

# Medical Devices Access in Asian Countries: Sustainable Growth Trajectory in India

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## Abstract

Technologically advanced solutions for treatment of diseases, scientific rigor and research has seen tremendous growth in therapeutic usage of medical devices. The role of 'Make in India' initiative becomes of utmost importance as a driving force for technological advancement of medical devices industry. However, challenges exist and need to be addressed in providing affordable healthcare by producing medical devices that are cost competitive and effective to increased access. Asian Countries like Japan, China and South Korea are foremost in the Medical devices sector. This paper probes the sustainability of Make in India policy with the growth trajectory of Asian countries in medical devices discusses ways of overcoming challenges through regulations, policies and other stakeholders contribution.

**Keywords:** Medical device; Make in India; Growth trajectory; Sustainable model

## Introduction

Technologically advanced solutions for treatment of diseases, scientific rigor and research has witnessed tremendous potential in therapeutic usage of medical devices [1]. Medical devices play a significant role in screening, diagnosing and treating patients as well as in restoring patients to normal lives [2]. Globally, the medical device industry has witnessed impressive growth and plays a vital role in the healthcare ecosystem reaching USD 520 billion by 2020 [2]. Since the last few decades, the Indian healthcare industry has seen improved growth scale with a greater need to better the quality of healthcare and provide affordable healthcare solutions as a result of which the medical device industry has also grown considerably. The compound annual growth rate (CAGR) of Indian medical device industry is around 15% of health care as compared to CAGR of 4-6% of healthcare in other countries. Even though there is improved access and affordability of healthcare services, India faces high level of dependency on imports of medical devices [1]. Although Asian countries like Japan, China and South Korea are foremost in the Medical devices sector there is a sufficient opportunity in medical devices manufacturing and development of industries in India [2].

The Government of India's 'Make in India' initiative presents a platform for the medical device industries to revisit the operating model, identify key aspects for sustainability and explore possibilities for creating a transformative change in the medical devices sector. The role of 'Make in India' initiative has become the game-changer for technological advancement in the medical devices industry [3]. It therefore becomes necessary to probe the sustainability of 'Make in India' policy with the growth trajectory of Asian countries in medical devices and devise methods of overcoming challenges through regulations, policies and other stakeholder contribution.

**Index Terms:** Affordable, leveraging, local innovation, manufacturing hub.

## Growth Trajectory of Medical Device Market in Asian Countries

### China-A leader in the Asian market

China's medical device market ranks second in the world (Table 1). The driving force behind the growing market of medical devices in China

is the increase in income and expanding population. The medical device market growth in China is about 20 percent every year since 2009. By 2050, China will have 1.4 billion population above 60 years thereby increasing the demand of medical devices for these Chinese ageing baby boomers. A tremendous gap between urban and rural healthcare system in China exists, as well as between various types of hospital care. Almost 1 million health care organizations in China have been upgraded or newly constructed towards the end of 2014. There is an inflow of huge number of population towards well-resourced and prominent healthcare centers in urban areas, due to poor health care systems in rural areas [4,5].

Chinese medical device market value is estimated to be around USD 11 billion in 2015. The value is well below that of American (USD 160 billion) and European (USD 115 billion) markets. Chinese government needs to bridge the gap between quality healthcare and promote domestic manufacturing [5], as a result of which healthcare expenses is estimated to grow at 5.2% of the GDP in the next few years [6]. Faster healthcare sector development is possible due to the introduction of Healthcare Reform in 2008 [6].

**Market challenges in China:** Chinese government must revise and

S. No.	Countries	Public Healthcare Expenditure as a % of GDP	Population size
1	India	1.407	1.31 billion
2	China	3.09	1.37 billion
3	Japan	8.55	126.96 million
4	South Korea	3.98	50.62 million

**Table 1:** GDP and Population size between the four giants of Medical devices countries [14].

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relook at the basic laws of foreign investment to ease investor influx and prevent the Medical Device sector growth trajectory from getting foiled by a robust regulatory framework. Business or administrative approvals must be improved and delegated to local/provincial governments. Efforts must be made to improve enforcement of intellectual property (IP) rights and protection should be provided to the trademark owners. Financial controls on foreign exchange must be liberalized to attract foreign investors. Registration charges for foreign entrepreneurs must be reduced and online system of registration must be implemented, basic insurance coverage should be expanded and National essential drug system can be set up. Infrastructure for small scale healthcare industries should be developed at grass root level, equitable access should be provided for basic healthcare services and Public Healthcare reforms must be implemented [5].

