

A Case Study on Marketing Strategies of the Pharma Industry with Reference to Smilax Labs, Haryana

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Abstract – The Indian pharmaceutical sector has come a long way, being almost non-existent before 1970 to a prominent provider of healthcare products, meeting almost 95 per cent of the country's pharmaceuticals needs. The 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. 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. India is getting recognition as a strong, and fast growing economy. Thus the industry is attracting many global entrants. Increasing purchasing power of the growing middle class population, high orientation towards health consciousness, quality and price driven mindset have reshaped the market structure of pharmaceutical business. The behavior and bargaining power of different interest groups like patients, healthcare providers and regulatory authorities are expected to reinforce sectoral growth and scope. Smilax is a genus of about 200 species of climbing flowering medicinal plants. Smilax is a vine that bears flowers and berries with many useful therapeutically properties. It is commonly known as „Sarsaparilla.“ Smilax is a 100 crores turnover company and is a research driven, vertically integrated pharmaceutical manufacturing company that manufactures Active Pharmaceutical Ingredients (APIs), API Intermediates and NDDS/Pellets for the global generics market. Smilax has incepted its journey in the world of Pharmaceuticals during the year 2005. Within three years Smilax has become a reliable supplier of its products across the globe because of its Quality of products and Customer Service. Smilax is extending its foot prints in the world of pharmaceuticals day by day.

Keywords: Marketing Strategies, Pharma Industry, Smilax Labs, Indian pharmaceutical sector, drug manufacture and technology

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INTRODUCTION

The Pharmaceutical industry in India is the world's third-largest in terms of volume. According to Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, the total turnover of India's pharmaceuticals industry between 2008 and September 2009 was US\$21.04 billion. While the domestic market was worth US\$12.26 billion. According to Brand India Equity Foundation, the Indian pharmaceutical market is likely to grow at a compound annual growth rate (CAGR) of 14-17 per cent in between 2012-16. India is now among the top five pharmaceutical emerging markets of the world. Exports of pharmaceuticals products from India increased from US\$6.23 billion in 2006-07 to US\$8.7 billion in 2008-09 a combined annual growth rate of 21.25%. According to PricewaterhouseCoopers (PWC) in 2010, India joined among the league of top 10 global pharmaceuticals markets in terms of sales by 2020 with value reaching US\$50 billion. The government started to encourage the growth of drug

manufacturing by Indian companies in the early 1960s, and with the Patents Act in 1970. However, economic liberalization in 90s by the former Prime Minister P.V. Narasimha Rao and the then Finance Minister, Dr. Manmohan Singh enabled the industry to become what it is today. This patent act removed composition patents from food and drugs, and though it kept process patents, these were shortened to a period of five to seven years. The lack of patent protection made the Indian market undesirable to the multinational companies that had dominated the market, and while they streamed out, Indian companies carved a niche in both the Indian and world markets with their expertise in reverse-engineering new processes for manufacturing drugs at low costs. Although some of the larger companies have taken baby steps towards drug innovation, the industry as a whole has been following this business model until the present. India's biopharmaceutical industry clocked a 17 percent growth with revenues of Rs. 137 billion (\$3 billion) in the 2009-10 financial year over the previous fiscal. Biopharma was the

biggest contributor generating 60 percent of the industry's growth at Rs. 88.29 billion, followed by bio-services at Rs. 26.39 billion and bio-agri at Rs. 19.36 billion. In 2013, there were 4,655 pharmaceutical manufacturing plants in all of India, employing over 345 thousand workers. The number of purely Indian pharma companies is fairly low. Indian pharma industry is mainly operated as well as controlled by dominant foreign companies having subsidiaries in India due to availability of cheap labor in India at lowest cost. In 2002, over 20,000 registered drug manufacturers in India sold \$9 billion worth of formulations and bulk drugs. 85% of these formulations were sold in India while over 60% of the bulk drugs were exported, mostly to the United States and Russia. Most of the players in the market are small-to-medium enterprises; 250 of the largest companies control 70% of the Indian market. Thanks to the 1970 Patent Act, multinationals represent only 35% of the market, down from 70% thirty years ago.

