

MARKET ENTRY STRATEGIES FOR A MEDICAL DEVICE COMPANY IN CARDIAC VERTICAL

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in

Pharmaceutical Management

By

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Under the Supervision and Guidance of

Dr. Ashok Peepliwal

2024

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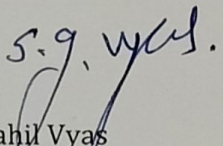
Experience Certificate

This is to certify that **Mr. Shubham Soni**, pursuing MBA from IIHMR University, Jaipur, has successfully completed his internship of three months starting from March 18, 2024 till June 17, 2024 at our organization based at Delhi.

He has successfully completed his project titled "**Market entry strategies for a medical device company in the cardiac vertical**" under the guidance of Ms. Richa Sharma, Assistant General Manager – Marketing & KOL Management in the Cardiology Department.

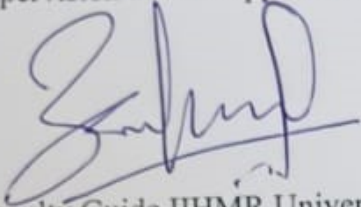
Mr. Shubham is a responsible and committed individual. We wish him all the best in all his future endeavors.

Best Wishes,


Sahil Vyas
General Manager -HR

CERTIFICATE

This is to certify that dissertation titled. is a record of the research work undertaken by Mr. Shubham Soni in partial fulfillment of the requirements for the award of the degree of MBA - Pharmaceutical Management from the IIHMR University, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific, and analytical.



Faculty Guide IIHMR University, Jaipur

Date



School Dean IIHMR University, Jaipur

Date

01/07/2024

ACKNOWLEDGEMENT

I would like to take this opportunity to express my sincere gratitude to all those who have contributed to the completion of this paper.

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CHAPTER 1- Organization Overview

Polymed cutting-edge facilities develop devices and consumables and disposables that reach millions of patients worldwide on a daily basis. For more than two decades, the company has served patients and healthcare professionals, cementing its position as India's largest medical equipment manufacturer and exporter. Polymed has been named the "Medical Devices Company of the Year 2018" by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, as well as the largest exporter of medical devices from India for six years in a row.

Manufacturing Excellence

Polymed has a proven track record of producing high-quality medical equipment from its eight cutting-edge manufacturing locations around the world. These facilities include the following:

India has eight facilities, including three in Faridabad and one each in Jaipur and Haridwar. International operations include three facilities: one is in the form of a wholly-owned subsidiary in Italy and the other in China, and a joint venture in Egypt.

Product Portfolio

One can state that polymed comes up with a vast product line covering several medical fields.

1. Infusion Therapy: IV Cannulas, IV Sets, Extension Lines, and Stop Cocks
2. Transfusion Therapy: Blood Transfusion Sets with Leukocyte Filters
3. Dialysis: Hemodialysis. Catheters and Peritoneal Dialysis Products
4. Gastroenterology: Feeding tubes and enteral feeding bags.
5. Anesthesia and Respiratory Care: Breathing Filters
6. Surgery and Wound Drainage: Surgical Drainage Systems and Surgical Kits
7. Urology: catheters and urine bags

Commitment to Quality and Innovation

We have the vision to be a qualified and leading company in turning out quality products with a focus of safe sophisticated medical devices embracing the medical fraternity to be more effective in their practice and at the same time offering the best health care to the populace. The company maintains effective quality assurance measures that will meet the international certifications including ISO, USFDA and CE marks. Polymed has a dedicated and focused CorD team that constantly finds new solutions for its specialized biomedical products, as well as continuously enhances existing goods, which underlines the uniqueness of the company's 'innovation-safety-quality' triad.

Global Reach and Impact

Polymed was established as a company with international operations where most of its products are exported to over one hundred countries are the global market. distribution network and the connection and with most hospitals across the world. This broad outcomes and access to healthcare underline Polymed's determination of enhancing the quality of health systems. worldwide.

Awards & Recognitions

Due to their commitment to deliver excellence in their products, the following is a list of awards that Polymed has received. Notable recognitions the accolades received during the financial year are, Medical Devices Company of the Year 2018. International supplier of medical instruments in the largest quantity in India for consecutive six years.

Hence, Polymed gives a priority to the liability known as Corporate Social Responsibility (CSR) by sponsoring the improvement of community health and wellbeing. Such efforts extend to peoples' healthcare, education as well as goalt and contributions to society embracing team work, innovation for sustainable future.

Environmental factors, thereby, depicting Polymed's concern with social accountability.

Vision and Mission:

The vision that Polymed holds for the company is to provide proper and quality healthcare to the population. They, on the other hand, have one clear aim- to be the best in manufacturing and launching new effective, safe, and high-quality medical products that enable providers of health care and improve their performance in handling the patients.

The vision that Polymed has adopted is to deliver superior value to all the stakeholders through patient focused Medical Technology for a healthier world.

CHAPTER 2- INTRODUCTION

The medical gadget market is growing rapidly on the global level, and new advanced technologies, innovations and the need for new approaches to healthcare and new products and services in this sphere. The cardiac vertical is especially prominent in this business because of this growing trend in the occurrence of cardiovascular diseases (CVDs).

around the world. Chronic diseases especially cardiovascular diseases have been defined by the World Health Organization as; leading cause of death globally; this underlines the critique for efficient and enhanced cardiac medical equipment. Therefore, opportunities in the cardiac medical device business are these: a great opportunity and daunting challenges that underlie the attempt by different organizations to satisfy this growing healthcare demand.

