

A DIAGNOSTIC VIEW OF INDIAN PHARMA INDUSTRY-

NEED FOR CLINICAL APPROACH

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ABSTRACT

It is often said that the pharma sector has no cyclical factor attached to it. Irrespective of whether the economy is in a downturn or in an upturn, the general belief is that demand for drugs is likely to grow steadily over the long-term. The Indian pharmaceutical industry is fragmented, but has grown rapidly due to friendly patent regime and low cost manufacturing structure. Intense competition, high volumes and low prices characterize the Indian domestic market. Exports have been raising at around 30% Compounded Annual Growth Rate (CAGR) over last few years. There is a shift in export profile towards value added formulations from low value bulk drugs. The drug pricing control order (DPCO) has been mile stone around the neck of Indian industry as its severely restricted profitability and hence innovation. This paper focuses on the three important issues; i) Diagnostic Analysis ii) Challenges faced by pharma industry and iii) Future prospects.

KEYWORDS: Pharma Industry: Problems, Challenges, Future Growth.

INTRODUCTION

The Indian Pharmaceutical Industry today is in the front rank of India's science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. A highly organized sector, the Indian Pharma Industry is estimated to be worth \$ 4.5 billion, growing at about 8 to 9 percent annually. It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. From simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made indigenously. In 2006, the market size of India's pharmaceutical logistics segment (distribution) was valued at around \$200 million and the logistics/distribution industry has been growing at an average annual growth rate of 4% since 2002. According to the Indian Retail Druggists and Chemists Association, in 1978, there were roughly 10,000 distributors and 125,000 retail pharmacies in India. Today, the total number of stockists in India is around 65,000 and the number of pharmacies is about 550,000, an increase of around 6 and 4fold, respectively.

Playing a key role in promoting and sustaining development in the vital field of medicines, Indian Pharma Industry boasts of quality producers and many units approved by regulatory authorities in USA and UK. International companies associated with this sector have stimulated, assisted and spearheaded

this dynamic development in the past 53 years and helped to put India on the pharmaceutical map of the world.

The Indian Pharmaceutical sector is highly fragmented with more than 20,000 registered units. It has expanded drastically in the last two decades. The leading 250 pharmaceutical companies control 70% of the market with market leader holding nearly 7% of the market share. It is an extremely fragmented market with severe price competition and government price control. The pharmaceutical industry in India meets around 70% of the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectibles. There are about 250 large units and about 8000 Small Scale Units, which form the core of the pharmaceutical industry in India (including 5 Central Public Sector Units). These units produce the complete range of pharmaceutical formulations, i.e., medicines ready for consumption by patients and about 350 bulk drugs, i.e., chemicals having therapeutic value and used for production of pharmaceutical formulations.

Following the de-licensing of the pharmaceutical industry, industrial licensing for most of the drugs and pharmaceutical products has been done away with. Manufacturers are free to produce any drug duly approved by the Drug Control Authority. Technologically strong and totally self-reliant, the pharmaceutical industry in India has low costs of production, low R&D costs, innovative scientific manpower, strength of national laboratories and an increasing balance of trade. The Pharmaceutical Industry, with its rich scientific talents and research capabilities, supported by Intellectual Property Protection regime is well set to take on the international market.

India's US\$ 3.1 billion pharmaceutical industry is growing at the rate of 14 percent per year. It is one of the largest and most advanced among the developing countries. Over 20,000 registered pharmaceutical manufacturers exist in the country. The domestic pharmaceuticals industry output is expected to exceed Rs260 billion in the financial year 2002, which accounts for merely 1.3% of the global pharmaceutical sector. Of this, bulk drugs will account for Rs 54 bn (21%) and formulations, the remaining Rs 210 bn (79%). In financial year 2001, imports were Rs 20 bn while exports were Rs87 bn. The businesses not only have the economic responsibility of being profitable and the legal responsibility to follow the laws or ground rules that guide their ability to achieve their economic requirements. They also have ethical responsibilities that include a range of societal norms, or standards.

INDIAN DISTRIBUTION SYSTEM: THE CURRENT STATE

India is a geographically diverse country with extreme climates that make distribution a critical function. The long channel of distribution and high incidence of brand substitution makes it mandatory for a company to make all its stock keeping units (SKUs) available at all levels at all times. In India, most brands have generic versions of drugs and retailers can usually obtain higher margins with generics than for branded products. To reduce risks of substitution, innovator companies must make sure their products are made available to the stockists and retail shops. Drug distribution in India has witnessed a paradigm shift. Before 1990, pharmaceutical companies used a different distribution system, in which they established their own depots and warehouses that now have been replaced by clearing and

forwarding agents (CFAs). These organizations are primarily responsible for maintaining storage (stock) of the company's products and forwarding SKUs to the stockiest on request. Most companies keep 1–3 CFAs in each Indian state. On an average, a company may work with a total of 25–35 CFAs. Unlike a CFA that can handle the stock of one company, a stockist (distributor) can simultaneously handle more than one company (usually, 5–15 depending on the city area), and may go up to even 30–50 different manufacturers. The stockist, in turn, after 30–45 days (a typical credit or time limit) pays for the products directly in the name of the pharmaceutical company.

