these devices influence clinical outcomes, and patient experience offers practical guidance for improving public health infrastructure.

Additionally, this research integrates the analysis of **technological innovation, private sector participation, and government policy**—all of which collectively influence the trajectory of the industry. By understanding the ecosystem that fosters or restricts innovation, the study empowers stakeholders to build an environment that encourages affordability, scalability, and quality.

Methodology Overview

The methodology employed in this research is grounded in a comprehensive and systematic analysis of **secondary data sources**. This approach is ideal for exploring a vast and multi-dimensional domain such as the Indian medical device industry, especially where large-scale primary data may be difficult to access. The study draws upon a variety of authoritative and validated sources, including but not limited to industry white papers, market intelligence reports, peer-reviewed journals, government policy documents, and data from healthcare and regulatory institutions.

The research follows a **descriptive and analytical framework**, which enables the identification of market segments, assessment of industry performance, and evaluation of regulatory structures. It emphasizes a qualitative and quantitative review of existing literature to recognize trends such as investment flows, adoption of new technologies, regional market variations, and policy shifts. By mapping historical developments with current industry scenarios, the methodology aids in projecting future trends and market opportunities.

A special emphasis is placed on analyzing the **impact of the COVID-19 pandemic**, which served as a critical stress test for India's healthcare and medical technology systems. The study reviews how the crisis affected supply chains, increased demand for diagnostic and monitoring devices, and created momentum for local manufacturing. Lessons learned from the pandemic are integrated into the evaluation of both vulnerabilities and potential reforms in the sector.

Furthermore, the study explores the **synergistic relationships between public and private stakeholders**, including their roles in manufacturing, innovation, financing, and policy execution. This includes evaluating initiatives such as the "Make in India" campaign, the Production Linked Incentive (PLI) scheme, and the creation of medical device parks. By analyzing such initiatives through secondary sources, the study builds a holistic picture of how collaborative efforts can shape the future of the Indian medical device market.

Overall, this structured and multifaceted methodology ensures that the research offers credible, insightful, and actionable information for academics, industry leaders, and decision-makers aiming to engage with this critical sector.

Chapter 2

LITERATURE

REVIEW

2.1 LITERATURE REVIEW

2.1.1 Introduction

1. The *Make in India* initiative presents a critical opportunity to strengthen indigenous manufacturing of medical devices. NATHEALTH and Deloitte (2021) emphasize that enhancing local production capabilities can reduce dependency on imports, decrease costs, and improve accessibility to medical devices across India. The report highlights that increasing awareness and acceptance of Indian-made devices among healthcare professionals is vital for expanding both domestic and export markets, which would concurrently support healthcare infrastructure development and economic growth [1].
2. Ensuring the safety and quality of medical devices is a major concern globally and particularly in India. The World Health Organization's (WHO) *Technical Series on Safer Medical Devices* (2020) stresses the importance of implementing rigorous safety standards and continuous performance monitoring. It highlights the necessity for healthcare professionals to be well-informed about device-related risks and for a robust regulatory framework that ensures all devices meet required safety and efficacy standards to prevent adverse clinical outcomes [2].
3. Regulatory policies significantly impact the availability and usage of medical devices. The Ministry of Health and Family Welfare's Draft Medical Device Rules (2016) introduced important provisions on classification, registration, and post-market surveillance. However, gaps between policy formulation and on-ground implementation have created challenges for healthcare providers, who must navigate regulatory uncertainty. These challenges can reduce confidence in device quality and limit adoption rates, especially in smaller hospitals and clinics [3].
4. The growing healthcare market in India presents significant investment potential, driven by increased healthcare spending and the rising burden of chronic diseases. NITI Aayog (2016) underscores the need for targeted investment to stimulate innovation, improve supply chains, and enhance technology transfer in the medical devices sector. This investment environment directly influences the variety and quality of devices accessible to healthcare professionals in both public and private sectors [4].
5. Access to medical devices remains inequitable, especially in resource-constrained settings. The WHO Global Report on Effective Access to Medical Devices (2021) identifies affordability, infrastructure limitations, and lack of trained personnel as key barriers to effective device utilization. This correlates with evidence showing that healthcare

professionals' use and preference for medical devices often reflect the availability of financial and infrastructural resources within their institutions [5].