This dissertation seeks to explore the entry strategies of medical device firms in the cardiac niche. The paper examines the factors and challenges that are inevitable in entering and establishing operations in this strictly governed and competitive market. Owing to these aspects such as stringent legislation, enhancement of the technology, and the necessity of extensive clinical evaluation, the organizations have to devise concrete and varied strategies to ensure remarkable market establishment and sustained growth.

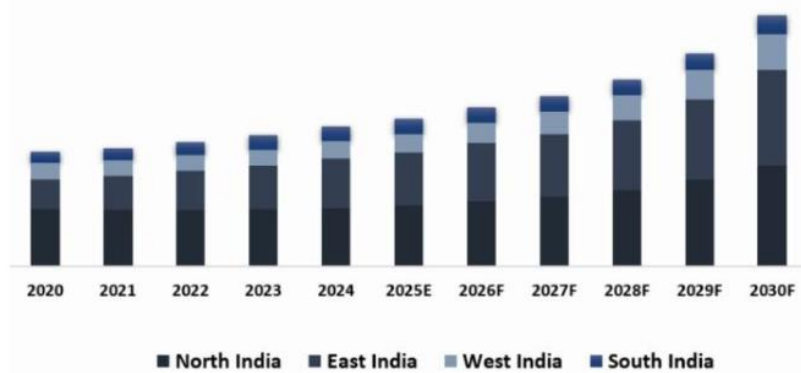
Moreover, the role that collaborations, mergers & acquisitions, and strategic alliances play in facilitating entry into the market will be investigated. The impact of market segmentation, product differentiation, and focused marketing on market penetration and acceptance will also be researched.

In Summary this dissertation thus provides the basis for an in-depth study of market entry strategies in the cardiac medical device industry. It is aimed at the basic feasibility of strategic planning, innovation, and This dissertation focuses on the analysis of market entry strategies of medical device organizations in cardiac segment. In fact, it takes into consideration the factors and aspects of maintaining the efficiency of the highly regulated and rather competitive business sphere. The proper and differentiated strategic plans have to be kept with assurance in the target

market and the future growth of the organizations due to certain rules, regulations, technical enhancements and expectations of extensive clinical trials. It resulted in better health outcomes for people who are suffering from cardiovascular diseases in having navigated this complicated and vital sector with regulatory compliance.

India Cardiovascular Devices Market

India Cardiovascular Devices Market Size, By Region, By Value, 2020-2030F



Research Question:

How specifically can Poly Medicure improve its marketing strategy for cardiac catheters so as to reach healthcare providers and improve access to innovative solutions in cardiac care?

Objectives:

- Evaluate the current marketing strategies for cardiac catheters or any other products used by Poly Medicure.

- Identify key target segments within the healthcare industry for cardiac catheter products.
- Develop innovative marketing approaches to enhance product visibility and accessibility.
- Evaluate the impact of marketing initiatives on customer engagement and market penetration.

Aim:

Devise and recommend efficient marketing plans of cardiac catheter products of Poly Medicure, which would enhance the sales and active interaction with its clients and increase the company's market share in the medical field.

CHAPTER 3- REVIEW OF LITERATURE

❖ Cardiac Market Size

1.Global Cardiac Device Market Size

For 2023, the value of the cardiovascular device market was pegged at \$52.94 billion, with an expected surge to \$106.54 billion by the end of 2032 at a CAGR of 8.1% during the period of 2024 to 2032. (3)

The global interventional cardiology devices market was valued at \$12.91 billion in 2022, and it is expected to rise at a 7.2% CAGR from 2023 through 2030. (4)

The precision cardiology market was valued at \$1,011.5 million in 2021 and is predicted to increase at a 12.8% rate between 2021 and 2030. (1)

2. Indian Cardiac Device Market Size

The Indian cardiovascular devices market is estimated to develop at a 6.6% CAGR from 2024 to 2029. (5)

The Indian structural heart device market is currently tiny, valued at \$12.4 million in 2020, but is expected to develop rapidly at a 31% CAGR due to poor penetration. (5)

Key drivers of market growth include:

- Rising prevalence of cardiovascular diseases globally, driven by factors like aging populations, unhealthy lifestyles, obesity and diabetes. (3)
- Increasing burden of cardiac failures due to COVID-19 (5)
- Technological advancements in cardiac devices (5)
- However, challenges like pricing pressures, reimbursement barriers and shortage of specialists may restrict growth in some regions. (5)

3. Regulatory Perspectives and Market Research on the cardiac Device Sector

Regulatory Collaboration Between the FDA and EMA(2)

A few important points are:

Since 2003, the FDA and EMA have maintained confidentiality agreements that permit them to exchange non-public, commercially sensitive data at any stage of the product lifecycle (2). This contains information about pharmacovigilance, inspections, and applications for marketing authorization.

To closely cooperate on particular therapeutic areas and regulatory problems, the FDA and EMA also take part in frequent "cluster" meetings with other international regulators(2).

