

Evolution of Indian Pharmaceutical Industry – Overview

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Abstract

The Indian Pharmaceutical Industry has witnessed many twirls and swirls in last three to four decades. It is one of the most efficient industry in India it provides employment and health care to the nation. The paper mainly concentrates on the evolution of the industry, its growth and recent trends. The Pharmaceutical Industry of India is one of the world's major and most advanced country, ranking fourth in terms of volume and thirteenth in terms of value. The government of India in its Pharma Vision 2020 aspires to make India a foremost hub for end-to-end drug discovery. The Union Budget has also Increased its allotment to the Ministry of Health and Family Welfare by 11.5 per cent to Rs 52,800 crore (US\$ 8.16 billion). The Indian Pharmaceutical Industry is divided into three major revenue sectors, Over The Counter medicines, Patented drugs and generic drugs. Their share in the revenue is 9%, 21% and 70% respectively. The generic drugs are the key source of earnings which is anticipated to stretch to US\$ 27.9 billion by 2020.

Key Words: Evolution, growth, trends, generic drug.

1. Introduction

Pharmaceutical industry over the years has resulted to one of the most unique industry as it serves the society to the core, it not only provides employment but it also saves millions of lives with its medicines and vaccinations. Pharm. Industry has been marked as most innovative industry in the past and present for the world development. India is the world's fastest growing economy with its second largest population in the world makes India a thrust for the development of the Indian Pharmaceutical sector. India today has a unique demographic advantage and disadvantage at the same time, owing to its tremendously large population. India is home to around 1.3 billion people or about 1/7th of the world's population. The advantage remains that such a huge population makes us a very large and attractive market, not to mention that population is young, or we may not be wrong in stating it as the youngest in the world. The disadvantage certainly is that the per capita necessary medication is also very high owing to the challenging economic conditions that exist. Indian

Pharmaceutical Industry has travelled an elongated journey from mere recognition to world's third-largest pharmaceutical marketplace internationally in terms of size and thirteen largest in terms of its worth. The industry also plays a vital role in socio-demographic-economic wellbeing of the country. The 'UN Millennium Development Goals' has identified pharmaceutical industry as an economic contributor as it amongst of the most advanced and capital-intensive industry. It is observed as the key industry in any economy due of the health related products it produces, it plays a fundamental role in treating the agony of ailing people. It is also a noteworthy benefactor in empowering economy by generating jobs for masses and adding in earnings of foreign exchange by its growing exports.

2. Review of Literature

(Akhtar, 2013) according to the authors research, by end of 2008 the capital investment in Indian Pharmaceutical industry is of about US\$4.1 billion. It produced bulk drugs of value of US\$3.5 billion and formulations worth US\$15.4 billion. Bulk drugs have grown at a rate of approximately 14%, and formulation by 24% when compared to its nineties. The pharmaceutical companies have enlarged their interest and investment in the field of Research and Development (R&D). It is also a provider of employment to 29 million people. The contribution of pharmaceutical sector in India's GDP is 2% and 12% of manufacturing sector GDP. (EXIM BANK, 2015) The formulation and bulk drugs act as catalyst in the growth of the industry in national as well as in global market. The formulation segment and bulk drug segment can further be categorized into domestic and export consumption. It is examined that from the account of total production only 40-50% of the formulation is used domestically and rest all is exported. The formulation drugs can be sold by two ways either by the contract of supplies or directly to the retailers. Where as in the case of bulk drugs only 10-20% of the total production is consumed domestically and rest all is exported. In order to sell bulk drugs there can be a supply contracts in case of patent drugs or can be sold out rightly in case of expired patents. The total contribution of exports recorded in 2013-14 was dominated by the by both drug formulations and bulk drugs. (Umesh Chandra, 2016) The Indian Manufactures have also been recognized as global manufacturing hub due to the accessibility of huge human resource of scientist and professionals, for the contract research and manufacturing services (CRAMS) and outsourced clinical research. The global market for CRAMS recorded was USD 3.8 billion in 2012 and was projected to raise to an probable growth of USD 8 billion by the year 2015. (PHARMACEUTICALS, 2017) The report by Make in India highlights that the government's thrust towards manufacturing has led to increase in exports of the pharmaceutical industry by 9.7 percent. This increase in turn has

lead to record growth of 15.1 percent in pharmaceutical sales, in the financial year (FY) 2014-15 to 2015-16. India contributes to 20 percent of the global exports volume and is a world leader in supply of economic generic medicines.