6. To improve healthcare outcomes, the WHO Priority Medical Devices Program (2011) provides a list of essential devices that support critical health services. This program guides hospitals and policymakers in prioritizing procurement and capacity-building efforts, balancing clinical needs with cost considerations. The program's relevance is particularly notable in India, where healthcare providers must often optimize device use in the face of budgetary constraints [6].
7. The Indian medical devices market is expanding rapidly due to rising demand, favorable government policies, and shifts in global supply chains. Invest India (2023) reports growing acceptance of innovative technologies by healthcare professionals, although preferences are frequently influenced by cost, reliability, and vendor support. The sector's evolution underscores the importance of understanding healthcare providers' perceptions and procurement behaviors to improve device uptake [7].
8. The recently introduced National Medical Devices Policy (2023) by the Department of Pharmaceuticals aims to promote self-reliance through domestic manufacturing, standardization, and skill development. The policy also seeks to simplify regulatory processes and encourage innovation. Its implementation is expected to enhance healthcare professionals' confidence in Indian-manufactured devices and shift procurement preferences towards domestically produced options [8].
9. The COVID-19 pandemic exposed critical weaknesses in medical device supply chains worldwide, including India. WHO's Pandemic Supply Chain Network report (2020) emphasizes the need for resilient local manufacturing and diversified sourcing strategies to maintain steady device availability during crises. These supply chain considerations significantly affect healthcare professionals' access to medical devices and their sourcing preferences in everyday clinical practice [9].
10. Harmonizing regulatory frameworks in line with global standards is essential for ensuring device safety and performance. The WHO Global Model Regulatory Framework (2017) provides comprehensive guidelines to facilitate uniform regulation and improve device quality assurance. Adoption of such frameworks in India can bolster healthcare professionals' trust in medical devices and support wider usage and better clinical outcomes [10].

Chapter 3

METHODOLOGY

METHODOLOGY

Research Questions

The study was guided by several key research questions aimed at exploring perceptions and usage of medical devices within India's healthcare ecosystem:

- 1) To what degree do you support the use of medical devices in healthcare?
- 2) How significantly do medical devices facilitate and simplify surgical procedures?
- 3) To what extent do you prefer medical devices over traditional medical treatments?
- 4) How dependent is India on the importation of medical devices?
- 5) Do you believe that medical devices contribute to improved patient health outcomes?
- 6) In your opinion, is the cost of medical devices justified by the benefits they provide?
- 7) Would you Favor domestically manufactured medical devices as opposed to imported ones?

These questions were crafted to assess both qualitative attitudes and quantitative evaluations relating to medical devices' acceptance, utility, and market dynamics.

Objective

The main objective of this study is to analyze the current trends in the usage, acceptance, and preference of medical devices among healthcare professionals in India. The research specifically aims to:

- 1) **Assess the level of awareness and usage** of various categories of medical devices (diagnostic, therapeutic, surgical, and monitoring) by healthcare professionals in public and private healthcare settings.
- 2) **Evaluate healthcare professionals' perceptions** regarding the effectiveness, safety, and clinical performance of medical devices used in day-to-day practice.
- 3) **Analyze cost-related preferences and concerns**, including cost-effectiveness, affordability, and value-for-money perceptions associated with different medical devices.
- 4) **Understand sourcing preferences**, i.e., the inclination toward indigenous (Indian-manufactured) versus imported medical devices and the factors influencing this preference.
- 5) **Identify key barriers and challenges** in the procurement and usage of medical devices in Indian hospitals, such as regulatory issues, supply chain limitations, or technical support.

- 6) **Explore the influence of government policies and initiatives** (e.g., Make in India, National Medical Devices Policy 2023) on the acceptance and adoption of Indian-manufactured medical devices.
- 7) **Recommend strategies** for improving the perception, accessibility, and adoption of medical devices in the Indian healthcare system based on the findings.

Materials and Procedures

- **Research Design:** This study employed a descriptive research design aimed at capturing detailed insights and perspectives. It primarily involved collecting and analyzing data through both primary and secondary sources.
- **Setting:** The research was conducted using existing data from published reports, regulatory documents, survey findings, and supplemented with primary data collection from healthcare industry personnel.
- **Study Population:** The target population included individuals actively engaged in India's healthcare sector, such as medical practitioners, hospital administrators, medical device manufacturers, and regulatory professionals.

Sampling Method: A non-probability convenience sampling technique was used, allowing for the selection of readily available respondents within the healthcare industry. This approach enabled efficient data collection despite potential limitations in representativeness.

Data Collection Technique: The study utilized a mixed-methods approach combining primary data gathered through structured surveys and interviews with secondary data sourced from government reports, industry publications, and regulatory guidelines.

Plan for Data Analysis

Collected data were systematically compiled and analyzed using Microsoft Excel. Quantitative survey responses were statistically evaluated to identify trends, frequencies, and correlations, while qualitative responses were reviewed for thematic insights. The analysis aimed to provide both descriptive statistics and interpretative understanding to inform conclusions about the medical device sector.

Ethical Considerations

The research was conducted in strict adherence to ethical standards governing academic and industry research. Prior to participation, all respondents were fully informed about the study's purpose and assured of confidentiality. Informed consent was obtained, with explicit permission sought before disclosing any identifying information. Data privacy and respondent anonymity were rigorously maintained throughout the study to protect participant rights and promote honest, unbiased responses.

Operational Definition

For the purposes of this research, a **medical device** is defined as any instrument, apparatus, implement, machine, appliance, or related article used individually or in combination for disease prevention, diagnosis, treatment, or health monitoring. Medical devices function to measure, restore, correct, or modify bodily structures or functions to improve health outcomes. Key regulatory bodies referenced include the **Central Drug Standards Control Organization (CDSCO)**, the **Ministry of Health and Family Welfare (MoHFW)**, and the **Medical Device Regulatory Authority (MDRA)** in India.

