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Medical Device Industry: At Present and the Road Ahead

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INTRODUCTION

A medical device defined as any material, software, appliance, instrument, apparatus, used in combination or alone proposed for use in diagnosis and treatment purpose to prevent, support life and cure disease. Medical devices are used in various indications such as Diabetes. Arthritis. obstetrics and gynaecology, COPD etc. Medical devices are a vital part of patient care. The medical device is a huge system having categorized products such as therapeutic devices, diagnostic & monitoring medical devices and so on. Medical devices include a wide range of products for example; Bandages, pacemakers. Glucose meter, stethoscope, incubators, cardiac stents, nebulizer [1, 2]. Medical devices help people live with less pain & enhancing the quality of life [3]. To encourage

regulatory standards and practices with respect to quality, safety and effectiveness of medical devices, the Global Harmonization Task Force (GHTF) was founded in 1993 with the help of governments of five countries -Canada, Australia, European Union, Japan & United States [4]. Pharmaceuticals were costly and timeconsuming before the development of medical devices. Various countries introduced their own independent regulatory bodies to regulate the process of manufacturing, registration, licensing, labeling & marketing of medical devices and pharmaceutical products. The few such regulatory bodies are USFDA(USA), MHRA(UK), TGA(Australia), CDSCO(India), MHLW(Japan), EMEA (European Union), KFDA(Korea), SFDA (China), MCAZ (Zimbabwe) and so on (Figure-1) [5].



Fig-1: Regulatory Agencies Worldwide

MEDICAL DEVICES CLASSIFICATION

As per Schedule M-III, Medical devices are classified into four different classes based on their risk level in Table-1 – Class A (low risk), Class B (lowmoderate risk), Class C (moderate-high risk) & Class D (high risk). Class A devices are simple in manufacturing & design associated with minimal risk. These devices do not pose any threat to life & easy to handle such as thermometers, bandages, medical gloves etc. Class B contains devices having a low-moderate risk with added regulations than class A. Some examples of class B are Needles, Tracheal tubes, Urinary catheters etc. Ventilators and Intensive care monitoring equipment will lie under class C as these have moderate to high-risk level. Class D devices undergo more rigorous regulation & complex process as these possess the highest risk which can be lifethreatening. Pacemakers, Valves, Cardiac stents etc are the examples of class D devices [4, 6].

Table-1: Classification of Medical Devices								
	Class A	Class B	Class C	Class D				
Risk	Low	Low-Moderate	Moderate-High	High				
Level								
Examples	Medical Gloves,	Needles,	Ventilators And Intensive Care	Balloon Catheters, Prosthetic				
	Bandages	Tracheal Tubes	Monitoring Equipment.	Heart Valves, Pacemakers				

Table-1: Classification of Medical Devices

Significance of Medical Devices

Development of medical devices has brought robust change in the healthcare industry. Medical devices provide a great platform for diagnosis & treatment of ailments. It helps patients by cost reduction of treatment as well as physicians by increasing their capacity to analyze and treat the ailment. Medical devices have associated with quality and different problems according to different cases. Medical devices are related to humans as well as animals hence quality is one of the essential factors for medical device industry. Medical device industry is one of the most regulated and innovative industry and its stringent regulation and standards help to maintain the quality of medical devices. Regulations are not only important for

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maintaining the quality of products but also help to streamline the procedures and create a standard process to follow. Drug Controller General of India (DCGI) & Central Drugs Standards Control Organization (CDSCO) are the regulatory bodies which help to meet quality & standards of devices in India [7].

In today healthcare system, healthcare devices and equipment are needed even after the discharged of patients from the hospital hence it becomes important for both patients and physicians to be aware of the advantages and usage of medical devices. These technologies offer help in disease prevention and disease management. Medical devices provide support for maintaining both acute as well as chronic medical conditions. Consumers manage their own health more independently and conveniently with the help of medical devices and apps hence medical devices have been used & produced as consumer products these days. For example, various types of testing kits (pregnancy test, cholesterol test), meters and monitors such as Glucose meter for diabetes, blood pressure monitor, CPM machines [8, 9].

