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INDUSTRY ANALYSIS: A STUDY OF INDIAN PHARMACEUTICAL SECTOR ENVIRONMENT WITH THE HELP OF STRATEGIC TOOLS: PESTL AND SWOT ANALYSIS

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ABSTRACT

Purpose:

The liberalization, privatization and globalization (LPG) era in India has made revolutionary changes in the Indian corporate sector. The breeze of LPG in India has made maximum impact on banking, IT, pharmaceutical sector. The Indian pharmaceutical sector recently has witnessed halt in terms of its growth. This paper tries to identify and examine the impact of internal and external Variables that influence the Indian pharmaceutical Industry. The macro environment tends to have a long lasting impact and hence require extensive research. This research is carried out with the help of SWOT and PESTL strategic tools. These tools play an important role in the value creation opportunities of strategy.

Design / Methodology/ Approach*-The present research paper is conceptualized and is based on secondary data collected from various resources like management journals and internet. In order to identify the internal and external variables that influences the Indian pharmaceutical industry.*

Findings: *By identifying and examining the internal and external variables that influence the Indian pharmaceutical industry by using PESTL and SWOT strategic tools, organizations can formulate effective strategies to overcome these influence.*

Limitations: *Present research is conceptualized and is purely based on secondary data; ergo the limitations of this paper is lack of primary data*

Practical implications: *with the help of this paper organizations can cope up with the dynamic environment and can formulate their strategies as per the situations.*

Keyword: *SWOT, PESTL, Strategy, Value Creation, Pharmaceutical.*

1. Introduction

The Indian pharmaceuticals market is the third largest in terms of volume and thirteenth largest in terms of value, as per a report by Equity Master. Branded generics dominate the pharmaceuticals market, constituting nearly 70 to 80 per cent of the market. India is the largest provider of generic drugs globally with the Indian generics accounting for 20 per cent of global exports in terms of volume. Of late, consolidation has become an important characteristic of the Indian pharmaceutical market as the industry is highly fragmented.

India enjoys an important position in the global pharmaceuticals sector. The country also has a large pool of scientists and engineers who have the potential to steer the industry ahead to an even higher level.

The Indian pharmaceutical industry has shown lot of development in terms of infrastructure development, technology and in terms of wide range of products. The Indian domestic industries have recently achieved a milestone through leadership position and global presence as a world class cost effective generic drugs manufacturer of AIDS medicine. Also, the Indian pharmaceutical firms have set high standards in terms of purity, stability and international safety, health and environment (SHE) protection in production and supply of bulk drugs. A lot of pharmaceutical firms of India have got international regulatory approvals from agencies like USFDA, MHRA-UK, TG-Australia, MCC-SA etc. outside USA India has the highest number of USFDA approved plants for manufacturing generic drugs. A number of leading Indian Pharmaceutical companies derive 50% of their turnover from International business.

1.1. Market Size

According to India Ratings, a Fitch company, the Indian pharmaceutical industry is estimated to grow at 20 per cent compound annual growth rate (CAGR) over the next five years. The Indian pharmaceutical industry, which is expected to grow over 15 per cent per annum between 2015 and 2020, will outperform the global pharmaceutical industry, which is set to grow at an annual rate of 5 per cent between the same period1. Presently the market size of the pharmaceutical industry in India stands at US$ 20 billion. As on March 2014, Indian pharmaceutical manufacturing facilities registered with the US Food and Drug Administration (FDA) stood at 523, highest for any country outside the US.

Indian pharmaceutical firms are eyeing acquisition opportunities in Japan's growing generic market as the Japanese government aims to increase the penetration of generic drugs to 60

per cent of the market by 2017 from 30 per cent in 2014, due to ageing population and rising health costs.

India's biotechnology industry comprising bio-pharmaceuticals, bio-services, bio-agriculture, bio-industry and bioinformatics is expected grow at an average growth rate of around 30 per cent a year and reach US$ 100 billion by 2025. Biopharma, comprising vaccines, therapeutics and diagnostics, is the largest sub-sector contributing nearly 62 per cent of the total revenues at Rs 12,600 crore (US$ 1.9 billion).

1.2. Challenges Faced by Indian Pharmaceutical Industry

The value of Indian pharmaceutical market is valued at Rs. 72069 crores in 2013 as compared to Rs. 65654 crores in 2012. It has experienced a halt with its growth going down to 9.8 % from 16.6 % in 2012 due to new policies formulated by government of India. The implementation of NPPP National Pharmaceutical Pricing policy 2012 has resulted in profit reduction of retailers from 20 % and 10 % to 16 % and 8 %. This decrease in profit margin has created a substantial uncertainty among many retailers regarding the probability of staying in the business. Also the pharmaceutical industry is struggling with the issues like delays in clinical trials, FDI policy, and the new pharmaceutical pricing policy, a uniform code for sales and marketing practicing and compulsory licensing.

