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Pharmaceuticals Export Industry of India: An Overview

One of the fastest growing industries in the world, the pharmaceutical industry is also one of the biggest contributors to the world economy. The major sales of the pharmaceutical products come from the "Triad" (US, EU and Japan) in the world. The size of the world pharmaceutical market in 2014 was around USD 1.2 Trillion and is estimated to be USD 1.4 trillion by 2020. The largest share of pharmaceutical revenues is by far made by the branded and patented medicines. More than any other industry, the pharmaceutical sector is highly dependent on its research and development segment. Pharmaceutical companies worldwide invest 20 per cent or more of their revenues in R&D measures. Brazil, Russia and India put together contribute about 6 per cent of global consumption of medicine.



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India's pharmaceutical industry has been growing at record levels in the recent years but now has remarkable/unprecedented opportunities to expand in a number of fields. Governments worldwide are seeking to curb their escalating prescription drug costs through greater use of generics. These opportunities are presenting themselves not only in India's traditional wealthy client markets such as the US and European Union nations but also in emerging economies with vast populations such as Africa, South America, Asia, and Eastern and Central Europe. According to a study, the domestic Indian pharmaceutical industry is estimated to be USD 26 billion in 2014 growing at nearly 20 per cent and is expected to reach nearly USD 50 billion in 2020.

Pharmaceutical Export: Growth of the Indian industry

With the growth in India's domestic pharmaceutical industry, the country is also rapidly flourishing with respect to pharma export. India has surpassed China in pharma export and is currently the second largest market worldwide in terms of export of medicines and drugs to other economies. According to a study, the country's pharma exports rose 7.55 per cent, from USD 11.66 billion in 2014 to USD 12.54 billion in 2015, whereas China's pharma exports rose 5.3 per cent from USD 6.59 billion to USD 6.94 billion in the same period. The US is the leading consumer of Indian pharmaceutical exported medicines followed by the UK. To contribute to this growth both in value and volume, many of the top 50 domestic Indian pharmaceutical companies export medicines to these countries.

India has always had the advantage of a strong generic pharmaceutical industry which supplies drugs to the world for the cheapest prices. Manufacturing costs in India are approximately 35-40 per cent of those in the US due to low installation and the abundance of generics. The country's growing capabilities in contract manufacturing, R&D and clinical trials also make it a preferred outsourcing

partner for global pharma at every stage of the value chain. According to a study, Indian pharmaceutical exports amounted USD 15.2 billion in 2014-15. US alone accounted for around 28 per cent of total pharma exports from India followed by European Union and Africa.

Challenges Faced by India in Terms of Pharma Export

Most of the challenges in the pharma export industry arise out of the enviable reputation of India as a reliable supplier of generic medicines. Some of the other challenges are; problems faced from the US Food and Drug Administration (USFDA) for non-compliance of regulatory framework, over dependence on some sources for active pharmaceutical ingredients, pricing policies forcing Indian exporters to price their products with extremely low margins, etc. In order to tackle these challenges, Government has been taking many measures such as awareness programme about Indian pharma industry in the key markets and workshops organised with US Food and Drug Administration (USFDA) for Indian drug regulators and the industry.

To ensure traceability and tracking of the drugs manufactured in India, bar-coding for all exports except primary level packaging have been made compulsory.

A study points out that, the influence of physicians in India in terms of prescribing branded medicines and the lack of drug pricing control laws have limited the consumption of non-branded generics in the domestic market, hence the major generic making firms of India target international markets for revenue. India exports more than half of its production of pharmaceutical products and procures raw materials from domestic and foreign sources, with China being the largest exporter of APIs to India. Globally, investments in Research & Development (R&D) is about 15 per cent of sales turnover and the Indian pharmaceutical companies