4. Major Med Tech companies' insight

Prominent medical device corporations such as Abbott Laboratories, Boston Scientific, and Medtronic offer significant insights into the cardiac device business via their financial filings and annual reports. The following are some important lessons learned:

- Medtronic

A 5.6% rise in reported and organic revenue was recorded by Medtronic during the fourth quarter of FY2023 (\$8.544 billion), primarily due to good results in the Cardiovascular, Medical Surgical, and Neuroscience portfolios.

Medtronic reported \$31.227 billion in revenue for the entire fiscal year 2023, an organic 2.1% rise. (6)

- Abbott Business

There are no precise revenue numbers for the cardiac device division in Abbott's annual reports. The business does, however, emphasize its leadership positions in important cardiac device categories, including as heart failure, electrophysiology, and structural heart.

The Portico TAVR system for aortic valve replacement and Abbott's Mitra Clip device for mitral valve repair are mentioned as major development drivers in the structural heart arena. (7)

- Boston Scientific

The Cardiac Rhythm Management (CRM) sector of Boston Scientific, which makes pacemakers and defibrillators, brought in \$2.3 billion in revenue in 2021, according to the company's annual report.

The company believes that the use of high-end devices such subcutaneous implanted cardioverter defibrillators (S-ICDs) and leadless pacemakers will present growth prospects in the CRM market. (8)

❖ Strategies Used

1. Innovation In Technology

- Incorporating cutting-edge technologies into cardiac devices, such as machine learning and artificial intelligence (AI), to enhance patient monitoring, diagnosis, and treatment planning creating cutting-edge cardiac devices with improved features and functionalities, like remotely monitored pacemakers, minimally invasive surgical instruments, and leadless pacemakers. (9)
- Putting a lot of money into R&D to develop cutting-edge items and beat the competition (10)

2. Increasing Access to Markets

- Concentrating on lowering the cost and increasing the availability of cardiac devices, particularly in developing nations like China and India
- Collaborating with regulatory agencies to expedite the new cardiovascular device approval procedure

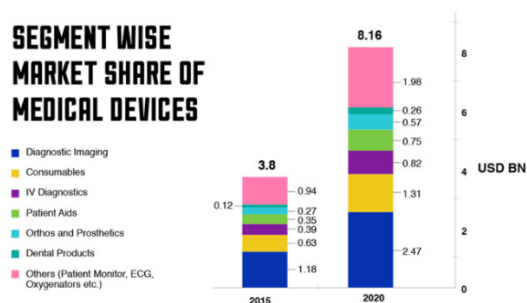
- Expanding alliances and distribution networks to increase device availability(10)

3. Conceptual Structures

- Transaction cost economics (TCE) recommends that businesses select entry strategies for cardiac devices in order to reduce costs and hazards.
- Utilizing firm-specific advantages like technology and brand in international markets is the main goal of the resource-based perspective.
- The eclectic framework incorporates location-specific elements like market size and laws along with resource-based views and TCE (11).

4. Purchases

- Purchasing a local competitor gives cardiac devices immediate access to the market, synergies, and proven distribution.
- Nonetheless, necessitates a large initial investment and presents integration issues.
- Case study: Percutaneous Valve Technologies acquisition by Edwards Lifesciences to gain market share in transcatheter heart valves [12].



5. The Regulatory Environment

- According to the Federal Food, Drug, and Cosmetic Act, higher-risk cardiac devices (Class II and III) in the US are required to provide a "reasonable assurance of safety and effectiveness" prior to going on sale.
- On the other hand, manufacturers are required by the EU regulatory framework to determine the "safety and performance" of proposed cardiac devices, which is a slightly different criterion. [13]
- Entry into the market is hampered by this "globally discordant patchwork" created by the US and EU's divergent regulatory frameworks.

6. India's New Regulations

- The Indian government intends to amend the Drugs and Cosmetics Act to include advanced cardiac devices such as pacemakers, defibrillators, and CT, MRI, and PET scanners.
- As a result, the Central Drugs Standard Control Organization will be able to control permits for manufacture and importation, establish quality standards, and handle issues pertaining to patient safety with these devices.
- It is unclear, nevertheless, if the new rules will apply to devices that have been implanted for fewer than 30 days. [14]

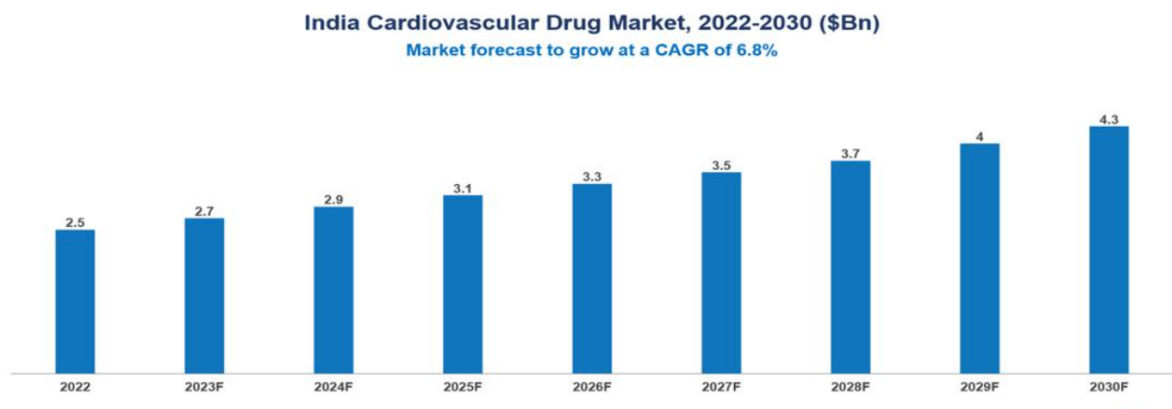
❖ **Current Indian Cardiac Market Depth**