Medical Device Industry: An Introduction

Healthcare is one of the largest sectors of not only India but other countries as well. It comprises medical devices, pharmaceuticals, clinical trials, medical tourism, outsourcing, hospitals, health insurance, telemedicine and medical equipment. It is growing massively in terms of employment, new research & revenue. The healthcare industry in India is growing extraordinarily due to its services, increasing expenditure and strengthening coverage by players involved in this sector. Healthcare sector has impressive growth prospects at a CAGR of 22% during 2016-2022 to reach USD 372 billion by 2022. There is a great scope for enhancing penetration of healthcare services in India, thus presenting ample prospect for growth and development of the healthcare sector. Geriatric population, improving perception towards healthcare, increasing health awareness and growing earning levels are expected to enhance demand for healthcare services in upcoming years. Medical tourism helps to attract patients from all over the world results in great marketing strategy and a low price of medical services. Low expenditure of clinical research has caught the interest of various international players and provides India, a sustainable competitive advantage over rest of the countries. Healthcare sector has reached home due to development in technology and collaboration with medical devices which has made the treatment inexpensive and provide high-quality services at home. It reduces the expenses up to 20-50 % of the cost for the customers. The market for home healthcare equipment and device, valued at USD 3.2 billion in 2016 and is approximate to achieve USD 4.46 billion by 2018 and USD 6.21 billion by 2020. The healthcare sector has the maximum employer globally, among the sum of the all working people in each sector all over the world. Moreover, Healthcare sector employment growth rate is greater than that of other sectors in various countries. In the healthcare industry, there is no monopoly on the market due to small market share [10].

The medical device and equipment industry has become one of the leading & growing industries in healthcare, focused on new research & development, technology, and innovation. The previous decade has shown an impressive growth in medical device industry and shows immense advancement in the market [11]. Medical device industry doesn't deal with single products as it has a wide range of medical equipment used in hospitals and at home. It utilizes new as well as existing technologies such as smartphones to provide

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services. There is huge aging population worldwide which becomes an important factor in the growth of medical device industry as orthopedics, diabetes etc are the largest segment of the medical device industry. In medical device sector, high returns and diversification are provided by exchange-traded funds (ETFs). Medical device industry has become a very stringent and serious trade as the healthcare system has become more patientcentric, responsive and responsible than earlier. There is a complete 360-degree shift in the industry as it has started focusing on patient outcomes and value for services rather than rewarding sales volume. Various mobiles applications, software, and wearable technologies are new trends for low-risk devices in the segment of medical devices. Despite various risks and challenges of medical device sector, the growth rate of this industry is double-digits [12, 13].

The market size of Indian medical device industry, currently valued at USD 5.2 billion, earned USD 4 billion in 2016 and expected to raise USD 11 billion by 2022 supported by low cost and high-quality services, an aging population and development & advancements in medical awareness and tourism. Indian healthcare industry is worth USD 96.7 billion in which 4-5% is contributed by medical device industry. The current range of medical device manufacturers in India is 750-800 with a revenue of Rs 450-500 million & average venture of Rs 170-200 million [10, 14, 15]. Medical device industry has entered into a growth phase and a high growth curve has been seen from the previous decade. It is growing at a rate of 16 % from 2018 to 2023. Both public and private sectors have contributed their funds and innovation to overcome the challenges of the industry. There is a significant gap between demand and supply in progress due to the high amount of importation of medical devices worldwide. As a result, in-house R & D activities are performed by many private and public firms to meet the demand in the future [14, 15]. According to the estimation of the industry in India, medical devices industry will raise up to USD 50 billion by 2025. India has revolutionized its name among the top 20 medical devices market globally in the present times. In the list of prime medical devices sector in Asia. India comes 4th after China, Japan, and South Korea. As per the medical device market, 53% of the segment is non-surgical and surgical instrument having worth of USD 2.7 billion in 2017 whereas the market size (estimated) of the durable and consumer sector is USD 1404 million [15].

