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IDENTIFYING MEDICAL DEVICE MARKET DRIVERS FOR EMERGING MARKETS-A STUDY IN CONTEXT TO INDIAN MARKET

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ABSTRACT

As mentioned in the section above, with the convergence of breakthroughs in science and technology, the pace of medical invention is accelerating, inspiring better clinical outcomes with less invasive procedures and shorter recovery times. All of this helps lower cost and thereby create tremendous value. These changes drive demand for new lower cost diagnosis, monitoring and treatment procedures. The disease patterns, modern technology and other drivers push the medical device industry and finding radical solutions for the abysmally low hospital beds to population ratio, shortage of doctors and nurses. Globally, nations are struggling to meet healthcare costs. This is a challenge that we need to meet without compromising on the sustenance of the business. The medical technology industry has been thriving on innovations. While the focus has been on better outcome and quality oflife, it is time that the focus also includes affordability. The emergence of BRICS (Brazil, Russia, India, China, and South Africa) nations have resulted in plethora of opportunities for the MDMs (Medical Device Manufacturers). It is important for the MDMs to understand the emerging market dynamics to excel there and hence there is a need for this study. There is a growing interest to understand the pain areas and needs of the emerging medical device markets. As the competition gets tougher, there is pressure on organizations to be a differentiator and excel. Emerging markets are providing enormous business opportunities for market expansion and consolidation. There is tremendous competition in developed nations and it is important for organizations to find avenues for revenue.

KEYWORDS: MDMs (Medical Device Manufacturers), BRICS (Brazil, Russia, India, China, and South Africa), Emerging Market, Medical Devices.

1. INTRODUCTION[1-3]

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

However, the opportunities for innovation-led growth are immense. Medical professionals rely on medical technology for tests and investigations to aid their clinical decision-making. Innovation in medical technology can therefore be crucial for the Indian healthcare system to improve access, enhance quality and reduce costs.

The sector however does face significant challenges. Mahatma Gandhi had a dream that India would be a land of self-sustaining villages. 'The true India is to be found not in its few cities, but in its seven hundred thousand villages. If the villages perish, India will perish too', said Mahatma Gandhi. But here are some of the stark realities about the lives of Indian rural population:

- 50% of all villagers have no access to healthcare providers.
- 37% are chronically starved
- 10% of all babies die before their first birthday
- 50% of all babies are likely to be permanently stunted due to lack of proper nutrition
- 33% people have no access to toilets, while 50% defecate in the open
- A mother dies every ten minutes in India
- Over 1.25 million children die annually in India.
- 48% of all children have stunted growth due to malnutrition.

With the convergence of breakthroughs in science and technology, the pace of medical invention is accelerating, inspiring better clinical outcomes with less invasive procedures and shorter recovery times. All of this helps lower cost and thereby create tremendous value.

These changes drive demand for new lower cost diagnosis, monitoring and treatment procedures. According to WHO, India is expected to lose a whopping US$ 225 billion, over a fifth of the country's current GDP, in 10 years up to 2016 by way of the national income

foregone due to productivity loss from the increase of heart diseases and diabetes. India will be the diabetes capital of the world. This poses a huge challenge for the government and the healthcare industry in giving a fillip to the medical device industry and finding radical solutions for the abysmally low hospital beds to population ratio, shortage of doctors and nurses. Globally, nations are struggling to meet healthcare costs. This is a challenge that we need to meet without compromising on the sustenance of the business.

1.1. An overview on medical device markets[4-6]

The dynamic medical devices market is intricately interwoven into the healthcare landscape. Various facets of the industry are increasingly becoming interdependent whereby various products and services are being integrated to provide patients with better treatments and high quality care. As the number of people with chronic diseases continues to escalate, demand for devices for a variety of conditions will continue to escalate. While cardiovascular devices market remains the largest medical device sector, orthopedic devices are a close second. Driven by the baby boomer population and the demand for reconstructive surgery, growth rates in the orthopedic spinal and biologics segments will be significant. As reduction in healthcare costs and faster recovery times become a high priority, devices that enable minimally invasive procedures in all areas of medicine will witness strong growth, with the goal of becoming the standard of care for many treatments.