1. Market Capacity and Expansion

- The growing number of heart attacks and strokes is predicted to propel the Indian cardiovascular devices market's growth at a compound annual growth rate (CAGR) of 7.16% from FY2017 to FY2027.
- At a compound annual growth rate of 6.8%, the Indian market for cardiovascular pharmaceuticals is expected to reach \$4.26 billion by 2030 from \$2.52 billion in 2022.[15]

2. Important Motivators

- Lifestyle changes contributing to an increase in the prevalence of cardiovascular illnesses such as hypertension
- Better access to healthcare is made possible by a growing economy and rising disposable income.
- Greater knowledge of cardiovascular illnesses and the risk factors associated with them
Continuous improvements to healthcare facilities and infrastructure are driving increased demand for cutting-edge gadgets [15].



3. Important Players

- The market for cardiovascular medications is dominated by large domestic pharmaceutical companies including Cipla, Torrent, Glenmark, Sun Pharma, and Dr. Reddy's.
- Global medical technology behemoths with a significant market share include Boston Scientific, Abbott, and Medtronic [16].

4. Infrastructure for Healthcare

- Around 60% of hospitals in the field of cardiology are located in metropolitan regions, indicating an inefficient and inadequate public healthcare infrastructure.
- The government is making steps to collaborate with hospitals in the private sector that provide tertiary cardiac care.
- Hospitals are implementing cutting-edge business strategies, like Narayana Hrudayalaya's "High Volume Low Cost" strategy, to offer specialized cardiac treatment at affordable costs [17].

5. Heart Disease Frequency

- Cardiovascular diseases (CVDs) currently account for one in four fatalities in India, with ischemic heart disease and stroke accounting for more than 80% of this burden. Compared to Western populations, Indians typically experience CVDs at least ten years earlier. [18]
- The growth in CVDs is being caused by altered lifestyles, rising incidence of risk factors like hypertension, and a lack of knowledge.

6. New Developments

- Medical technological advancements such as CT angiography, beating-heart surgery, and minimally invasive operations are increasing results.
- Manufacturers of equipment are introducing affordable, straightforward solutions specifically designed for the Indian market, like GE's portable ECG machine.
- The government is encouraging the creation of domestic, reasonably priced medical gadgets through its Make-in-India and AtmaNirbhar Bharat programs.

❖ How to Introduce a Medical Device into cardiac Market

1.Regulatory Compliance:

- Understand regulatory requirements and approval processes in each target market, including FDA, EMA, and PMDA.
- Ensure that the medical device satisfies all required quality and safety criteria for regulatory approval, which may necessitate additional clinical trials or product revisions.

2.Strategic partnership:

- Partner with established local distributors, agents, or healthcare providers with years of in-depth knowledge of the marketplace for cardiac devices.
- Utilize their current networks, infrastructure, and knowledge of the market to help clients overcome the local business environment. [19].

3. Product customization:

- It involves customizing the medical device to local health infrastructure, procedures, and cardiac patients.
- In the course of product development, considerations concerning price, usability, and compatibility with respect to already running systems should be developed.

4.Pricing strategy:

- Balance cardiac device affordability against the value it is perceived to bring to each market.
- When setting pricing, local economic realities and institutional healthcare and ultimate purchasing power in the hands of end users should be taken into consideration.

5.Distribution network:

- Build a solid distribution network in metros as well as in remote areas so that the same products are made available.
- Ensure that the cardiac device is delivered to health facilities in time.

6.Educational initiatives:

- There are specific programs for education to create awareness regarding the benefits of cardiac devices and how they are to be used with care.
- Provide training and support to healthcare professionals for such product adoption.

7.Stakeholder Engagement:

- Network with local opinion leaders and health authority bodies, representing cardiac market groups to establish credibility and facilitate access to the market.
- Leverage their support and endorsement for maximum publicity to increase its adoption.

❖ Opportunities in the Cardiac Device Market:

1. Technological advancements:

- New technologies such as artificial intelligence (AI), machine learning, and remote monitoring are driving innovation in cardiac devices.
- Product capabilities are being increased by developments like leadless pacemakers, longer battery life, and device programmability.
- These improvements provide an opportunity to create new, more effective cardiac devices.

2. Aging populations and increasing burdens of disease:

- The global prevalence of cardiovascular illnesses is rising, thanks to aging populations and bad lifestyle choices.
- The increased illness load is driving up demand for better cardiac therapy and monitoring technologies.
- Medical device manufacturers can profit on the increased need for novel cardiac devices.

3. Increasing Healthcare Expenditure:

- Spending on health is increasing across the globe, with special trends in developing countries where cardiac care has been invested in by both government and private payers.

This will present medical device companies with opportunities for new products and gaining further market share.

- Government regulatory reforms by way of supportive policies attract new cardiac technologies. It may thus spur market entry and the commercialization of new cardiac devices.

