

SWOT ANALYSIS OF INDIAN PHARMACEUTICAL INDUSTRY

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ABSTRACT

The global pharmaceutical market is undergoing rapid transformation. There has been a dramatic shift towards emerging markets as western markets slow down. Global Pharma multinational corporations are looking at new growth drivers such as the Indian domestic market to capitalise on the growing opportunity. The huge potential of the Indian pharmaceutical industry is impossible for global Pharma companies to ignore, given that India will be one of the top 10 sales markets in the world by 2020. Some of the largest Pharma companies in the world have been in the Indian market since the 1970s, and 5 out of the top 10 domestic Pharma companies are already foreign owned, with a consolidated share of 22 – 23%. India's domestic pharmaceutical market has recorded a CAGR of 13.5% over the past five years.(5) With considerable expertise in manufacturing of generics and vaccines, Indian companies have now also started significant research and development (R&D). The Indian economy is growing strongly and healthcare is expanding to meet the needs of a growing population with a changing disease profile. Increase in insurance coverage, aggressive market creation, growth in the income of the Indian population and steady government investment into medical infrastructure has further propelled the growth of the industry, such that it is on the threshold of becoming a competitor of global Pharma companies in some key areas, and a potential partner in others.

KEYWORDS: FDI in Pharma, generic drugs, export and import in pharma, SWOT analysis, pharma industry concentration.

INTRODUCTION

The Indian pharmaceutical industry ranks among the top five countries by volume (production) and accounts for about 10% of global production. The industry's turnover has grown from a mere US\$ 0.3 bn in 1980 to about US\$ 21.73 bn in 2009-10. Low cost of skilled manpower and innovation are some of the main factors supporting this growth. According to the Department of Pharmaceuticals, the Indian pharmaceutical industry employs about 340,000 people and an estimated 400,000 doctors and 300,000 chemists.

The Indian pharmaceutical industry is fragmented with more than 10,000 manufacturers in the organised and unorganised

segments. The products manufactured by the Indian pharmaceutical industry can be broadly classified into bulk drugs (active pharmaceutical ingredients - API) and formulations. Of the total number of pharmaceutical manufacturers, about 77% produce formulations, while the remaining 23% manufacture bulk drugs. Bulk drug is an active constituent with medicinal properties, which acts as basic raw material for formulations. Formulations are specific dosage forms of a bulk drug or a combination of bulk drugs. Drugs are sold as syrups, injections, tablets and capsules.

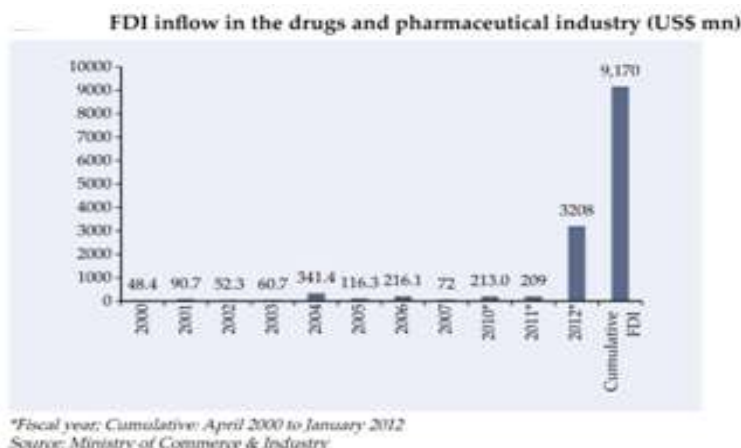
Based on the pharmaceutical customer base, the Indian API manufacturing segment can be divided into two sectors – innovative or branded and generic or unbranded. In 2009, the global generic drug market was estimated to be US\$ 84 bn, of which the US accounted for 42%. India's generic drug industry is estimated to be US\$ 19 bn and it ranks third globally, contributing about 10% to global pharmaceutical production.

Pharmaceutical manufacturing units are largely concentrated in Maharashtra and Gujarat. These states account for about 45% of the total number of pharmaceutical manufacturing units in India.



I. Investment In The Indian Pharmaceutical Industry

100% foreign direct investment (FDI) is allowed under automatic route in the drugs and pharmaceuticals sector, including those involving use of recombinant technology. Also, FDI up to 100% is permitted for brownfield investments (i.e. investments in existing companies), in the pharmaceuticals sector, under the Government approval route. The drugs and pharmaceuticals industry attracted foreign direct investment to the tune of US\$ 9.17 bn for the period between April 2000 and January 2012.