3. Objective of the study

The objective of the study is to investigate the progression of the pharmaceutical industry of India. The purpose is moreover to understand its recent growth and trends. The study will also help in to identify the areas of potential growth for the industry in the near future.

4. Brief History of Pharmaceutical Industry

The Indian Pharmaceutical industrial development can be categorized into four eras pre 1970, 1970-1990, 1990-2005, 2005 till date.

Pre 1970: Pharmaceutical industry in its early history mainly consisted of Ayurvedic medicines and therapies. It was the British rule which introduced the industry of allopathic medicines in India. The size of the industry in this remained smaller due to very less number of Indian firms which downsized the volume of the industry. This era was mainly dominated by the Multi National Companies (MNC's) as it was governed by the Patent Act 1911, which prevented both process and product patent for 16 years which further can be extended for 10 years. Thus it was illegal for the indigenous firms to manufacture the patented drugs.

1970-1990: This era was governed by Indian Patent Act 1970 which encouraged procedure patent and not product patent secured for seven years. It was the golden era for the Indian Pharmaceutical industry as the domestic companies adopted the method of “reverse engineering process” to manufacture drugs without giving any royalty to the patentee. In addition to the Act, release of the Drug Price Control Order gave a very less incentive to MNCs to introduce new drug in India. Several Indian Pharmaceutical companies came into existence, which in turn boosted the development of production infrastructure. The government also came forward to promote exports with various export initiatives.

1990-2005: In 1991 India adopted the policy of globalization, liberalization, and privatization which had impact on almost all the sectors of the country. The liberalized markets encouraged MNC's to enter the domestic market. Many Indian companies entered the foreign countries by launching new operations in their markets. India got recognition as world's major destination for the manufacturing of generic drugs. In the year 1995 India became the founder colleague of World Trade Organization (WTO). According to the norm of WTO, Trade Intellectual Property Right (TRIPS) the government was forced to bring amendments its Patent Act from process patent to product patent. Approval of Patents amendment was

done to the patent act 1970 the year 2005 which was further known as Patent Act 2005, led to the implementation of product patents in India for the period of 20 years. The level of competition raised. The framework of production changed totally. The companies willing to produce any drug, which is patented, before the expiry patent needed to procure license for production by paying heavy fees. As a result, the Indian pharmaceutical companies encountered many changes and shifted their orientation from merely coping drugs with re-processing pattern to research and development. The pharmaceutical market showed phenomenal growth despite of many changes. Reasons for the growth are low cost of labor when compared overseas. India being the hub of technical and management personnel, there was no need for overseas management skills. Local availability of equipment required for manufactured.

Post 2005: Despite of the challenges in the early phases, Indian Pharmaceutical sector proved to be the world class generics industry. It is still being encouraged to focus more on research and development for new molecules which earlier was only on re-processing of generic drugs. The Indian pharmaceutical sector witnessed major investments in 2005-06 which gradually dropped down in the future. Many MNCs turned towards India as their potential market giving rise to the competition to domestic producers. The New Patent Act 2005 boosted the confidence level of global players in India. There were series of regulations which were developed in 2005 apart from the patent act, such as the implementation of value added tax (VAT), shifting of excise duty based levy system to MRP based levy system and schedule M was introduced which was the Drug and Cosmetics Act, instructs about factory premises and materials, plants and equipment's in general and specific needs for the setup. The industry witnessed major changes in the policies such as The National Pharmaceutical Pricing Policy 2012 (NPPP-2012) which aimed to control the pricing of the essential drugs which were not covered under Drug Price Control Order. Such medicines shall have an MRP lower than the ceiling price as notified by the government. Another policy was framed and implemented by the director of food and drugs, New Drug price control Order 2013 which intended to reduce the price of the drugs. The government also allowed 100 percent Foreign Direct Investments (FDI) in the medical industry. During the growth phase, the pharmaceutical companies in order to face the increased competition adopted aggressive marketing strategies for the sale of new molecules such as channel management, Key Account Management (KAM i.e. defines relationship between business and the customers of the business. It is basically personal touch to the sales by appointing sales person to develop everlasting business relationship), and contract sale organization.

5. Trends in production

Even though there is a wide scope in the development of the pharmaceutical industry it is necessary to understand the basic value chain on which the manufacturer stand and have been witnessing growth over the years. Michael Porter explains Value Chain is the whole sequence of actions that generate and construct its worth at each step. The total value of output by the company is equal to the aggregate value of inputs used in the process for achieving the final product. The analysis of the value change of the ultimate formulation is given below.

