

Indian Pharmaceutical Industry: Issues, Challenges and Opportunities

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Abstract—*The pharmaceutical product may be either for diseases and disorders for which there is currently no treatment, or for better ways of treating disorders for which there exist treatments that are very expensive or are intrusive to administer. India is a key supplier of low cost generic version of drugs to developing countries. HIV/AIDS treating drugs also have been supplied by India to economically poor countries like Africa. Pharmaceutical industry in India is one of the most developed industry of the country and third largest in the world. Pharmaceutical industry is an innovative industry, dependent upon investment in research and development. Indian pharmaceutical industry is technologically strong and totally self-reliant. The low cost of manufacturing, and research and development is an advantage that India has along with world class laboratories and innovative scientists that we have. Today, we are making all types of medicines and pharma formulations indigenously from simple pills for the headache to complex cardiac compounds. But this industry face many issues and challenges of industry-specific in important areas like insufficient R&D techniques, clinical research, pre-clinical and clinical studies, manufacturing quality assurance, besides pricing and affordability. Besides this Indian pharmaceutical industry have potential to grow, and assuming leadership position in many therapies and segments in the Indian market as well creating strong international exports strength because of outstanding national laboratories specializing in development of cost effective technologies and process development.*

Keywords: *Pharmaceutical Industry, Drugs, Medicine, Research and Development, Innovation.*

1. INTRODUCTION

The pharmaceutical industry in India has been a glowing example of success over the last four decades. It has shown tremendous progress in terms of infrastructure development, technology base and a wide range of production. Even while undergoing restructuring, it has establishing its presence and determination to flourish in the changing environment.

India is home to about 10,500 drug manufacturing units and more than 3,000 pharma companies. After the USA, India has highest no. of health industry related products filed in the USA. India is known as a major destination for generic drug manufacturing. Now product patents have been introduced in

India, secured MNCs are expected to launch their patented drugs in India too. Across India, there are numerous Special Economic Zones for the pharmaceutical sector including the (JNPC) Jawaharlal Nehru Pharma City in Visakhapatnam, Andhra Pradesh, Zydus Infrastructure's Pharma and Cadila Pharma's Park in Gujarat.¹¹

India enjoys important position in the global pharmaceutical sector. The country also has a large pool of scientists and engineers who have the potential to steer the industry ahead to an even higher level. The UN-backed Medicines Patent Pool has signed six sub-licences with Aurobindo, Cipla, Desano, Emcure, Hetero Labs and Laurus Labs allowing them to make generic anti-AIDS medicine for 112 developing countries. A McKinsey report (2016) projected that the Indian pharmaceutical sector is stated to grow to US\$55 billion by 2020.

2. REVIEW OF LITERATURE

Croix Summer L.A and Ming L.U (2008) investigate the U Shaped association among GDP per capita and country exclusive rights protection for the pharma industry using the Pharmaceutical Intellectual Property Protection (PIPP) Index. They were used the scatter plot and Tobit regression lines to confirm a U shaped association. They found the increasing relationship between GDP and PIPP.

Dilip Shangu, (2016) said that industry must focus on innovation and adopt international practice. India has potential pharmacy hub for the world if we make a few changes in the way we do and manage business in India we accelerate that process. The regulatory frame work must be strengthened and brought on par with international practices.

Lee Yen-Chun and Chou C. James (2016) revealed that, according to recent report by Taiwan's Ministry of Economic Affairs, in the year 2014 Taiwan's medical device market was value about US\$4.1 billion in terms of sales and growing 8.5 per cent in CAGR between 2005 to 2014. This study mainly focus on research method and the obscure decision making

trial and evaluation laboratory method for exploring critical influence factors and investigating their influential relationships. They found that manufacturing excellence and innovation competence are the two major critical influence dispatchers in the cause group, while service quality is the major critical influence receiver in the effect group.