Rationale for the Study Design

A descriptive research design was selected due to its effectiveness in capturing real-world perceptions, preferences, and practices without manipulating variables. This approach aligns well with the exploratory nature of the study, allowing the researcher to document and interpret stakeholder insights in a structured yet flexible manner. Given the complexity of India's healthcare landscape, descriptive methods help unpack nuanced information from varied sectors including regulation, clinical practice, and manufacturing.

Additionally, this approach supports the integration of both quantitative (numerical data from surveys) and qualitative (opinions from interviews) inputs, thus facilitating a more holistic view of the medical device sector. This triangulation of data sources enhances the credibility of findings and enables a more accurate strategic assessment.

Sampling Strategy Justification

A non-probability convenience sampling method was employed primarily due to logistical constraints such as time, access, and resource limitations. While this sampling strategy may limit generalizability, it enables targeted engagement with stakeholders possessing relevant insights. For exploratory and preliminary research, such as this study, the strategy is appropriate to derive directional findings.

Moreover, participants were carefully selected from professional networks, conferences, and institutional affiliations to ensure their relevance and familiarity with the medical device industry. These respondents are considered informed and therefore capable of providing credible and meaningful responses.

Structure and Design of the Questionnaire

The questionnaire was designed using a combination of Likert-scale questions, binary (Yes/No) responses, and open-ended prompts. Likert scales were particularly useful in measuring the degree of agreement or disagreement with statements related to the utility, cost, and preference for medical devices. Binary questions were used for quick judgments and decision-making responses, while open-ended questions allowed participants to elaborate on their views and provide anecdotal evidence or sector-specific examples.

Tools and Software Utilized

All data were compiled and analyzed using Microsoft Excel due to its accessibility and efficiency in handling both numerical and qualitative datasets. Functions such as pivot tables, frequency distribution, and conditional formatting were used to identify trends and segment data by stakeholder category. For qualitative insights, thematic analysis was manually performed, with key themes being coded based on frequency of occurrence and relevance to the research objectives.

Excel was also used to create visual representations such as pie charts, bar graphs, and tables to aid in the interpretation and presentation of findings.

Limitations of the Methodology

This study, while robust in approach, acknowledges several limitations:

Sample Size: With 48 respondents, the sample may not adequately reflect all regions or sectors within India's diverse medical device ecosystem.

Sampling Bias: The use of convenience sampling can introduce selection bias, as participants may not be representative of the broader population.

Response Bias: Given that some responses were self-reported, there is potential for bias in how individuals perceive and articulate their experiences or preferences.

Despite these limitations, the insights generated are valuable for drawing initial conclusions and identifying patterns that warrant further investigation in subsequent studies.

Ethical Review and Approval

Although the study was not affiliated with a formal Institutional Review Board (IRB), all ethical practices aligned with standard academic protocols. Participants were provided with a detailed informed consent form outlining the purpose of the research, their rights, and the voluntary nature of their participation. No sensitive personal data were collected, and anonymity was strictly maintained during data handling and presentation.

All survey results were stored securely, and access was limited to the research team to safeguard confidentiality and ensure data integrity.

Operational Context

The definition of medical devices used in the study aligns with India's Medical Device Rules, 2017, and the globally recognized guidelines provided by bodies such as the WHO. This consistent framework ensures that the scope of research remains clear and relevant across stakeholder responses. The inclusion of India-specific regulatory bodies such as CDSCO and MoHFW further contextualizes the findings within the domestic policy landscape.

Insights from the Sample Size

Although the study utilized only 48 participants, the demographic distribution ensured that insights were drawn from across multiple verticals of the medical device supply chain. For instance:

Healthcare professionals provided real-time perspectives on clinical usage and efficacy.

Industry experts highlighted challenges in manufacturing, innovation, and policy compliance.

Hospital administrators shared insights into procurement patterns and economic considerations.

Regulatory personnel offered views on compliance, approval timelines, and market entry barriers.

The varied representation enabled triangulated insights that helped validate trends observed across different types of institutions.

Validity and Reliability

Efforts were made to enhance the **validity** of the study by:

Pre-testing the questionnaire with five experts to ensure clarity.

Ensuring alignment between research questions and survey instruments.

Using multiple sources for triangulation.

Reliability was supported through consistent question phrasing and standardized data collection procedures. All participants received identical instructions, and the survey was administered digitally to reduce interviewer bias.

SAMPLE SIZE

This study utilized a sample size of **48 respondents** to gather comprehensive insights into various facets of the Indian medical device market. The sample included a diverse group of stakeholders such

as healthcare professionals, medical device industry experts, hospital administrators, and regulatory personnel to ensure a multifaceted understanding of market dynamics.

Respondents were asked a series of questions designed to capture their perceptions on the value of medical devices, their impact on surgical procedures, and their preference for modern devices over traditional medical practices. Additionally, the study explored opinions regarding India's current reliance on imported medical devices and preferences toward locally manufactured alternatives.

To strengthen the research scope, yes/no format questions were also included to efficiently gauge support levels for specific aspects of the medical device sector. While the relatively small sample size limits the generalizability of findings, the collected data provide valuable preliminary insights into trends and challenges faced by the industry. The study establishes a solid foundation for future research efforts, with recommendations to expand the sample size and include a broader array of participants to validate findings and explore the market more thoroughly.