Current Scenario

India's US\$ 9.4 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. The Indian pharmaceutical industry can reach a market size of US\$ 11.6 billion by 2009. A beginning has been made with the signing of General Agreement on Tariffs and Trade in January 2005 with which India began recognizing global patents. Soon after, the Indian pharmacy market became a sought after destination for foreign players. Foreign direct investment into the country's pharmacy industry touched US\$ 172 million during 2005-06 having grown at a CAGR of 62.6 per cent during the period beginning 2002-06. The sector recorded strong growth in the second quarter ended September 2006, driven by launch of new generic drugs with 180 days exclusivity period in the US market. The top ten pharmacy companies reported an impressive 57 per cent growth in consolidated net profit at US\$ 314.3 million, as against US\$ 200.7 million in the same quarter of the previous year, while consolidated net sales were up 51 per cent at US\$ 1.7 billion. There are 74 U.S. FDA-approved manufacturing facilities in India, more than in any other country outside the U.S, and in 2005, almost 20 per cent of all Abbreviated New Drug Applications (ANDA) to the FDA were filed by Indian companies. Growth in other fields notwithstanding, generics is still a large part of the picture. London research company Global Insight estimates that India's share of the global generics market will have risen from 4 per cent to 33 per cent by 2007. The focus of the Indian pharmaceutical companies is also shifting from process improvisation to drug discovery and R&D. The Indian companies are setting up their own R&D setups and are also collaborating with the research laboratories like CDRI, IICT etc.

The Pharma Industry

The pharmaceutical industry in India is going through a major shift in its business model in the last few years in order to get ready for a product patent regime from 2005 onwards. This shift in the model has become necessary due to the earlier process patent regime put in place since 1972 by the Government of India. This was done deliberately to promote and encourage the domestic health care industry in producing cheap and affordable drugs. As prior to this the Indian pharmaceutical sector was completely dominated by multinational companies (MNCs). These firms imported most of the bulk drugs (the active pharmaceutical ingredients) from their parent companies abroad and sold the formulations (the end products in the form of tablets and capsules, syrups etc.) at prices unaffordable for a majority of the Indian population. This led to a revision of Government of India's (GOI) policy towards this industry in 1972 allowing Indian firms to reverse engineer the patented drugs and produce them using a different process that was not under patent. The entry of MNC's was also discouraged by restricting foreign equity to 40%. The licensing policy was also biased towards indigenous firms and firms with lesser foreign equity¹. All these measures by GOI laid foundations to a strong manufacturing base for bulk drugs and formulations and accelerated the growth in the Indian Pharmaceutical Industry (IPI), which today consists of more than 20,000 players¹. As a result the Indian pharmaceutical industry today not only meets the domestic requirement but has started exporting bulk drugs as well as formulations to the international market. Smilax has the capability of manufacturing APIs and API Intermediates in its state-of-the art manufacturing facilities located in Hyderabad and Visakhapatnam, Andhra Pradesh, India. Currently the main activities of Indian pharmaceutical industry are broadly restricted to producing (i) Bulk drugs and (ii) Formulations with very few companies risking investing in primary research aimed at developing and patenting new drugs. The bulk drug business is essentially a commodity business, whereas the formulation business is primarily a market driven and brand oriented business. Multinational companies which have entered the Indian market have mostly restricted themselves to formulation segment till date. The domestic pharmaceutical industry (MNC's and Domestic) meets about 90% of the country's bulk drug requirement and almost the entire demand for formulations. The economics of bulk drug business and that of formulation business are quite different. Since a majority of the Indian companies are producing both bulk as well as formulations, these are considered together for the purpose of the present study. The Indian Pharmaceuticals sector has come a long way, being almost non-existing during 1970, to a prominent provider of health care products, meeting almost 95% of country's pharmaceutical needs. Indian pharmaceutical sector is one of the fastest growing sectors. Initially India

had to wait for imports of bulk drugs from global majors for re-processing and now it has become an industry which is driving product development and breaking new ground in medicine research worldwide. Indian pharmaceutical industry is undergoing fast paced changes. The Indian Generics market is witnessing rapid growth opening up immense opportunities for firms. This is further triggered by the fact that generics worth over \$40(1820) billion are going off patent in the coming few years which is close to 15% of the total prescription market of the US. The Indian pharmaceutical companies have been doing extremely well in developed markets such as US and Europe, notable among these being Ranbaxy, Dr. Reddy's Labs, Wockhard, Cipla, Nicholas Piramal and Lupin. The companies have their strategies in place to leverage opportunities and appropriate values existing in formulations, bulk drugs, generics, Novel Drug Delivery Systems, New Chemical Entities, and Biotechnology etc. The industry ranks fourth globally in terms of volume and in terms of value, it is ranked thirteenth. The industry has thrived so far on reverse engineering skills exploiting the lack of process patent in the country. This has resulted in the Indian pharmaceutical players offering their products at some of the lowest prices in the world. The quality of the products is reflected in the fact that India has the highest number of manufacturing plants approved by US FDA, which is next only to that in the US. Multinational companies have traditionally dominated the industry, which is another trend seeing a reversal. Currently, it is the Indian companies which are dominating the marketplace with the local players dominating a number of key therapeutic segments. The market is also very fragmented with about 30,000 entities and the organized sector consisting of about 300 entities. Consolidation is increasing in the industry with many local players building a global outlook and also growing inorganically through mergers and acquisitions.

