

**PHARMA EXPORT: COMFORTS AND CONFRONTS IN INDIA**

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**ABSTRACT**

The objective of this study is to know the comforts and confronts faced by pharma companies in India. It is of case study approach and presented the Indian pharma export advantages, the Government initiatives toward the export market, problems, the recent US trademark legislation issues, and the opportunities in a nutshell. The predicted growth of Indian pharmaceutical market size is US\$ 100 billion by 2025, because of spending habit of the customer on health care and their awareness on health insurance. Indian companies have focused on export prospects in both formal and informal markets globally. This approach has made the pharma industry to achieve US\$ 45 billion by 2020 and aimed to position as sixth largest market among the world. Keeping the high credibility of serving quality products in the complex market, India has gained a strong reputation among the global place.

**Keywords:** Indian pharmaceutical, Pharma export, US trademark legislation, Indian pharma initiatives.

**INTRODUCTION**

India is identified as the one of the emergent pharma markets in the world and has world-class manufacturing and research hub. The availability of skilled workforce and raw materials provides competitive advantage to the firms. The pharma industry in India is predicted to have a net worth of US\$ 26 billion. This growing segment is still expected to achieve US\$ 45 billion by 2020 to positions itself as the leading sixth largest at international level. The country holds the third position in the volume of production and 14<sup>th</sup> in terms of value globally [1]. 40-70% of the Indian produced vaccines are exported to various countries demanded by the World Health Organization [2]. As the generic medicines predominate, the pharma market nearly 70-80%, 20% of the global exports is based on the generic medicines, which creates an opportunity to export generic medicines in various countries [3]. Now, of late, strengthening of these firms is very crucial as the industry is totally disjointed.

The country is highly acquired a significant place in the global market as it has a wide range of applied scientists and engineers mind to keep the industry at different levels. The UN-supported Medicines Patent Pool has approved six sublicenses with Aurobindo, Cipla, Desano, Emcure, Hetero labs and Laurus labs, permitting to make generic anti-AIDS medicine and tenofovir alafenamide for 112 developing countries. Based on the India ratings, a Fitch company, the pharma market is perceived to estimate to nurture at 20% on the basis of compound annual growth rate (CAGR) during the forthcoming 5 years. The annual expected growth rate is 15% per annum from 2015 to 2020, and perceived to grow over 15% per annum between 2015 and 2020, will smash the counterpart pharma industries, which is perceived to mature only at 5% with the same periods [4]. As per the report, Indian pharma facilities registered with the US Food and Drug Administration (USFDA) stood at 523, highest for any country outside the US.

Indian pharma firms are focusing opportunities of Japan's generic market and planning to acquire it based on the policy changes of Japanese government to improve the market share of generic drugs to 60% by 2017 from 30% in 2014, because of the ageing population. To support this, India's biotechnology industry consisting of bio-industry, bio-pharmaceuticals, bio-informatics, bio-agriculture, and bio-services is perceived to reach US\$ 100 billion by 2025 at an annual growth rate of 30%. Within the spectrum, biopharma, comprising diagnostics, vaccines, and therapeutics are the contributory sector by 62% of the total revenues at Rs. 12,600 crore (US\$ 1.9 billion) [5].

**EXPORTS AND ADVANTAGES-INDIA**

India sells abroad to over 200 countries. Pharmaceutical exports reached a CAGR of 10.3% to US\$ 15.5 billion during 2014-15 from US\$ 10.4 billion during 2010-11 [6](Fig.1).

The US market is identified as the largest importer and the growing trend of exports to the UK at 11.9% between 2009 and 2010, 2013 and 2014. Other than the US-India has got more plants approved by USFDA and the registered numbers would be nearly 584. Most of the firms have got a regulatory sign from the Medicines and Healthcare Products Regulatory Agency in the UK; the Medicines Control Council in South Africa; and the Therapeutic Goods Administration in Australia. The manufacturing cost in India is comparatively low (approximately 35-40%) with US [1].

**GOVERNMENT INITIATIVES**

Indian pharmacopoeia commission supported by Ministry of Health and Family Welfare is assumed the responsibility to play a predominant role in improving the quality of medicines that would support the further growth of pharma sector. The Government of India introduced "Pharma Vision 2020" with the vision of promoting India a global leader in drug manufacture. Reduction of government approval for additional facilities, the drug price control order and the National Pharmaceutical Pricing Authority to handle the availability of medicines [5].

