The Growth of Indian Pharmaceutical Industry

Dr.Bindusha H C
Department of Management Studies
Sri Ramakrishna Engineering College

Abstract-*Indian pharmaceutical industry is growing at the faster rate. On the other hand, Indian pharma companies are looking for global business opportunities in the form of export business, contract research and clinical trials. Many Indian companies started realizing the importance of Intellectual Property Rights. The volume of money spent on R&D also growing to a greater extent. There are many challenges faced by the Indian pharma companies' right from their initial investment to strengthen their R&D and up to obtainment of Patent and other IP Protection for their new innovations. There are many legal formalities are to be carried out for drug discovery, documentation, clinical trials etc., Cost of investment, expiry of patented drugs, lack of clinical trials, more legal formalities, complications in obtaining IP Protection are the major problems faced by Indian Pharmaceutical Companies.*

Keywords-Pharama,Growth of Indian Pharma,Pharma & R&D,Trends in Pharma

I. INTRODUCTION

The Indian pharmaceutical industry is a successful, high-technology-based industry that has witnessed consistent growth over the past three decades. The current industry players comprise several privately owned Indian companies that have captured a substantial share in the domestic pharmaceutical market due to factors such as favorable government policies and limited competition from overseas. However, the liberalization of the Indian economy is revolutionizing Indian industries as they begin to emerge from domestic markets and gear up for international competition. The Indian pharmaceutical industry is a prime example of an industry that is being forced to revisit its long-term strategies and business models as India opens its markets to global trade. Factors such as protection of intellectual property are increasing in significance due to the growing recognition of the need to ensure protection of valuable investments in research and development (R&D). Efforts are being made in India to curb problems of weak enforceability of existing intellectual property legislations, and the Indian government is moving towards establishing a patent regime that is conducive into technological advances and is in keeping with its global commitments.

India is already among the top six producers of pharmaceuticals of the world. The Government of India has announced a host of measures to create a facilitating environment for the Indian pharmaceutical industry. The policies of the Government of India are aimed at building more hospitals, boosting local access to healthcare, improving the quality of medical training, increasing public expenditure on healthcare to 2-3 per cent of GDP, up from the current level of

1 per cent. At the same time, the growth in healthcare insurance industry in India is also expected to complement the overall growth in the pharmaceutical market. The healthcare insurance industry in India is expected to grow at a CAGR of

15 per cent till 2015. Investments in R&D in India have grown from US$ 52.5 million in 2000 to US$ 646.5 million in 2010. Of this, nearly 80 per cent or

US$ 505 million is accounted for by the domestic companies while 20 per cent or US$ 141.5 million comes from foreign companies. The Government of India has made tax breaks available to the pharmaceutical sector and a weighted tax deduction of 150 per cent for any R&D expenditure incurred. This is in league with Indian Government's Pharma Vision 2020 which aims at making India a global leader in end-to-end manufacture by 2020. India is home to 10,500 manufacturing units and over 3,000 pharma companies. India exports all forms of pharmaceuticals from APIs to formulations, both in modern medicine and traditional Indian medicines. Globally India ranks among the top exporters of formulations by volumes. India's generics exports have been growing at a rate of nearly 24 per cent annually over the last four years. India's pharma exports stood at US$ 14.7 billion in 2012-13, registering a growth rate of 11 per cent. India plans to increase its total exports to US$ 25 billion by 2016.

II. TRENDS IN THE INDIAN PHARMACEUTICAL SECTOR

Indian Pharmaceutical Industry is growing in different dimensions.

In addition to production and marketing of drugs, special focus on Research and Development is also given by almost all companies to develop new drugs based on their own research. On the other hand, clinical trials are also playing the

major role in obtaining the approval for the drug. More and more focus is also extended to concentrate in clinical trials so as to bring quality medicine. Many hospitals availability and wide spectrum of disease profiles are facilitating the smooth conduct of clinical trials by Indian Pharmaceutical companies. It is also one of the greatest strength for our Indian companies. Export trade also increasing day by day. The companies involved in domestic business alone also started concentrating on export revenue after the liberalization and globalization. Patents holding status by the Indian Pharmaceutical companies are also in an increasing trend. As a result of market potentials in India, Joint ventures and collaborative measures are also facilitating the growth of Indian Pharmaceutical Companies. The notable trends which are emerging in to Indian Pharmaceutical Industry is listed in the following Table 3.1.