Chapter 4

RESULTS

RESULTS

This chapter presents the findings from the primary research that was done to understand the dynamics and growth potential of the Indian medical device market. A standardised questionnaire was completed by 48 respondents, comprising healthcare professionals and industry experts, in order to collect data. The main goals of the investigation are covered, including the degree to which respondents favour medical devices, how these devices affect surgical operations, if they prefer them over conventional treatment, and how dependent India is on imported medical devices. Using yes/no questions, the survey also looks at respondents' support for several facets of the medical device business.

Extent to which respondents favour medical devices:

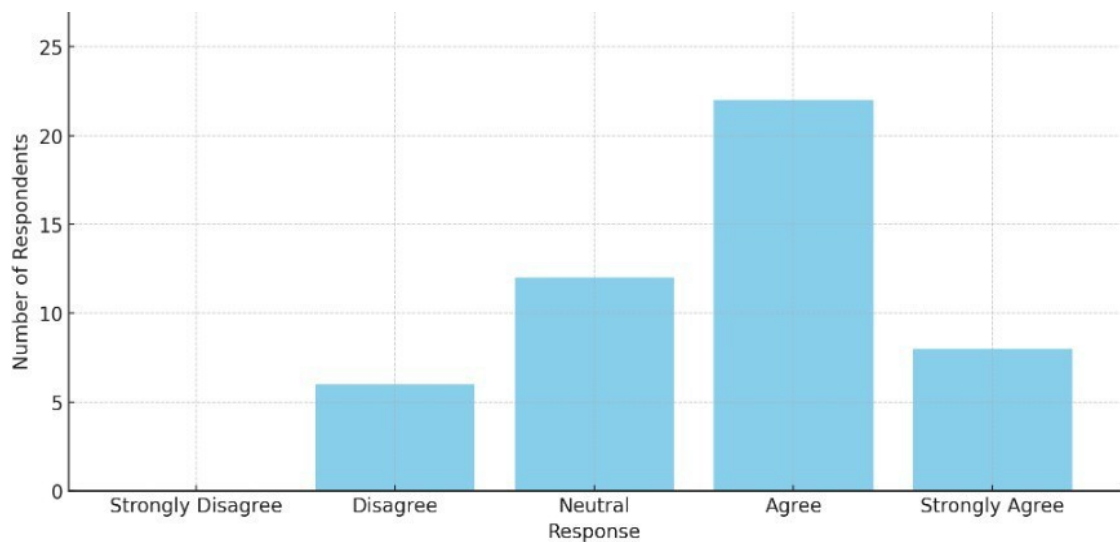


Fig 4.1: Extent to which respondents favour medical devices.

Out of 48 respondents the chart shows that 22 agree 8 strongly agree with favouring medical devices.

12 respondents are neutral, 6 disagree, and none strongly disagree.

Extent to which medical devices ease the process of surgery:

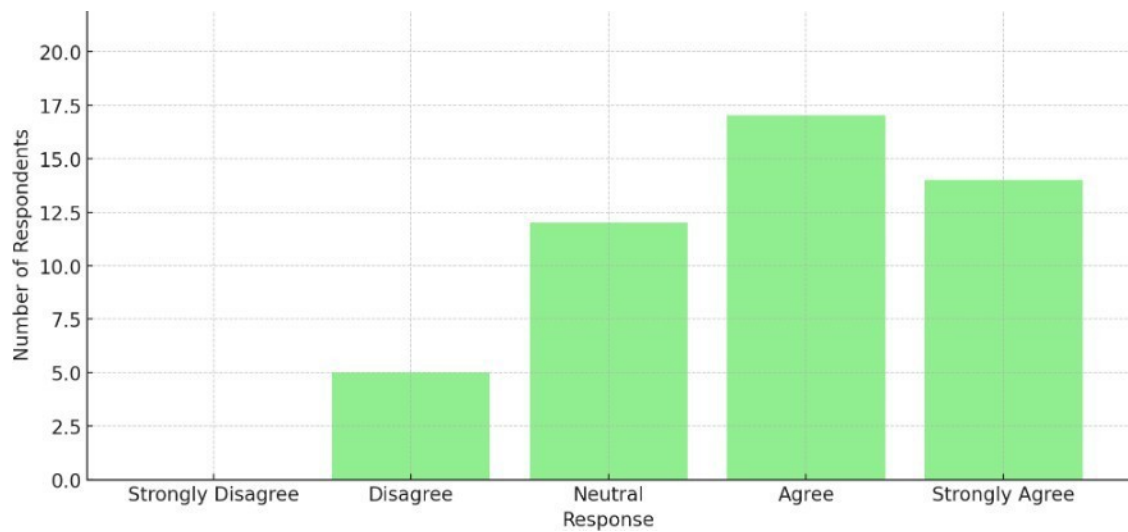


Fig 4.2: Extent to which medical devices ease the process of surgery

- The chart indicates that a majority of respondents agree (17) or strongly agree (14) that medical devices ease the process of surgery.
- A similar number of respondents are neutral (12), with fewer disagreeing
- (5) and none strongly disagreeing.