1.2.1. Clinical Trials

Clinical trials are the standard processes which decide the safety and effectiveness of the drugs. Clinical trials are also required for the Indian pharmaceutical industry to develop cost effective drugs for diseases like TB, malaria, etc. it also helps the aspiration of developing a sound R&D center.

The delays and regulatory uncertainties have disrupted the innovation curve and the growth of clinical trial industry. In order to become a major contributor in the global pharmaceutical industry, India needs to speed up clinical trials as well as address other issues which disrupt the growth of Indian pharmaceutical industry.

1.2.2. National pharmaceutical pricing policy

The recommendations made by Dr. Pronab Sen have been considered which resulted in the formation of NPPP. The government has implemented the NPPP to control the pricing of essential drugs. With the help of NPPP government has increased the scope of Drug price control order (DPCO). The NPPP included all the drugs in the National List of Essential Medicine (NLEM) 2011. The purpose of drafting NPPP was to promote research and

development of new drugs along with the availability and affordability of new patent medicine for effective treatment of the masses in case of diseases like Cancer and HIV.

1.2.3. FDI Policy

FDI, up to 100 per cent, under the automatic route, is allowed for green field investments in the pharmaceuticals sector.

FDI, up to 100 per cent, is permitted for brown field investment (i.e. investments in existing companies), in the pharmaceutical sector, under the government approval route. The approval for brown field investment comes under Foreign Investment Promotion Board (FIPB). The conditions laid by FIPB for 100 % brown field investment are as follows:

i. To maintain the production level of National List of Essential Medicine (NLEM) at the highest level for three years preceding the FDI.
ii. To maintain the R&D expenses at the highest level for three years preceding FDI.
iii. To share the information regarding the need for transfer of technology to the administrative ministers and FIPB.

1.2.4. Uniform Codes for Sales and Marketing

To prevent the unethical practices and corruption in the pharmaceutical sector the Department of Pharmaceutical (DoP) has issued certain guidelines on a uniform sales and marketing for pharmaceutical companies which are different from MCI guidelines. Tax authorities use the information given by Central Board of Direct taxes which follow the rules laid by MCI. To remove corruption and unethical practices there is a need for clarity in terms of guidelines issued by both DoP and MCI.

1.2.5. Compulsory Licensing

Compulsory licensing is an important tool in the hands of government to control the price hikes of patent drugs. The objective of compulsory licensing is to ensure the availability and affordability of patent drugs at reasonable prices. The compulsory licensing allows third parties to produce and market patented drugs without the consent of patent holder. The compulsory licensing can be revoked in India due to non affordability and unavailability of patent drugs in masses. This will help in protection of public health especially in case of chronic diseases like Cancer and AIDS.

Also India has adopted it on the following grounds under section 84 of patent act:

i. The drug did not meet reasonable requirements of citizens.
ii. The drug was not reasonably priced, and

iii. The patent was not locally manufactured.

However due to these restrictions there is a derailed growth in the pharmaceutical sector. Government needs to find a right balance between the need for affordability and protection of intellectual property rights.

1.3. Objectives of the Study

- To study the Political, Economic, Social, Technological & Legal factors which influence the Indian pharmaceutical Industry
- To study the strengths, weaknesses, opportunities and threats of Indian Pharmaceutical Industry

1.4. Research Methodology

The research type is of exploratory in nature and uses the PESTL and SWOT analysis tools for reaching a conclusion.

1.5. Hypothesis

i. To identify the internal and external variables that influence the indian pharmaceutical sector

1.6. PESTL (**P**olitical, **E**conomic, **S**ocial, **T**echnological & **L**egal Aspects**) Analysis:**

PESTL analysis helps in evaluating the performance of Indian pharmaceutical sector. The external variables play a important role in shaping any industry performance. These variables have a long term impact and thus require in-depth analysis and research. PESTL analysis helps to sum up the external environment in which the pharmaceutical business operates.

According to the definition of Investopedia, *"PESTL is aimed at determining how an organization is affected by these six forces: political, economic, sociocultural, technological, and legal." PESTL is also used to help develop business strategies for exploiting opportunities, as well as for evaluating the potential of new markets.*

1.6.1 Political Aspect:

The political scenario of India is uncertain and dynamic. Hence it has a key impact on the Indian Pharmaceutical industry. Here the Political aspect of PESTL analysis undertakes evaluation of regulatory issues in the Indian Pharmaceuticals industry. To have a keen

indication of regulatory set-up is vital due to the rapid and ongoing changes. The major bodies regulating drugs and Pharmaceuticals in India are:

- CDSCO (Central Drugs Standard Control Organization (CDSCO), Ministry of Health & family welfare), Government of India provides general information about drug regulatory requirements in India.
- NPPA Drugs (Price Control) Order 1995 and other orders enforced by National Pharmaceutical Pricing Authority (NPPA), Government of India.
- D & C Act, 1940 The Drugs & Cosmetics Act, 1940 regulates the import, manufacture, distribution and sale of drugs in India.