❖ **Cardiac Device Market Threats and Challenges:**

1. Regulatory Complexity:

- The medical device sector is heavily regulated, with different approval processes and quality standards for each target market.
- Navigating these legal frameworks can be a considerable hurdle to market access and growth.

2. Pricing Pressure and Reimbursement Barriers:

- Healthcare systems and payers are increasingly examining medical equipment prices, placing pressure on manufacturers.
- Obtaining acceptable reimbursement coverage for innovative cardiac devices can be difficult, restricting market access.

3. Established player competition:

- Established businesses with sufficient resources dominate the cardiac device industry.
- New entrants may confront fierce competition, struggling to differentiate their products and establish popularity.
- In some parts of the world, such as India, there is an observed lack of qualified human health-related staff to operate modern cardiac devices. This may act as a barrier to market entry and expansion.

CHAPTER 4 – METHODOLOGY

Research Design

This will be a descriptive and analytical study based on secondary data to analyze the current techniques of market entry. The objective of the study would be to identify effective tactics and provide actionable insights for medical device businesses in the cardiac vertical.

Data Collection Method Sources of Secondary Data

Secondary data taken from these sources:

- Industry studies are market research reports compiled from many sources.
- Academic journals include peer-reviewed papers from databases such as PubMed and Google Scholar.
- Government publications: reports and statistics published by agencies such as the FDA (United States Food and Drug Administration), WHO (World Health Organization), and other health regulatory bodies.
- Company Reports: Annual reports, news announcements, and strategic documents from top cardiac device businesses.
- Trade publications include articles and whitepapers from industry-specific journals like Medical Device and Diagnostic Industry and Cardiovascular Business.

Data Selection Criteria:

- Relevance: Data must be related to market entry strategy, particularly in the cardiac medical device sector.
- Data from the last five years will be prioritized to ensure current market conditions and initiatives are reflected.

- Source credibility: Sources are credible, ensuring that the information is reliable and legit.

Analytical Framework

This will be done through a simple qualitative content analysis of the secondary data. It involves identifying, categorizing, and summarizing major themes and trends on market entry strategies.

Steps for Data Analysis

- Data Extraction: Using the collected sources, extract useful data about market entry tactics, difficulties, and success factors.
- Categorization: Sort the data into categories such market analysis, regulatory environment, competitive landscape, and strategic approaches.
- Thematic Analysis: Determine common themes and patterns within each category, noting similarities and contrasts between sources.
- Summary and interpretation: Summarize the findings and discuss their significance for medical device firms in the cardiac vertical.

Duration of Study

The study will cover a three-month period: March 18th to June 18th, 2024. This timeframe allows adequate data collection, its analysis, and reporting.

Ethical considerations

- To avoid plagiarism, ensure that all sources are properly cited and referenced.
- When discussing a company's strategies, remember to respect its confidentially and sensitive information.
- Recognize potential biases in data sources and interpretations.

Limitations

- Data Availability: Relies on the quality and availability of secondary data sources.

- Bias: Sponsoring organizations may have an influence on the content of industry reports and publications.
- Generalizability: Results may be limited to specific geographic regions or market situations and may not apply generally.
- Time constraints apply to the timing and breadth of available secondary data.

CHAPTER 5– RESULTS

Cardiac Market Size:

Global Cardiac Device Market Size

The global cardiovascular device market was valued at \$52.94 billion in 2023 and is expected to grow at an 8.1% CAGR between 2024 and 2032, reaching \$106.54 billion by 2032. The global interventional cardiology devices market was valued at \$12.91 billion in 2022 and is predicted to increase at a 7.2% CAGR between 2023 and 2030. The precision cardiology market, which was valued at \$1,011.5 million in 2021, is expected to grow at a 12.8% rate between 2021 and 2030.

Indian Cardiac Device Market Size

The Indian cardiovascular devices market is expected to develop at a CAGR of 6.6% from 2024 to 2029. The Indian structural heart device market, which is currently valued at \$12.4 million in 2020, is predicted to grow fast at a 31% CAGR due to low penetration. The expanding global prevalence of cardiovascular disorders, increased cardiac failures as a result of COVID-19, technological improvements in cardiac devices, pricing pressures, reimbursement obstacles, and a shortage of specialists are all key market growth drivers.

Regulatory perspectives and market research for the cardiac device sector, including collaboration between FDA and EMA

Since 2003, the FDA and EMA have maintained confidentiality agreements that permit the interchange of non-public, commercially sensitive data at any stage of the product lifecycle. This covers details on pharmacovigilance, inspections, and marketing authorization applications. The FDA and EMA also hold periodic "cluster" meetings with other foreign authorities to work closely together on certain therapeutic areas and regulatory issues.

Med Teach Giants

Medtronic

Announced a 5.6% increase in reported and organic sales (\$8.544 billion) in the fourth quarter of FY2023, driven by strong performance in the Cardiovascular, Medical Surgical, and Neuroscience portfolios. The corporation recorded \$31.227 billion in revenue for the entire fiscal year 2023, representing an organic 2.1% increase.

Abbott Laboratories

Abbott's annual reports do not provide sales figures for its cardiac device sector. However, the firm stresses its leadership in key cardiac device areas such as heart failure, electrophysiology, and structural heart. Abbott's Portico TAVR system for aortic valve replacement and MitraClip device for mitral valve repair have been identified as key development drivers in the structural heart arena.