Advocacy of Medical Devices Over Traditional Medicine:

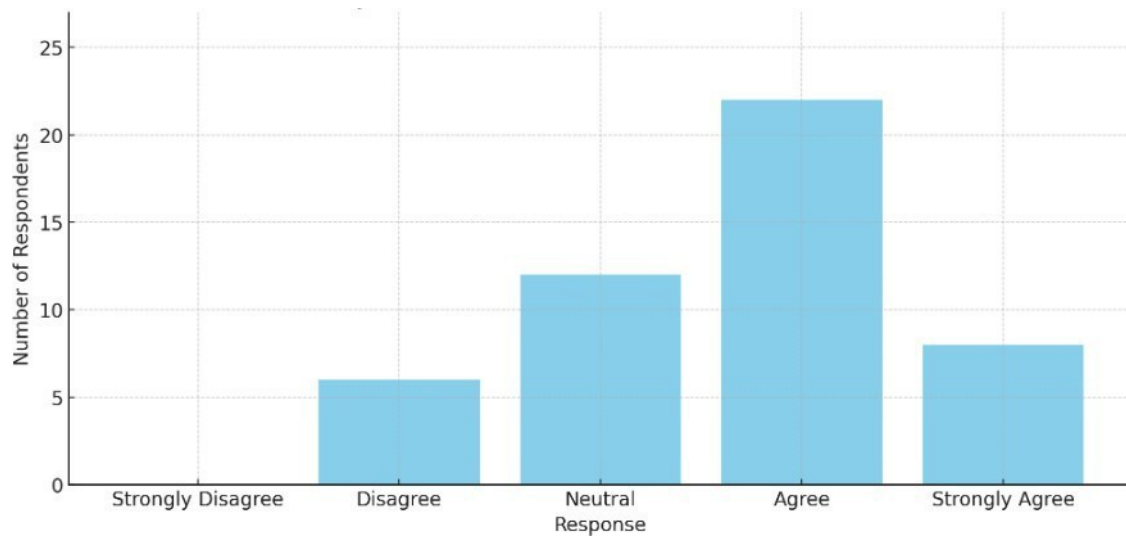


Fig 4.3: Advocacy of medical devices over traditional medicine

The chart shows that most respondents either agree (22) or strongly agree (8) with advocating medical devices over traditional medicine.

A smaller number of respondents are neutral (12), disagree (6), and none strongly disagree

Reliance on Importation of Medical Devices in India:

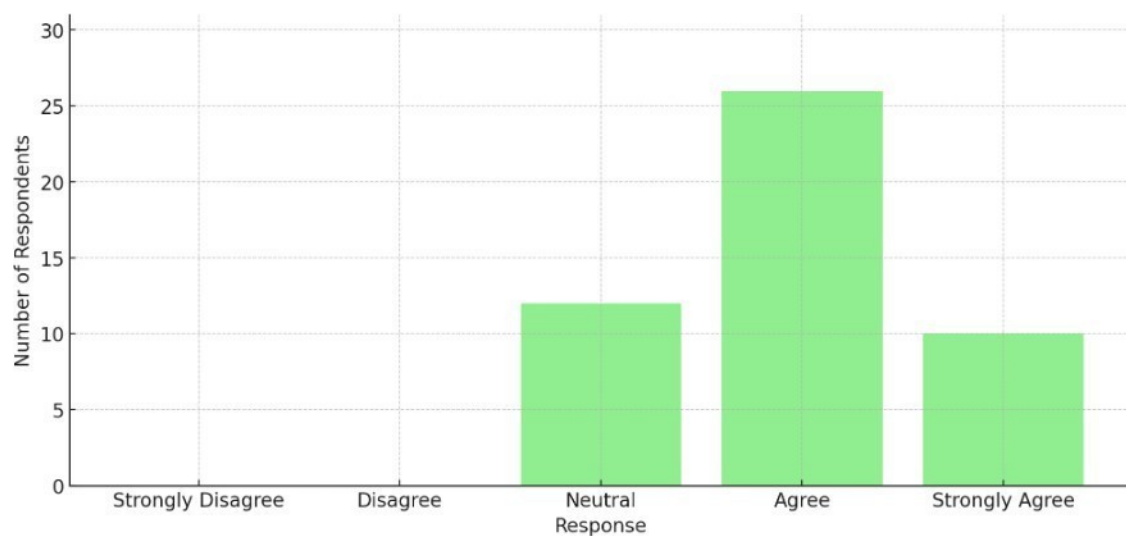


Fig 4.4: Reliance on import of medical devices in India

The chart clearly reflects that a significant portion of respondents acknowledge India's heavy reliance on imported medical devices. Specifically, 26 individuals agreed, and an additional 10 respondents strongly agreed with this statement, highlighting a shared perception of dependency on foreign technologies in the medical device sector.

Interestingly, 12 respondents remained neutral, suggesting either a lack of definitive knowledge on the subject or a more balanced view regarding the origin of medical equipment used in India. Notably, there were no responses in the categories of "disagree" or "strongly disagree," indicating that there is little to no opposition to the idea that India currently depends on imported medical devices. This consensus underscores the importance of addressing this issue through policy reforms, enhanced local manufacturing capabilities, and increased investment in indigenous research and development.