  Schedule M : Schedule M of the D&C Act specifies the general and specific requirements for factory premises and materials, plant and equipment and minimum recommended areas for basic installation for certain categories of drugs.

  Schedule T: Schedule T of the D&C Act prescribes GMP specifications for manufacture of Ayurvedic, Siddha and Unani medicines.

  Schedule Y: The clinical trials legislative requirements are guided by specifications of Schedule Y of The D&C Act

The Patent Act, 1970: The Act's stated objective was to foster the development of an indigenous Indian pharmaceutical industry and to guarantee that the Indian public had access to low-cost drugs. The Act replaced intellectual property rights laws left over from the British colonial era and ended India's recognition of Western-style "product" patent protection for pharmaceuticals, agricultural products, and atomic energy. Product-specific patents were disregarded in favor of manufacturing "process" patents that allowed Indian companies' to reverse engineer or copy foreign patented drugs without paying a licensing fee. This allowed the domestic industry build up considerable competencies and offers a large number of cheaper "copycat" generic versions legally in India at a fraction of the cost of the drug in the West, as long as they employed a production process that differed from that used by the patent owner. The Act protected process patents for 7 years instead of the usual 15 years needed to develop and test new drugs.

Patents (Amendment) Act 2005: To meet its TRIPs obligations, India amended its patent law on March 22, 2005, abolishing its "process" patents law and reintroduced Western style "product" patents for pharmaceuticals, food, and chemicals. This action effectively ended 36 years of protection for Indian pharmaceutical companies and stipulated that Indian companies selling copycat drugs must pay foreign patent holders a "reasonable" royalty for copies sold in the Indian market. The amendment made reverse engineering or copying of patented drugs illegal after January 1, 1995. The Act allowed for only two types of generic drugs in the Indian market: off-patent generic drugs and generic versions of drugs patented before 1995. At present, nearly 97 percent of all drugs manufactured in India are off patent and therefore will not be affected by this Act. It also introduced a provision establishing compulsory licenses for exports to least developed countries with insufficient pharmaceutical manufacturing capacities.

The Amendment grants new patent holders a 20-year monopoly starting on the date the patent was filed and, without a compulsory license, no generic copies can be sold during the duration of the patent. The WTO also required India to establish a "mailbox" where patent applications could be filed between January 1, 1995 and 2005

The following are the key political aspects which affect the performance of the industry:

- **Political uncertainty:** Indian politics is dynamic in nature. With the recent FDI policy of government, the Pharmaceutical industry has opened doors for foreign players to enter the market and create a competitive environment.
- **Stringent price control rules**: there are some highly important Pharmaceutical drugs which are priced under severe government regulations.
- **PSU segments:** The Indian government has some sick PSUs which are inefficient and their performance is degrading day by day and with due to this they are unable to stand the private competition. The government hopes to revive these sick units by transferring the funds from the healthy units.

1.6.2. Economical Aspect:

The economic aspects of PESTL analysis is discussed under the following points:

- **Contribution to GDP**: the Indian Pharmaceutical sector contributes to approximately 1% of the GDP. Considering the huge population of India, the contribution is very low and thus economic policies needs to be more focused on the industry.

- **Low Per capita income:** the per capita income of an Indian per month is very low. Hence the spending on Pharmaceutical products decreases.
- **Taxation:** The burden of taxes is very high. Taxes such as excise duty, custom duty, service tax, professional tax, license fees, royalty, pollution clearances tax, hazardous substance license, income tax etc. make up about 40-45% of the cost.
- **Storage and Transportation facilities:** the adequate storage and transportation is lacking. This makes the Pharmaceutical products more susceptible damage, spoilage and also unavailable to large portion of population.
- **Pricing:** The setting up and scheming of the prices of mass drugs and formulations under the Essential Commodities Act is prepared by the National Pharmaceutical Pricing Authority (NPPA).

1.6.3. Socio-Cultural Aspect

India contributes almost 16 % of the world's population and a large number of Indian population remains below poverty line.

- India faces the problem of poverty and malnutrition and thus makes a large population susceptible to diseases.
- Lack of proper sanitation facilities in cities and villages.
- Polluted water resources in cities and villages.
- Preference over household treatments for common ailments reduces the scope of pharmaceutical drug consumption.

1.6.4. Technological Aspect:

After LPG, the Indian pharmaceutical industry has seen a rapid growth in terms of technological advancements. The Indian pharmaceutical industry has become technologically strong, which allows them to manufacture and develop low cost drugs.