The global medical device market is on a high growth trajectory has evolved significantly in the last decade. One of the reasons behind this growth is the immense opportunities provided by public and private hospitals. The estimated global medical device industry turnover is expected to attain USD 409.5 billion by 2023, with the CAGR of 4.5% from 2017 to 2023. Healthcare expenditure, increased prevalence of lifestyle-related diseases, rapidly growing population

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and technological development are the key drivers for this market growth [16]. In the medical device and equipment industry, orthopedics is known as the biggest segment among other segments. The top segment of the industry are Diagnostics, valued at USD 60 billion in 2016, and is to reach at USD 84 billion by 2023 with CAGR of 4.6% from 2017 to 2023 whereas fastest growing segment is neurology, increasing by 6.1% annually [17, 18]. The top three segments of the medical device industry are- minimally invasive devices, neurology and cardiology devices [18].

United States is one of the major medical device industries, with the largest market share valued at USD 125.4 billion. In 2012, the market value of U.S. had represented 38% (approx.) of the medical device industry globally. The second major industry with the value of USD 66 billion is the European medical devices industry. Currently, China is the third key market for medical devices. It is growing at an annual average of 20% since 2009 and worth of USD 48 billion. In medical device industry, dental equipment

Consumables and Disposables

It consists of products such as disposable plastic syringes, IV fluid sets and blood bags. It is fast growing industry with the need of low technology.

Equipments and Instruments

It is the largest segment of the medical device sector and 54% are importdependent. MRI machines, Ultrasound, Dental chairs, X-ray machines etc are the products of this sector. It needs high and advanced technology for the development of the sector. account has a minimum share. Initially, Respiratory and Cardiac diseases affect people age of 65 or above however this age criterion is going down nowadays due to which young people are prone to these diseases. One of the major reasons is environment and lifestyle choices. According to the World Bank data, the percentage of the aging population expected to rise up to 2% by 2023, the growth of age-related ailments medical devices will be significant in terms of revenue [19].

Market Segmentation of Medical Device Industry

Medical devices sector is a vast industry as currently, it contains more than 1.5 million varieties of medical devices (according to the WHO media center 2010) thus it can be projected into numerous segments. Medical device industry can be segmented by many ways- by application, by geography or regions, byproducts etc. It is primarily segmented into following segments – consumables and disposables, equipment and instruments, implants, patient aids and stents catheters (figure-2).

Implants

It grows massively at a CAGR of 25% in the India.It is popular in both domestic and MNC's and witnessed extreme competition between players.

Stents

Bare metal stents and Drug-eluting stents are the key producs(70% market share) of the market. It is sourced from Europe and the USA. Domestics players are Medtronic, Boston Scientific and Meril life sciences.

Patient Aids

Prosthetics, Pacemakers and Hearing aids are constitute 70% of the patient care and aids segment collectively. Key players of sectors are Australia, Singapore, China & South Korea.

Segments of Medical Device Industry

Fig-2: Segments of Medical Device Industry

Geographical Segmentation

Environment and culture have a significant role in the development of an industry. Different countries have their own culture and environment which have an impact on the health of customers. Medical device industry is a huge industry with the worth of billions. It is spread all over the world. The major geographic markets of medical device industry are United States, Europe, China, Africa/ Middle-east& Asia-pacific (Figure-3). Germany, Spain, France, the United Kingdom & Italy are the leading markets of European medical device industry.



Fig-3: Geographic Segmentation of Medical Device Industry

The United States' Medical Device Market

The United States medical device market is the global leader worth of USD 140 billion as it makes the United States, biggest medical device market worldwide. It represents approximately 45% of the global market of the medical device. With more than 5800 medical device organizations in the U.S. which are mostly small and medium firms (nearly 80%), that employ around 356,000 people directly and around 2 million people indirectly. Medical devices firms are positioned all over the United States, however, Massachusetts, Florida, New Jersey, New York, Pennsylvania, Georgia, Michigan, California, and Minnesota has the largest number of the companies of medical devices and equipment (Figure-4). The U.S. is a developed country with high technologies, high regulated policies and innovation. Major players in

medical device field often enter into alliances and mergers & acquisition with small firms very carefully to expand their market segmentation and raise profit by providing more value and focused healthcare solutions. By 2030, US aged population (above 65) has predicted to increase to 20% from 15% results in demand for medical devices to grow [20].

The United States has а sustainable competitive advantage in numerous industries over which device market relies on such as telecommunications, biotechnology, microelectronics and medical software development. The US collaborations have provided numerous advancements including Health IT, stent technologies, implantable edevices, biomarkers, Neuro-stimulators etc.