According to a recent report issued jointly by the Department of State and the Department of Health and Human Services, National Institutes of Health, National Institute UK on Aging, almost 1 billion people worldwide will be 65 and older by 2030., As new medical devices offer tremendous promise to the world's aging population, some global trends are directly affecting the competitive industry — particularly the increasing emphasis on medical device design.

The healthcare delivery system is under tremendous pressure to identify and commercialize simple medical solutions quickly to lower costs, control infections, reduce liability and eliminate preventable errors. The trend toward more user-friendly home health care products will also spur the demand for innovative medical devices. With the convergence of scientific, electronic and digital technologies; new breakthroughs in medical devices will play a critical role in solving the problems in healthcare and enhancing the human condition. The global market for medical products and hospital supplies is over $220 billion. Innovation is the life-blood of the industry. The medical supply industry has had a consistent growth rate of over

10% for the last several years. The leading companies struggle to maintain 30% of their revenues from new products introduced in the last 3 years.

An innovation process that insures consistent leading-edge medical solutions at low-cost will create tremendous value in medical supply markets. Surgeries increased in both number and complexity, creating a need for new medical devices. Such devices included a variety of surgical instruments, catheters, and intravenous infusion equipment, as well as an array of peripheral health care products, including sterile surgical caps, gowns, masks, and gloves. Further growth in the overall medical device industry was spurred by the proliferation of community hospitals, which have become the primary market for medical equipment.

2. U.S. Medical devices market[7,8]

The U.S. medical devices industry continues to witness solid growth, aided significantly by an ageing baby boomer population. Moreover, technological advancements such as the advent of minimally invasive surgery have altered the landscape for treatment. Medical device industries expect to continue to drive technological advancements as companies are investing heavily in research and development by devoting 7.9 percent of sales on such expenditures.

A positive indicator considered for the demand of medical devices is the aging population Industry sources reveal that 12.4 percent of the total U.S. population (36.7 million people) was above the age of 65 in 2005. This expects to further increase to 20.7 percent of the total U.S. population (86.7 million people) by 2050.

In the U.S., medical and dental instruments and supplies include five specific industries: surgical and medical instruments, surgical appliances and supplies dental equipment and supplies X-ray apparatus and tubes and electrometrical equipment .It also includes diagnostic products, classified under In Vitro and In Vivo Diagnostic Substances; surgical gloves, condoms, and similar latex based products, under Fabricated Rubber Products, Not Elsewhere

Classified. In the U.S. market, growth levels are driven by national health care expenditures. These include the costs of new regulatory requirements to ensure product safety and effectiveness, and changes in insurance coverage. An example of the former is the 1990 Safe Medical Devices Act, which redefined many of the procedures for bringing medical devices to the market. Meanwhile, insurance programs have dictated the need for medical providers

to purchase capital items such as computed tomography scanners (CT) and other high-cost radiology products.

Hospitals, the largest end-users of medical equipment, face extreme pressures by the government and other third-party payers to curtail rising health care expenditures. These cost containment efforts have affected the overall financial status of the hospital industry. Total hospital margins have been affected. As a result, health care delivery will continue to change, which, in turn, will determine the types of products purchased by hospitals and other end-users.

For example, inpatient admissions have declined while outpatient visits have grown. The supply of competing providers like ambulatory surgical centers, urgent care centers, comprehensive outpatient rehabilitation facilities, and diagnostic imaging centers have increased rapidly, and are providing significant new markets for medical equipment. In addition, items for home care, such as nutritional therapy products are growing.

3. European medical device market[8,9]

The European medical device industry is highly competitive, where new and smaller participants find it extremely challenging to make a significant impact. It is also a dynamic industry with continued scope for expansion, given the ageing population and consequent in the number of people suffering from cardiovascular diseases, cancers, musculoskeletal disorders and diabetes.