VALUE CHAIN OF DRUG MANUFACTURERS

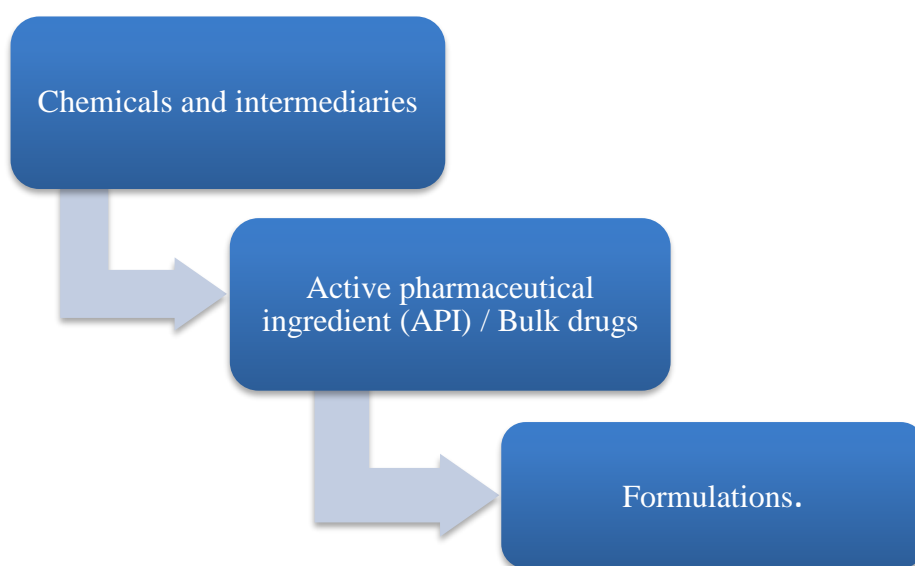


Figure 1(Source: (EXIM BANK, 2015))

Here in order to make the final formulation the manufacturer first of all needs the basic chemicals and intermediaries from which the API or the bulk drug is formed which further can be developed into the final formulation of the drug. From the above mentioned value we can conclude that the manufactures have two different segments of manufacturing opportunities API/Bulk drugs and formulations. The formulation and bulk drugs act as catalyst in the growth of the industry, not only in national market but globally also. The formulation segment and bulk drug segment can further be categorized into domestic and export consumption. It is examined that from the account of total production only 40-50% of the formulation is used domestically and rest all is exported. The formulation drugs can be sold by two ways either by the contract of supplies or directly to the retailers. Where as in the case of bulk drugs only 10-20% of the total production is consumed domestically and rest all is exported. In order to sell bulk drugs there can be a supply contracts in case of patent drugs or can be sold out rightly in case of expired patents. India was identified as the third largest

supplier of generic API in 2016, with the market share of 7.2 per cent. India is the chief exporter of formulations in terms of size, it has a market share of 14 per cent. As a results it has emerged as a remarkable exporter standing on the 12th position in terms of export worth globally. In the year April 2017 to February 2018 the export of Drug formulation from India has moved to US\$ 11.61 billion. It has also shown a remarkable growth in the countrywide market size to US\$ 11.2 billion currently.