**Developmental factors of China's medical device market:** China consists of state specific incentives, cheaper access to land and training subsidies to develop medical devices manufacturing base [1]. Digital Medicine facilitates healthcare services in the remote areas. It will also facilitate establishment of electronic medical record system linked directly through medical devices thereby enabling smooth sharing and storage of patient's data especially in the remote areas, relieving overcrowding in the hospitals and shortening wait lists [5]. About 70% of advanced medical devices in China are exported from the European, American and Japanese markets that are in great demand in the hospitals especially in the private and tertiary care hospitals [7]. Telecommunication and use of information technology provides healthcare delivery services at remote locations as well.

China possesses highly competitive and fragmented medical devices market [7]. Imaging, patient monitoring, *in vitro* diagnosis and high valued consumables possess greater growth potential in China's market. One-third of China's med-tech market consists of medical equipment like x-ray, ultrasound and other imaging equipment. Products such as consumables, implantable dental products, endoscopy and *in-vitro* diagnostics (IVD) accounts about one-fifth of the market value in China and its growth is projected to at least 20% per annum over next three years [5]. These higher gain segments demonstrate a progressively growing Chinese healthcare market and inspires manufacturers to move their product varieties to serve the future healthcare ecosystem.

**Opportunities in China:** With increase in per capita incomes China's consumers are demanding more sophisticated and reliable medical devices. There is rise in the cases of heart diseases, cancer, diabetes and other chronic diseases in China's population, creating a conducive environment for medical devices companies and healthcare products. Ageing population, affordability to healthcare products and growing health care needs are the key growth drivers in China's medical device industries. To spearhead business in China, medical devices companies are further benefitted by the changing environment in the Chinese healthcare system:

Restructuring and privatization of hospitals is the predominant motive in healthcare delivery in China. The Chinese government is supportive through its various schemes thereby reducing the cost of healthcare spending. Doctors are rated according to the number of patients they treat as well as the research output they produce which is linked with the performance appraisals, salary and career advancement. As a result of which physicians need highly efficient medical products and devices information as they are constantly acquiring knowledge to provide quality healthcare delivery to their patients. Telecommunication and use of technology has reduced face to face consultation between the physician and the patients. A well-orchestrated coordination is

provided for the physician-patient interaction through the use of digital solutions like mobile, social network, web, wireless devices, and physician portals [5].

### Japanese invasion in the medical devices industry

Japan ranks third largest medical device market, having more ageing population driving the medical device manufacturing companies. It is expected to have 40% population above 65 years' age by 2050. Prime Minister Shinzo Abe's economic renewal and developmental plan introduced in June 2013 comprises of promotion of pharmaceutical and medical device industries, hence, these two sectors are the key areas for business promotion and development in Japan. Manufacturers have to follow Japanese Pharmaceutical Affairs Law to develop and market their products [4].

The Japanese medical devices market was approximately USD 32.5 billion in 2012, primarily dependent on import of sophisticated medical equipment with a whopping import size of approximately USD 7.4 billion from U.S.A. According to the American Medical Devices and Diagnostics Manufacturers' Association (AMDD); a trade association with Japanese operations enabled approval of 58% of "new medical devices" in Japan during the last 7-year period [4]. A 2.5% CAGR in Japan's medical device manufacturing is estimated by Espicom Business Intelligence from year 2013 to 2018 year [5].

**Market challenge in Japan:** Factors affecting the degree of penetration in Japan's Market are the local competition, regulatory norms to be overcome, language and social factors, type of product, its quality and serviceability and commercial practices. Other factors affecting market entry in Japan includes level of competition between domestic manufactures and international players, import authorization necessities, restricted or banned imports, provisional entrance of goods, certifications, principles and classification requirements [5].

**Market opportunities in Japan:** Japan's aging population and continuous demand for advanced medical devices is the key determinant of vertical growth of Japan's medical device market. Domestic medical device production in Japan includes: diagnostic imaging tools; therapeutic and surgical kits; monitoring systems, home therapeutic equipment, dialyzers, and endoscopes. Some of the world's leading companies like Nipro, Toshiba Medical Systems, Hitachi Medico and Nihon Koden are some of the highest performing Japanese Medical Devices Companies. Most major U.S. and foreign medical device firms have an office in Japan or at least a Japanese official [5].

### South Korean medical devices growth landscape

Korean medical devices market is third largest in Asia continent. In Korea, healthcare market is focused in five major cities of Seoul, Pusan, Daegu, Daejeon and Kwangju. These cities contain about 60% of Korea's hospital beds [8]. About 49.8 million are growing older thereby providing a good opportunity for medical device market headway [9]. The medical device market is estimated to be around USD 3.9 billion dollars and growing at an average rate of 13.5% [10].

**Opportunities in Korea:** The Korean government aims to increase the medical device exports to achieve USD 12.5 billion growth by 2020 making a 3.8% contribution in the global markets. This will enlist Korea into the top 7 countries in the global medical device market. Korea presents unique opportunities for medical device companies due to a population of 49.8 million people who are growing older and whose average income is on the rise. Currently costly medical devices like digital X-ray, MRI, CT and ultrasound diagnostic systems are

manufactured locally and are marketed in more than 50 countries in and around the world including USA and European nations [11]. Due to sophisticated technology and more features, Korean medical devices are in higher demand in the global market.

**Challenges in Korea:** Korea promotes electronics and medical engineering courses in its colleges and graduation schools. This has enabled them to possess huge number of technical experts spear heading the electro-medical equipment industry [11]. There has been a steep rise in the number of hospitals and medical equipment in Korea thereby creating huge number of local manufacturers. Highly sophisticated and reliable medical products of the Korean domestic manufacturers have made them worthy competitors in the overseas market landscape. The Korean domestic equipment industries perform continuous market monitoring in overseas as well as local markets [11].

**Regulatory aspects of the growing Korean medical devices industry:** Introduction of electronic filing system for medical devices and ease in tracing of the Medical Device-Korea Food and Drug Administration (KFDA) Commissioner has the right to track medical devices that possess critical risk for the human health are some regulatory parameters laid by the Korean government. Manufacturers in Korea recall medical devices that cause incurable serious adverse side effects or death [9].

### Indian Medical Device Ecosystem

Regulatory measures and medical device manufacturing policy decisions create a conducive atmosphere for large scale manufacturing of products (Figure 1). These are the key aspects that are essential in driving the evolving medical technology hub in India.

### Challenges in the Indian scenario

Indian medical devices industry follows outdated regulatory standards which needs amendments and improvements. Indian manufactured products are substandard and give poor compliance, causing the Indian markets to have high level of dependency on medical devices exports. The Indian manufactured medical products are highly

taxed and expensive with a lack of motivation from government to promote manufacturing. Poor tax incentives policy to encourage home grown manufacturing, inadequate funding policy from the government to sponsor innovation and lack of expertise in manufacturing high end quality medical products are the major challenges for the Indian Medical Devices industry [12].

### Support from Indian healthcare industry

The Indian medical industries must align themselves with the 'Make in India' initiative of the Indian government. Other stake holders like healthcare providers and health insurers should also contribute and play their part in the Make in India plan and leverage Government policies and regulate the changes. The role of industry associates and funding agencies is also critical in supporting the development plan. MNCs and other Indian organizations must encourage local productions and innovations which will be beneficial to both India and other emerging markets. Design and development of medical products with total customer satisfaction will lead to high quality creation, provide attractive solutions and generate cost effective innovations [13].

### Backing from other sectors enabling growth of medical devices

Indian insurance sector must provide wider coverage to both diagnostics and screening products. This will increase demand and provide reimbursed medical devices. Local production will be enhanced by increasing the insurance over indigenously manufactured devices. Industry-academia interface must be enhanced to foster research, consultancy, entrepreneurship and innovation in medical devices industry. This would also aid to improve marketing and scalability of innovated Indian medical products. Private equity and venture capital firms should encourage innovative business models of medical device industries. Associative work between industry and academia will enable exchange of ideas, facilitate partnerships, fragmentize and regulate the manufacturing process [13].

### Strategies and Sustainable Growth Model for India from Asian Countries

State specific incentives can be started similar to China to develop a medical devices manufacturing base that includes economical production of high gain medical devices. Provision of cheaper access to land and training subsidies will greatly motivate new entrants in the medical devices manufacturing sector. Use of high tech and sophisticated technologies like telemedicine and the use of digital solutions like wireless devices and physician portals will enhance the quality of healthcare delivery system. The medical devices market should be well structured and organized. It should promote research and innovation in the medical devices manufacturing sector.

India must aim for having world class manufacturing facilities similar to that in Japan. India should promote generation of technical expertise in electro-medical equipment manufacturing similar to Korea to manufacture highly refined and reliable medical products.

### Sustainable Growth Model for Indian Medical Devices Industry

Amendments in policy and strategic implementation of regulatory mechanism can bring about tremendous opportunities for the MNCs and local companies in India. The changes in the regulatory design will attract more investment and bring technological upgradation in the medical devices industries. Self-governing regulatory system acts as

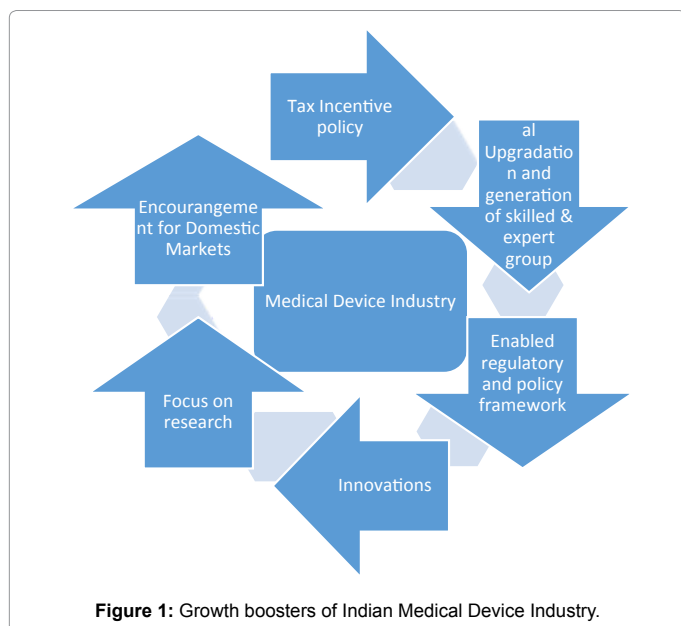


Figure 1: Growth boosters of Indian Medical Device Industry.

a catalyst for sustainable growth. One of the regulatory aspect can be adoption of lower market rates for the medical devices by MNCs and commercial firms. Technological collaborations between MNCs and domestic associates can leverage their product's reach in the market and domestic manufacturers can explore contract-manufacturing setting up international standards of infrastructure, enabling India to become a global center for medical devices manufacturing in the world [14]. Financial measures must be taken to develop and nurture the emerging medical device-manufacturing ecosystem to attract investors. Provision of Duty credits on import of raw materials for medical device manufacturing and a favorable government policy to introduce concession on VAT for imported equipment will act as an enabling environment for Medical devices growth in India.

Superior segment manufacturing and incentivizing of low to medium technology products will create a conducive environment for large-scale medical device manufacturing. Low and medium technology products that can be incentivized may include disposables, consumables, certain imaging equipment, implants, stents, some categories of laboratory diagnostics equipment and innovative mHealth based solutions [12]. Indian Government should promote and make policies that are conducive to a macro - economic environment for medical device manufacturing. The Indian government through Make in India initiative must achieve 100% foreign direct investment for Greenfield (setting up new manufacturing facilities) and brownfield (acquisitions) entries. Changing market needs and demand for medical devices across all the medical set ups in the country and overseas must be understood well. Low and middle level companies should be partnered with giants in medical device manufacturing firms and supported well to manufacture efficient and reliable medical devices and flourish in the market [15].

Strong bonding between the customer and the seller should be established to have good sales and marketing. Apart from sales and marketing, installation, servicing and maintenance of the medical devices should be done efficiently and regularized well. Accuracy and efficacy of screening and diagnosis should be improved. Portable diagnostic devices should be manufactured on a larger scale to meet the demands of homecare and remote locations. Advanced sophisticated assistive and rehabilitation devices that would reduce the healing time and restore patients to healthy state should be produced by Indian manufacturers. Homecare screening devices for early detection of diseases should be produced on a larger scale [12].

## Conclusion

The traditional US and western European markets are under regulatory scrutiny and pricing pressure providing the Asian markets an opportunity to leverage accessibility in medical devices. The Indian medical devices market is fourth in Asia after Japan, China and South Korea [2]. Best practices in these countries in terms of access to health care services, fast track approach, tax holidays, can be adopted by India and design a holistic ecosystem for medical devices for sustainable growth. Leveraging 'Make in India' initiative for medical devices and incorporating best practices of the Asian giants in medical devices will provide local innovation and make India a global center for medical device manufacturing.

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