The average cost of bringing a single new drug to the market is as high as \$800(35560) million. Patent protection is more limited than in other industries: because of the lengthy gap between discovery and approval of a new drug, the effective monopoly protection is estimated, since the 1990s, to last only 12 years, apart for extensions. Indeed, according to industry surveys, the only industry in which patents are thought to play an important role in bringing new products to market is the pharmaceutical industry. The pharmaceutical industry is worthy of special consideration also for another, opposite, reason. The technology operated by the pharmaceutical industry – the chemical and industrial processes, through which medicines are produced, packaged, and shipped, seems to fit the constant returns to scale hypothesis almost perfectly. That is, the cost of shipping the ten millionth container of medicine is about the same as that of shipping the first. This is

why, after all, everyone complains about the pharmaceutical companies not shipping medicines to poor countries.

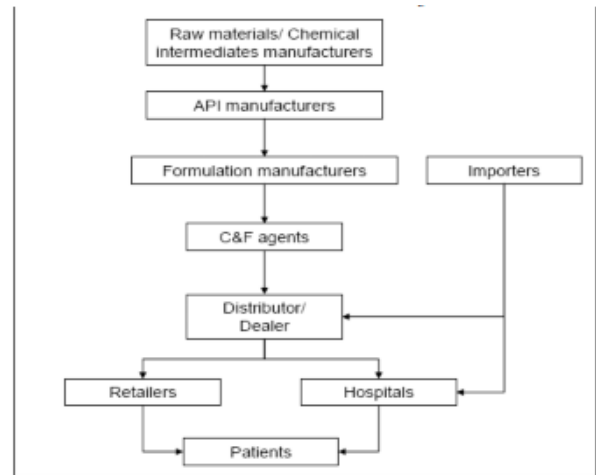


Chart-1: Distribution Structure of Indian Pharmaceutical Industry

Pharma Marketing Process and Its Challenges

Pharma Marketing Process and its Challenge The pharmaceutical industry is the world's largest industry due to worldwide revenues of approximately US\$2.8 trillion. Pharma industry has seen major changes in the recent years that place new demands on payers, providers and manufacturers. Customers now demand the same choice and convenience from pharma industry that they find in other segment. Indian Pharmaceutical Industry is poised for high consistent growth over the next few years, driven by a multitude of factors. Top Indian Companies like Ranbaxy, DRL, CIPLA and Dabur have already established their presence. The pharmaceutical industry is a knowledge driven industry and is heavily dependent on Research and Development for new products and growth. However, basic research (discovering new molecules) is a time consuming and expensive process and is thus, dominated by large global multinationals. Indian companies have only recently entered the area. The Indian pharmaceutical industry came into existence in 1901, when Bengal Chemical & Pharmaceutical Company started its maiden operation in Calcutta. The next few decades saw the pharmaceutical industry moving through several phases, largely in accordance with government policies. Commencing with repackaging and preparation of formulations from imported bulk drugs, the Indian industry has moved on to become a net foreign exchange earner, and has been able to underline its presence in the global pharmaceutical arena as one of the top 35 drug producers worldwide. Currently, there are more than 2,500 registered pharmaceutical producers in India. There are 25,000 licensed pharmaceutical companies. Of the 465 bulk drugs used in India, approximately 430 are manufactured here. India has more drug-

manufacturing facilities that have been approved by the U.S. Food and Drug Administration than any country other than the US. Indian generics companies supply 85% of the AIDS drugs that Doctors without Borders uses to treat 65,000 patients in more than 35 countries.