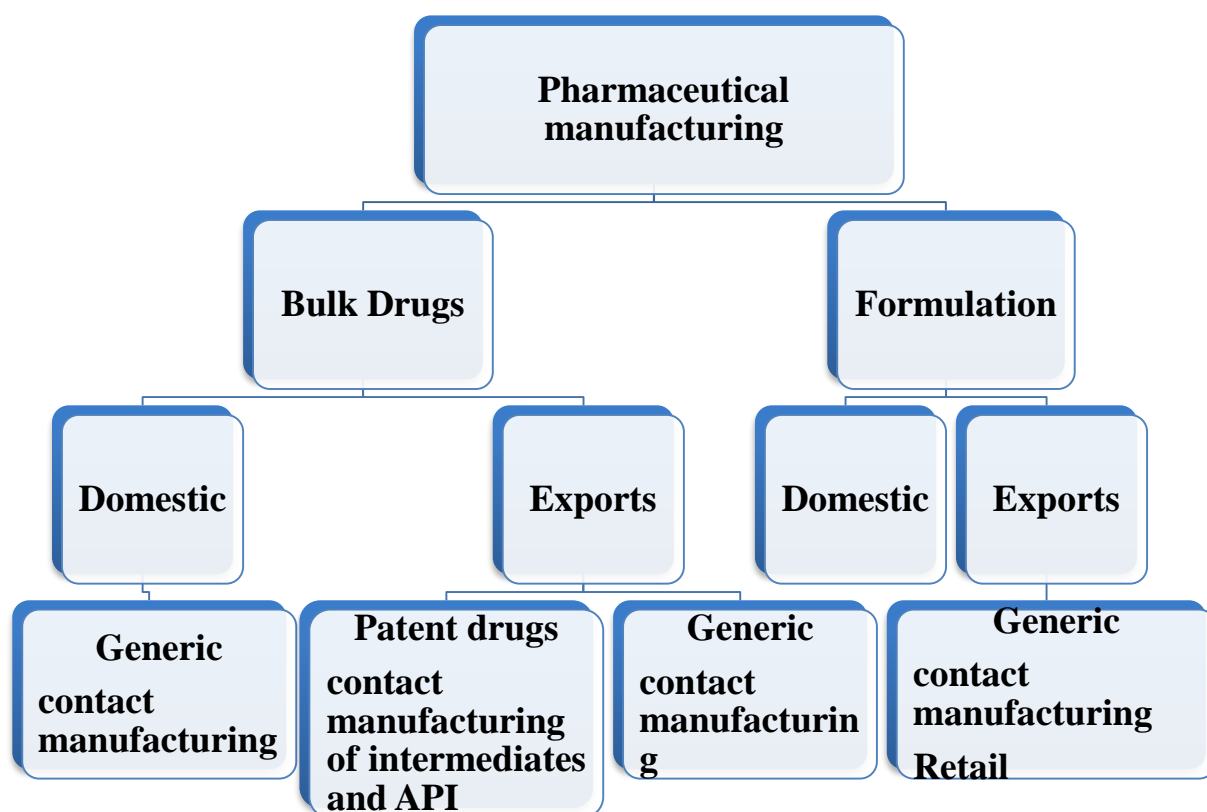


Figure 2: Manufacturing by Indian Pharmaceutical Players (Source: (EXIM BANK, 2015)

(Indian equity brand foundation, 2016) According to the new revenue data of 2015 generic drug yield 70% of the total revenue resulting as the largest segment of the Indian Pharma market when compared to other segments, Over the Counter (OTC) with total revenue of 9% and patent drugs 21%. Around 20% of global generic medicine demand is fulfilled by generic drugs supplied from India and is expected to expand in the near future.

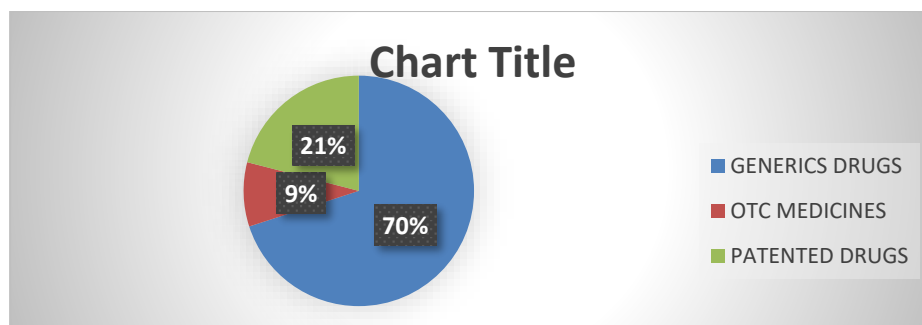


Figure 3:Contribution of revenue by sub-segments of pharmaceutical industry, India in 2015(%)

The Indian companies witness flaw of underdeveloped new molecules due to very less investments in research and development field. Companies like Ranbaxy and Dr. Reddy invest only five to ten percent of their total revenues on Research and Development, lagging far behind the western companies for example Pfizer, who invest an amount equivalent to the sum total of the revenue of entire pharmaceutical industry of India. In the end of year 2017 the expenditure recorded amongst the top pharmaceutical companies showed that the Indian firms have made research and development a major concern to survive with the international competition. The maximum outflow on research and development was done by Sun Pharma, further trailed by Lupin. The total expenditure incurred by Sun Pharma, on research and development was 7.6 per cent of the total sales done by the company in the year 2017, it exhibited the growth of a CAGR of 38.3 per cent from the financial year 2011 to financial year 2017.