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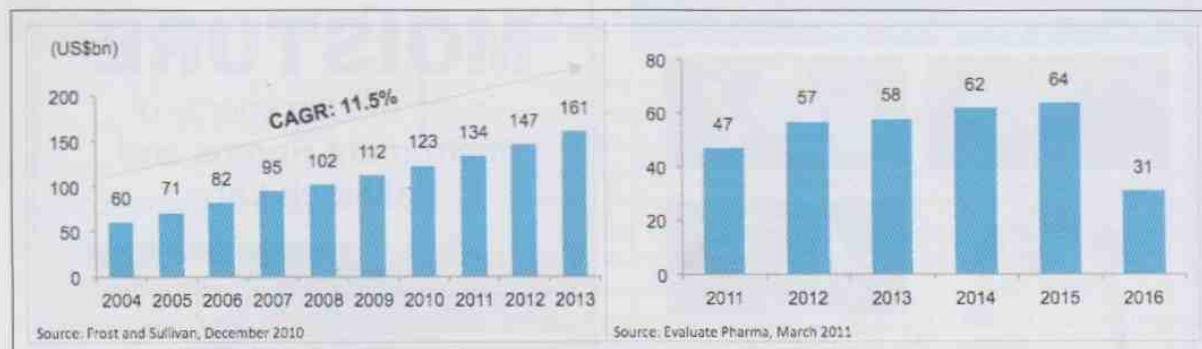


Figure 1: Global Generics Market Size

invested about less than two percent of sales turnover until beginning of the new millennium. Presently, R&D investment in India is about 8-11 percent of total turnover, which is less than the global investment in R&D and it is expected to increase further because of increasing competition in the pharma export industry.

Opportunities

The US and EU markets have been the largest importers of Indian products, but increasing scrutiny in these geographies is threatening export revenues. Hence, as part of risk mitigation strategies, Indian companies need to explore untapped

markets such as South America, Japan, Gulf Cooperation Council (GCC) and Commonwealth of Independent States (CIS) etc. in addition to the US and Europe.

Indian pharmaceutical sector offers a wide range of opportunities for the pharmaceutical companies to establish their units and market their products in India. Supportive regulatory framework and availability of large number of scientists and professionals is an added advantage for the pharmaceutical companies in India. The huge investment in infrastructure and larger domestic market makes India as one of the favorite destinations for pharmaceutical companies.

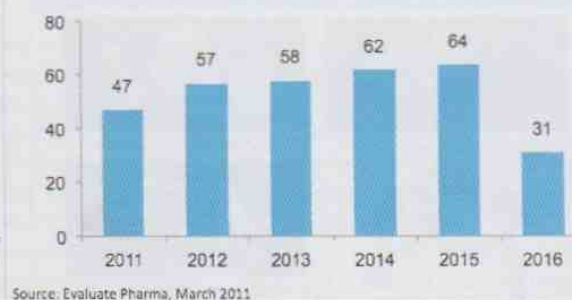


Figure 2: Number of Drugs Going Off-Patent in 2011-16

Pharmaceutical Export Industry: The Government's Role

To promote investments and exports in the pharmaceutical sector, the government has been undertaking several proactive measures. Important reforms have been introduced with respect to FDI norms, setting up pharmaceutical zones and promotion of ease of doing business for pharmaceutical firms. The government is also considering setting up specified pharmaceutical zones to increase domestic production of Active Pharmaceutical Ingredients (APIs), to reduce the country's dependence on China for the raw materials used to produce drugs. Along with this, a huge emphasis is also been put in the packaging of pharmaceutical exports to maintain and preserve the quality of drugs.