Fig-4: Number of Companies by US regions

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Europe's Medical Device Market

European medical device market is the 2nd major medical device sector after the US. The European market mainly includes orthopedics, respiratory, dental fittings, consumables and ophthalmic medical devices (Figure-5). These devices are manufactured by various companies situated in France, Spain, Germany, the

United Kingdom and Italy as these are the largest medical device provider in Europe. Being a developed country, Europe has upgraded facilities, developed infrastructure, and highly regulated authorities for medical devices which help to provide quality and more value-focussed medical devices [21].



Fig-5: Europe Medical Device Market

European countries are one of the biggest suppliers of medical devices to the other markets. European medical device industry is worth of € 100 billion and represented 31% of market share in the global market. All over Europe, there is approximately 25,000 medical technology (including medical devices and in-vitro diagnostics) companies providing work for more than 575,000 individuals. Western Europe has contributed more than Eastern Europe in the medical device industry globally. Western Europe is expected to grow at a compound annual growth rate (CAGR) of 3.7% by 2019. As the Europe population survey, more than 25% people will be more than 60 years old by 2030 which creates demand for medical devices. There are numerous challenges for medical device market in Europe such as cost-containment measures, challenging regulatory practices, pricing, operating environment and reimbursement controls however European medical device market are working on the personalized solutions to obtain the desired outcomes [22].

China's Medical Device Market

China has become powerful in terms of economy, trade, and developments. It is medical device market is growing rapidly. China medical device market is one of the fastest developing markets among Asia-Pacific regions. Figure 6 outlines the growth of China medical device industry over the period of 2001 to 2017. The Chinese medical device market was valued at 244.8 billion Yuan and is estimated to raise 290 billion Yuan in 2018 [23].



Fig-6: Market Size of China Medical Device Industry

Rising Healthcare awareness and consumption, growing medical expenditure and regulatory improvements are the major factors which promote the growth and development of medical device industry of China. The high amount of medical devices have imported from other countries, therefore, the export value of Chinese medical device market is higher than the import one. In China, Medical treatment and diagnosis devices market has 29.05% share of overall import volume. One-quarter of the volume of import value i.e. 6.8% of total import volume of the medical treatment and diagnosis market include medical dressings, health recovery, and protection products, dental materials and equipment etc. Key growth drivers of medical device market of China including the impact of government policies on diseases, 65+ population and hospitals located in different regions etc. Table-2 outlines the export and import value of different trade, for example, traditional Chinese medicines, pharmaceuticals and medical devices (including disposable market, medical dressings, medical diagnosis and treatment devices, Health recovery and protection products and dental equipment. It provides information about the export and import value annually (YOY) with their share percentage in total export and import volume [21, 23, 24].

Trad	e name	Export value	Export value YOY(year-on- year) growth (i.e. annually)	Share in total export volume (%)	Import value	Import value YOY(year-on- year) growth (i.e. annually)	Share in total import volume (%)
Total		39,733	24.87	100	20,464	23.98	100
1.Tra	ditional Chinese	1,945	22.78	4.89	688	22.61	3.36
medi	cine						
2.Pha	armaceuticals	23,930	28.17	60.23	12,442	20.53	60.79
3.Me	dical devices	13,859	19.83	34.88	7,336	30.45	35.85
	Disposable	1,923	15.42	4.84	881	27.73	4.3
a.	products						
	Medical	4,688	11.95	11.8	208	25.63	1.02
b.	dressings						
	Medical	4,544	25.56	11.44	5,945	30.34	29.05
с.	diagnosis and						
	treatment						
	Dental materials	289	16.51	0.73	153	21.37	0.75
d.	and equipments						
	Health	2,416	30.87	6.08	149	83.83	0.73
e.	protection an						
	recovery						
	products						

Table-2: China Export & Import Value of Medical Devices, 2010 (Unit-Million USD)

Source: cccmhpie, 2011

Medical Device Industry Analysis of India: Strengths, Weaknesses, Opportunities & Threats

Medical device industry provides services to hospitals, clinics, and patients. It affects the living of several human beings as well as animals. Like any other sector, medical devices also have to make improvement and adjustments to uphold optimum and efficient services. It is necessary to understand the area of improvements, to gain knowledge about the external and internal environment and their impact on medical device industry and to analyze the current situation of the industry about the market growth, current goals, and objectives, strategic planning, and implementation.