The global market for medical devices is currently estimated at EUR 184 billion, of which EUR 55.2 billion is attributed to the European market. This is around 30 per cent of the global total making it the second largest market following the United States. Germany, France, Italy and United Kingdom.

In Europe, an average of 8.6% of GDP is spent on health. Of this figure, 6.4% goes to medical technology. Worldwide, it is accepted that this expenditure does deliver an exceptional return on investment. These gains depend on constant innovation, but increasing pressure on the cost of patient treatment and the cost of operating the healthcare system means that even significant break- through in treatment possibilities might face a poor commercial perspective, if the 'willingness/ability to pay' from society or patients is not available. Part of the problem for the medical technology sindustry is not the capability of innovation itself, but

the difficulty in bringing the fruits of that innovation to the patient and the economy

4. Overview of the medical device sector in different other countries[10-13]

The global medical device sector is large, intricate, complex, and highly segmented. In other words, it is a rather complex and atomized industry. The uniqueness of the medical device sector resides in its enormous diversity and in its innovativeness. Generally, the sector's products are based on mechanical, electrical and/or materials engineering, where an average product lifecycle (and investment recovery) is around 18 months before an improved product becomes available. Compared to consumer electronics products or cell phones, medical devices offer manufacturers lower volumes but a relatively steady income and high profit margins. Besides, since product life cycles are relatively stable and alternative supplier qualification is costly, medical device players tend to build more stable relationships with their suppliers. The user training and technical support that the sector provides are often indispensable, just as feedback from doctors, nurses and patients enables it to constantly develop its technology and new scientific areas. Thus, the majority of new products typically bring added functions and clinical value based on incremental improvements.

Obviously, an efficient ongoing access to relevant knowledge and highly skilled employees/competencies through close contact to universities/research institutions and market are fundamental issues for the sector companies' ongoing successes. However, most fundamental seems the companies' access to adequate and relevant finance due to high costs of e.g. scientific research, clinical assessment, technological development, protection of IPR, distribution/marketing/sales, and related user training and education.

Europe is, after the United States, the world's second largest market for medical devices. The latest facts & figures estimate that more than 386,000 highly skilled people are working in more than 8,500 European medical device enterprises that generate annual revenues of around 55 billion Euro compared to a global market value of over € 184 billion. Recent information indicates that Europe in 2006 is expected to account for about 26 per cent of the US$176 billion global medical devices market1. The more than 8,500 medical device original equipment manufacturers (OEMs) in Europe range from household names such as Siemens and Smith & Nephew to innovative single-product start-ups. Around 80% of the enterprises are SMEs. However, as concentration is one of the main trends in the European medical device sector, the top five enterprises in the European medical device sector represent nearly 60% of the market, and the indications are that this consolidation will continue.

Overall, the medical device sector, by global standards, is a high- tech and high R&D investment per net-sales industry. R&D investments are concentrated primarily in the US, the European Union and Japan. The sector invests almost 7% of every net sales in R&D. This can be contrasted with the investment in R&D of the following global industries: automobiles 4%; pharmaceuticals 16%; software 15%; hardware 10%. The US industry is the largest investor in R&D in medical devices, which is contributing to the country's industry sustaining the largest share of the world market for the foreseeable future.

In describing the actors within the medical device industry we have chosen to list them in relation to a "classic cluster diamond", thus underlying that the medical device industry is best understood as a dynamic sector where several actors interact and are dependent on each other. Taking the point of departure of the firm level there are evidently the large companies, SMEs, start-ups and incubators.

France

France is the fourth largest market for medical equipment in the world and the second largest in Europe, valued at US$4.7 billion in 2004. Prospects for medical equipment manufacturers, however, remain promising as a result of several initiatives intended to allow France to make good its shortfall in some equipment areas, most notably imaging and radiotherapy equipment as part of a €10 billion euro hospital investment programme. There has been an influx of foreign medical companies, and many larger manufacturers are now subsidiaries of multinational groups. The acquisitions process has opened up new distribution channels for foreign-manufactured equipment and imported products now supply over 80% of the market.