Figure 3

A major threat to the India pharmaceutical export industry is the counterfeiting of drugs. The World Health Organisation (WHO) estimates that up to 30 per cent of branded drugs sold in developing nations are counterfeit which can have profound implications for patients. The Organisation of Pharmaceutical Producers of India (OPPI) has spearheaded various initiatives to combat the problem of availability of counterfeit drugs. It has conducted several seminars and has worked closely with the Ministry of Health to develop policies for controlling the production and sale of "spurious" drugs. It has also published a series of anti-counterfeiting guidelines for the industry as a whole. Recognizing the potential for growth, the Government of India took up the initiative of developing the

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Figure 4

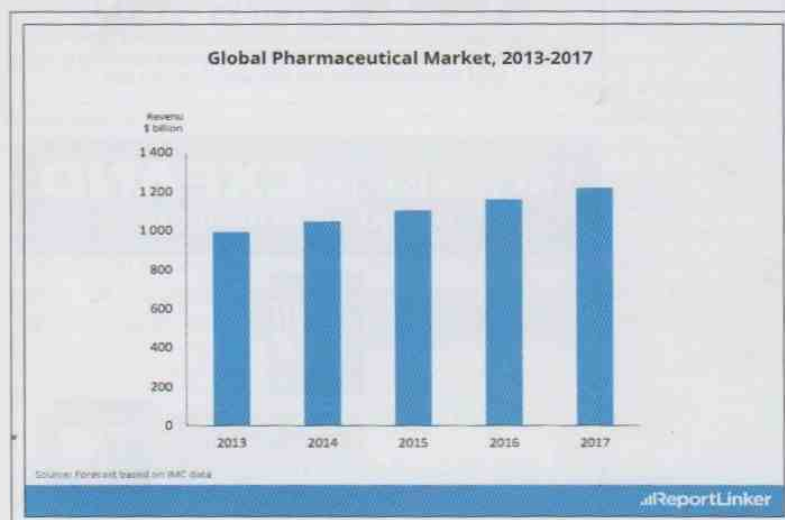


Figure 5

Indian Pharmaceuticals sector by creating a separate department. The department is entrusted with the responsibility of policy, planning, development and regulation of pharmaceutical industries.

Trends in the Indian Pharmaceutical Sector

Focus shift on Research and Development: At the beginning stage of setting up pharmaceutical industry in India, research and development was given a comparatively lesser importance. However, today, with

the rising competition worldwide, R&D has become one of the crucial aspects of Pharmaceutical Sector's growth in India, and it is expected to increase further. Through R&D, the industry will be able to understand the semi and de-regulated markets which form 45 per cent of India's export. A considerable importance is provided on the R&D in the pharma packaging sector as well, in order to meet needs of different markets. India can achieve growth if it uses innovative packaging design and development whilst maintaining a standard by prioritising safety measures.

Export: Due to India's strong presence in the generic market, Indian Pharmaceutical export market is booming at present. Furthermore, Pharmaceuticals Exports Promotion Council is estimated that, export will reach about USD 18.02 billion in 2016.

Joint Venture: The latest trend in the industry is observed as the rising number of joint ventures between foreign countries and India. Many reputed foreign countries are joining hands with Indian companies to develop new drugs, to share best practices and improve their efficiency and reduce operating costs.

Less time for approval: In order to compete with global market, the drug approval process has been simplified and approval time for new plant has been reduced. In the draft Patent (Amendment) Rules 2015, the time period of patent grant has been reduced from 12 months to 4 months.

Government is looking towards small and medium enterprises (SMEs) for revival of exports in India. At present, the SME sector already contributed about 35-40 per cent of the country's exports, and the same is expected to rise further. India, along with Brazil and China has carved a niche for itself by being a top generic player in the pharma market. Major share of Indian pharma exports, going to highly developed western countries bears testimony to not only the excellent quality of Indian pharmaceuticals but also its price competitiveness. More than 15 Per Cent of Indian scientists being present in the U.S is also enhancing better network hence making India one of the largest and leading players in the pharma export industry. Along with the U.S and U.K, the use of Indian pharmaceutical generic drug is also increasing in other nations like Canada, France, Germany, Brazil and Japan. With the continuing growth of the pharmaceutical export industry, India can soon be the largest economy in terms of exporting generic and lifesaving drugs to other countries of needs.

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