P.V Appaji Director General Pharmexcil (2016) stated that pharmexcil India's pharmaceutical export promotion council has approached the commerce ministry, requesting authority to intervene the issue. The issue comes at a time when API exports have been slowing down. Sourcing of API is done according to the DMF Drugs Master Files which means API will have to be registered with U.S food and Drugs Administration. U.S government purchase of medicine they prefer local companies because many Indian companies have subsidiaries in the U.S now. But manufacture of API in the U.S will be a difficulty to meet for many of these Indian generic drugs manufacturers.

SmetackRajan (2015) examined that under threat, three fourth part of the total production of pharma products is awaiting. Out of which more than 11 are under the contravention, and five patents have been revoked. Additional seven products are involved in pending opposition proceeding, while one patent under compulsory licensing and dozens of other patents are pending without review.

Mathew Jeo C. (2013) discussed that India's manufacturing clout has made it a massive threat to established generics firms. They found that more than 20 per cent of the world's generics drugs producing by Indian pharmaceutical companies, around US\$70 billion value of the drugs are usually go to off patent more the next three years in USA. India has extensive share of the resulting innovative generic marketplace. These Indian pharmaceutical companies have great future in global market.

Mahajan Dinesh (2013) described that Indian known as one of the fundamental target for Foreign Direct Investment (FDI). Pharmaceutical sector have greater than before in the current year has been the great supplier to the FDI inflows and also exporter of the pharmaceutical products. This is possible just because of authoritative hub, huge market size and ease of access of low-cost labour force. But the U.S.A, United kingdom, Mauritius and Singapore dominated Indian Pharmaceutical sector usually.

3. PRESENT STATUS OF INDIAN PHARMACEUTICAL INDUSTRY

The Indian pharmaceutical markets are the third largest in terms of volume and thirteenth largest in terms of value, as a report by Equity Master (2016). Branded generics dominate the pharmaceuticals market, constituting nearly 70 to 80 per cent of the market. India is the largest provider of generic drugs globally with the Indian generic accounting for 20 per cent of global export in terms of volume. Presently the market

seize of the pharmaceutical industry in India stands at US\$20 billion. As on March 2014, Indian pharmaceutical manufacturing facilities registered with the US Food and Drug Administration (FDA) stood at 523, highest for any country outside the US.

In the financial year alone, pharma exports stood at US\$ 15 billion. Similarly, the pharma sector has brought over US\$ 13 billion in FDI in the past 15 years starting 2000. The Indian pharmaceutical industry is today recognized as the 'Pharmacy to the World' as it is one of the lowest-cost producers of essential medicines globally; catering to nearly 30 percent of the demand for generics drugs worldwide (The Hindu. Feb 5, 2016).

According to Indian Ratings a Fitch company the Indian pharmaceutical industry is estimated to grow at 20 per cent compound annual growth rate (CAGR) over the next five years. The Indian pharmaceutical industry which is expected to grow over 15 per cent per annum from 2015 to 2020, this will be better the global pharma industry which is set to grow at an annual rate of 5 per cent between the same periods.

But Indian pharmaceutical industry is likely to witness moderation in growth in the next three years mainly due to decline in revenues from the USA and its largest overseas market and increased competition, according to rating agency ICRA 7.4 per cent growth in aggregate revenue in financial year 2017 as against 10.1 per cent posted in FY 2016 of 21 leading players.

The first reason for decline is slowing growth from the USA, increased competition leading to price erosion, generic adoption reaching saturation levels and regulatory overhang along with base effect catching up. Second one is analysis and consolidation of supply chain in the USA resulting in pricing pressures and increased research and development expenses will also have an impact on profitability. Third reason is continued regulatory interventions will put some pressure in near term though long term growth prospects remain healthy.

4. ROLE OF PHARMACEUTICAL INDUSTRY IN THE INDIAN ECONOMY

Indian pharmaceutical industry meets 70 per cent of the domestic requirement of bulk drugs and almost all the demands for formulations. It may also be pertinent to point out here that although branded pharmaceutical products accounted for nearly two-third of global spending on medicine.