1. From organizational perspective following are the most prominent performance related issues:
 - a) Unethical practices adopted by some of the Propaganda base companies.
 - b) Low level of customer knowledge (Doctors, Retailers, Wholesalers).
 - c) Poor customer (both external & internal) acquisition, and Retention strategies
 - d) Varying customer perception.
 - e) The number and the quality of medical representatives
 - f) Very high cost of territory development. g) High training costs of sales personnel.
 - h) High attrition rate of the sales personnel.
 - i) Busy schedule of doctors making them unable to give time to sales calls.
 - j) Poor knowledge of medical representatives regarding the territory.
 - k) Unknown value of revenue from each retailer in the territory
 - l) Lack of ideal mechanism of sales forecasting at field sales level, resulting in huge deviations
 - m) Lack of analysis on the amount of time invested on profitable and not-so profitable

Customers and lack of time-share planning, for developing customer base for future and un-tapped markets.

2. Patents

The pharmaceutical industry develops, produces, and market drugs or pharmaceuticals licensed, for use as medications. Pharmaceutical companies are allowed to deal in generic and/or brand medications and medical devices. They are subject to a variety of laws and regulations regarding the patenting, testing and ensuring safety and efficacy and marketing of drugs. Most of today's major pharmaceutical companies were founded in the late 19th and early 20th centuries. Key discoveries of the 1920s and 1930s, such as insulin and penicillin, became mass-

manufactured and distributed. Switzerland, Germany and Italy had particularly strong industries, with the United Kingdom, the United States, Belgium and the Netherlands following suit. Legislation was enacted to test and approve drugs and to require appropriate labeling. Prescription and nonprescription drugs became legally distinguished from one another as the pharmaceutical industry matured. The industry got underway in earnest from the 1950s, due to the development of systematic scientific approaches, understanding of human biology (including DNA) and sophisticated manufacturing techniques. Numerous new drugs were developed during the 1950s and mass-produced and marketed through the 1960s. These included the first oral contraceptive, "The Pill", Cortisone, blood-pressure drugs and other heart medications. MAO inhibitors, chlorpromazine (Thorazine), haloperidol (Haldol) and the tranquilizers ushered in the age of psychiatric medication. Diazepam (Valium), discovered in 1960, was marketed from 1963 and rapidly became the most prescribed drug in history, prior to controversy over dependency and habituation. Attempts were made to increase regulation and to limit financial links between companies and prescribing physicians, including by the relatively new U.S. Food and Drug Administration (FDA). Such calls increased in the 1960s after the thalidomide tragedy came to light, in which the use of a new anti-emetic in pregnant women caused severe birth defects. In 1964, the World Medical Association issued its Declaration of Helsinki, which set standards for clinical research and demanded that subjects give their informed consent before enrolling in an experiment. Pharmaceutical companies became required to prove efficacy in clinical trials before marketing drugs.

NON REGULATED MARKETS

- There are no regulations
- The pricing will lower than all the markets.
- The time duration will be 1- 2 months for completing the contract.

The countries that come under the Non-regulated market are Bangladesh, Pakistan, Nepal, Bhutan, and India.

Growth of Indian pharmaceutical industry during the year 2002-03 to 2008-09 (in Rs Crore)

Years	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09
Type of market	30365	32575	34128	39989	45367	50946	55454
Domestic Market							
Exports	12826	15213	17857	22216	24942	30760	38433
Imports	2865	2956	3139	4515	5867	6734	8552
Total Market Size	42326	47332	52029	62566	68442	78610	89335

Annual Report 2008-09, Department of Pharmaceuticals, Government of India

India currently exports drug intermediates, Active Pharmaceutical Ingredients (APIs), Finished Dosage Formulations (FDFs), Bio-Pharmaceuticals, Clinical Services to various parts of the world.

Growth rates of domestic drugs and pharmaceuticals during the year (2003-04 to 2008-09)

S.No	Domestic Indian market (figure in RsCrore)	Growth Rates (%)
2003-04	32575	7.28
2004-05	34128	4.77
2005-06	39989	17.17
2006-07	45367	13.45
2007-08	50946	12.30
2008-09	55454	8.85

Key Strengths of Pharma Sector

- Low cost of innovation/Manufacturing/Capex costs/expenditure to run a CGMP compliance facility.
- Low cost scientific pool on shop floor leading to high quality documentation.
- Proven track record in design of high tech manufacturing facilities.
- Excellent regulatory compliance capabilities for operating these assets.
- Recent success track record in circumventing API/formulation patents.
- About 95% of the domestic requirement being met through domestic production.

Benefits of Exporting (Through Government of India)

1. DEPB Benefit
2. Duty draw Benefit
3. Advance authorization
4. EPCG Benefit

New Drug Approval (NDA):

A pharma company has to undertake patent registration to protect its own interests, prior to launching its products in any country. To protect the interests of the consumers, it is necessary that the product be approved by the drug authorities in that country. Mostly the process for seeking approval is initiated alongside the patent registration process.