Notable Trends in Pharmaceutical Industry

Category	Nature of trends
Research and Development	• Indian pharma companies spend 2 percent of their total turnover on R&D. • Expenditure on R&D is likely to increase due to the introduction of product patents; companies need to develop new drugs to boost sales.
Clinical Trials	Due to its cost advantage, India is increasingly becoming a hub for clinical trials. Clinical trials market is estimated to be worth USD 685 million in 2016 and projected to grow at 17 percent CAGR over 2014-20.
Export Revenue	The pharmaceutical export market in India is thriving due to strong presence in the generic space.
Joint ventures	• Several Multi-national Companies are collaborating with Indian pharma firms to develop new drugs. • Pfizer partnered with Aurobindo Pharma to develop generic medicines.
Product Patents	• The Introduction of Product patents in India in 2005 has boosted the discovery of new drugs. • India has reiterated its commitment to IP production following the Introduction of product patents.

Source: India brand Equity Foundation Report on Pharmaceuticals 2013, pp 6-8.

India's pharmaceutical sector will touch US$ 45 billion by 2020, according to a major study by global management and consulting firm, McKinsey & Company. The reasons for this optimism are well founded.

In the period 2002-2012, the country's healthcare sector grew three times in size, touching US$ 70 billion from US$ 23 billion. India's pharmaceutical market experienced a similar boom, reaching US$ 18 billion in 2012 from US$ 6 billion in 2005. The report further states that the Indian pharmaceutical market will be the sixth largest in the world by 2020. The rise of pharmaceutical outsourcing and investments by multinational companies (MNCs), allied with the country's growing economy, committed health insurance segment and improved healthcare facilities, is expected to drive the market's growth. India is today one of the top emerging markets in the global pharmaceutical scene. The sector is highly knowledge-based and its steady growth is positively affecting the Indian economy. The organized nature of the Indian pharmaceutical industry is attracting several companies that are finding it viable to increase their operations in the country.

III. MARKET SIZE

From a market size of US$ 12.6 billion in 2009, the Indian pharmaceutical market will grow to US$ 55 billion by 2020, with the potential to reach US$ 70 billion in an aggressive growth scenario. In a pessimistic scenario characterized by regulatory controls and economic slowdown, the market will be depressed but is still expected to reach US$ 35 billion. India currently exports drug intermediates, Active Pharmaceutical Ingredients (APIs), Finished Dosage Formulations (FDFs), Bio-Pharmaceuticals, and Clinical

Services across the globe. The exports of pharmaceuticals from India grew to US$ 14.6 billion in 2012-13 from US$ 6.23 billion in 2006-07, registering a compound annual growth rate (CAGR) of around 15.2 per cent. Among the top pharma companies, Abbott with total sales of Rs 452 crore (US$ 74.76 million), Cipla with Rs 322 crore (US$ 53.26 million), Sun Pharma with Rs 313 crore (US$ 51.77 million), and Zydus Cadila with Rs 268 crore (US$ 44.32 million) were the fastest growing companies in the month of September 2013. In terms of growth, Sun Pharma (17.8 per cent) is ahead of peers such as Cadila (1.8 per cent), Cipla (0.8 per cent) and McLeod (0.7 per cent).