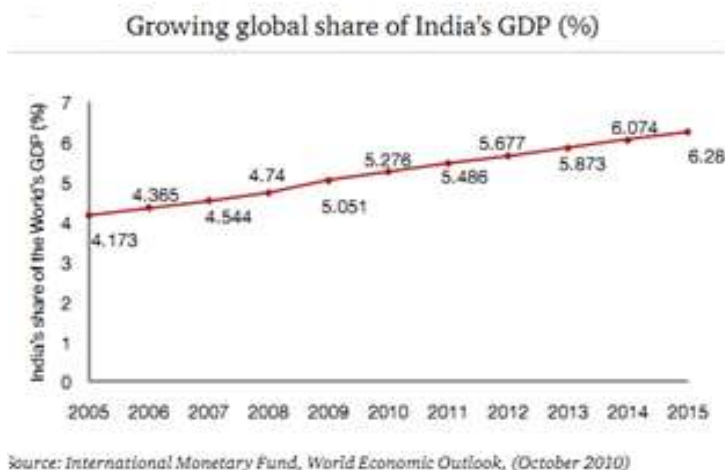
The Indian pharmaceutical industry enjoys certain advantages, which attracts FDI in the country:

- 1) low cost of innovation and capital expenditure (to operate good manufacturing practices-compliant facilities) which provides leverage in pricing of drugs
- 2) transparency in the regulatory framework
- 3) proven track record in bulk drug and formulation patents
- 4) strong domestic support in production, from raw material requirements to finished goods
- 5) India emerging as a hub for contract research, bio-technology, clinical research and clinical data management.

II. Factors Influencing Growth Of The Industry

The Indian pharmaceutical industry ranks 14th in the world by value of pharmaceutical products. With a well-established domestic manufacturing base and low-cost skilled manpower, India is emerging as a global hub for pharma products and the industry continues to be on a growth trajectory. Moreover, India is significantly ahead in providing chemistry services such as analogue preparation, analytical chemistry and structural drug design, which will provide it ample scope in contract research and other emerging segments in the pharmaceutical industry. Some of the major factors that would drive growth in the industry are as follows:

1. **The Growing Indian Economy:** The Indian economy is growing fast, and is valued at US\$1.430 trillion in 2010. GDP growth, calculated on a Purchasing Power Parity basis has reached 9.66% in the year 2010, and the International Monetary Fund (IMF) expects it to remain consistently above 8% till 2015. Furthermore, India’s share in the world GDP has been steadily increasing, and is expected to reach 6.28% in 2015, up from 4.17% in 2005.



2. **Increase in domestic demand:** More than half of India's population does not have access to advanced medical services, as they usually depend on traditional medicine practices. However, with increase in awareness levels, rising per capita income, change in lifestyle due to urbanisation and increase in literacy levels, demand for advanced medical treatment is expected to rise. Moreover, growth in the middle class population would further influence demand for pharmaceutical products.

3. **Rise in outsourcing activities:** Increase in the outsourcing business to India would also drive growth of the Indian pharmaceutical industry. Some of the factors that are likely to influence clinical data management and bio-statistics markets in India in the near future include: 1) cost efficient research vis-à-vis other countries 2) highly-skilled labour base 3) cheaper cost of skilled labour 4) presence in end-to-end solutions across the drug-development spectrum and 5) robust growth in the IT industry.

4. **Growth in healthcare financing products:** Development in the Indian financial industry has eased healthcare financing with introduction of products such as health insurance policy, life insurance policy and cashless claims. This has resulted in increase in healthcare spending, which in turn, has benefitted the pharmaceutical industry.

5. **Demand in the generics market:** During 2008-2015, prescription drugs worth about US\$ 300 bn are expected to go off patent, mostly from the US. Prior experience of Indian pharmaceutical companies in generic drugs would provide an edge to them.