UK

The UK market vies with France as the third largest in Europe, although per capita expenditure is relatively low in comparison with other Western European countries. The market is dominated by the National Health Service (NHS), accounting for approximately 80% of healthcare expenditure. In an effort to reduce hospital waiting lists, private healthcare groups have been allocated preferred supplier status to provide resources in the fields of ophthalmology, orthopedic, general surgery, primary care services and local procurement. The UK has for many years maintained a balance of trade surplus in the medical device and amounted to US$234.1 million.

Germany

Germany is the third largest medical device market in the world and accounts for 6.8% of the total world market, ranking behind the USA and Japan. Government funding of hospitals in recent years has remained static. Hospitals are maintaining existing equipment rather than investing in new appliances. This has led to domestic producers becoming increasingly reliant on the export market, which accounts for 80% of domestic production. In a turnaround of fortunes, health insurance companies demonstrated a surplus of €4 million in 2004 after a €3 million deficit at the end of 2003. The Health Minister claimed that this result justified the changes to health and social care that were introduced at the beginning of 2004.

Italy

The size of the medical device market in Italy is estimated to be approximately US$4.4 billion, equal to US$77 per capita. Italy's share of the world market is estimated to be 2.8%. The medical device market is expected to increase by 4.3% year on year to 2010. Recent forecasts suggest that GDP will increase by 2.0% in 2006, from 1.2% in 2005, as a result of increasing levels of investment and exports. Consumer prices are forecast to increase by 1.8% in both 2005 and 2006.In an effort to increase efficiency in the healthcare sector, the use of an electronic 'health card' is being tested in Northern Italy. This is similar to the system recently introduced inAustria.

Singapore

Singapore's medical device market is expected to grow as the island state strengthens its reputation as the region's healthcare hub and center of healthcare excellence. Demand for state of the art medical technologies is high as Singapore strives to provide first class healthcare delivery systems and facilities to its residents aswell as serve the international patient market. The Government of Singapore is targeting 1 million foreign patients each year, contributing S$2.6 billion (US$1.55) of value-added or 1% of GDP.

The U.S., Japan and Germany are the top three leading suppliers of medical equipment in Singapore. There are a significant number of companies that have established a presence by setting up there regional headquarters here in an effort to be closer to and better serve their customers.

The U.S., Japan and Germany are the top three leading suppliers of medical equipment in Singapore. There are a significant number of companies that have established a presence by

setting up there regional headquarters here in an effort to be closer to and better serve their customers. The U.S. enjoys a good reputation and is recognized by the industry as technologically superior, providing high quality, advanced and reliable equipment. However, the relatively higher cost of equipment has dampened the demand for U.S. products, which has driven Singapore companies to seek suppliers from otherestablished markets.

5. Indian medical device market[13-15]

For a long time, India was closed to many foreign markets through government protectionism and a nationalistic tariff system. Today, however, India is ripe for market entry for many industries, especially medical devices. Entering soon (or expanding one's business there) will help keep Western enterprises from being left out of India's exponential growth.

India is a country of billions of people, with its $4 trillion GDP making it the fourth biggest economy in the world. After being stuck at a low rate of growth for many years, it has been booming since the 1990's. To understand the medical markets in India the first thing to remember is that, for foreign market entrants, the consumer base is not one billion people. Even today, a majority of Indians are too poor to afford more than the most rudimentary health care. Rather, the market is the middle and upper classes in the teeming cities, numbering around 150 million and counting. With no comprehensive national health insurance, and an inadequate public health network, it is mostly the private sector fulfilling their new demands for quality health care. About 75% of medical expenditures in India are paid privately. India is home to a number of large, modern private hospital chains (Apollo, Wockhardt, Fortis, and many others). These groups purchase high end medical equipment to serve both their demanding local customers and India's many annual "medical tourists" from other countries.