DIAGNOSIS OF INDIAN PHARMA INDUSTRY

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

Strengths

Indian with a population of over a billion is a largely untapped market. In fact the penetration of modern medicine is less than 30% in India. To put things in perspective, per capita expenditure on health care in India is US\$ 93 while the same for countries like Brazil is US\$ 453 and Malaysia US\$189. The growth of middle class in the country has resulted in fast changing lifestyles in urban and to some extent rural centers. This opens a huge market for lifestyle drugs, which has a very low contribution in the Indian markets. Indian manufacturers are one of the lowest cost producers of drugs in the world. With a scalable labor force, Indian manufactures can produce drugs at 40% to 50% of the cost to the rest of the world. In some cases, this cost is as low as 90%. Indian pharmaceutical industry possesses excellent chemistry and process reengineering skills. This adds to the competitive advantage of the Indian companies. The strength in chemistry skill helps Indian companies to develop processes, which are cost effective.

Weakness

1. The Indian pharma companies are marred by the price regulation. Over a period of time, this regulation has reduced the pricing ability of companies. The NPPA (National Pharma Pricing Authority), which is the authority to decide the various pricing parameters, sets prices of different drugs, which leads to lower profitability for the companies. The companies, which are lowest cost producers, are at advantage while those who cannot produce have either to stop production or bear losses.
2. Indian pharma sector has been marred by lack of product patent, which prevents global pharma companies to introduce new drugs in the country and discourages innovation and drug discovery. But this has provided an upper hand to the Indian pharma companies.
3. Indian pharma market is one of the least penetrated in the world. However, growth has been slow to come by. As a result, Indian majors are relying on exports for growth. To put things in perspective, India accounts for almost 16% of the world population while the total size of industry is just 1% of the global pharma industry.

4. Due to very low barriers to entry, Indian pharma industry is highly fragmented with about 300 large manufacturing units and about 18,000 small units spread across the country. This makes Indian pharma market increasingly competitive. The industry witnesses price competition, which reduces the growth of the industry in value term. To put things in perspective, the industry actually grew by 10.4% but due to price competition, the growth in value terms was 8.2% (prices actually declined by 2.2%)

Opportunities

1. The migration into a product patent based regime is likely to transform industry fortunes in the long term. The new patent product regime will bring with it new innovative drugs. This will increase the profitability of MNC pharma companies and will force domestic pharma companies to focus more on R&D. This migration could result in consolidation as well. Very small players may not be able to cope up with the challenging environment and may succumb to giants.
2. Large number of drugs going off-patent in Europe and in the US offers a big opportunity for the Indian companies to capture this market. Since generic drugs are commodities by nature, Indian producers have the competitive advantage, as they are the lowest cost producers of drugs in the world.
3. Opening up of health insurance sector and the expected growth in per capita income are key growth drivers from a long-term perspective. This leads to the expansion of healthcare industry of which pharma industry is an integral part.
4. Being the lowest cost producer combined with FDA approved plants, Indian companies can become a global outsourcing hub for pharmaceutical products.

Threats

1. There are certain concerns over the patent regime regarding its current structure. It might be possible that the new government may change certain provisions of the patent act formulated by the preceding government.
2. Threats from other low cost countries like China and Israel exist. However, on the quality front, India is better placed relative to China. So, differentiation in the contract manufacturing side may wane.
3. The short-term threat for the pharma industry is the uncertainty regarding the implementation of VAT. Though this is likely to have a negative impact in the short-term, the implications over the long-term are positive for the industry.

CHALLENGES AHEAD

As pharmaceuticals require great handling care during storage and transportation, the demand for temperature-controlled transport in particular will continue to grow substantially in the coming years. While the growing demand for temperature-sensitive freight transport has spurred an opportunity

for logistics providers, the market poses various challenges. The foremost is the dearth of time-bound and temperature-sensitive services from the point of origin to the point of consumption. In addition, India's cold-chain market is still developing and is further marred with low capacity utilization. Another bottleneck is created by the lack of modern transport infrastructure and the delay in customs clearance in India. In order to compensate for these hurdles, logistics service players in India will need to improve their performance in various areas by providing cost-effective, customized packaging services and expertise in handling pharmaceutical cargo. In addition to this the following are some important issues to be focused by the industry.