Boston Scientific

Boston Scientific's Cardiac Rhythm Management (CRM) segment, which manufactures pacemakers and defibrillators, generated \$2.3 billion in revenue in 2021. It also sees growth in the CRM market through high-end devices like S-ICDs and leadless pacemakers.

Strategies:

1. Technological innovation:

Advanced technologies involving machine learning and artificial intelligence in cardiac devices are helpful in monitoring patients and giving them the right diagnosis, treatment plan, and proper medication. Companies also invest much in research and development to come up with advanced products such as remotely monitored pacemakers, minimally invasive surgical equipment for cardiovascular therapy, and leadless pacemakers.

2. Growth in the market access.

Efforts are aimed at lowering costs and boosting availability of cardiac devices, particularly in emerging countries such as China and India. Collaborations with regulatory bodies help to hasten the approval of new cardiovascular devices. Expanding alliances and distribution networks are also effective techniques for increasing device availability.

3. Conceptual Structures.

Transaction cost economics (TCE) helps businesses on selecting entry tactics for cardiac devices to reduce costs and risks. The resource-based perspective focuses on using firm-specific assets such as technology and brand in international markets. The eclectic framework combines location-specific factors such as market size and rules with resource-based perspectives and TCE.

4. Purchases.

Acquiring local competitors provides quick market access, synergies, and established distribution for cardiac products. However, this strategy requires a significant upfront expenditure and poses integration issues. Edwards Lifesciences' acquisition of Percutaneous Valve Technologies to increase market share in transcatheter heart valves serves as a case study.

The Regulatory Environment:

1. US regulations

The Federal Food, Drug, and Cosmetic Act requires higher-risk cardiac devices (Class II and III) in the United States to demonstrate "reasonable assurance of safety and effectiveness" prior to sale.

2. EU Regulations.

The EU regulatory framework requires manufacturers to assess the "safety and performance" of proposed cardiac devices, which is a slightly different criterion than the US. The "globally discordant patchwork" formed by disparate regulatory regimes can impede market entry.

3. India's new regulations

The Indian government plans to alter the Drugs and Cosmetics Act to cover modern cardiac equipment like pacemakers, defibrillators, and CT, MRI, and PET scanners. This will allow the Central Drugs Standard Control Organization to control manufacture and importation permits, set quality standards, and address patient safety concerns. However, it is unclear if the new guidelines will apply to devices implanted for less than 30 days.

Indian Cardiac Market Depth:

1. Capacity and Expansion

The rising occurrence of heart attacks and strokes is expected to drive the Indian cardiovascular devices market up at a CAGR of 7.16% between FY2017 and FY2027. The Indian cardiovascular medicines market is predicted to grow to \$4.26 billion by 2030, up from \$2.52 billion in 2022, at a 6.8% CAGR.

2. Important Motivators.

Lifestyle changes, improved access to healthcare as the economy grows and disposable income rises, increased awareness of cardiovascular diseases and their risk factors, and ongoing improvements to healthcare facilities and infrastructure are all key drivers of increased demand for cutting-edge devices.

3. Healthcare Infrastructure.

Around 60% of cardiac hospitals are located in metropolitan regions, indicating that the public healthcare infrastructure is inefficient and inadequate. The government is cooperating with private sector hospitals to provide tertiary cardiac care. Hospitals are implementing commercial methods such as Narayana Hrudayalaya's "High Volume Low Cost" approach to provide expert cardiac care at a reasonable cost.

4. Heart Disease Frequency.

Cardiovascular diseases (CVDs) account for one in every four deaths in India, with ischemic

heart disease and stroke accounting for more than 80% of the burden. Indians often develop CVDs at least ten years earlier than Western people. The CVDs are on the increase due to changed lifestyles and an increased prevalence of risk factors such as raised blood pressure, with most people remaining uninformed.

How to Introduce a Medical Device in the Cardiac Market

1. Regulatory Compliance.

Know the regulatory requirements and approval processes for each target market—e.g., FDA, EMA, PMDA—ensure the conformance of your medical device according to all quality and safety requirements foreseen for regulatory approval. This may happen with some additional clinical trials or product adjustment.

2. Strategic Partnership.

Partner with a local distributor who knows the Cardiac Device business, an agent, or other health providers to share some of the vectors from the local business that their network and infrastructure and expertise would enable the company to overcome.

3. Product customization

Customize the medical equipment offered to the healthcare infrastructure, process, and patient demographics. At the time of making the product, manufacturers should consider things like cost, functionality, and compatibility with pre-existing systems.

4. Price Strategy

Give a price in every market that is affordable to both urban and rural users and manage perception of cardiovascular devices' values. The prices set shall be based on local economics and buying power by healthcare institutions and end users.

5. Distribution Network.

A strong setup of distribution to both urban and rural centers guarantees the constant availability of the product in the market. In ensuring the cardiac device reaches healthcare facilities, it's distributed on the right track.

Opportunities for the Cardiac Device Market:

1. Improved Technology

Next-generation cardiac devices will be developed, enabled by new technologies such as artificial intelligence, machine learning, and remote monitoring. Some of the key advances in leveraging capabilities relate to leadless pacemakers, extended life of batteries, and device programmability. These advancements come with possibilities of evolving new and more efficient cardiac devices.