Do you believe that medical devices improve patient outcomes?

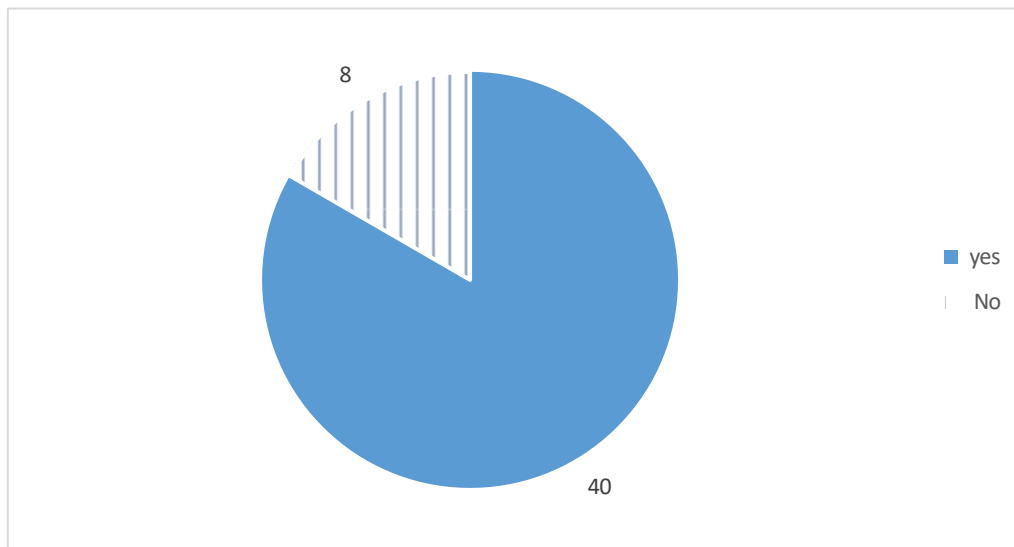


Fig 4.5: Perception of respondents regarding medical devices improving patient outcomes

The chart reveals that out of a total of 48 respondents, a substantial majority—40 individuals—either agree or strongly agree that medical devices play a significant role in improving patient outcomes. This widespread agreement highlights a positive perception regarding the effectiveness of medical technologies in enhancing the quality of healthcare, aiding in faster recovery, and supporting accurate diagnosis and treatment.

On the other hand, 8 respondents expressed disagreement, indicating a level of skepticism or concern about the effectiveness, accessibility, or practical benefits of medical devices in real-world clinical settings. This minority viewpoint suggests that while the overall sentiment is highly favorable, there remains a need for continued education, awareness-building, and evidence-based demonstration of how medical devices contribute to better healthcare delivery.

Do you think the cost of medical devices is justified by their benefits?

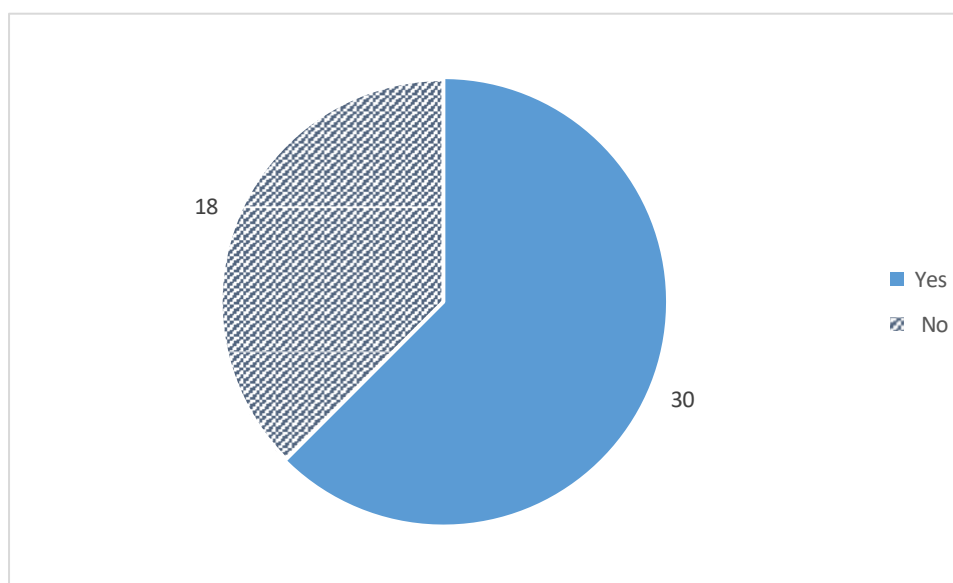


Fig 4.6: Perception of respondents regarding whether the cost of medical devices

The chart shows that out of 48 respondents, 30 individuals agree or strongly agree that the cost of medical devices is justified by the benefits they offer. This suggests that most participants recognize the value these devices bring in terms of improving patient care, streamlining medical procedures, and contributing to overall healthcare efficiency, thereby making the investment worthwhile.