**INDIA'S POTENTIAL MARKET**

The Indian Ministry has given the positive sign for the amendment of present foreign direct investment (FDI) policy in the pharmaceutical sector up to 100% for an automatic route for mechanized medical

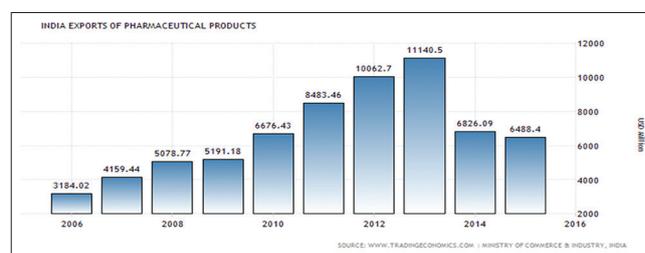


Fig. 1: Exports of pharmaceuticals products-India

devices with specific conditions. As per the report by Department of Industrial Policy and Promotion, the pharmaceuticals sector engrossed collective FDI inflows worth US\$ 13.32 billion from April 2000 to September 2015 [5].

The major changes in the global market with the reason of drying research and development (R&D) pipelines have created a new dawn for Indian pharma players. Although the US and European markets are the target, the regulatory issues are frightening the export revenues and Indian players have to workout new strategies. Along with this, perspective of business is varying rapidly which has made the Indian pharmaceutical companies to go in for their own new business models to operate or they could go for expansion strategy. Focusing on the market with a lever of quality, still certain markets such as Japan, parts of South America, Gulf Cooperation Council, and Commonwealth of Independent States (CIS) remain untapped and could be explored.

India's credibility raises in the area of biotechnology and pharmaceuticals, the CIS nations are opening prospects to make good relations with India. The Pharmaceutical Promotion Council of India (Pharmexcil) is involved in various activities to Flourish exports to the CIS nations. Notably, the council has planned a buyer-seller meets with CIS countries of Russia, Belarus, Moldova and Turkmenistan, and the export reached to Azerbaijan, Armenia, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Uzbekistan and Ukraine. But still export constitutes only 1.2% of the total export annually.

The Russian market is will provide a double-digit growth of 10-11% during 2012-2016. As a whole, the provision of drug insurance system is not present, resulted in high out-of-pocket expenditures of 60-70% of pharma sales. The region is mostly dominated by local pharma chains. Achieving higher export proportion in the CIS nation countries could be possible by customizing services of offering branded generics and over-the-counter drugs at multilevel. Thus, the future penetration of market is possible by innovative products and insurance and focusing on the local retail sales.

India's market in Japan, the second-largest pharma market in the world and difficult to access is only about 1%. However, Lupin's entry in Japan has gained momentum to sprawl the market. India's strategic move to other manageable markets such as South East Asia and Africa is facilitated by collaboration with international agencies and with government involvement [7].

#### CHALLENGING FACES IN EXPORT

In recent days, the USFDA has taken action for non-compliance of a regulatory framework to the Indian pharma industry. Notably, many domestic generic drug makers, including Sun pharma and Wockhardt, have faced the consequences. As the Indian pharma has a considerable proportion in exports, but still it has beset with challenges. The challenges include campaigns to harmful generic products, which are in the purview of violation of India's India intellectual property rights formalities; suspected generic medicines coming out of India, with degraded quality standards; dependence on pharmaceutical raw material ingredients; and its pricing models compelling the exporters to fix the lower margins for their quality products. To ensure the tag of product made in India, bar-coding for all export products other than primary packaging which has made compulsory from July 01, 2015 [8].

#### ROAD AHEAD

Indian social and macro- and micro-economic environment supporting the growth of pharma and act as driving forces for exports. In 2005, it was about only \$6 billion has tremendously grow over a period of 7-year with CAGR of 17%. It is predicted to reach to \$45 billion by 2020. Although few Indian companies are in pessimistic view, even in the most pessimistic scenario, still the sector stands to benefit from various industry specific support factors. In the context of domestic

sales, continued growth in generic medicines, chronic therapies and focused to capture the rural market. The conditions of affordability to buy medicines and the penetration of insurance products in rural were the key driver for the rural market. On account of exports, "patent cliff," the forthcoming expiry of patents worth \$148 billion is likely to make changes in Indian generic companies. Compared with other sectors, the recent happening of rupee depreciation has made a dynamic reflection in pharma as every dollar of sales has got better rupee value.