IV. MARKET SHARE OF INDIAN PHARMACEUTICAL INDUSTRY

Market share status of Indian pharmaceutical industry

Rank	Company	Sales (Rs. in Crore)	Market Share (in %)	Ownership
1	Abbot	1977.54	6.84	MNC
2	Cipla	1545.91	5.35	Indian
3	Daiichi Sankyo (Ranbaxy)	1448.59	5.01	MNC
4	GSK	1261.96	4.36	MNC
5	Zydus Cadila	1060.72	3.67	Indian
6	Sun	1042.19	3.60	Indian
7	Alkem	918.56	3.18	Indian
8	Pfizer	881.56	3.05	MNC
9	Lupin	794.08	2.75	Indian
10	Mankind	778.55	2.69	Indian
11	Aristo	698.72	2.42	Indian
12	Wockhardt	657.77	2.27	Indian
13	Dr.Reddys Labs	652.24	2.26	Indian
14	Torrent	591.54	2.05	Indian
15	Sanfi(Shanth a)	581.58	2.01	MNC
16	Merck	296.68	1.03	MNC

Source: MP Advisors, Report on Hold of Foreign Firms on Indian Pharma Market 2009, pp 36-42.

V. INVESTMENTS

The allowance of foreign direct investment (FDI) in India's pharma sector has been well received by foreign investors. According to data released by the Department of Industrial Policy and Promotion (DIPP), the drugs and pharmaceutical sector attracted FDI worth Rs 60,100.91 crore (US$ 9.94 billion) between April 2000 and June 2014. Some of the major investments in the Indian pharmaceutical sector are as follows:

a) Cipla has planned to invest £ 100 million (US$ 165.74 million) in its British subsidiary. This investment will fund the launch of a range of drugs in the areas of respiratory, oncology and antiretroviral medicines, as well as research and development (R&D), clinical trials and further expansion internationally and in the UK.

b) GeneOmbio Technologies and Resilient Cosmeceuticals have launched the country's first comprehensive nutrigenomics support lab in collaboration with DNA LIFE under the GeneSupport brand.

c) Cipla announced its fifth global acquisition deal, within a span of a year, by picking up a 51 per cent stake for US$ 21 million in a pharmaceuticals manufacturing and distribution business in Yemen.

d) Meiji Holdings has acquired Medreich for Rs 1,720 crore (US$ 284.51 million). Temasek had earlier in 2005 invested Rs 109 crore (US$ 18.03 million) for a 25 per cent stake in Medreich, which manufactures therapeutic generic and branded drugs.

e) Glenmark Pharmaceuticals has opened its new monoclonal antibody manufacturing facility in La Chaux-de-Fonds, Switzerland. The facility supplements Glenmark's existing in-house discovery and development capabilities and will supply material for clinical development.

f) Arvind Remedies has obtained the rights from SRM University to access patented technology for the commercial manufacture of drugs to combat Type II diabetes and cardiovascular diseases.

VI. GOVERNMENT INITIATIVES

As per extant policy, FDI up to 100 per cent, under the automatic route, is permitted in the pharmaceutical sector for Greenfield investment. Hundred per cent FDI is also permitted for investments in existing companies under the government approval route. Further, the Government of India has also put in place mechanisms such as the Drug Price Control Order and the National Pharmaceutical Pricing Authority to address the issue of affordability and availability of medicines.

India plans to set up industrial parks in the pharmaceutical and information technology (IT) sectors in China to strengthen India-China trade and investment ties. The Union Cabinet of India has cleared foreign investment proposal worth US$ 400 million by KKR to acquire stakes in two pharmaceutical companies, Gland Pharma and Gland Celsus Bio Chemicals. The growth in Indian domestic market will be boosted by increasing consumer spending, rapid urbanization, and increasing healthcare insurance and so on. The lifestyle segments such as cardiovascular, anti-diabetes, anti-depressants and anti-cancers will continue to be lucrative and fast growing owing to increased urbanization and change in lifestyle patterns. Going forward, better growth in domestic sales will depend on the ability of companies to align their product portfolio towards these chronic therapies as these diseases are on the rise.

In various global markets, governments have been taking several cost-effective measures in order to bring down healthcare expenses.

