

# Status of Biomedical Devices Industry: Current Scenario, Way Forward in India a Wider Perspective.

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## ABSTRACT

Medical Devices (MD) are instrument, apparatus, appliance, software, implant material etc used alone or in combination in diagnosis, treatment to prevent and cure diseases. They comprise of vast system which is categorized into products starting from the therapeutic devices to highly modified computerized medical technologies and diagnostics. In line with objective to fulfill the sustainable development goal 3 of 2030 agenda i.e. “ensuring healthy lives and promoting well-being for all at all ages” and India’s national developmental goals and its “**sab ka saath, sab ka vikas**” policy initiatives for inclusive development, the need for affordable, sustainable high tech biomedical instruments, devices and technologies is meant to rise in near future. It is reported that the Indian medical device market had a share of 1.7% of the global medical device market in 2015 which is proposed to rise substantially in near future. Studies have reported that import of medical devices has grown from \$2.46 bn in 2012 to \$2.87 bn in 2016, whereas the export of medical devices has grown from \$0.78 bn in 2012 to \$0.98 bn in 2016. Growing number of aging population, increasing disease burden of chronic diseases, everyday expanding medical tourism, demand for healthcare infrastructure are some of the key areas requiring immediate attention. With the implementation of Ayushman-bharat pertaining to 50 cr population the need for such devices and instruments are likely to rise in future. Innovation, productive research environment, favorable regulatory policies, suitable public investment and handholding the nascent startups is the need of an hour.

**Key Words:** Innovation, Affordable Treatment, , Medical Device Industry, Digital Health, India, Health Technology.

## INTRODUCTION

Our country's 2017 national health policy involves accelerating healthcare for all citizens, contemplating non-discriminatory health and well being for all fragments of society. The policy intends to increase access, adoption, improve quality and lower healthcare delivery costs in the country. In this new era changing disease patterns has been duly recognized by the country's government, further there is a need to address the ever growing burden of non communicable diseases due to changing lifestyle and emergence of successful private health care model <sup>[1-5]</sup>.

The government in near future is likely to be in an active role by being a provider rather than a player thereby resulting in improved outcomes with better and rational health care expenditure in the country <sup>[5, 10]</sup>. Current estimates value the medical device industry to approximately \$6 b which is stated to have expanded in a significant double digit growth over past few years <sup>[6, 7]</sup>. Studies have demonstrated that health care industry has registered a compounded growth of 20% over the past few and is expected to reach \$175b by 2020 <sup>[8]</sup>. However the industry is still at an incipient stage with minimal penetration and usage of medical devices. Currently India comprises of only 1.7% of the world market, the industry is significantly import dependent and the current demand does not offer scale in various product categories. With the emerging times the industry is stated to metamorphose as the demand escalates to realize its full potential <sup>[8-9]</sup>.

Health technology has come to play a critical role in prevention and treatment of disease conditions in modern day health systems. It has been widely acknowledged that health technology, in particular medical devices and equipment, is necessary for an efficient and effective healthcare system in terms of equipping healthcare providers with more tools for diagnostic, preventive and curative care. Medical devices can range from a simple surgical needle, to complex orthopedic implants or sophisticated ultraviolet or infrared ray apparatus used for medical purposes. In vitro medical devices are one such class of medical devices that are used for in vitro examination of specimens derived from the human body to provide information on various aspects such as for diagnostic, monitoring, or compatibility purposes <sup>[3-4, 9-10]</sup>.

The medical device industry is a multi-product industry, involved in production varying products devices. Coming years has witnessed rapid growth in manufacturing and trade of medical devices with a steady speed. Its importance in the health care sector can be witnessed via double digit growth rates. Medical device industry in many countries including India mostly depends on imports. Role of well developed eco-system and innovative cycle is noticed in the development of most hi-tech innovative products and technology <sup>[10, 12]</sup>. Such innovative models need to be developed in India to promote indigenous industry and self dependency thereby eventually leading to significant reduction on imports and easing the fiscal situation of our country and excessive dependency on imports <sup>[9]</sup>.

## **INDIAN SCENARIO: PLETHORA OF OPPORTUNITIES**

The Indian healthcare and medical device Industry are at a critical threshold, where growth if accelerated significantly can ensure that India reaps the benefit of advancing medical technologies which will uplift the standards of healthcare sharply in the next decade. Main drivers to work upon include availability, affordability, and accessibility in terms of affordable health care as India still lags in these drivers even among its counterparts. Numerous studies have highlighted the research and development aspect in the field of new and innovative medical devices for e.g. Status of patents in the medical devices sector contributes to only 17% to the total patent applications filed in last 10 years <sup>[2]</sup>. Studies have demonstrated the important role of industry and academic filing patents in the field of medical device domains despite being quite small in number compared to foreign counterparts. Recent policy initiatives by government of India such as make in India, startup India, relaxing FDI norms support to start ups for IP filing has resulted in an enabling environment for the Indian medical device industry which is expected to witness an aggressive IP filing trend as well as innovation and is expected to grow exponentially to a US\$50 billion industry by 2025 <sup>[15]</sup>.