In the US, the president Obama's health-care plan, Obamacare has made a momentous development as it augments the supply of quality products to the US market. In India, the proposed Foreign Investment Promotion Board pinpointed that "25% of investment must be sanctioned toward R&D activities and if the projects deal with rare facilities and critical verticals, only 49% FDI should be allowed post-government approval." The core prospect of the scheme is that more number of entry of multinationals will affect the availability and the price of off-patent medicines in India because of its patchy nature. Interestingly, 7% of Indian market is hold by the largest domestic market shareholders, while 40% of the market is with top 10 companies. At the same time, the penetration of both large and small players are equally higher (over 99%) in generic medicines. The domestic share of Indian pharma is close to 73% in Indian market and the remaining 27% is vested with foreign players. This statistics clearly pointed that the domestic sale is distributed properly among large and small companies. To keep track of foreign players, India needs to invest in R&D, strengthen the recognized Contract Research and Manufacturing Services, grasp technical advancements and new drug delivery system through collaborative approach [9].

#### RECENT ISSUES IN EXPORT

The European Union (EU) recently made its trademark law more stringent by introducing enforcement measures on goods in transit within its territories. This means that not only will goods with logos similar to the ones registered in the EU countries be disallowed from being sold in the bloc, but such items could also be seized by customs officials at EU ports and airports even if they are meant for a third country. "The new trademark legislation is unwarranted and unfair as the registration of a trademark is territorial and manufacturers in other countries may not have any idea that these exist," the official said. In its meeting with EU officials, the Indian team argued that a pharmaceutical manufacturer in India, selling items in Latin America or Africa, may be inadvertently using a logo similar to a registered trademark in the EU. "It is wrong to seize such items while in transit to other markets on the ground that it violates trademark protection given to a particular item in the transit country," the official said [10].

India also fears that the new law could be an attempt to check its exports of cheap generics (copied versions of off-patent medicines) to markets in Latin America and Africa as large pharma companies, many of them based in the EU, feel threatened by the country's cheap but high-quality medicines. In addition to that, the US has made it compulsory for Active pharmaceutical ingredients (APIs) to be manufactured locally though nearly 80% of the raw material requirement is supplied by China and India. The decision has already sent Indian pharmaceutical exporters into a tizzy, as it will significantly impact Indian drug exports. Before the new norms came into effect, US - based companies were allowed to procure APIs from countries like India and China, make the fixed formulations (final product) in the US and sell the drugs to the US government. Pharmexcil-India's pharmaceutical export promotion council and has approached the Commerce Ministry, requesting authorities to intervene and resolve the issue. The issue comes at a time when Indian API exports have been slowing down.

Commerce Minister Nirmala Sitharaman said, "Pharmaceutical exporters raised concerns on restrictions in the US regarding APIs. India will take up this issue (with the US)." "Sourcing of APIs is done according to the drug master files (DMF) - which means APIs will have

to be registered with the USFDA" said PV Appaji, Director-General, Pharmexcil. "For (US) government purchase of medicines, they (US) prefer local companies. That was alright because many (Indian) companies have subsidiaries in the US now. But having to manufacture APIs in the US will be a difficult requirement to meet for many of these Indian generic drug manufacturers," added Dr. Appaji. The changes in the norms have been made under the DMF - A submission to the USFDA, "made solely at the manufacturers' discretion to provide confidential information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. Now Indian companies may not be allowed to quote for any government based contracts in the US. "Since India is not a signatory to the World Trade Organization's (WTO's) government procurement agreement. However, this change will affect companies which have subsidiaries in the US that procure APIs from their Indian counterparts and make the finished product in the US Further, the decision would impact availability of affordable generics in the United States," said DG Shah, secretary-general, Indian pharmaceutical alliance. "This would seriously impact availability and prices of medicines in the United States. As things stand, nearly 80% of the US requirement for APIs is imported and due to these norms, the US government procurement prices will go up significantly. This will also be a setback for Indian companies that have subsidiaries or holdings in the US [11]." Sources said the government would first try to resolve the trademark legislation issue bilaterally, failing which it would consider approaching the WTO's dispute settlement panel [4].

## CONCLUSION

As the Indian pharma market is perceived to achieve US\$ 100 billion by 2025 determined by spending habit of consumer on health issues, infra facilities and deep roots of health insurance awareness, this predicted growth in domestic sales would also depend on the need arising from consumer side which decides the portfolio of products in curing chronic diseases such as cardiovascular, anti-diabetes, anti-depressants, and anti-cancers that are on the augment state. In addition to this, the robust awareness of health programs, lifesaving drugs and preventive vaccines also promises the future of pharma exports. The intervention of government in regulatory issues and could not restrain the inflow of money which would have a cascading effect and have its impact on the outflow. At present, the sector is at the verge of incremental growth; it should continue to create a win-

win approach to capture and sustain both in the domestic and foreign market [9].

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