Research & Development

. Currently, however, the industry's R&D pipeline is relatively sparse, with few potential blockbuster products, that represent the industry's primary source of growth, in view. This has led to some consolidation within the industry with many key industry players purchasing either existing product lines or biotech firms with a few products in the later stages of development, rather than relying exclusively on their own R&D operations. The mainstay of the pharmaceutical industry's long-term competitiveness is its ability to pay for Research & Development. Pharma R&D is extremely costly and has a high failure rate, even at the later testing stage. The time taken to develop a new drug varies, but recent evidence suggests the average is around 12 years. It has also led to a process of concentration of R&D in the US, the fastest-growing pharmaceutical market.

However, the pharma industry is faced with stakeholders such as pressure groups, NGOs and international organizations — notably the WHO — that are demanding further evaluation of and philosophical debate on the social and ethical implications of biotechnology in medicine. Their goal is to ensure a balance between scientific progress and public accountability, respect and transparency in terms of the potential future risks in research in this area. The pharma industry also faces social and ethical questions in both clinical research and animal testing. As research becomes driven by ever more costly technologies, stakeholders are asking whether pharma companies and their external partners are ensuring the safety, rights, integrity, confidentiality and well being of clinical trial subjects. Following successful clinical trials, the next step concerns government scrutiny and regulatory requirements. In this area, first, the Food and Drug Administration (FDA) must approve the new drugs.

Manufacturing

Pharma companies' manufacturing facilities are often in many locations around the world, including many developing countries. Companies are, therefore, challenged to ensure consistently high quality manufacturing standards on a global level. Pharma manufacturing quality is an important driver in successful and timely product launches, the optimization of revenue streams, the enhancement of a company's reputation, and ultimately the maximization of shareholder value. The Good Manufacturing Practices Regulations (GMP), promulgated by the FDA, denotes good practices and addresses issues including record keeping, personnel qualifications, sanitation, cleanliness, equipment verification,

process validation, and complaint handling. Pharma companies are widely expected to address the corporate

Sales and Marketing

Pharma Companies should focus their sales and marketing efforts towards different groups in order to maximize the use of their products. Unlike many other goods, the end consumer of pharma products—the patient—does not usually purchase or pay for the product directly. End payers tend to be either public bodies or private organizations. Various groups influence which drugs are purchased and prescribed. The influencers vary, depending on different countries' local regulatory and legal environments.

Counterfeiting

Counterfeit drugs have been a serious issue in India. The Organisation of Pharmaceutical Producers of India (OPPI) has spearheaded various initiatives to combat the problem. It has conducted several seminars and 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 anticounterfeiting guidelines for the industry as a whole.

Infrastructure

Insufficient energy infrastructure and inadequate transport infrastructure has historically posed challenges for companies operating in India. The situation is definitely improving, as the Government focuses attention on infrastructure needs. The Indian infrastructure sector continues to be viewed as an investment opportunity, despite the global slowdown.

Tax Related Issues for Special Economic Zone (SEZ)

In an effort to attract companies to SEZs, some of these are located in modern industrial areas. The Jawaharlal Nehru Pharma City, India's first and largest pharma industrial estate, includes a SEZ. The facility is located near Visakhapatnam, in close proximity to many chemical manufacturing hubs, and offers common infrastructure for resident pharma companies. There are three other pharma SEZs located in Andhra Pradesh, and four in Maharashtra, as well as one on the outskirts of Dehra Dun in Uttarakhand, so global pharma companies have a range of options. At this stage, it may also be pertinent to note that the draft Direct Tax Code Bill published by the Government presently does not provide for SEZ-related incentive schemes. However, recent press releases suggest that the Finance Minister has identified proposed incentive provisions as one of the areas for detailed examination prior to finalisation of the Direct Tax Code.

FUTURE VISION

Under its Vision 2020 initiative the Indian government aims to spend up to \$20bn a year on research and development (R&D), in an effort to establish India as a global pharmaceutical hub. Various R&D centers are also being set up in Chennai, Kolkata, and Mumbai. Initiatives such as these will help

the Indian healthcare market to become self-sufficient, ending its reliance on foreign imports. The resultant growth in pharmaceutical exports is expected to strengthen the demand for logistics in the country, creating an opportunity for logistics service providers. The market is expected to grow to a value of \$48m in 2014 from \$33m in 2010, recording a CAGR of around 10% over 2010-14.

CONCLUSIONS

The Pharmaceutical industry is a knowledge driven industry and is heavily dependant on research and development for new products and growth, However, basic research is a time consuming and expensive process and is thus, dominated by large global multinationals. Indian companies have recently entered the area and initial results have been encouraging. In the global pharmaceutical market, western markets are the largest and fastest growing due to introduction of newer molecules of higher prices.

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