Indian pharmaceutical products earn on average US\$ 3902.05 million from 1996 until 2016 through export. Industry reaching an all-time high of US\$ 11140.50 in 2013 and record low US\$ 672 million in 1996. Export of pharmaceutical products of India decreased US\$ 6488.40 million to US\$ 2086.32 million from 2015 to 2016.¹⁵

Indian pharmaceutical industry currently employed 4,50,000 peoples and has contributed in creating a rich talent in the

form of project managers, researchers, scientist, doctors. The Indian pharmaceutical industry has massive in India's GDP. In the past few years pharmaceutical industry perform well.¹⁶

5. GLOBAL GENERIC MARKET VS INDIAN PHARMA GENERIC DRUG EXPORTS

The Indian pharmaceutical industry has publicized unbelievable escalation in generic drugs markets. The Indian pharmaceutical industry is the mainly important facts-base industry, which has recorded a compound growth rate 19.22 per cent in exports in the last decade (UNTAD, April 2013). India has 17th rank in the World for the export of pharmaceutical products and rank IVth in terms of total pharma market share in the Asia Pacific.¹⁷

Global Drug Market

Table-1

	2012-2013	2016-17	% Growth
Global Pharma Market (in US\$ bn.)	962	1200	24.7%
Global Generic Market (in US\$ bn.)	274	432	57.7%
	2012-2013	2014-2015	% Growth
Indian Pharma Generic Drug Exports (in US\$ bn.)	15	25	66.7%

Source: Business Standard, 06 Jan., 2016.

As evident from table one, the growth rate of Indian pharmaceutical exports far exceed from 2012 to 2015. Global generic drug market growth rate is 57 per cent and Indian pharmaceutical generic drug export growth rate is 66.7 per cent. Indian pharmaceutical generic drug export growth rate is much higher than the global generic market.

6. MAJOR ISSUES AND CHALLENGES OF INDIAN PHARMACEUTICAL INDUSTRY

(A) Major Issues of Indian Pharmaceutical Industry

Indian pharmaceutical industry has some major issues, which works as an obstacle in the glowing path of this industry.

Compliance issues and good manufacturing practices has always been a problem for the companies. United States Food and Drug Administration (USFDA) is trying to block the growth of the Indian pharmaceutical companies. The approval of USFDA is important because the largest consumer of pharma products is the USA and India is a major exporter. The opinion of the USFDA is considered to be the standard in the sector as well. The companies are trying to improve their standards and this issue can be solved by having officials who are more stringent and inspections on a regular basis can be done.¹⁹

Intellectual Property Rights (IPRs) in the pharmaceutical has been a contentious issue globally. Previously the IPRs debates were typically between branded pharma companies and generic pharma companies. India was no exception to this IPRs tassel and in view of the large poor population in need of basic healthcare; the Indian authorities were initially not keen on granting substantial IPRs protection. However, over become more sensitised to the need and importance for the long-term good of industry. All the instrument of IPRs patent is the most contentious issue which deliberated in several international forums. Patents are mostly debated for their role in pharmaceutical field. In the US, India's alleged violation of IPRs best practices had become a big issue.¹²

The Indian pharma industry is highly fragmented. The market is overloaded with generic manufacturer's this is problematic because high fragmentation causes instability, volatility and uncertainty. This is not a good sign for the pharma sector. Pharmaceutical companies can review their strategies to survive in a volatile environment. Some of the actions that can be taken by the companies are they can periodically review their product portfolio and build more customer centric products.

Ethical concern related to the pharmaceutical industry spanning across clinical trials to ethical industry spanning across clinical trials to ethical marketing practices are hugely bothering a large section of the stakeholder's solely for the interest of the patients. New clinical trial were halted after the Indian Ministry of Health and Family Welfare adopted rules that require broader compensation for participants who claim to have been injured due to a clinical trial. India is a major channel for the export of counterfeits to consumers worldwide. Anti-counterfeiting enforcement is further undermined by poor interagency coordination and India failure to provide administrative remedies for drug safety violation.¹⁹

The main issue raised by most of the pharma companies is that profits which they earn are basically peanuts and this income is not sufficient enough. The company prospect reform of the government, for the essential medicines has caused them to lower the price of drugs. This has been done by the government for betterment of the public.