2. Aging populations and growing burdens of disease

With increasing aging populations and the practice of unhealthy lifestyle habits, cardiovascular diseases have reached a high global prevalence. The increasing illness load is driving up demand for cardiac therapeutic and monitoring technology that is more advanced in nature. Against this backdrop, medical device manufacturers can advance by capitalizing on the growing requirement for new cardiac devices.

Cardiac Device Market Threats and Challenges:

1. Regulatory Complexity.

The medical device industry is heavily regulated in terms of market target clearance processes and quality criteria. The latter poses a formidable challenge to market access and growth.

2. Pricing Pressure and Reimbursement Barriers

Healthcare systems and payers pressurize the prices of medical equipment. Novel cardiac devices may not have appropriate reimbursement coverage, which challenges market access.

3. Competition from an Established Player.

Cardiac device companies are dominated by established houses, well versed with abundant resources and therefore may go all out against the new entrant in their quest to differentiate products and recognition. In several regions like India, lack of capable healthcare personnel is likely to hinder the use of contemporary cardiac devices.

CHAPTER 6 – DISCUSSION

Cardiac Device Market Analysis in India and Globally

Global Market Insights

The growth in the cardiovascular devices industry has been responsive to technical improvisations and an increase in cardiovascular disorders. The global cardiovascular devices market is projected to reach almost two-fold from \$52.94 billion in 2023 to \$106.54 billion by 2032, at a compound annual growth rate of 8.1 percent, thus showing a robust requirement for new cardiac treatment modalities. This growth is supported by the expansion of the interventional cardiology devices market and the precision cardiology market at 7.2% and 12.8% respective CAGRs.

Therefore, growth in CVDs at the global level is attributed to an aging population, changes in lifestyle, and improved awareness about cardiovascular health. Artificial intelligence and machine learning are making a difference in this new landscape by locating better ways of patient monitoring, diagnosis, and therapy. The trend has bright prospects for developing and launching sophisticated cardiac devices that will help reduce the burden of CVD and improve patient outcomes.

Indian Market Dynamics

The cardiovascular devices market of India will grow at a strong pace, witnessing a CAGR of 6.6% during 2024-2029. With under-penetration, the Indian structural heart device market would grow at a maximum CAGR of 31%. The growth drivers include the rising prevalence of CVDs, improving technology, and bridging the lack of infrastructure in healthcare. Notwithstanding, the problems associated are pricing constraints, reimbursement hurts, and an inadequate number of professionals.

The efforts of the Indian government in trying to amend the Drugs and Cosmetics Act to cover the new cardiac devices can be termed as a much-warranted change in regulations for betterment in quality and safety in cardiac care. Partnerships with institutions in the private sector, introductions like Narayana Hrudayalaya's "High Volume, Low Cost," have been some such innovations to bring specialized cardiac care to remotest corners and make it affordable.

Regulatory Perspectives:

The FDA-EMA regulatory partnership allows sharing confidential commercial information that is key to ensuring cardiac devices meet high standards of safety and effectiveness. Closely aligned with these surrounding agreements are periodic "cluster" meetings for coordination on therapeutic areas and regulatory challenges, providing efficiencies that ensure advances in cardiac devices are safe and effective for general use.

Successful Strategies in the Cardiac Device Market:

Technological Innovation

Advanced technologies like AI and machine learning should find their implementation in cardiac devices to ensure improved patient satisfaction. They have expedited remote monitoring of patients efficiently, accurately, and treatment-driven. Further investment in R&D on new technologies like remotely monitored and leadless pacemakers will increase the growth of this market and help serve the needs of the patients.

More Market Access

Cost-reduction strategies and increasing the reach of cardiac devices in emerging markets, especially in China and India. Regulatory partnerships for faster approvals of devices would be supported by further expansion in partnerships and distribution networks, thereby going deeper into the market and reaching the latest cardiac innovations to a larger number of patients.

Strategic Partnerships and Acquisitions

Entry and expansion in the marketplace are supported by strategic cooperation with local distributors and healthcare providers. Also, local competitors offer an acquired company with rapid market entry, established distribution channels, and potential synergies. This entry method is fraught with integration issues and needs a large initial investment.

The Cardiac Device Market

Opportunities and Threats:

Better Prospects through Technological Advances: Artificial intelligence, machine learning, and remote monitoring of cardiac devices open a wide range of possibilities for more efficient and newer products—improving patient outcomes, which will augment demand in the market.

Aging populations and increasing burdens of diseases: As the prevalence of CVDs increases due to aging populations and sedentary lifestyles, so is the demand for cardiac treatment and monitoring technology. It is in this rising demand that the opportunities lie for medical device manufacturers to focus on developing some niche solutions and gain from them.

Threats: The complexity of regulatory requirements within the medical devices industry, with various clearance procedures and quality requirements across different target markets, might become very challenging and act as a barrier to entering a target market or looking to expand.

Pricing Pressure and Reimbursement Challenges: Pricing pressure on medical devices by healthcare systems and payers has grown enorm, and these factors weigh highly on medical device manufacturers. In turn, gaining paternal coverage for suitable remuneration of innovative cardiac devices remains a challenge, hence limited market access.

Established Players' Competition: With established businesses that have abundant resources, it becomes rather difficult for a new entrant to differentiate his offerings and gain market share.