However, 18 respondents expressed disagreement, indicating that a significant portion of the sample remains unconvinced about the cost-effectiveness of medical devices. These individuals may have concerns regarding affordability, accessibility, or whether the high prices truly correspond to the practical benefits delivered. This division in opinion underscores the need for further evaluation of pricing strategies and greater transparency about the long-term health and economic advantages provided by medical technologies.

Would you prefer locally manufactured medical devices over imported ones?

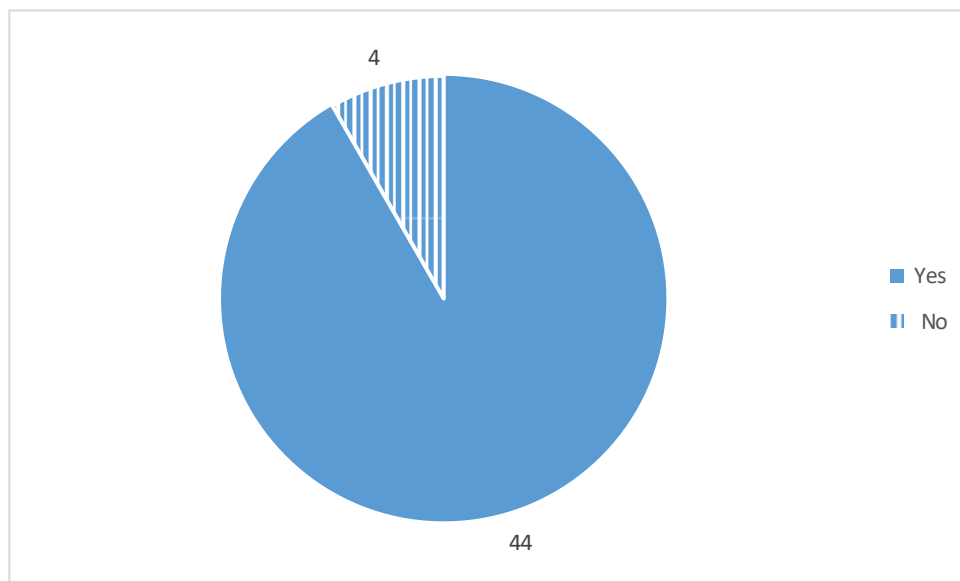


Fig 4.7: Preference of medical devices over imported ones

According to the chart, out of 48 respondents, a significant majority—44 individuals— expressed agreement that they would prefer locally manufactured medical devices over imported alternatives. This overwhelming support highlights a strong sense of trust and confidence in domestically produced medical technologies. It also reflects a growing sentiment of self-reliance and encouragement for indigenous innovation within the healthcare sector.

On the other hand, 4 respondents disagreed, suggesting that a small segment of the population may still perceive imported devices as being more reliable, advanced, or of higher quality. This minority opinion points to the need for continuous improvements in the standards, innovation, and branding of locally manufactured devices to match or exceed global benchmarks. Overall, the results indicate a promising opportunity for the Indian medical device industry to expand and thrive by aligning with national preferences and expectations.

Chapter 5

DISCUSSION

5.1 **DISCUSSION**

1. Awareness and Usage of Medical Devices

Healthcare professionals in India exhibit varying levels of awareness and usage of medical devices across different categories:

Diagnostic Devices: A study highlighted that while diagnostic tools like MRI and CT scanners are prevalent in urban tertiary care centers, their availability and usage in rural settings remain limited due to infrastructure constraints .

Therapeutic Devices: The adoption of therapeutic devices, such as infusion pumps and ventilators, has increased, especially during the COVID-19 pandemic. However, consistent usage is hindered by maintenance challenges and lack of trained personnel .

Surgical Devices: Advanced surgical instruments, including laparoscopic tools, are more commonly used in private hospitals compared to public ones, primarily due to budgetary constraints .

Monitoring Devices: The use of monitoring devices like ECG machines and pulse oximeters has become widespread. Nonetheless, their optimal utilization is often compromised by inadequate training and maintenance issues .

2. Perceptions of Effectiveness, Safety, and Clinical Performance

Healthcare professionals' perceptions significantly influence the adoption of medical devices:

A cross-sectional study revealed that approximately 71.2% of healthcare professionals were aware of post-market surveillance programs, indicating a growing consciousness about device safety .

Despite awareness, concerns persist regarding the reliability and durability of certain devices, especially those lacking robust clinical validation .

3. Cost-Effectiveness, Affordability, and Value-for-Money Perceptions

Cost considerations play a pivotal role in the selection and usage of medical devices:

The high cost of importing medical devices has been a significant barrier, leading to increased healthcare expenses for patients .[Public Health Foundation of India -](#)

Health Technology Assessment (HTA) initiatives have been introduced to evaluate the cost-effectiveness of medical devices, aiming to inform procurement decisions and ensure value for money .htain.dhr.gov.in

4. Sourcing Preferences: Indigenous vs. Imported Devices

The preference between indigenous and imported medical devices is influenced by multiple factors:

India imports approximately 70% of its medical devices, indicating a heavy reliance on foreign products.[NewsMeter](https://www.newsmeter.in)

The "Make in India" initiative aims to boost domestic manufacturing, but challenges such as quality assurance and regulatory approvals affect the acceptance of indigenous devices .