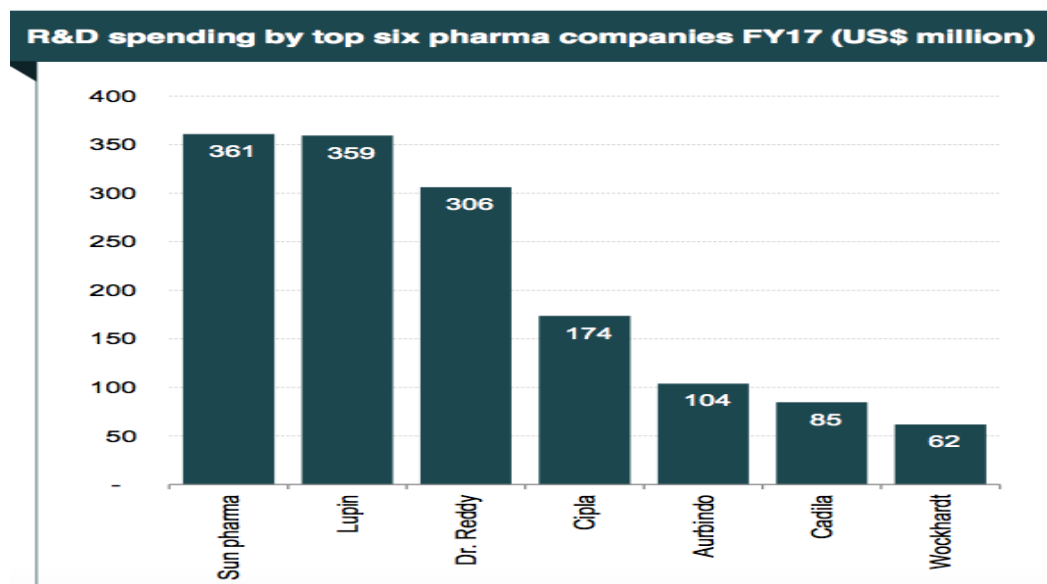


Figure 4 (Source (Indian equity brand foundation, 2016))

The Indian Manufactures have also been recognized as global manufacturing hub due to the accessibility of huge amount of educated human resources like scientists and specialized personnel's for the contract research and manufacturing services (CRAMS) and outsourced clinical research. The global market for CRAMS recorded was USD 3.8 billion in 2012 and was projected a growth of USD 8 billion in the year 2015.

6. GOVERNMENT SUPPORT TO THE INDUSTRY.

The Department of Pharmaceutical (DoP) under the control of Government of India (GOI) has its own foresight for growth of the industry as major focus from end-to-end drug discovery by year 2020. To pave the path for the growth and development GOI have introduced certain policies and incentives. In order to promote domestic drug manufacturing, the government has corrected the duty structure in medical device industry. The customs duty has been brought down to 25% along with full exemption of Special Additional Duty (SAD) on raw material of medical device. In order to boost domestic manufactures, the basic custom duty on certain medical devices has been increased from 5% to 7.5%. Custom and excise duties of HIV/AIDS, TB, Malaria are fully exempted. In order to upgrade technology zero duty to be levied on the imports of capital goods for technological enhancement. 100% FDI is allowed through automatic route of green field pharmaceutical projects. The approval time for new facility and NOC is also reduced to two weeks from 12 weeks. In order to promote generic medicines government has initiated the scheme of "Jan Aushadhi Store" so that the supply of generics is more to the masses when compared to costlier patent medicines. There are around 683 Jan Aushadhi Stores in operations as on Dec 31, 2016. The government has also enlarged its expenditure on health care from USD 14 billion in 2008 to USD 30.4 billion in 2015. The Compound Annual Growth Rate (CAGR) is expected to grow to 18.1 over the year 2008 to 2016.

7. RAISING SHARE OF GOVERNMENT EXPENDITURE.

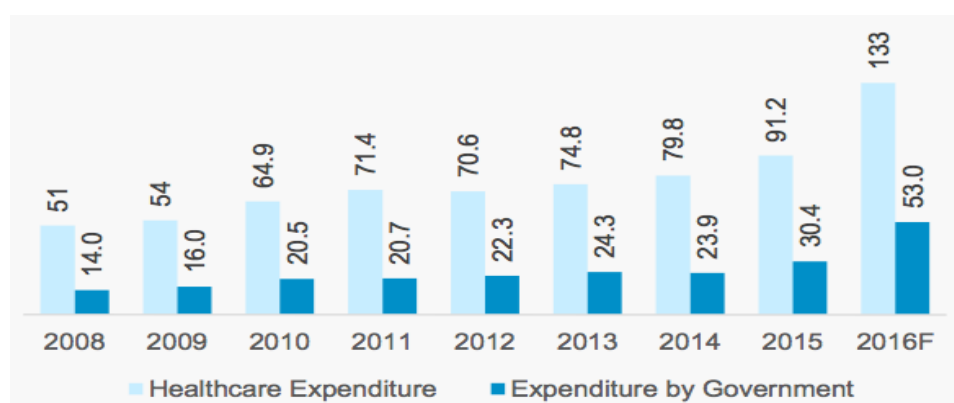


Figure 5 (SOURCE: (Indian equity brand foundation, 2016))