(B) Major Challenges of Indian Pharmaceutical Industry

Pharmaceutical industry faces some major challenges, to establish India as a world leader in global pharma industry.

Many international pharmaceutical companies want to invest in India, although due to inappropriate patent system, cost rule and unyielding manual labour laws, they don't spend their money in R&D.

As promising as the future is far a whole, the outlook for Small and Medium Enterprises (SMS) is not as bright. The excise structure changed so that companies now have to pay a 16 per cent tax on the maximum retail price (MRP) of their products. Consequently, larger companies are cutting back on

outsourcing and what business is left is shifting to companies with facilities in the four tax-free states. They are Himachal Pradesh, Jammu & Kashmir, Uttaranchal and Jharkhand. Consequently a large number of pharmaceutical manufacturers shifting their plant to these states, as it become almost impossible to continue operating in non-tax free zones.¹⁰

Even after the increased investment, market leaders such as Ranbaxy and Dr. Reddy's laboratories spent only 5-10 per cent of their revenue on R&D, lagging behind Western pharmaceuticals like Pfizer, whose research budget last year was greater than the combined revenues of the entire Indian pharmaceutical industry. This disparity is too great to be explained by cost differentials, and it comes when advances in genomics have made research equipment more expensive than ever.⁴

Due to disconnect between curriculum and industry, Indian pharma sector also lack the academic collaboration that is crucial to drug development in the West and so far.

India is a major market for pharmaceutical companies with population of 1.2 billion yet the country and impressive export turnover of US\$ 10 billion spread over 200 countries. Indian pharmaceutical products export increase day by day but still Indian pharmaceutical sector depends on China. India's imported APIs worth is US\$ 3.9 billion in 2014-2015. The Indian government want to reduce dependence on China (Economic Times, 16 Nov, 2015).

7. MAJOR OPPORTUNITIES IN INDIAN PHARMACEUTICAL INDUSTRY

Indian pharmaceutical industry has many opportunities which makes stronger contender in the global market.

Indian pharmaceutical industry acting's a critical task for wellbeing state. Indian pharmaceutical industry has faster growth rate than any other industry, after the IT industry it has fastest growing industry. The Indian pharmaceutical company has specialization in generic drugs. India is the major manufacture of generic drugs in global market.

Taking into account India's status as a developing country, India was granted a transition period of ten years from 1995 to 2005 to switch over from process patent to product patent. With this shift, it was very important for Indian pharmaceutical companies to embrace product patents.

On one hand, the implementation of TRIPS put restrictions on Indian pharmaceutical industry in terms of producing generic drugs, it opened up opportunities for the industry in terms of investment in R&D of new molecules. Many Indian pharmaceutical companies viewed patent system with a positive attitude and started gearing up for the same. It is in the recent years that Indian companies started charting their growth path. Some big companies on the one hand are involved in the basic research while on the other hand they manufacture generic versions of off patent molecules. Indian

pharmaceuticals gained it footholds on the international pharmaceutical market, through its generic drugs and API. Now it is a major participant in subcontract clinical research, like the agreement manufacturing and research in pharma sector.¹⁴

According to Economics Times, India is the third largest global pharma producer has near ten thousand drugs units with less than a sixth of them mostly exporters companies. India currently exports over 94,000 crore worth of medicines and more than two-thirds of the products go to various member countries. India has evolved into a worldwide exporter of high-quality generic drugs. India is also a leading supplier of AIDS drugs to the world. Some of the countries that import medicines from India include Germany, Russia, France, U.K, Brazil, Indonesia and U.S.A.

Indian government is quite productive in boosting growth of the industry. For most of the drugs and pharmaceutical products approved by the Drug Control Authority, manufacturers do not require industrial licenses. The government also allows 100 percent FDI in the sector, under the automatic route.