SWOT analysis allows the detailed assessment of the strengths, weaknesses, opportunities, and threats of an industry from a neutral outlook. In the 1960s, Albert Humpley designed this method to analyze the condition of an industry. It makes the assessment simple, realistic, competitive and directional towards changes if needed. It contains certain steps to create the SWOT analysis as mentioned in figure-7.



Fig-7: Stages of SWOT Analysis Process

Indian Medical Device Market

India has become the center of attraction for its proficiency in medical device sector. It contributes approximately 5 % out of USD 97.6 billion produced by the healthcare industry in a year. Currently, Indian domestic players of medical device sector majorly rely on importation because of harsh legislation; however, a regulatory structure is going to develop by the government and followed by the manufacturers. Current structure needs a proper attention of government hence it's preparing a transparent platform for the medical device industry. Some of the leading companies of Indian medical device industry are Johnson and Johnson, 3M, Medtronic, Baxter, Zimmer India. In Mumbai. in-vitro diagnostic instruments have developed by Transasia Biomedicals. Growth drivers of Indian medical device industry are new model development in healthcare, increasing funds for public and private segments in healthcare and health insurance penetration. 'Make in India' program helps India to find out the potential, vision, and objectives.

Indian medical device sector has a huge potential to grow. It has several strengths like population, educated employee to grab the opportunities and weaknesses like a low R&D investment which can be overcome.

Overview of SWOT Analysis of Indian Medical Device Industry

In a SWOT analysis, strengths illustrate the assets and positive attributes of an industry such as competencies, unique selling point (USP), strategic factors. As we know, India is a developing country. It is growing day by day in terms of economy, employment and education. Being a developing and second largest populated country in the world, it provides a huge market for the medical device industry [26]. Competitiveness is a significant factor in every industry. The increment in the number of private hospital market by domestic players aiming to attract health tourists is one of the strengths of device sector. Low-cost clinical research provides costcompetitiveness. India has successfully positioned itself in top 20 medical device industries in the world. It is growing massively in pharmaceutical and paramedical sectors with the enormous advancements in supporting like telecommunications, software industries development, microelectronics etc.

Cost-competitiveness

India has a high number of qualified personnel due to increased education level. India has the capability to produce products at low cost due to low labor and low clinical research cost. India production wages are the lowest than any other countries which provide advantages of cost- competitiveness [25].



Fig-8: SWOT Analysis of Indian Medical Device Industry

High population rate

India stands second in the population among in the world. It creates a vast market for neonatal, elder people due to a large population. Due to a large population, there are severe untapped markets in India. Many rural areas are out of reach of medical device sector by acquiring these areas, the growth of the sector will occur.

Weaknesses

To maintains the market position and to become a global leader, Indian medical device industry must overcome the weaknesses including low R&D investment, extreme reliance on import, low excellence view towards products, less promotional policies of the government, no market penetration.

Low R&D investment

In the top 10 R&D sectors, India has no organizations whereas China has more than two companies on the list. Israel and South Korea spend >4% of GDP on R&D of new technologies and products while India spends less than 1% on R&D.

Extreme reliance on import

Indian medical device market is conquered by imported devices (75% of medical devices & equipment) which cover 70% of total revenue. One of the main reasons for import is lack of successful domestic manufacturing environment however domestic players are working on to boost their ecosystem with unique strategies.

No market penetration

India is one of the most populated countries worldwide. There are many regions which remain undiscovered as there is no market penetration in many rural areas. Opportunities are the external factors which can provide a competitive advantage. To obtain the advantage will have to grab the opportunities offered by increasing incidence of lifestyle diseases, mergers and acquisitions, MNCs investment and recent technologies.

Increasing incidence of lifestyle diseases

Currently, millions of people are suffering from lifestyle diseases worldwide. It includes stroke, diabetes, obesity, atherosclerosis and various medical conditions related to alcohol, smoking, unbalanced diet and drug abuse. According to the global survey, 2.5 million deaths have been recorded due to lifestyle diseases in 2015. Hence it provides opportunities to increase the market share.