8. Exports of Pharmaceutical Sector

Indian pharma houses are utilizing their resources on export opportunities that are available in structured and semi- structured markets. In the year 2017, the pharmaceutical products exports were recorded worth US\$ 16.8 billion, with an anticipated growth of US\$ 40 billion by the end of financial year 2020. India exported pharmaceutical products of worth Rupees 696.84 billion (US\$ 10.76 billion) during the period of April 2017 to January 2018. The Indian drugs are exported to more than 200 countries across the world, with the United States of America being its key market. India has marked it self as the biggest supplier of generic medicines globally, the export of generic drugs accounts to 20% of total exports of generic drugs across the globe in terms of volume. The American contentment is the top most importer of the Indian pharmaceuticals accounting around 40.6 per cent i.e US\$ 16.8 billion, followed by Europe, Africa, and Asian countries i.e 19.7 percent, 19.1 percent and 18.8 per cent respectively of the total exports of India.

Category	2015-16	2016-17	2017-18
Ayush & Herbal Products	363.99	401.69	455.86
BULK DRUGS AND DRUG INTERMEDIATES	3597.28	3383.52	3539.38
DRUG FORMULATIONS AND BIOLOGICALS	12647.84	12666.44	12908.76
Grand Total	16912.01	16785	17275.8

Source: (India, 2018)

REGIONAL EXPORT OF INDIA'S PHARMACEUTICAL IN \$ MILLION

Region	2014-15	2015-16	2016-17	Change % 2016-17	Contbn% 2016-17
North America	4518	5715	5787	1.25	34.36
Africa	3220	3491	3209	-8.07	19.06
EU	2445	2548	2533	-0.6	15.04

Asean	1056	1030	1088	5.59	6.46
LAC	1077	1035	995	-3.8	5.91

Middle East	825	833	828	-0.57	4.92
South Asia	616	636	723	13.73	4.3
CIS	701	613	633	3.22	3.76
Asia Excluding Middle East	512	512	567	10.82	3.37
Oceania	263	294	297	1	1.76
Other European Countries	140	137	130	-4.79	0.77
Other America	59	64	48	-24.41	0.29
Others	0	4	1	-76.95	0.01
Grand Total	15433	16912	16840	-0.43	100

Source: (India, 2018)

9. CONCLUSION

India Pharmaceutical industry has evolved to over the years and has become a key supplier to world's needs and demand of drugs. It has shown a tremendous growth in the sales per capita of pharmaceuticals in India. The Industry offers sufficient prospects for companies to grow and thrive with international competition, around 120 blockbuster drugs are going off patent over the next eight to ten years giving an edge to the generic drug manufactures to earn a tentative revenue of USD 80 to 250 billion. The recorded sale per capita of pharmaceuticals increased to US\$ 33 in 2016 growth rate of 17.6 per cent CAGR. The generic medicine market has anticipated to grow continuously. The national market is likely to enhance further

to USD 27.9 billion by the end of 2020. The growth of economic wealth in the domestic market and across the world, would enhance the living standard and better health care. It has been witnessed that in the period of 2010 to 2016 the total spending on health care is approximately USD 133 billion in 2016, registering the compounded annual growth rate (CAGR) of 12.70 percent. The Research and Development have also shown potential growth as the top companies have increased their expenditure to encourage R&D. The Contract Research and Manufacturing Services industry (CRAMS) has recorded a phenomenal development of US\$ 19 billion in 2018 with more than 1000 players in the market. The Indian pharmaceutical exports recorded by April 2017 to January 2018 was worth 696.84 billion rupees i.e. USD 10.76 billion. The growth of Exports is also furcated to grow to USD 40 billion by the end of year 2020. The government has also enlarged its expenditure on health care from USD 14 billion in 2008 to USD 30.4 billion in 2015. In order to promote generic medicines government has initiated the scheme of “Jan Aushadhi Store” so that the supply of generics is more to the masses when compared to costlier patent medicines. There are around 683 Jan Aushadhi Stores in operations as on Dec 31, 2016. The Rural India has also become a potential market for future growth.

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