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

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I. Introduction

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 rangingcapabilities in the complex field of drug manufacture and technology. It ranks very high inthe 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.

It is playing a key role in promoting and sustaining development in the vital field of medicines, TheIndian Pharmaceutical 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 fragmented with more than 20,000 registered units with severe price competition and government price control. It has expanded drastically in the last two decades.

There are about 250 large units that control 70 per cent of the market with market leader holding nearly 7 per cent of the market share and about 8000 small scale units together 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 total Indian production constitutes about 13 per cent of the world market in value terms and, 8 per cent in volume terms. In all its activities the pharmaceutical industry believes that high standards should be defined and respected and is convinced that, so far as its marketing activities are concerned, self- discipline is the process which best serves the public interest.

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 sect oral 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.

II. 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.

III. Scope Of The Study

The Scope of the study focuses on the marketing strategies followed by Smilax labs for its marketing activities. The study concentrates on the methods and techniques followed by the company which include the standard operating procedure, Export procedure & Benefits at smilax laboratories The study appraises the company's success in meeting requirement of the company and supplying the modernized and innovated medical equipment and drugs to the world. The data required for the study is collected from the past year published annual reports of the company.

Need For The Study

The study is intended to know the marketing strategies of the company. Since, the company growth depends upon their sales conditions only. The study mainly deals with the marketing activities of the company. The main objective of the study is to know how the company performs its marketing activities for the attainment of its goals. The study covers the standard operating procedure, exporting and benefits, types of markets available for the smilax labs.

Objectives Of The Study

The following basic objectives are under below

- > To study the present standard operating procedure of the smilax labs.
- To study procedure for exporting and the benefits of the exporting of the smilax labs.
- > To study Different types of markets available to sell the products.
- > To offer valuable suggestions.

Methodology Of The Study

A market research study has been taken from the institute (ICRA) for the purpose of above study. The research data has been collected throughout this procedure.

Primary Data

a) Data collection

- The success of any research project depends critically on data. So data collection is the most important aspect of the project. Sales data and its comparison with previous financial years.
- > The report from the ICRA about the market potential to assess potential for the companies market.
- > Previous financial year sales as a comparative data to design a strategy to reach company's goal.

b) Market Survey

- Market Survey has been conducted after preparing the checklist and the focus was to know the market share for the company.
- We have conducted survey based on IMS data, BDR data and other reports and finally evaluated that there is a very good scope and business opportunity for the product range of smilax laboratories.

Secondary Data

Company's documents, Brochures, Various journals, pamphlets and companies portals were studied for relevant information regarding the subject of the projects. These documents were very useful for theoretical, conceptual and organizational background. Detailed analysis of information and data collection was carried on and then it has been possible to complete the task.

Limitation Of The Study

- The export benefit that the company has gained varies from one product to another product so the exact benefit had not been taken.
- ➤ The benefit from the exports sales is taken only on the average of the sales made in the regulated markets as on 2006 2011.
- Executives cannot spare enough time for our present work.

The organization should maintain a master list of all SOPs. This file or database should indicate the SOP number, version number, date of issuance, title, author, status, organizational division, branch, section, and any historical information regarding past versions. The QA Manager (or designee) is generally the individual responsible for maintaining a file listing all current quality-related SOPs used within the organization. If an electronic database is used, automatic "Review SOP" notices can be sent. Note that this list may be used also when audits are being considered or when questions are raised as to practices being followed within the organization.

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, where as 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.

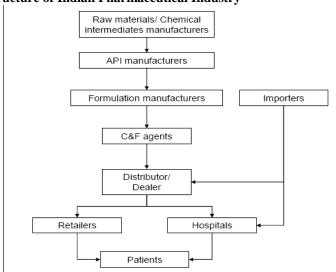


Chart: Distribution Structure of Indian Pharmaceutical Industry

The above illustration depicts the market structure of Indian market. It depicts how the structure is close knit and the system is well connected.

Pharma Marketing Process And Its Challenges

While many pharmaceutical companies have successfully deployed a lot of staple strategies to target the various customer types, recent business and customer trends are creating new challenges and opportunities for increasing profitability. In the pharmaceutical and healthcare industries, a complex web of decision-makers determines the nature of the transaction (prescription) for which direct customer (doctor) of pharmaceutical industry is responsible. Essentially, the end-user (patient) consumes a product and pays the cost.

Use of medical representatives for marketing products to physicians and to exert some Influence over others in the hierarchy of decision makers has been a time-tested tradition. Typically, sales force expense comprises an estimated 15 percent to 20 percent of annual product revenues, the largest line item on the balance sheet. Despite this other expense, the industry is still plagued with some very serious strategic and operational level issues.