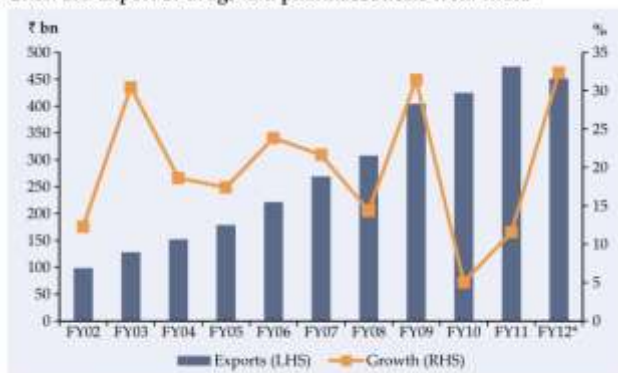
6. **Demand from emerging segments:** Some of the emerging segments such as contract research and development, bio-pharma, clinical trials, bio-generics, medical tourism and pharma packaging are also expected to drive growth of the Indian pharmaceutical industry.

III. Foreign Trade In Pharmaceutical Products

The Indian pharmaceutical industry's growth has been fuelled by exports. Its products are exported to a large number of countries with a sizeable share in the advanced regulated markets of the US and Western Europe. India currently exports drug intermediates, active pharmaceutical ingredients, finished dosage formulations, bio-pharmaceuticals and clinical services to various parts of the world. The top five export destinations of Indian pharmaceutical

products are USA, Germany, Russia, UK and China. Indian exports of drugs and pharmaceuticals grew at a CAGR of 16.5% to ` 451.4 bn over FY02-FY12 (up to Dec 2011).

Chart 2.4: Export of drugs and pharmaceuticals from India



*Up to Dec 11
 Source: Directorate General of Commercial Intelligence and Statistics (DGCIS) Kolkata

Import of drugs and pharmaceuticals into India recorded a CAGR of 17.6% during FY02-FY12 (up to Dec 2011). During FY12 (up to Dec 2011), pharmaceutical products worth ` 102.2 bn were imported into India. India is almost self sufficient in formulations; its imports mostly comprise bulk drugs and some intermediaries. These imports are freely permitted, except those that are restricted in the foreign trade policy. Import restrictions are mostly on drugs that contain narcotics and psychotropic components.

Import of drugs and pharmaceuticals into India



*Up to Dec 11
 Source: Directorate General of Commercial Intelligence and Statistics (DGCIS) Kolkata

IV. Partnerships And Licensing Deals

Although long-term supply deals between innovators and generic-producers have been taking place for a while now, the frequency of these deals has been growing at an increasingly rapid rate in the recent past. Deals between Pfizer and Aurobindo, and GlaxoSmithKline and Dr. Reddy's Labs are recent examples of out-licensing deals where generic makers are signing distribution and marketing contracts, so their products reach foreign regulate and developing markets. Due to the large number of drugs going off-patent in the next few years, this trend is expected to increase even further.

Table 1: Key recent mergers & acquisitions

Year	Indian Player	MNC	Nature of deal	Details
2010	Piramal Healthcare	Abbott	Sale of domestic branded formulations	Abbott acquired Piramal's domestic branded formulations division, along with its 350 brands, Baddi facility and about 5,200-strong sales force for US\$3.72 billion
2010	Strides Acrolabs	Pfizer	Licensing and supply arrangement	To supply 40 off parent products, mainly oncology ingestibles that would be commercialised by Pfizer
2009	Shantha Biotech	Sanofi-Aventis	Acquisition	Acquired for about US\$820mn and got access to Shantha's vaccines pipeline and access to emerging markets
2009	Aurobindo	Pfizer	Dossier licensing & supply contract	Formulations and injectables for US,EU and ROW markets on exclusive and co-exclusive basis
2009	Biocon	Mylan	Development & supply contract	To develop, manufacture, supply and commercialise many high-value generic biologic compounds for the global markets.
2009	Dr. Reddy's Labs	GSK Pharma	Supply contract	To develop and market more than 100 branded products on an exclusive basis across an extensive number of emerging markets, excluding India.
2008	Strides-Aspen JV	GSK Pharma	Upfront milestone & supply contract	To manufacture and supply branded generics to GSK which would be marketed in about 80 emerging markets.
2008	Ranbaxy	Daiichi Sankyo	Acquisition	Daiichi acquired Ranbaxy and got access to Ranbaxy's diversified product portfolio and vast geographical presence.