Mergers and Acquisitions

Mergers and acquisitions have become trends in the industry globally. It helps companies to expand their product and strengthen their position in the market. It allows firms to enter into a completely new therapeutic market without dealing with notorious lengthy regulatory methods. For e.g., Stryker Corporation is to acquire Entellus Medical, Inc for USD 660 million as it expands the presence of Stryker in minimally invasive treatments of ENT (ear, nose, and throat) diseases. In the medical device industry, mergers and acquisitions lead to a decline in competition all over therapeutic segments.

Threats are the factors which can pose risk or adversely affect the industry. It can cause damage to the market, venture or companies, therefore, it is important to face or predict it well to mitigate their impact or avoid them exclusively. Threats of Indian medical device industry are tax and policies, increasing regulation inquiry and lack if specifications leading to spurious products [27].

Increasing regulatory inspection

Incidence of medical device recalls are increased due to faulty procedures or lacking regulatory procedures hence increase in regulation procedures poses a threat to manufacturers of medical devices.

Competition from foreign markets

Foreign markets like US and EU have a strong market presence in the market. The US is the global leader in the medical device industry. They have latest technologies and strong R&D investments which make them more competent to grab the market and create competition. The US and EU have stringent quality standards and processes which always pose threat to Indian medical device market.

Key players in the global medical device industry

The medical device market is constantly growing with a huge momentum, credit goes to advancement in medical technologies. There are a lot of organizations that work vigorously to treat numerous diseases such as Diabetes, cancer, COPD etc by providing novel healthcare solutions. In India, the incredible foreign venture has observed in medical device sector. [28] There are numerous key players in medical device industry globally which devotes their time and money to make an impact in the medical device market (Table-3).

Rank	Company's Name	Headquarter	Revenue (USD Billion)	CAGR (%)
1	Medtronic	Dublin, Ireland	29.36	3
2	Johnson and Johnson	New Jersey	25.1	3
3	GE Healthcare	Illinois, US	18.3	5
4	Fresenius Medical Care	Massachusetts	18	8
5	Philips Healthcare	Netherlands	16	4
6	Siemens Healthineers	Germany	14.1	3
7	Becton Dickinson	New Jersey	12.42	9.4
8	Cardinal Health	Ohio	12.15	3.9
9	Stryker	Michigan	11.3	5
10	Baxter International	Illinois, US	10.16	4

 Table-3: Top 10 Key Players in Global Medical Device Industry, 2018

Medtronic

It is the world's biggest medical device company operates in more than 140 countries. Medtronic's headquarters is located in Dublin, Ireland. It generates revenue of USD 29.36 billion in 2018 and employs 88,000 people working in the different segmentation of diabetes, cardiovascular, surgery, biologics and spinal diseases.

Johnson & Johnson

Johnson and Johnson is a second major innovative and well-recognized pharmaceutical and medical device manufacturer with headquarters in New Jersey. It makes revenue of USD 25.1 billion and deals in numerous therapeutic areas – vision care, orthopedic, diabetes and cardiovascular.

GE Healthcare

General Electric is an MNC having a prosperous healthcare segment named as GE Healthcare, with headquarters situated in Chicago. Its annual turnover is about USD 18.3 billion currently and treats patients in more than 100 countries with their extensive range of medical devices including incubators, x-rays, and CT image machines. It provides sustainable solutions to the healthcare with their disruptive technologies.

Fresenius Medical Care

Fresenius Medical Care is a German-based organization specializes in developing medical equipment and services related to renal diseases (mainly dialysis). It treats more than 190,000 patients all over the world. It grew workforce from 60,000 to 104,233. It is the largest renal care provider in the USA, making sales revenue of USD 18 billion.



Fig-9: Top 10 Companies of Medical Device Industry

Phillips Healthcare

Phillips is a well-known entity in the all over the world. It operates in over 100 countries. Their medical device segment is highly progressive in areas like cardiology, anesthesia, and oncology. It income stands at USD 16 billion and employs 71,000 people.

Siemens Healthineers

It is a branch of MNC Siemens with headquarters in Germany. It has various centers all over the world with segments like diagnostic imaging. Their major markets are China and USA. It brought revenue of USD 14.1 billion in 2018.