Technological capability procured by the Indian pharmaceutical industry since its origin may be categorized under the following headings:

- Process development capabilities for bulk drug and
- Product development capabilities for formulations and
- New drug discovery research.

The low cost of manufacturing represents India as an attractive destination for research and the availability of large patent pool makes it appealing for clinical trials.

1.6.5. Legal Aspect:

There are well-established legislative, administrative, and legal frameworks to preserve intellectual property rights in India. India has complied with its obligations under TRIPS by passing necessary legislations and making amendments to the existing legislations like Patent act, 1970 and patent (Amendment) act 2005.

1.7. SWOT Analysis (**S**trength, **W**eakness, **O**pportunities, & **T**hreats)

SWOT analysis is a strategic tool used for understanding strengths and weaknesses, and for identifying both opportunities available to you and threats you face. Strengths and weaknesses are often internal to the organization, while opportunities and threats are generally related to the external environment of the organization. That's why SWOT analysis is sometimes called Internal-External analysis.

According to the definition of Investopedia, "*A SWOT analysis is a tool that identifies the **s**trengths, **w**eaknesses, **o**pportunities and **t**hreats of an organization. Specifically, SWOT is a basic, straightforward model that assesses what an organization can and cannot do as well as its potential opportunities and threats. The method of SWOT analysis is to take the information from an environmental analysis and separate it into internal (strengths and weaknesses) and external issues (opportunities and threats). Once this is completed, SWOT analysis determines what may assist the firm in accomplishing its objectives, and what obstacles must be overcome or minimized to achieve desired results."*

1.7.1. Strengths

- India ranks amongst the top global generic formulation exporters in volume terms due to low manufacturing and installation cost.
- Huge untapped population
- Higher GDP growth leading to increased disposable income in the hands of general public and their positive attitude towards spending on healthcare
- Cost Competitiveness
- Low-cost, highly skilled set of English speaking labor force
- Growing treatment naive patient population
- Well established network of Laboratories and R & D infrastructure which provides a strong network for new drug discovery & development.

1.7.2. Weaknesses

- Slow clinical trials
- Poor all-round infrastructure is a major challenge as India accounts for almost 16% of the world population while the total size of industry is just 1% of the global Pharmaceutical industry.
- Stringent price controls
- Lack of data protection
- Indian Pharmaceutical sector has been adversely affected by lack of product patent, which prevents Global Pharmaceutical companies to introduce new drugs in the country and discourages innovation and drug discovery.

1.7.3. Opportunities

- FDI allowed up to 100% in Indian Pharmaceutical sector
- Global demand for generics rising
- Rapid OTC and generic market growth
- Increased penetration in the non - metro markets
- Large demand for quality diagnostic services
- Increase in healthcare insurance coverage
- Significant investment from MNCs
- Public-Private Partnerships for strengthening infrastructure

1.7.4. Threats

- The highest pharmaceutical pollution is measured in India
- Labor shortage
- Threats from other countries like China and Israel exist as they also produce Pharmaceutical products at lower cost
- Wage inflation
- Government expanding the umbrella of the Drugs Price Control Order (DPCO)
- Considerable counterfeiting threat
- Competition from other emerging economies

- Exports efforts are hampered by procedural formalities in India as well as Non-Tariff Barriers imposed abroad.

1.8. Summary and Conclusion

The following conclusion can be drawn about Indian pharmaceutical industry with the help of SWOT and PESTL analysis.

Indian pharmaceutical companies have continued to invest significant resources in the development and manufacturing of generic drugs. The cost of establishing a USFDA approved plant in India is lower than developed countries. As a result, India currently has the highest number of USFDA-approved plants outside the US.

Production costs in India are lower than developed countries due to local equipment sourcing, tax incentives, and focus on process innovation. Labor costs in India are lower than developed countries due to the availability of a large pool of highly qualified personnel specializing in chemistry and process reengineering skills.

On the other hand, SWOT analysis suggests that the focus of the government should be on the increase in penetration and access of health insurance. All forms of infrastructure, medical, educational and physical, need improvement through Public Private Partnership programmes.

Focus on price monitoring rather than price control, along with resolution of data exclusivity laws will help in increasing confidence among foreign companies.

Technology capabilities can be used to increase efficiency across the value chain, and increase medical services accessibility.

Expansion into the high potential rural and semi-urban markets will require decisive strategies to fit these markets. Companies will be required to build a networked operational model with various stakeholders in order to squeeze. The government should increase its spending on healthcare sector as it has a huge potential and will eventually contribute to its GDP.

The PESTL formwork analyses the sustainability of industry. Hence the Political, Economical, Socio- cultural, Technological and Legal variables are favorable for firms to operate and perform in Indian pharmaceutical industry.

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