Source: *Centrum. Pharmaceuticals update, (June 2010).*

V. Major Challenges Faced By The Industry

The Indian pharmaceutical industry was on a strong growth trajectory in the last decade. It has achieved several milestones and is well positioned to leverage emerging opportunities. However, the industry needs to tackle various issues related to its operations and regulations. It faces several challenges in the form of pricing of pharmaceutical products and impact of some agreements. This section touches upon several key issues and challenges faced by the industry:

- **Impact of GATT-TRIPS agreement:** The General Agreement on Tariffs and Trade¹ (GATT) and Trade Related aspects of Intellectual Property Rights (TRIPS) have an adverse impact on pricing of pharmaceutical products. Pharmaceutical companies are not allowed to re-generate existing drugs and formulations and change the existing process and manufacture the same drug. New investments are required to perform research. This is a major obstacle for pharma companies, especially the micro, small and medium enterprises. Moreover, transfer of technology from abroad is difficult and expensive. Consequently, revenue of the pharma companies is impacted. Hence, adequate measures should be taken to support the industry's revenue and minimise losses.
- **Pricing:** At present, pricing of 74 bulk drugs and their formulations, which account for a large share in the retail pharma market, are controlled by the Drug Price Control Order (DPCO)-1995. The Government had considered reducing the number of regulated drugs, but it has not been implemented. There is a need to reduce the number of regulated drugs to facilitate the growth of the pharmaceutical industry.
- **Drug diversions by institutions:** Most of the institutional clients of the Indian pharmaceutical companies comprise

¹ GATT was the only multilateral instrument governing international trade from 1948 until 1995, when the WTO was established

government hospitals, the Indian defence service and private hospitals; the defence sector is mandated to buy drug stocks through tenders in quantities twice as large as the projected demand for those drugs in the following year at a discounted price. At the year-end, surplus available at the institutions is pushed to regular channels by leveraging the price discounts, resulting in a loss for companies through the regular distribution channel.

VI. SWOT Analysis of the Industry

The SWOT analysis of the industry reveals the position of the Indian pharmaceutical industry in respect to its internal and external environment.

a) Strengths

- Higher GDP growth leading to increased disposable income in the hands of general public and their positive attitude towards spending on healthcare.
- Low-cost, highly skilled set of English speaking labour force and proven track record in design of high technology manufacturing devices.
- Growing treatment naive patient population.
- Low cost of innovation, manufacturing and operations.

b) Weaknesses

- Stringent pricing regulations affecting the profitability of pharma companies.
- Poor all-round infrastructure is a major challenge.
- Presence of more unorganised players versus the organised ones, resulting in an increasingly competitive environment, characterised by stiff price competition.
- Poor health insurance coverage.

c) Opportunities

- Global demand for generics rising.
- Rapid OTC and generic market growth.
- Increased penetration in the non - metro markets.
- Large demand for quality diagnostic services.
- Significant investment from MNCs.
- Public-Private Partnerships for strengthening Infrastructure.
- Opening of the health insurance sector and increase in per capita income - the growth drivers for the pharmaceutical industry.
- India, a potentially preferred global outsourcing hub for pharmaceutical products due to low cost of skilled labour.

d) Threats

- Wage inflation.
- Government expanding the umbrella of the Drugs Price Control Order (DPCO).
- Other low-cost countries such as China and Israel affecting outsourcing demand for Indian pharmaceutical products
- Entry of foreign players (well equipped technology-based products) into the Indian market.

VII. Conclusion

Overall growth outlook for the Indian drugs and pharmaceutical industry appears positive. Pharma manufacturers are likely to benefit from rise in demand for generic products. Some of the factors that would drive growth in the domestic pharma industry are: 1) low cost operations 2) research-based processes 3) improvements in API and 4) availability of skilled manpower.

The domestic formulations and bulk drugs markets are currently facing price pressure as benefits of cheaper drugs have been shifted to end-users and trade channels. Hence, consolidation, partnership and alliances are expected to gather momentum in the near future. Off patenting of branded drugs would increase demand for generic drugs. This provides immense opportunities to the Indian pharmaceutical companies especially given their prior experience in generic drug development. Some other factors such as high penetration in the global markets and increase of share in Abbreviated New Drug Application (ANDA) filings are likely to power growth of the formulations market. Major growth drivers for the Indian bulk drug industry include rise in demand for contract manufacturing, increase of share in Drug Master Files (DMF) filings and process innovation.

Furthermore, initiatives of the Government will act as a backbone for growth. Some such initiatives include: 1) allowing 100% FDI under the automatic route in drugs and pharmaceuticals including those involving use of recombinant technology 2) increasing weighted tax deduction on expenditure in in-house R&D activities to 200% in the Budget 2010 and 3) setting up a US\$ 639.56 mn venture capital fund to support drug discovery and strengthen pharmaceutical infrastructure.

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