Being recognized as a sunrise sector, Indian medical device industry has huge market potential if grown in a right direction at a right time. In 2013 the medical device and equipment market in India was valued at US\$6.36 billion it is now experiencing an annual growth rate of 15%. The fast growth of this sector can be attributed to numerous factors such as revamped healthcare infrastructure, increased healthcare spending, increased medical tourism, growing healthcare insurance and enhanced penetration of private sector. If compared with the world markets the Indian medical device market although small ranks among top 20 in the world by market size and is fourth in Asia after Japan, China and South Korea <sup>[4, 5, 13]</sup>. Since long time any concrete regulatory framework pertaining to medical device industry was absent in India and the devices were currently regulated as drugs, however with the recent medical device rules significant changes have been made. Slow penetration of the medical device industry is also associated with high dependency on import accounting for approximately 70% of demand <sup>[7, 15]</sup>. Being an emerging market India is emerging as a manufacturing hub for many key global medical device players and medical device industries such as Philips, GE Medical systems etc. Such medical device leaders not only consider India as marketing hub but also an innovation driven economy with an aim to manufacture along with more patents. Encouraging policies backed by government, population size, easing regulations can result in a flip in the medical device industry<sup>[16]</sup> for e.g. the government has overhauled the regulatory framework for medical device in 2017 and has brought it at par with international norms by introducing the concept of ‘risk-based’ regulation. The regulatory licenses issued for import, manufacture or sale of medical devices have been made perpetual in nature to cut down on unnecessary and time-consuming paper-work, in a bid to increase ease of doing business in India <sup>[14, 15]</sup>. The FDI sector has been liberalized and eased to a larger extent to make a conducive and hassle free environment for investment in medical manufacturing thereby helping business to quickly scale-up existing operations by providing more capital or engage in time-sensitive strategic acquisitions <sup>[17]</sup>. It has been observed over the last two years the intellectual property rights regime has been strengthened and grant of patents and other intellectual property rights have been made more Hassel free.

Efforts by Indian Government such as introducing various fiscal measures to promote research, development, manufacturing and import of medical devices have started to bear fruitful results. For instance, the Government has incentivized scientific research and development by providing weighted deduction for the expense incurred on various fronts, further there is minimal or no import duty on certain medical devices of vital and prevalent use to make them affordable to all <sup>[18]</sup>.

## **CHALLENGES FACED BY MEDICAL DEVICE SECTOR**

Many challenges in doing business in the medical devices sector still exist in India. Challenges such as price control of certain medical devices maintained and monitored by the Government of India via either price fixation controls or by restricting the ability of the marketer of the medical device to increase its price by more than a prescribed percentage at any given time poses a great problem<sup>[19-21]</sup>. Presence of multiple regulators results in making simple tasks, such as rectification of erroneous declaration on the label, quite a tumultuous affair. Further presence of archaic laws restricts manufacturers and importers of medical device to promote their product directly to the customers for certain critical conditions and illness <sup>[22, 24]</sup>. Many multi-nationals have set up operations in India in the recent years, however majority of the operations only include the distribution of imported devices and to provide support function. Few multinationals have started domestic production but on a limited scale. It is seen that the major factors affecting the penetration and flourishing of the medical device industry are the lack of regulatory systems, harmonized standards, accreditation, legal requirements, proper guidance on quality and best practices to be followed <sup>[20]</sup>.

It has been observed that a major percentage of purchases of cutting edge medical devices are from private medical institutions and hospitals. Private enterprises have now started focusing on Tier II and Tier III cities, a market of which is still untapped in India. In the coming years as private enterprises expand in lesser explored markets, the demand for medical devices will expand proportionally<sup>[23,24]</sup>.

## **GROWTH PROSPECTS OF MEDICAL DEVICE INDUSTRY**

India being an emerging economy is witnessing higher economic growth with more disposable income in the hands of population, further growing and aging population needs geriatric care and hospitalization. Socio-economic transition and inclusion of rural economy and demand for affordable and adequate healthcare, improving medical infrastructure via increased government spending and penetration of health insurance resulting in affordability of healthcare services are concerns which needs to be addressed. Promotion of manufacturing innovation for creation of customized products to meet needs of all segments of society and changing patterns of diseases among the population with increasing no. of ailments are the challenges in hand <sup>[25, 26]</sup>. In this era of 4<sup>th</sup> industrial revolution rapidly growing awareness among middle class focusing on early detection and prevention of diseases and increased demand for medical tourism are some the factors which will result in rapid acceleration, promotion and penetration of medical device industry <sup>[27]</sup>.

The nascent medical device sector is also witnessing strong **FDI** inflows, reflecting the confidence of global players in the Indian medical device market, further development of infrastructure, easing regulations, outsourcing of manufacturing and R&D activities to India are needed. Moreover government's initiatives to improve healthcare access through insurance via different schemes will help in acceleration of the sector. Some multi-nationals have also entered India by acquiring domestic manufacturers, for e.g. Alpha X-Ray Technologies, a leading manufacturer of cardiovascular X-Ray systems was recently acquired by Netherland-based Royal Philips Electronics demonstrating a positive outlook of the Indian medical device sector <sup>[28-30]</sup>.

## **WAY FORWARD**

The way forward for India is to reinvent in terms of their traditional business and operating standards in terms to adapt to future and there is need of investing in enabling technologies to connect with customers, patients and consumers. Further there is strong need to reconfigure the multiple value chains of medical device industry also there is a need to reposition there stands in terms of competitive landscape and dynamic industry environment.

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