It is believed that India has an advantage of low drug manufacturing costs. Drugs costs here are about 35-40 per cent less than those in the USA. In the last decade, a pharmaceutical export has grown to the compound annual growth rate (CAGR) of 68 per cent. According to a report by the Indian Brand Equity (2016) revealed that India's cost of production is significantly lower than that of the US and almost half of that Europe. It will give a competitive circumference to India over others.

8. SUGGESTIONS FOR THE BETTER GROWTH OF INDIAN PHARMACEUTICAL INDUSTRY

India has potential pharmacy for the world. If we make few changes in the way of Indian pharmaceutical industry, we can accelerate the growth process of this industry.

Fragmented Indian pharma market is facing high volatility and uncertainty. Increasing number of drugs in National list of Essential Medicines (NLEM) and price controls, changing FDI policy, compulsory licensing aggressive acquisition investment by MNCs and declining global generic market opportunity is creating a new normal.

Pharma companies need to revisit their traditional growth strategies to succeed in a volatile world. Currently, India exports drugs to more than 200 countries and vaccines and biopharmaceutical products to about 151 countries (Business standard 2014). Indian pharmaceutical industry is fairly fragmented with top 10 companies contributing to 41 per cent of the total sales.⁵

The pricing mechanism would impact earnings of companies. The pharma companies depend on Indian market, premium pricing approach. The impact of pricing policy would not be substantial on companies that have sizeable share of earning

from regulated market, especially US generics. Therefore, it will be vital for companies to retake at its geographic spread and to renew their portfolios by focusing on, therapeutic class synergies, increasing shares of prescription, adding innovative and better margin products.

Companies will need to revisit their operation to ensure that no complacency has set in. The legacy process might be driving up costs due to outdated technologies or high environmental factors. Companies will need to focus on process innovations by adopting latest technologies such as micro reactors or critically evaluating and reducing the number of process steps.

Companies need to look for inorganic value creation and set to market opportunities. Alliance could help in deeper customer and market penetration with value creation happening in many forms such as co-production to reduce compliance costs, co-marketing through use of common marketing channels and co-promotion to reduce advertisement and promotion costs.

It also help full to companies to capitalise on licensing opportunities presented by international pharmaceutical players as they increasingly invest in emerging economies. M&A activities highlight the consolidation trend in the industry.

The Indian laws should support the development of clinical trial services, which it, until recent, has not encouraged. As compared to western countries, India has an abundance of people, who have never been treated for their ailments, along with abundance of physician, investigators and support staff to conduct trials and also cost of conducting clinical trials is much lower than US or Europe. So, India can become a generator of new intellectual property and more business may move to India, especially in pre-clinical and clinical area.¹³

Collaboration between pharmaceutical forms and universities should be encouraged to inculcate research attitude and efficiency in the young researchers.

The private sector should come up with models that can render an acceptable level of quality and wholesome healthcare to the masses at affordable prices.

This is herculean task, but possible. We must get into development of new molecules and have new drugs discovery which is currently lacking. We should reach this level if we concentrate on states where growth is less, we should be able to achieve the infrastructure requirement of the pharmaceuticals industry.

9. CONCLUSION

India was dependent on other countries in 1970's for its pharmaceuticals requirements and in 20 years Indian pharmaceutical industry become self sufficient to meet its own requirements. India has now become superpower as far as generic drugs are concerned. India can become a US\$ 300 billion industry including medical devices by 2030 according

to a FICCI Report. Indian pharmaceutical industry has potential to grow up as hub for the world but they companies false. Indian pharmaceutical companies will inevitably be affected by turbulent conditions now confronting the global industry. In such an increasingly competitive and rapidly changing environment companies need a strategic approach that enables them to respond to current challenges as well as future uncertainties.