The device categories poised for the highest growth in India are those connected to its changing disease profile. As Indians increasingly lead sedentary lifestyles, smoke, and eat more, lifestyle diseases such as cardiovascular disease and cancer are on the rise. Imaging, diagnostic, and surgical devices to treat these diseases are well-situated.

Cardiac monitoring equipment currently makes up about 20% of India's total device market, while imaging equipment is about 15%. Other growth sectors include ophthalmological equipment, general surgical devices, orthopedics, and plastic surgery equipment. Imports make up over 60% of all devices by value and dominate the high-end market, with foreign

devices seen as more effective and reliable. Though India's business environment has improved markedly over the last 15 years, in some ways it is still a difficult country to work in. Assistance on the ground by experts with medical device experience is indispensable. India's regulatory system is complex and can be difficult to navigate. Up until very recently, there were no regulations for medical devices as a class. Today, though, various devices (i.e., hypodermic syringes, cardiac stents, and orthopedic implants, among others) are designated as needing registration as drugs under the Drugs and Cosmetics Act. A few specific devices, such as diagnostic X-ray equipment, have individual registration requirements instead. The government has drafted a medical device law, which may streamline the process but include many more medical devices (requiring registration) within a year or two. India has no comprehensive national reimbursement system. However, a patchwork of different government programs sometimesreimburses for devices, but more to public hospitals than to private ones. Large Western medical companies often choose to create a joint venture with similarly large companies.

India's health insurance market has grown significantly and is around $3 billion in 2013. National healthcare spending is expected to reach $143 billion by 2014, more than double the 2008 level. A portion of this money is expected to finance health insurance for 400 million rural citizens. U.S. companies are increasingly becoming active participants in India's healthcare sector, as evidenced by General Electric's plans to invest $3 billion over the next six years to finance research and development, develop healthcare information technology capacity, and invest in delivering healthcare services to the rural sector.

Vijay Govindarajan, GE's chief innovation consultant, described in his GE reports - Localized breakthroughs go global the rise of emerging markets such as India and China mark a new phase of globalization. In similar lines is a study by Dr. Anurag Srivastava Chief Technology Officer, Wipro which proclaims that emerging market constitutes 80% of global population which is young (50% less than 25 years) and largely rural (65%) but has high mobile adoption and thus poses great opportunities. This is an important point and it emphasizes the point why a medical device company must focus in emerging market.

According to an important study by Cegedim five years ago, emerging markets were responsible for just 5% of pharmaceutical companies' profits; today, they make up 20–30% of profits. They have a great suggestion that to protect and grow company's investments in BRIC markets, know what brought you there and where you're headed. As mentioned in

WTO study innovation in medical technologies requires a complex mix of private and public sector inputs; it differs from innovation in general due to the ethical dimension of medical research, a rigorous regulatorframework, liability questions, and the high cost and high risk of failure. The healthcare sector in India will grow to $158.2 billion in 2017 from $78.6 billion in 2012. The healthcare sector is growing at a 15% CAGR and jumped from $45 billion in 2008 to$78.6 billion in 2012 and expected to touch $158.2 billion by 2017. The factors behind the growth is raising incomes, easier access to high- quality healthcare facilities and greater awareness of personal health and hygiene, the report said. According to Frost & Sullivan report, mature economies across the globe grapple with reducing cost, towering budget deficits, and anemic growth, the BRICs are expanding rapidly and driving the global economy.

According to the Stanford India Biodesign program analysis, the average life expectancy of Indians at birth only reached 65 years in 2009, compared to the global average of 68 years. India also has some of the highest infant mortality and maternal mortality rates in the world, 44 per 1,000 births and two per 1,000 births respectively in 2012. India's disease profile is traditionally associated with communicable diseases, such as malaria and tuberculosis, or tropical diseases, such as Japanese encephalitis and dengue fever. However, coronary heart disease, diabetes, asthma, and other chronic non-communicable diseases are on the uptick.

Analysts predict some 60 percent of the world's heart patients will live in India by 2020. While these trends pose challenges for the country's healthcare system, they also present significant opportunities for medical device companies.