5. Barriers and Challenges in Procurement and Usage

Several systemic barriers hinder the efficient procurement and usage of medical devices in Indian hospitals:

Regulatory Issues: The lack of a robust regulatory framework has led to inconsistencies in device approvals and quality standards .

Supply Chain Limitations: Inadequate supply chain infrastructure results in delays and increased costs in device procurement .

Technical Support: The absence of adequate technical support and maintenance services hampers the optimal functioning of medical devices .

6. Influence of Government Policies and Initiatives

Government policies have a significant impact on the medical device sector:

The National Medical Devices Policy 2023 aims to strengthen the domestic manufacturing ecosystem and reduce import dependency .epw.in+1India Corporate Law+1

Production Linked Incentive (PLI) schemes have been introduced to encourage investment in the medical device sector .[Press Information Bureau](https://www.pib.gov.in)

7. Strategies for Improving Perception, Accessibility, and Adoption

To enhance the adoption of medical devices in the Indian healthcare system, the following strategies are recommended:

Capacity Building: Training programs for healthcare professionals to improve device handling and maintenance.

Regulatory Reforms: Establishing a dedicated regulatory body for medical devices to streamline approvals and ensure quality [.epw.in](https://www.epw.in)

Infrastructure Development: Investing in supply chain and maintenance infrastructure to support device functionality .

Public-Private Partnerships: Encouraging collaborations between government and private entities to foster innovation and accessibility .

Chapter 6

CONCLUSION & RECOMMENDATIONS

6.1 CONCLUSION

- **Awareness and Usage of Medical Devices:**

- There is varied awareness and usage of medical devices across diagnostic, therapeutic, surgical, and monitoring categories.
- Diagnostic and monitoring devices see wider use due to their essential role in patient care.
- Advanced therapeutic and surgical devices have lower penetration, especially in public hospitals with limited resources.
- Bridging these gaps requires targeted training, infrastructure improvements, and enhanced technical know-how among healthcare professionals.

- **Perceptions of Effectiveness, Safety, and Performance:**

- Healthcare professionals generally acknowledge the benefits of medical devices in improving diagnosis accuracy, treatment efficiency, and patient monitoring.
- However, concerns regarding device reliability, quality consistency, and maintenance issues remain significant.
- Such concerns impact trust and willingness to adopt certain devices.
- Strengthening quality control, regular audits, and better user training can improve confidence and clinical usage.

- **Cost-Related Preferences and Concerns:**

- Affordability and cost-effectiveness are major factors influencing procurement decisions.
- Imported devices are often seen as technologically superior but costly, limiting their use in budget-constrained public healthcare settings.
- Indian-made devices offer more affordable options but face skepticism regarding quality.
- Decision-makers emphasize value-for-money considering total costs, including maintenance and durability, beyond the initial purchase price.

- **Sourcing Preferences: Indigenous vs. Imported Devices:**

- There is a growing inclination toward indigenous devices driven by cost advantages, ease of availability, and faster technical support.
- This trend aligns with national initiatives promoting local manufacturing and self-reliance.

- The preference for Indian-made devices depends on assured quality, which remains a challenge needing continuous improvement.
 - Increasing certifications, innovation, and quality assurance will help build trust in domestic products.
- **Barriers and Challenges in Procurement and Usage:**
 - Regulatory uncertainties and complex approval processes hinder smooth procurement.
 - Supply chain inefficiencies, such as poor logistics and inconsistent inventory management, affect device availability.
 - Technical support and after-sales service gaps reduce device uptime and usage effectiveness.
 - Collaborative efforts are needed among regulators, manufacturers, and healthcare institutions to create streamlined, transparent, and supportive procurement systems.
- **Influence of Government Policies and Initiatives:**
 - Government programs like “Make in India” and the National Medical Devices Policy 2023 positively impact domestic device production and adoption.
 - These policies encourage innovation, reduce import dependence, and aim to improve affordability.
 - However, awareness of these initiatives among healthcare professionals is limited and requires enhancement.
 - Continued policy support combined with capacity building and market facilitation is essential for sustained growth.
- **Strategies for Improvement and Adoption:**
 - Expanding education and training programs will increase healthcare professionals’ competence and confidence in using diverse medical devices.
 - Streamlining regulatory frameworks will reduce delays and increase market predictability.
 - Strengthening supply chains and technical support services will ensure devices are available and functional when needed.
 - Promoting industry-academia collaboration and innovation will foster development of high-quality, affordable indigenous devices.
 - Awareness campaigns targeting healthcare professionals can improve perceptions and acceptance of Indian-made products.
 - Public-private partnerships can leverage resources and expertise to enhance healthcare infrastructure and technology reach.

- **Overall Implications:**

- The medical device sector in India is evolving with promising trends but faces significant challenges that need urgent attention.
- Addressing disparities in device access between public and private healthcare, enhancing trust through quality assurance, and balancing cost with clinical performance are critical.
- The synergy of government support, industry innovation, and healthcare professional engagement can transform India into a self-reliant hub for medical devices.
- Ultimately, these improvements will contribute to better healthcare delivery, patient outcomes, and long-term sustainability of the healthcare system.

Chapter 7

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