Becton Dickinson

Becton Dickinson is one the major players in the global medical device market. It focuses on innovation healthcare solutions in medical discoveries, gene research, and cancer therapies. It is famous due to a diverse portfolio, strategies and strong and efficient workforce. Becton Dickinson's headquarter is in New Jersey with a workforce of 50,928 people (collectively).

Cardinal Health

Cardinal Health focused on surgical instrument and equipment and brings in revenue of USD 12.15 billion. It employs more than fifty thousand employees. It diversifies its segments into surgical, wound care, laboratory etc.

Stryker

Stryker is one of the growing medical device manufacturers. It is US-based organizations having headquarter in Michigan. Its average revenue is USD 11.3 billion with 33,000 employees. One of the reasons for its market growth is their strategic acquisitions (Sage products + Stryker) by which it explores in various sectors including orthopedic, intensive care products, neuro-technologies.

Baxter International

Baxter International is a renowned medical device firm with the current revenue of USD 10.16 billion. It is involved in the development of renal, immune and hemophilia medical devices. It provides medical devices to clinics, hospitals and even at home. It provides innovated products to the world by expanding their services in the sector of the generic vaccine [29].

Role of technology in medical devices

Technology plays an important role in the development of an industry. It provides speed, less time-consuming procedures, effective and efficient approach towards the market and sustainable competitive advantage to the industry. Technology upgrades the medical devices and equipment and helps to identify the medical conditions early and precisely. The technology involves new research and development, software, high volume equipment to microchip medical devices such as microchip implants, drug delivery pump, nebulizers, Ultrasound. It increases the life cycle of the medical devices and provides devices a variety of functionalities. Diagnosis of conditions and determine the suitable treatment method has become easier for doctors due to development in medical software. Nowadays, software applications have become hardware-independent. With the help of the internet, the applications can be downloaded by connecting device to phone or computer. Wearable devices are widely used now. Wearable devices have push-button alert mechanism which helps in emergency. These devices attract interest of all age groups. Medical device has entered in fitness sector as well for example fitness bands. These bands take important data and transmit to user wireless devices. IoT provides an added value to the medical device industry. It reminds the user about their medication dose timings, monitoring blood pressure, exercises like

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cardio at a fixed time. It clarifies the queries about health issues and provides information about the procedures. Medical devices are used by patients and staff both. There are so much advancement in medical devices such as band-aid (capable of signifying about the wound conditions) or thermometers (tell the temperature only at one click). It is easy to operate and provide verbal solutions. Medical devices sector uses platform like cloud to transmits share and store the clinical data which help the healthcare sector in enormous ways [30].

Impact of GST on Medical Devices Sector

Medical device and equipment industry plays a significant role in the healthcare. Goods and services tax (GST) have made an impact on the trade all over the India. GST is the chief tax restructuring in the era of indirect taxation in the Indian industry. This reform will consider various taxes like VAT, CST, Octroi, excise duty. Medical equipments, including surgical devices and instruments, attract 6% excise duty (centrally) and 5% VAT and more than 13% including CST, entry tax, octroi etc. however in the current scenario, situation is different. GST provide a simplified tax structure to convey operational effectiveness. The current tax rate (GST) for medical device is 12 %. GST provides advantage by lowering the manufacturing cost and great services to consumers. It also increases the market size of the medical device sector [14, 31].

CONCLUSION

Medical device industry becomes progressive in last five years due to their innovation and advancements in medical technologies. Stringent regulatory procedures of authorities provide quality to their customers and consumers. Medical device manufacturers are keep on enhancing their standards by overcoming the challenges of the medical device industry. This article helps the readers to find knowledge about the medical device industry including various markets e.g. US, Europe, China and India. It tells about the growth drivers and threats of this industry globally.