The alarming increase in the number of diabetics in India point to the fact that there will be more cardiovascular disease cases too. In addition to the already increasing cardiac diseases, diabetes related cardiac disease will call for a huge demand in vital signs monitoring devices, diabetes monitoring (glucose monitoring) devices which are more portable and less power consuming. The devices should enhance the quality of lives of the patients as they do not want to be tethered to the devices but be connected wirelessly or via mobile phone connectivity.

6. CONCLUSION

The purpose of this article is to evaluate and identify the medical device market drivers for emerging Markets in context to Indian Market. What are the market drivers of medical

devices, what are the efforts done in identifying the needs of emerging markets as far as medical devices are concerned, how are the innovation patterns different etc. A comprehensive review of literature was done for Identifying medical device market drivers for emerging markets-A Study in context to Indian Market". Medical technology innovation requires a vibrant and participative ecosystem comprising patients, medical centers, universities, medical technology industry, health insurance companies and the Government. All stakeholders in the ecosystem have to act in concert for the sustained growth of the medical technology industry. To study the type of devices that are needed as per the disease patterns of the country. To study the persona of the people as far as usability of the devices are concerned. As technology and medical treatments continue to advance at a rapid pace, more products can be classified as combination products. This perspective on the evolution of combination products and what manufacturers need to know regarding the filling/labeling/packaging of such products.

7. REFERENCES

1. Peter L. Kolominsky-Rabas, A. D.-B. (August 2015). Technology foresight for medical device development through hybrid simulation. Technological Forecasting and Social Change, 2011; 97: 105 - 114.
2. 10 minutes on medical Innovation. PWC. PWC. PWC Study Enhancing access to healthcare through innovation- Medical technology in India. Pricewatercooper. report, U. (2011).
3. Medical Devices: The UK Industry and its Technology Development:. Ricafort, K. M., 2011.
4. Study of influencing factors that lead medical tourists to choose Thailand hospitals as medical tourism destination. School of Business and Technology, Webster University. Robinson, S. a., 2008.
5. Medical device users and their main interaction with devices. Rumbaugh, T. &. (2004). China: International Trade and WTO Accession. Washington. Santos, C. Factors influencing the adoption of medical devices, 2013.
6. Zelkha, S. Benchmarking of a medical device company's product development process. Boston University, 2004.
7. Brahmaiah Bonthagarala, Regulatory Requirements for Registration of Generic Drugs in "BRICS" Countries, International Journal of Pharmaceutical Science and Health Care, ISSN 2249 – 5738, 2016; 6, 6: 20 - 39.

8. Brahmaiah Bonthagarala, Current Regulatory Requirements for Registration of Medicines, Compilation and Submission of Dossier in Australian Therapeutic Goods Administration, International Journal of Advanced Scientific and Technical Research, ISSN 2249-9954, 2016; 6, 6: 144 - 157.
9. Brahmaiah Bonthagarala, Comparison of Regulatory Requirements for Generic Drugs Dossier Submission in United States and Canada, International Journal of Pharmaceutical Science and Health Care, ISSN 2249 – 5738, 2016; 6, 6: 1 - 19.
10. Brahmaiah Bonthagarala, Nanomedicine Clinical Use, Regulatory and Toxicology Issues In Europe, Journal of Drug Delivery and Therapeutics, 2019; 9(4-s): 846 - 848.
11. Brahmaiah Bonthagarala, A Review on global harmonization task force (GHTF) - principles of in vitro diagnostic (IVD) medical devices classification, The Pharma Innovation Journal, 2018; 7(7): 667 – 672. ISSN (E): 2277- 7695.
12. Brahmaiah Bonthagarala, Compilation of Chemistry Manufacturing Controls In Abbreviated New Drug Application, Journal of Pharma Research, 2019; 8: 8. ec.europa.eu/health/files/eudralex/vol-1O/application-form2009_en.pdf
13. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/chFR/CFRSearch.cfm?CFRPart-312&shpWFR-1
14. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDeveIOpedandApproyed/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm