

RESEARCH ARTICLE

Medical Device Industry in India: Past to Present

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ABSTRACT:

Healthcare of an individual is of prime importance as this is directly proportional to the productivity of a country. With the booming technological innovations, the healthcare sector is updating with the use of latest devices for the treatment of patients. However, compared to global scenario, medical device industry in India is still in the infancy stage, with lots of opportunities in this sector. Therefore, an attempt is made to understand the past and present updates in the area of medical device industry in India.

KEYWORDS: Medical devices, Indian market, global scenario, medical device regulations, Government initiatives.

INTRODUCTION:

There is a turning point in the healthcare industry due to the challenges such as increase in the price of medicines, lack of provision for good healthcare, increase in the prevalence of chronic diseases. In order to combat this crisis, there is required a major transformation, which is possible with the use of innovative information technology, good networking and use of biomedical and engineering principles in healthcare technology. Medical device industry has evolved by leaps and bounds from former use of scalpel and crutches to contemporary heart valve and artificial heart transplant. Medical device industry in India is growing with a CAGR of 15.8%. Indian market is in the top 20 list and the 4th major player in Asia with respect to medical devices market (1).

According to WHO medical device is as "an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose.

Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means." In the past the industry was more oriented towards the imports of the devices and currently the industries are closely working on the export of the devices. In the current scenario, there is a need to use medical devices effectively and to bridge the gap between demand and supply of healthcare services. The medical device market is governed by around 80% of total sales which is dominated by imported products. The internal companies predominantly involve in manufacturing cut-end products for not just local but for international consumption as well. Presently there are over 14,000 medical devices marketed in the India and the country is highly liable on imports from countries like the USA, Germany, UK, Japan, France and Finland.

The top among medical device competitors in Indian market are:

1. Phillips
2. Wipro GE Healthcare
3. Medtronic
4. Johnson & Johnson
5. Becton Dickinson
6. Abbott
7. Hindustan Syringes & Medical Devices

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History of Medical devices:

In the ancient time of Rome various types of medical devices were in widespread use and were indicated by the study of archeology and Roman medical literature. In the United States in 1938 the medical devices were regulated under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Medical Device Regulation (MDR) is the regulation in Europe which is into action since 2017. Medical device history in India:

In the 1960 the Indian medical devices were dominated by MNCs and had 90% market share. After 1970 the government took control by the Indian Patent Act-1970 and Drug Price Control Order and gradually Indian companies started emerging. The medical device industry in India attained independent status after the launch of the “Make in India” program in 2014 under the government scheme. In the past, there were no regulations for medical devices until the recent.

Segments of medical devices (2):

There are different segments into which medical device industry is classified based on the type of products produced.

1. Equipment and instruments: They contribute largely to the total market share and include devices like ophthalmic instruments, dental products, medical and surgical sterilizers, and therapeutic respiration apparatus.
2. Diagnostic imaging: The total market share of this segment is the second and categorizes devices like electro-diagnostic apparatus, radiation apparatus, and imaging parts and accessories
3. Patient aids: This segment mainly depends on orthopedic and prosthetics, portable aids, wheelchair and hospital furniture and these contribute to a small amount of total market share.
4. Consumable and implants: These are devices which are used internally or for injecting into the patient, such as syringes, needles, catheters, bandages, suturing materials etc. and a percentage of it contributing to the total market share is managed by these devices.

Clusters of medical devices in India (3):

- Karnataka: Mainly focuses on the manufacture of Insulin Pens, Cardiac Stents and implants, Medical IT, PCR machines and these products are developed by manufacturers such as Biocon, GE Medical, Skanray, Bigtec Labs etc.
- Haryana: Focuses on the manufacture of consumables and dental equipment's and the companies working are BD, Hollister and Poly Medicure.
- Delhi: Medtech Innovators such as Standford-India Bio design program.
- Gujarat: Manufacturing of stents is supported by

Envision Scientific, Invent Bio-Med.

- Tamil Nadu: This is a large hub for production of diagnostics, critical life support systems, and Ophthalmology products. Companies manufacturing these are Trivitron Healthcare, Opto Circuits.

Regulatory authorities for medical devices in India:

The Government of India has introduced Medical Device Regulation which has the task to regulate manufacturing and marketing of medical devices and the authorities governing it are:

1. Central Drug Standards Control Organization: Main regulatory body for pharmaceuticals and medical devices
2. The Drug Controller General in India is the crucial official under CDSCO
3. Drugs & Cosmetic Act and Rules govern the manufacture, import, sales and distribution of medical devices.

Government Initiatives (4):

The Government of India has promoted the manufacturing of the devices through initiatives like Make in India, Development of Medical Device Parks and Testing Labs. The Indian Government has introduced Medical Device Regulation to regulate Notified Medical Device. “Medical Devices” have no separate regulatory status in India, and CDSCO is responsible for its regulation. This secondary research was carried out to know the vast changes taking place from then to now in the area of medical devices.

The aim of the study was to do a systematic research on the development of medical device industry in India from past to present using primary data results.

Various articles from authentic websites and journals were screened for data collection. Every collected data was pooled on the basis of global and Indian scenario. The data was analyzed and tabulated in results and discussion. The final conclusion was drawn from the obtained results (Fig: 1).

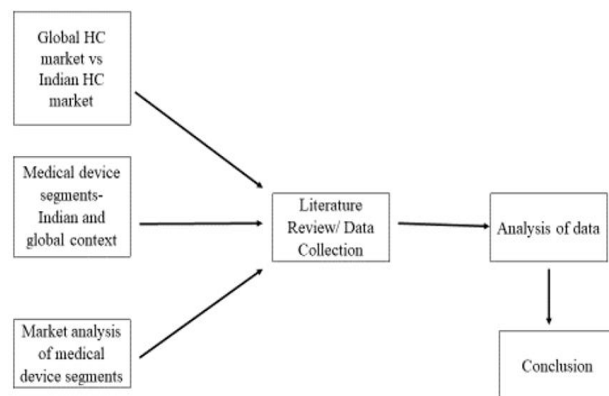


Figure 1: systematic approach towards data analysis, collection and conclusion

Total healthcare expenditure- comparison between few countries^[3]:

Table 1: Comparison of healthcare expenditure in some countries

Global Healthcare Expenditures				
Country	Expenditure on Healthcare*	Expenditure on Medical device*	Government (%)	Out of the pocket (%)
India	75	3	30.00	70.00
US	9892	415	48.30	11.00
UK	5267	313	77.00	13.20
China	420	178	55.80	32.00
Japan	4519	221	83.60	13.90

*(USD per Capita)

Total healthcare expenditure between a few countries listed above were found out through different sources. The results were tabulated as above. Out of all the 5 countries, the data showed that the expenditure was less in India for healthcare and medical devices when compared to other countries. 70% of the expenses were from the out of pockets by Indians in comparison to other countries (Table 1).

Total value of Indian medical device industry was \$ 2.02 billion which increased to \$ 3.9 billion in 2015 and is expected to rise upto \$50 billion in 2025 at an CAGR of 15.8% (Fig 3).

The first line of sales (Global) was in the area of diagnostic imaging followed by IV diagnostics. In Indian market also Diagnostic imaging sales was on top followed by sales of equipment and instruments (Fig 4).

Indian and global healthcare market segments:

