International Journal of Research in Economics and Social Sciences(IJRESS)
Available online at: http://euroasiapub.org
Vol. 9 Issue 10, October - 2019
ISSN(o): 2249-7382 | Impact Factor: 7.101 |

Current Scenario of the Indian Pharmaceutical Industry: An Evaluation

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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 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.

It is playing a key role in promoting and sustaining development in the vital field of medicines, The Indian 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.

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Indian 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 equity. 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 players. 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

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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.

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 the entire manner. Initially the competition is seems more at entry level

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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. 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

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

l) 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

n) Very high territory development costs.

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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.
- Highly reliable markets.

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- 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.

Semi Regulated Markets

- The countries that come under these semi regulated markets are the Korea, Thailand, Malaysia ,Egypt ,Mexico ,brazil
- The time required to complete the regulation and get approvals is 6-12 months.
- The semi regulatory market contains the limited regulation like registration.
- Semi regulations countries are like Latin America counties like Brazil, Mexico, Argentina, Columbia and middle east countries Egypt ,Saudi countries ,Africa.
- 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.

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.

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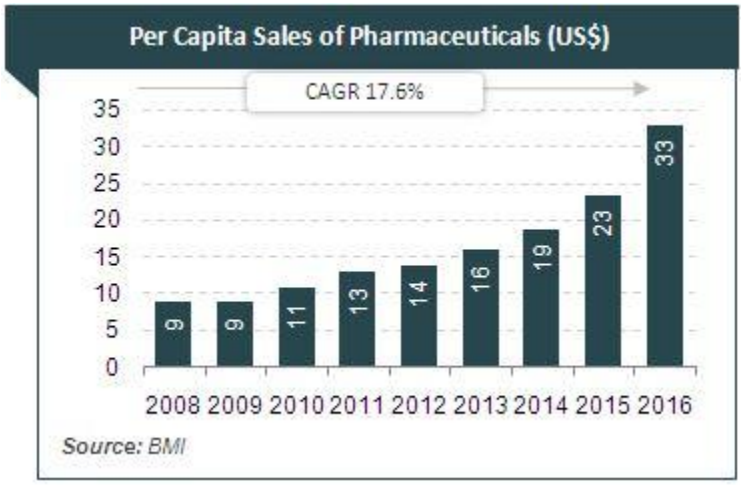

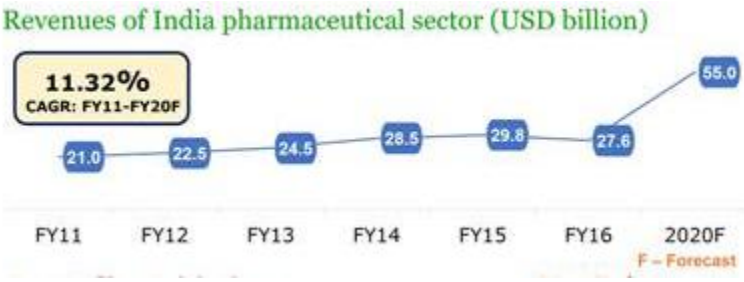

Conclusion

The acquisition of Indian pharmaceutical companies by global majors and the success of Indian firms in the generics markets have been prominent stories for the last few years. The tremendous growth potential of the huge Indian market and the focus on efficient healthcare in western markets are the primary reasons for these trends. This, however, is only a part of the entire picture. Indian firms have global ambitions and have acquired companies abroad not only to develop R&D capabilities and move into new drug development, but also to enter new markets. Despite this growth, concerns like the affordability of drugs for lower-income groups and the ability to rapidly respond to pandemics like swine flu still remain unaddressed. For sustained growth over the next few decades, firms should concentrate on tackling such concerns and coming up with innovative drug delivery mechanisms.

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