Medical Device for Emerging Markets: Potential Indian Market

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ABSTRACT

The developed countries dominate medical devices sales globally and the industry leaders view India as the next big market in the medical device sales for many good reasons, such as greater healthcare awareness, rising income, lifestyle changes, and lucrative healthcare schemes and initiatives taken by Indian government making India as a favourable investment destination.

The global medical device industry is showing strong growth amidst the changing regulatory landscape and shift towards value-based care. The traditional markets such as the USA and Western Europe still hold great potential, however growing competition in the region and industry’s appetite for growth are pushing companies to venture into new markets. Emerging markets such as LATAM, Eastern Europe, South Asia, and the far east are collectively an attractive proposition as their combined gross domestic product (GDP) exceeds the traditional markets.

India is amongst the top 20 global medical device markets and only lags behind Japan, China, and South Korea in Asia.[1] The Indian market has become one of the core focus areas of leading medical device makers.
INDIAN HEALTHCARE SECTOR

In India, Healthcare is the fourth largest business sector, both in terms of revenue and employment. It is poised to rank amongst the top three healthcare markets in the world in terms of incremental growth by 2020. At a CAGR of 22% during 2014-2022, the Indian healthcare sector is expected to reach USD 280 billion in 2020 and USD 370 billion by 2022.\(^2\)

The hospital segment is the largest in the Indian Healthcare sector, which stood at USD 61.79 billion in 2017. It is expected to grow at a CAGR of 16-17% to reach USD 132.84 billion by 2023. Telemedicine, a relatively new market in India, is expected to grow at a CAGR of 20% during the 2016-2020 period. It is likely to reach USD 32 million by 2020. Owing to increased affordability, the health insurance segment is witnessing growth in gross healthcare insurance premiums, which was USD 2.7 billion in 2017.\(^2\)

As per sector survey in 2017, the Indian medical device industry was valued at USD 5.2 billion, which makes 4-5% of the Indian healthcare industry.\(^3\)
MEDICAL DEVICE MARKET IN INDIA

The Indian medical device industry has grown at a CAGR of 15.8% and reached USD 3.9 billion in the year 2015 from USD 2.02 billion in the year 2009. As per the industry estimates, the Indian medical device market will surge to USD 50 billion by 2025. As of 2016, equipment and instruments (surgical and non-surgical), and diagnostic imaging segments were collectively 65% of the Indian medical device industry. [1]

![Indian Medical Device Market Segmentation-2016](image)

*Figure 3: Indian Medical Device Market Segmentation (Source: Deloitte, 2016)*

The Indian government has allowed up to 100% Foreign Direct Investment (FDI) in medical devices through the automatic route. India witnessed FDI of USD 1.57 billion in the period 2000-2017. An increasing number of MNCs are leveraging on this opportunity and are in the process of setting up their manufacturing bases in India.[4]

India is mostly dependent on imported medical devices as imports make up for ~75% of the entire medical device market. It is observed that manufacturers from EU nations and the USA dominate the imported devices market. It can be attributed to the rise of world-class hospital groups and their preference for quality medical devices adhering to stringent regulatory requirements in the developed nations. Moreover, relatively low customs duty rates (9.2% – 15%) on medical devices, along with an increasing number of tertiary and quaternary healthcare facilities offer opportunities for the direct supply of high-end technologies, specialized medical equipment, and other products to India.[4]
It is evident from the latest data, the Indian medical device industry is a desirable export sector for the US firms. Medical devices by the US-based manufacturers account for over one-quarter of imports in India.\[5\]

**DEMAND SIDE FACTORS**

Apart from changing economic and regulatory environments in India, there is a range of factors that are driving the growth of the Indian medical device industry.

**The rise in chronic diseases leading to higher demand for healthcare services**

India is aptly called the diabetes capital of the world. The country had about 46 million diabetes patients in 2017, an increase from 30 million in 2010. Around 62 million patients suffer from coronary heart disease (the leading cause of death in India), compared to 47 million in 2010. Similarly, India witnessed the rise of Chronic Obstructive Pulmonary Disease (the second leading cause of death in India) case. India registered 23 million cases of COPD in 2017 compared to 21 million in 2010. Moreover, non-communicable diseases are expected to comprise more than 75% of India’s disease burden by 2025, compared to 45% in 2010.\[6\]

**Aging population**

The share of the aged population (>65 years) is expected to increase to 7% (100 million) of the total population by 2020 compared to 5% (60 million) in 2010. This rise in the geriatric population will eventually lead to higher healthcare expenditure and increased demand for medical devices, both at health facilities and homes.\[6\]

**Increasing income resulting in higher need and utilization of healthcare services**

India is witnessing changing economic demographics. In 2010, the population size earning more than USD 5,000 per annum was 145 million (~12% of the total population), which is expected to further rise to around 450 million (~28% of the total population) by 2025. The urbanization in India stood at 32% in 2016 and is poised to reach 40% by 2030. Also, health insurance coverage is expected to increase from the present 300 million people to 655 million by 2020. This economic and demographic shift is leading to a rise in the share of spending on healthcare as a percentage of total household spending, which was 7% in 2005 and will reach 13% by 2025.\[6\]
BUSINESS ENVIRONMENT IN INDIA

India has jumped to 77th rank in the World Bank’s “Ease of Doing Business 2019” report compared to the 100th and 130th rank in 2018 and 2017, respectively. As of 2014, India became the third most active investment destination for foreign companies with a cumulative FDI inflow of USD 237 billion in the last decade with 70% equity inflows. The central government has taken multiple initiatives to boost FDI further and promote India as a new manufacturing destination for global MNCs.[7]