WTO

The developed countries of the world have put a pressure, across the world for uniformity in patent laws which is being implemented under WTO (World Trade Organization - earlier GATT i.e. General Agreement on Tariffs & Trade). Presently different countries have different Patent types and life period. WTO has decided upon a product patent life of 20 years in all countries.

RESEARCH & DEVELOPMENT (R&D)

Indian pharmaceutical industry is third largest in the world and is one of the most developed industries. 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. Indian pharmaceutical industry today is ranked world class, 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. The industry today can boast of producing the entire 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. The pharmaceutical industry in India is stated to be valued at approximately US\$ 12.26 billion as per industry estimates. This industry is growing @ 10-11% per annum on compounded growth rate basis. Although total turnover of pharmaceutical industry is estimated at 21.04 billion, about 65% of this revenue is from exports. It spends around 18 % of this revenue on research and development (R&D) activities. Additionally, India's clinical research industry is estimated to be a US\$ 2.2 billion with a high growth rate of 23%. Moreover, Indian pharmaceutical off-shoring industry is slated to become a US\$ 2.5 billion opportunity by 2012, due to low R&D costs and a high-talent pool. Through the introduction of a system of product patents since 2005, Indian industry has today become a worldwide exporter of high quality generic drugs. India exports pharmaceuticals to many countries across the world, including the U.S., Germany, France, Russia and UK. The Indian Government is very proactive for boosting growth and investment in Indian pharmaceutical sector. It allows 100 per cent FDI under the automatic route in the drugs and pharmaceuticals sector. The DIPP data suggests that the drugs and pharmaceuticals sector has attracted an impressive level of FDI worth US\$ 1,882.76 million during April 2000 to March 2011. Industrial licenses are not required in India for most of the drugs and pharmaceutical products. Manufacturers are free to produce any drug duly approved by the Drug Control Authority. This patent

regime has led to the investment from many pharmaceutical multinationals in India. Now they are looking at India not only for its traditional strengths in contract manufacturing but also as a highly attractive location for research and development (R&D), particularly in the conduct of clinical trials and other services. Indian and foreign companies are continuing with patented drug launches in India and between 2005 and 2010, the Indian Patent Office has granted 3,498 product patents, as per a KPMG report.

PHARMACEUTICAL COMPANY BUSINESS STRATEGIES

The days when the Indian pharmaceutical industry was synonymous with cheap generic drug production are passing. While generics continue to play a major part in the industry's success, many companies have started down the long road of drug discovery, novel product development and pharma services. With high-quality research, low-cost manufacturing facilities and educated personnel, the Indian pharmaceutical industry presents both a competitive threat and partnering opportunities. As a significant international industry India is the world's fourth largest producer of pharmaceuticals by volume, accounting for around 8.5% of global production. In value terms, production accounts for around 1.7% of the world total. The Indian pharmaceutical industry directly employs around 600,000 people and is highly fragmented. While there are around 280 large R&D based pharmaceutical companies in India, including multinationals, government-owned and private companies, there are also around 6000 smaller licensed generics manufacturers, and although in reality only around 3500 companies are involved in pharmaceutical production. Most small firms do not have their own production facilities, but operate using the spare capacity of other drug manufacturers.

CONCLUSION

Through various ways a business organization can achieve success in the market, but all those ways can be comprised into as above, we can rightly say that it revolves specifically around three parties or more, the relationship between these three parties (company, customers and competitors) determine the success and failure of business organization. From medium to long run, the domestic pharmaceutical market will be largely driven by the increasing prevalence of chronic segment. The domestic pharma industry is principally being driven by the chronic segment which has grown by 18.1% this year. Against the backdrop up- take of acute segments has been slow and has grown by 10.3% only. The basis of success in any competitive context can be, at elementary level commercial success; and commercial success can be derived from either a cost advantage or a value advantage or ideally from a combination of both. In other words, the companies with Competitive Advantage tends to be the cost

leader in the industry or a seller of most differentiated products will become the market leader amongst all the players. At last the role of supply chain is very important in both the phases (in acute as well as in chronic). The successes of any pharmaceutical industry; when a company changes its focus from —Acute to —Chronic therapy market depend on competitiveness of supply chain. Supply Chain Management can provide considerable value to their companies by understanding the customers' delivery requirements. A powerful tool for understanding these requirements is account segmentation. A company can use account segmentation to identify market segments Such as Acute & Chronic therapy market.

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