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REFERENCES

 Monika T, Geeta A, Harvinder P, Madhu A. Regulatory aspects of medical devices in India. International journal of drug delivery.2017;9(2):18-27

- 2. Sandeep G. Medical device regulations: a current perspective. J young pharm.2016;8(1):6-11
- The value of medical innovation: an overview, available from http://hinj.org/value-of-medicalinnovation/
- MD Regulations, available from http://www.who.int/medical_devices/publications/e n/md_regulations.pdf
- 5. Pharmaceutical regulatory agencies and organizations around the world: scope and challenges in drug development, available from https://www.pharmatutor.org/articles/pharmaceutic al-regulatory-agencies-and-organizations-around-world-scope-challenges-in-drug-development
- Nadimpalli R, Veeranna B, Teggina K, Valluru R. Regulatory guidelines for medical devices in India: an overview. Asian journal of pharmaceutics.2012; 10-17
- Anuja S, R. G. Current status of the regulations for medical devices. Indian j. Pharm. Sci.2008; 70 (6): 695-700
- 8. Medical devices in home health care, available from https://www.nap.edu/read/12927/chapter/11
- 9. Software design for medical devices global 2018 available from https://sdmdglobal.iqpc.co.uk/
- 10. Healthcare industry in India available from https://www.ibef.org/industry/healthcare-india.aspx
- 11. A must-read overview of the medical device industry available from https://marketrealist.com/2015/11/must-readoverview-medical-device-industry
- 12. Medical devices are the quiet growth sector available from https://seekingalpha.com/article/4108542-medicaldevices-quiet-growth-sector
- 13. 13. The medical device industry in India the evolving landscape available from https://www.advamed.org/sites/default/files/resourc e/medical_industry_in_india_-__the_evolving_landscape_oppurtunities_and_chall enges_white_paper.pdf
- 14. Sector survey: medical devices available fromhttp://www.makeinindia.com/article/-/v/sector-survey-medical-devices
- 15. Healthcare available from https://www.ibef.org/download/healthcare-April-2018.pdf
- 16. Global medical device market 2018 with forecasts to 2023 - driven by healthcare expenditure / technological development / aging population / chronic diseases available from https://www.prnewswire.com/newsreleases/global-medical-device-market-2018-withforecasts-to-2023---driven-by-healthcareexpenditure--technological-development--agingpopulation--chronic-diseases-300634442.html
- 17. In- vitro diagnostics market available from https://www.alliedmarketresearch.com/ivd-in-vitro-diagnostics-market

- 18. Global medical device industry overview available from https://www.ihealthcareanalyst.com/globalmedical-device-industry-overview/
- 19. Global medical device industry outlook Available from https://www.emergobyul.com/tags/2017global-medical-device-industry-outlook
- 20. The growing importance of quality in the medical device industry available from https://www.phaidoninternational.com/industryinsi ghts/the-growing-importance-of-quality-in-the-medical-device-industry-87415204022
- 21. Medical devices sectoral overview, available from http://galwaydashboard.ie/publications/medical-sector.pdf
- 22. The European medical technology industry available from http://www.medtecheurope.org/sites/default/files/re source_items/files/medtech_factfigures_online3.pd f
- 23. 23. China medical device market outlook available from https://chinameddevice.com/2018-chinamedical-device-market-outlook/
- 24. 24. The medical device market in China available from http://ccilc.pt/wpcontent/uploads/2017/07/eu_sme_centre_report_-_the_medical_devices_market_in_china_may_201 5.pdf
- 25. Despite low-cost talent pool India not leveraging R&D available from http://www.rediff.com/business/report/despite-lowcost-talent-pool-India-not-leveragingrd/20170412.htm
- 26. 26. Medical device industry strengths, weaknesses. Opportunities and threats available from https://www.mddionline.com/us-medicaldevice-industry-strengths-weaknessesopportunities-and-threats
- 27. swot analysis threats definition examples available from http://pestleanalysis.com/swot-analysisthreats-definition-examples/
- 28. The medical device industry in India, available from

http://www.skpgroup.com/data/resource/skp_the_ medical_device_industry_in_india_.pdf assessed

- 29. Top 10 most successful medical device companies, available on https://www.healthcareglobal.com/top10/top-10most-successful-medical-device-companies
- Connected medical devices apps leading IOT revolution, available from https://www.wired.com/insights/2014/06/connected -medical-devices-apps-leading-iot-revolution-viceversa/
- Impact of GST on healthcare sector, available from https://health.economictimes.indiatimes.com/news/ industry/impact-of-gst-on-healthcaresector/59828660.