Moreover, in some geographies, there is a dearth of skilled healthcare personnel that can correctly use advanced cardiac devices, thus limiting the penetration and growth of the market.

Critical Strategies of Key Medical Technology Companies

Medtronic:

Second, Medtronic had a reported and organic sales increase in FY2023 that shows good performance in the Cardiovascular, Medical Surgical, and Neuroscience portfolios. Its strategy focus on innovation and market expansion has helped generate growth in revenues, proving an overall market lead in the cardiac device industry.

Abbott Laboratories:

Although Abbott does not directly divulge the sales data for its cardiac devices, leadership in the most critical areas, such as heart failure, electrophysiology, and structural heart, is undeniable. The Portico TAVR system and the MitraClip device are just a few examples that typify Abbott's commitment to the development of treatments that zero in on critical needs along the cardiac care continuum in structural heart.

Boston Scientific:

In particular, Boston Scientific's growing prospects in the cardiac rhythm management segment, which includes high-end devices such as S-ICDs and leadless pacemakers, underscores the need to innovate in order not to be overtaken by competition. The company thus banks on cutting-edge CRM technologies in addressing increasing demand for sophisticated cardiac treatments.

CHAPTER 7– CONCLUSION

Global Cardiac Devices Market Outlook

The global cardiac device market is projected to rise from \$52.94 billion in 2023 to \$106.54 billion by 2032, at a compounded annual growth rate of 8.1%. This growth can be attributed to the steady demand worldwide for new treatments against cardiac diseases. Among the major driving factors for further growth are technology advancements, aging populations, and generally the rising prevalence of CVDs across the globe. AI and machine learning to be integrated into cardiac devices can completely transform the role of patient care with enhanced monitoring, diagnosis, and treatment capabilities. These are the innovations that will really decrease the burden of CVDs on patient outcome.

Dynamics of the Indian Cardiac Device Market

It will also see fast growth of the cardiovascular devices market in India, with a CAGR of 6.6% from 2024 to 2029. The outstanding structural heart device segment retains its huge growth rate of 31% for the base years, considering the low market penetration. Growth in this sector is driven by a number of factors, including the increasing prevalence of CVDs, advancements in technology, and improved support to health infrastructure. The Indian government's efforts toward amendatory legislation with respect to drugs and cosmetics to include modern cardiac devices are seen as one of the positive changes at the regulatory level to ensure that more quality and safety minor cardiac care in the country.

Perspectives in regulation

Safety and efficacy of cardiovascular devices depend on well-coordinated regulatory activity between FDA and EMA. Their collaboration, dating back to 2003, has allowed for the sharing of non-public commercially sensitive data, which underlines high standards in the development and clearance of devices. Regular "cluster" meetings between these key agencies and other overseas

authorities improve harmonization in both therapeutic areas and regulatory topics.

Harmonization of these factors is key to global success for cardiac device manufacturers looking for developments to be safe and effective for more general use.

Success Strategies

Technological Innovation:

It is necessary to invest in R&D for incorporating advanced technologies such as artificial intelligence and machine learning into cardiovascular devices. These provide better monitoring of the patient, accurate diagnosis, and treatment strategies that are more personalized and lead to increased market growth and improved care to the patient. Some such innovations include remotely monitored pacemakers and leadless pacemakers likely to improve significantly the quality of life for patients with these devices.

More Access to Markets

Thus, decreasing costs and increasing the cardiac device market in developing regions like China and India become very important. Collaboration with regulatory bodies for speedy device approvals, forming alliances, and distribution networks enable more significant market penetration. All these efforts ensure that advanced cardiac solutions reach larger numbers of patients.

Strategic partnerships and acquisitions

Forming strategic alliances with local distributors and healthcare providers might help with market entry and expansion. Acquiring local competitors allows you immediate market entry, proven distribution networks, and potential synergies. For example, Edwards Lifesciences' acquisition of Percutaneous Valve Technologies greatly enhanced the company's market dominance in transcatheter heart valves. However, such techniques necessitate careful consideration of integration issues and substantial upfront costs.

Major Medical Technology Companies' Strategies

Medtronic:

Medtronic has outperformed in its Cardiovascular, Medical Surgical, and Neuroscience portfolios, with reported and organic revenues increasing by 5.6% in FY2023. The company's strategic focus on innovation and market expansion has contributed to revenue growth, solidifying its position as a global leader in the cardiac device business.

Abbott Laboratories:

Although Abbott's cardiac device sales data are not publicly available, the company's leadership in critical areas such as heart failure, electrophysiology, and structural heart is clear. Abbott's Portico TAVR system for aortic valve replacement and MitraClip device for mitral valve repair demonstrate the company's dedication to improving structural heart treatments and meeting important requirements along the cardiac care continuum.

Final Thoughts

The cardiac device market, both globally and in India, is expanding rapidly, propelled by technical breakthroughs, rising prevalence of cardiovascular disorders, and changing regulatory landscapes. Companies that prioritize innovation, broaden market access, and develop strategic alliances are well positioned to capitalize on emerging opportunities. However, they must also deal with the difficulties of regulatory regimes, pricing pressures, and entrenched competitors. The future of the cardiac device market looks promising for improved patient outcomes and cardiac care, which will benefit both patients and healthcare systems around the world.

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