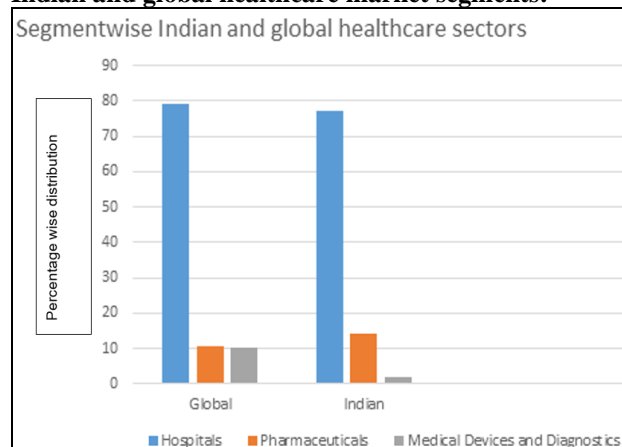


Figure 2: Segment wise Indian and global healthcare sector

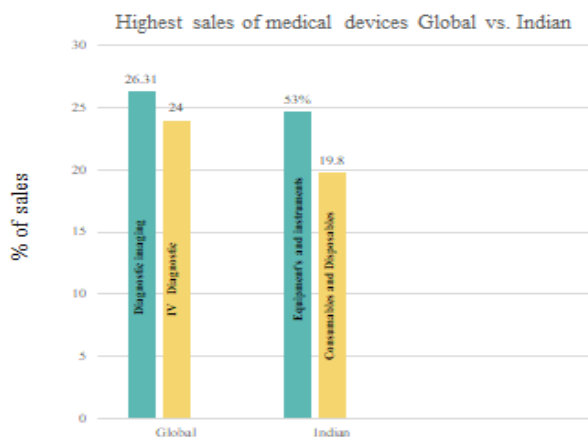


Figure 4: Comparison of sales of medical devices

The total value global medical device industry was estimated to be \$228 billion in 2015 and is expected to grow in the coming years (Fig 2).

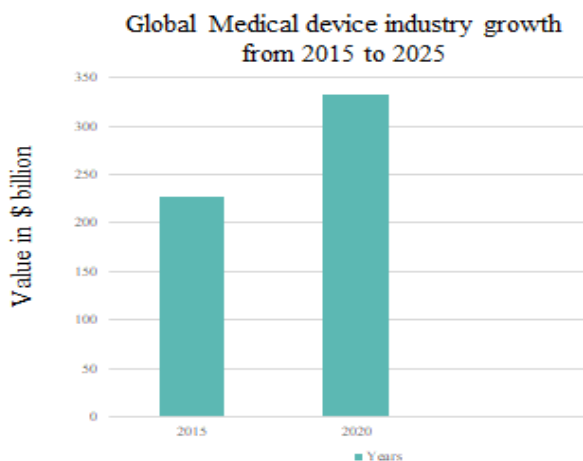


Fig 3: Expected global medical device industry growth from 2015 to 2025

Sector wise classification of Indian Medical Device industry:

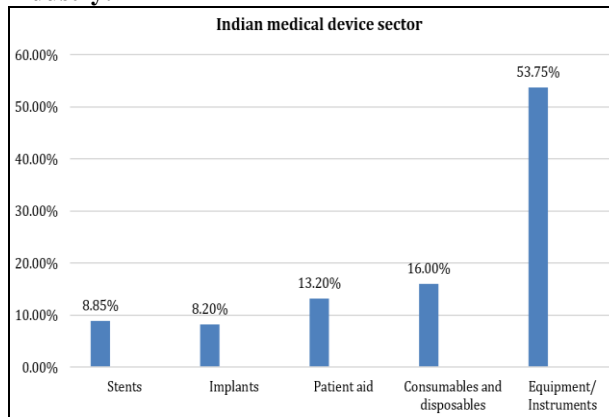


Figure 5: Indian medical device sector

From the study it was found that Equipment's and Instruments market share is huge followed by Consumables and Disposables (Fig 5).

Factors that drive the growth of medical devices in the Indian scenario (5):

1. Expanding population
2. Increasing age of the population
3. Increase in the number of chronic diseases
4. Rising of health insurance benefits to the patients.
5. International tourists for medical ailments.
6. Rapidly increasing need for healthcare infrastructure.
7. International quality standards adopted by Indian hospitals.

CONCLUSION:

Healthcare sector is far behind in India when compared to other countries and needs immediate attention and improvements in many ways. Although there is tremendous increase in medical device industry through initiatives such as “Make in India”, India is still lagging behind in terms of innovation and manufacturing. Technological innovations by the experts in the field along with Government support has shown drastic rise in medical device industries.

Limitations of the study:

1. The study focused on only few aspects such as market analysis and segment-wise research. Study on regulatory framework and export-import policy would have been more useful evidence from past to present improvement.
2. The study results were descriptive only. Statistics was not applied.
3. Study on impact of GST and VAT should have been studied.
4. The study should have focused on any one sector of medical device, as medical device as a whole is a very huge industry.

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