Recognizing the growth potential of the healthcare market in India, the government has launched initiatives such as Make in India campaign, special incentives for setting-up manufacturing plants at medical device parks, and fast clearance and approvals, to promote the conducive investment environment and boost FDI through greenfield, brownfield, and strategic entry options. FDI in the manufacturing of medical devices is allowed to the extent of 100% under the automatic route (without obtaining prior regulatory approval). During the period April 2000-March 2017, USD 1.57 Billion worth of FDI came into the country.[2] Moreover, the government of India has launched better health insurance schemes, such as Pradhan Mantri Jan Arogya Yojana (PMJAY), Ayushman Bharat-National Health Protection Mission and Mission Indradhanush in order to promote the Indian healthcare industry.

A range of medical device clusters has emerged due to supportive state-level policies as well as the availability of skilled labor. New “Medical Device Parks” are planned across India, namely, Andhra Pradesh MedTech Zone Limited (AMTZ), a park in Sultanpur village (Telangana), and HLL Lifecare Mediparks in Tamil Nadu, Maharashtra, and Gujarat.[2]

Medical Device Regulations in India

Central Drugs Standard Control Organization (CDSCO) is the national regulatory body for pharmaceuticals and medical devices that supervises manufacturing, import, sales, and after-sales of medical devices in India. Required licenses for marketing devices in India are acquired either by the manufacturer’s local sales subsidiary or distributor (typical for SMEs). If the devices are manufactured outside of India, then the local sales subsidiary or distributor has to obtain an import license from the regulatory body.

As per CDSCO, medical devices other than in-vitro diagnostic medical devices shall be classified by risk parameters in the following classes, namely:[8]

1. Low risk:- Class A
2. Low moderate-risk:- Class B
3. Moderate high risk:- Class C
4. High risk:- Class D

As stated by the Medical Device Rule 2017, "If the manufacturer has already been issued free sale certificate in respect of any medical device by the national regulatory authority or other competent authority of any of the countries namely, Australia, Canada, Japan, European Union Countries, or the United States of America, a license shall be granted without carrying out the clinical investigation.”[8]

After being granted import license by the regulatory authority, the manufacturer has to also comply with labeling requirements of medical devices (as per Chapter VI of Medical Device Rule 2017) and Sale of Medical Devices requirements (as per Chapter XI of Medical Device Rule 2017).[8]
CHALLENGES FOR THE MANUFACTURERS

Although the Indian market has grown substantially due to the factors discussed above, one also needs to consider the challenges associated with entering or developing the market.

The middle-class population is the vital driving force behind the Indian medical device market growth. It is expected to outpace the rest of the world as in eight years; the Indian middle class has doubled in size, from 300 million in 2004 to 600 million in 2012. This major part of the population is highly price-sensitive. Considering this, healthcare services in India are one of the most affordable in the world. Healthcare service providers indeed prefer quality devices for better clinical outcome, however, tend to have a bias towards the affordable or high ROI generating brands.

![Chart showing top six states by population and population distribution in million.](image)

*Figure 5: Census data, Government of India - 2018*

The disparity of the sub-continent population is also one of the critical challenges for the manufacturers. While half of the Indian population is distributed between major six states (Uttar Pradesh, Maharashtra, Bihar, West Bengal, Andhra Pradesh, and Madhya Pradesh), per capita purchasing power parity (PPP), differ drastically. Manufacturers need to recognize this factor before zeroing in on the target regions.

A comprehensive user study is required to create a balance between essential and good-to-have features to make the device brand more attractive to the buyers. Identifying the usage gaps helps in implementing the right set of features apt for the target market segment.

Companies intending to develop the market are putting greater emphasis on value analysis and value engineering of their existing devices to optimize the device production cost, which has an immense potential to increase the sales margin and at the same time maintain device quality.
CONCLUSION

India’s dependence on high quality imported devices is an attractive proposition for global medical device manufacturers. The positive shift in economic demographics owing to the increased per capita income, along with the medical insurance penetration, has paved the way for the large part of the population to afford superior healthcare services. This changing landscape has amplified the demand for quality medical devices. Moreover, business-friendly policies in India have attracted a lot of attention from the manufacturers who are exploring new markets for sustainable growth.

Choosing the right engineering partner for developing the emerging markets is of the most extreme significance. The partner should not only help in making the regional knowledge accessible to the manufacturer but also help in striking a perfect balance between the critical business, user, and clinical needs through engineering excellence.
ABOUT TATA ELXSI

Tata Elxsi is a company that blends technology, creativity, and engineering to help customers transform ideas into world-class products and solutions. Established in 1989, Tata Elxsi offers technology consulting, new product development, product maintenance, migration, testing, and regulatory compliance services to leading product companies, service providers, and niche technology start-ups.

Tata Elxsi has over 15 years of experience in helping companies launch medical imaging, in-vitro diagnostic, patient monitoring, therapeutic, and surgical devices in developed and emerging markets. Its expertise in niche areas such as optics, imaging, mechatronics, industrial design, artificial intelligence, communications, etc. combined with a mature ecosystem of partners makes it a preferred product engineering service partner for leading medical device manufacturers.
REFERENCES


9. "The Emerging Middle Class in Developing Countries", 2011, H. Kharas, Brookings Institution