REFERENCES

- [1] Andrade Maria A. (2009). *``Critical Factors for the Successful Management of Projects in the Pharmaceutical sector of Puerto Rico``*. Quiles Torres. Francisco. D.B.A. Universidad delTuraboo 2009. 239, ISBN: 978-1-109-19290-2.
- [2] ASSOCHAM (2011). *``Report on Pharmaceutical Industry of India``*. Business India. March 30-April 12, 2011.
- [3] Bhagwat Y & De Bruin M (2011). *``R&D and Advertising Efficiencies in the Pharmaceutical Industry``*. International Journal of Applied Economics. 8(1). 55-56.
- [4] Balasubramanian J. et al (2015). *``Product life Management: A Challenge in Pharmaceutical Industry``*. International Journal of Pharmaceutical Research Scholar (IJPRS). Vol.4. 2015. ISSN No. 2277-7873.
- [5] ChitravanshiRuchika (2015). *``Indian Rejects Lee Pharma's Compulsory Licence Plea``*. Economics Times. 18 August 2015. 5.
- [6] Divya and Rajagopal (2015). *``Whistle Blowers Ensuring Pharma COS' Compliance``*. Economics Times. New Delhi. Thursday, 4 June 2015. 8.
- [7] Grabowski Henry (2011). *``The Evolution of the Pharmaceutical Industry Over the Past 50 Years: A Personal Reflection``*. International Journal of the Economics of Business. July 2011. Vol.18. No.2. 161-176.
- [8] Higgins Brain Wm and Lessler Jay P. (2012). *``The Weakening of Pharmaceutical Method Patent: The federal Circuit Addresses the FDA Conundrum``*. Journal of Intellectual Property Rights. Vol.19. CSIR New Delhi. 89.
- [9] Lee Yen-Chun and Chou C. James (2016). *``Influence factor Analysis of Medical Manufacturing Industry``*. Journal of Scientific & Industrial Research. Vol.75. December 2016. 709-712.
- [10] Maki Umomura (2011). *``A Second tier Performance: Reflection on Japan's Pharmaceutical Industry. 1945-2005``*. Japan Forum Volume. Vol. 23. 207-233.
- [11] Mukherjee Rupali (2015). *``Lupin Buy's US Generics Company for \$ 880 million``*. Times of India. New Delhi/Agra. Saturday, July 25, 2015. 15.
- [12] Nair GupakumarG. And FerhadesAndreya (2014). *``India's Options for Improving Affordable Access to Life Saving Patented Medicine``*. Journal of Intellectual Property Rights. Vol. 19. January 2014. 79.
- [13] Narasimhan P. (2015). *``Generics to Double in Five Years``*. The Hindu. 12 September 2015. 16.
- [14] NarsanaBhavik and MukerjeeArijeet (2015). *``Issues and trends in the Indian Pharma Industry``*. Express Pharma, February 2015.
- [15] N.A (2016). *``Employment Trends in India``*. Retrieved on June 16, 2017. From <http://Tradingeconomics.com/india/exports-of-pharmaceutical-products>.
- [16] N.A (2017). *``Indian Pharma Sector growth to moderate in next three year``* The Indian Express. Tuesday, July 04, 2017.13.

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- [17] Pant Rashmi (2016). ``*Indian Pharmaceutical Export: The Growth Story*``. Business Standard. January 06, 2016.
- [18] Summner L.A Crooix and Ming Liu (2008). ``*Relationship between GDP Per Capita and Country Patent Protection*``. Retrieved April 2016. From http://socialsciencespeople.hawaii.edu/publications_lib/ARTICALE%20pdf1.pdf.
- [19] Sharma Cheshta (2015). ``*Five Challenges Faced by the Pharma Industry*``. Indian Institute of Patent and Trade Mark Attorney. Retrieved on March 2016. from www.iipt.com
- [20] Shah Sneha(2015). ``*Promoters Expect up to \$ 1.2 B from Sale of Gland Pharma*``. Economics Times. 20 August 2015. 8.
- [21] TyagiShilpi andMahajanat.al (2014). ``*Innovations in Indian Drugs and Pharmaceutical Industry: Have they Impacted Export?*`` Journal of intellectual Property Rights. Vol. 19. July 2014. 243-252.