Thus, governments are focusing on speedy introduction of generic drugs into the market. This too will benefit Indian pharma companies. For the US market, Indian companies are developing niche portfolios in various segments. High margin injectables, dermatology, respiratory, biogenerics, complex generics, etc., have become areas of interest. Most of the Indian pharma companies have been working on these niche drugs in order to optimize growth and margins. Moreover, generic penetration in the US is expected to peak out at 86-87 per cent over the next couple of years from 83 per cent currently.

The Pharmaceuticals Export Promotion Council (Pharmexcil), set up by the Ministry of Commerce and Industry, has recently recommended two new ports – Krishnapatnam in Andhra Pradesh and Kattupalli in Tamil Nadu – for export and import of drugs. The export promotion body has already requested the Ministry of Commerce and Ministry of Health and Family Welfare apart from the Drugs Controller General of India (DCGI) to notify these ports for import and export of drugs under the Drugs & Cosmetics Act. It may be noted here that a separate notification is required for handling drugs and DCGI is expected to authorize the ports to start handling the pharma products pending a notification from the concerned Ministries. According to estimates, close to two-third of the Indian pharma exports are being carried out though the seaports and the addition of these ports in the authorized list is expected to create an encouraging environment for the pharma exports from India. The total pharma exports from India stood at Rs 90,000 crore for 2013-14. Additionally, Pharmexcil is working on the proposed World Pharma Trade Centre at Hyderabad and is currently in talks with the Telangana Government to take it forward. The total pharma exports from the United Andhra Pradesh are close to 30 per cent of the total pharma exports from India is currently at the second position after Maharashtra. Measures like new ports being added up and the coming up of the World Pharma Trade centre is expected to build appositive ecosystem for pharma companies operating in the Indian market.

The Annual Report 1999–2000 of the Department of Chemicals and Petrochemicals, Government of India, describes it as one of the largest and most advanced among developing countries. The industry today possesses the largest number of US Food & Drug Administration (FDA) approved manufacturing facilities outside the US and has filed 126 Drug Master Files (DMFs) with the US FDA for drug exports to the US, which is higher than that filed by Spain, Italy, China and Israel taken together .

Against the above backdrop of increasing attention of the policy makers on global Competitiveness of the Indian pharmaceutical sector, the present study shall make an attempt to put the performance of the sector in a global setting. Most of the recent studies on Indian pharmaceutical industry deal with the impact of economic liberalization and new global Intellectual Property Rights (IPR) regime on industry performance like R&D and patenting, foreign investment, exports, and drugs prices and public health (e.g., Watal, 1996; Lanjouw, 1998; Pradhan, 2002a, b, 2006; Fink, 2000; Lalitha, 2002; Kumar and Pradhan, 2003; among others). However, the issue of global competitiveness of the industry is still not rigorously addressed. This issue, in turn, involves a comparative analysis of the Indian pharmaceutical industry in a cross□country setting and exploring its growth, productivity, technology and trade performance vis□à□vis global peers in the sector and an analysis of new competitive strategies that Indian firms are adopting to compete in the global market.

VII. EVOLUTION OF INDIAN PHARMACEUTICAL INDUSTRY

The pharmaceutical production in India began in 1910s when private initiatives established Bengal Chemical and Pharmaceutical Works in Calcutta and Alembic Chemicals in Baroda and setting up of pharmaceutical research institutes for tropical diseases like King Institute of Preventive Medicine, Chennai (in Tamil Nadu), Central Drug Research Institute, Kasauli (in Himachal Pradesh), Pastures Institute, Coonoor (in Tamil Nadu), etc. through British initiatives. The nascent industry, however, received setbacks in the post World War II period as a result of new therapeutic developments in the Western countries that triggered natural elimination of the older drugs from the market usage by newer drugs like sulpha, antibiotics, vitamins, harmones, antihistamine, tranquilizers, psycho pharmacological substances, etc. This culminated in the discontinuation of local production based on indigenous materials and forced the industry to import bulk drugs meant for processing them into formulations and for selling in the domestic market.

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