Marketing Strategies Can Be Best Described In These Two Models In Both Chronic And Acute Segments Super Core Model involving the search for, and distribution of a small number of drugs from Chronic Therapy Area that achieve substantial global sales. The success of this model depends on achieving large returns from a small number of drugs in order to pay for the high cost of the drug discovery and development process for a large number of patients. Total revenues are highly dependent on sales from a small number of drugs. This model incorporates highly specialized approach in all the manner. Initially the competition is seems more at entry level but since growth is stable and more in this area; every company is striving very hard to enter in this area. The major strategy in this model involves right focus to highly specialized customer by well-trained team.

Core Model in which a larger number of drugs from **Acute Therapy Area** are marketed to big diversified markets. The advantage of this model is that its success is not dependent on sales of a small number of drugs. Here presenting a large number of products and taking the advantage of opportunity cost is one of the important strategies. Other strategy includes daily reminders to cross the perceptual filter and get the brand name in to the sub-conscious state of mind.

From **organizational perspective** the most prominent performance related issues are listed below:

- a) .Increased competition and 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, development and

Retention strategies

- d). Varying customer perception.
- e) The number and the quality of medical representatives
- d). Very high territory development costs.
- f). High training and re-training costs of sales personnel.
- g) Very high attrition rate of the sales personnel.
- h). Busy doctors giving less time for sales calls.
- i). Poor territory knowledge in terms of business value at medical representative level.
- j). Unclear value of prescription from **each doctor** in the list of **each sales person**.
- k). Unknown value of revenue from each retailer in the territory
- 1). Absence of ideal mechanism of sales forecasting from field sales level, leading to huge deviations
- m). Absence of analysis on the amount of time invested on profitable and not-so profitable

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

Markets Available For The Pharma Business

Types of markets for Smilax labs

- 1. Regulated markets
- 2. Semi regulated markets
- 3. Non regulated markets

Regulated Markets

Regulated market or controlled market is the provision of goods or services that is regulated by a government appointed body. The regulation may cover the terms and conditions of supplying the goods and services and in particular the price allowed to be charged and/or to whom they are distributed. It is common for a regulated market to control natural monopolies such as aspects of telecommunications, water, gas and electricity supply. Often regulated markets are established during the partial privatization of government controlled utility assets.

In the Pharmaceutical industry, US, Europe and Japan are considered as Regulated markets.

- > The markets are like USA and Europe
- ➤ The matured time is about minimum about 3 years
- The main works that are in involved are registration filing
- ➤ Customer visit to our facilities
- ➤ The price will be premium

Advantages

- Long term and stable business
- Highly paid markets: Price realization is more in these markets.
- Even customer also cannot change the source due to regulatory procedures involved in the same.
- Customers can not change the source easily because it is pretty expensive process and time taking process. It is also depends upon the regulated body approvals and their schedules.
- Highly cultured and systematic people. (Once upon a time, there was no documentation required in the Europe Union. People were obliged to take the even purchase orders only on oral basis. Because every European's word is almost a legal word...)
- Highly reliable markets.
- Rich markets as these markets are well developed economic countries
- Stringent regulations even for selection of the vendors which will streamline the process before starting the business itself. This will help not to have any surprises / problems at the last moments or where the problems are really create lot of hell.

There are some regulatory certifications provided by Government of India. These certificates will be used to claim certain benefits in those countries by customers in abroad.

Semi Regulated Markets

- 1. The countries that come under these semi regulated markets are the Korea ,Thailand ,Malaysia ,Egypt ,Mexico ,brazil
- 2. The time required to complete the regulation and get approvals is 6-12 months.

- 3. The semi regulatory market contains the limited regulation like registration.
- 4. Semi regulations countries are like Latin America counties like Brazil, Mexico Argentina, Columbia, and middle east countries Egypt , Saudi countries , Africa.
- 5. The pricing structure will be better from non regulatory markets and lower than regulatory price.

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, India.

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

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

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	Growth Rates		
	(figure in RsCrore)	(%)		
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		

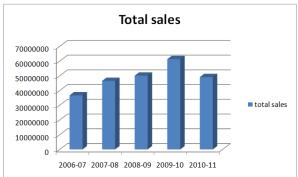
Key Strengths Of Pharma Sector

- 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

Graphical representation of total sales



IV. Analysis

The graphical representation of total sales denotes that the total sales are high in the year 2009-10 and low in the year 2006-07.

- 1. The company Smilax laboratories follows the standard operating procedure that are for the
- Sales plan of smilax
- Generation of the enquiries
- Execution of the orders
- 2. Had been observed and understood and found that the present standard operating procedures need to have some changes in their procedures
- 3. The company operates in all the markets that regulated ,semi regulated and non regulatedmarkets the standard operating procedures are same for the all these markets
- 4. The company is getting the benefits of export around 17% 21%, the regulated markets are difficult to operate but the premium pricing and above that the export benefits are making the market interesting to operate since it is a difficult market that operations in these type of the market is not so easy.

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