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Indian Pharmaceutical Industry Based on SWOT Analysis (2023): A Review

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Abstract

Indian pharmaceutical companies are developing at a very fast pace and contributing to the national economy. India accounts for 10% of world production and ranks third in the world in terms of volume. COVID has changed the whole perspective of "Pharmaceuticals" globally and a SWOT analysis in these newer times is a tool for a company's strengths, weaknesses, opportunities and threats. There are many pharmaceutical companies in India. Among them, few are the giants of the market and technically more enlightened. Few firms are diminutive as well as conventional. Some companies dominate the whole medicine market in India, as a result, they must contend with fierce rivalry in the drugs sector. Any industry's SWOT analysis examines the key variables that could affect the sector and have an impact on how businesses operate. This review article aims to figure out realizable path to overcome the weakness and threats of company and to make use of the strength and opportunity optimally.

Keywords: SWOT analysis, Indian pharmaceutical companies, statistical data, capital and technology, medicine market

INTRODUCTION

Pharma industry is capital-intensive and technology-driven industry because of the intrinsic complexities like developmental challenges for new drugs, regulatory challenges for commercialization, huge capital requirement, longer gestation period, delay in return on investments and frequent changes in disease trends. This industry has been bestowing its richness on both human and fiscal health of the world. Pharmaceutical industry provides medicines to be used as medications for humans and animals. This involves various processes like manufacturing, extraction, processing, purification, packaging and logistics.

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India a self-consumed economy owing to the rising population, and increase in per capita income has led to rise of consumption levels in the country followed by strong demand from export markets, which makes India a bastion of pharmaceuticals. The industry currently generates bulk drugs belonging to all major therapeutics groups and has also evolved excellent GMP (good manufacturing practices) to produce different doses forms.

Bengal Chemicals and Pharmaceutical Works, the first government owned drug manufacturers started much before India's independence, in 1930, and is still running, has paved the way for private players to enter into this business of saving health and lives.

Early in the 1960s, the government began to support the expansion of Indian enterprises producing drugs, and in 1970, the passage of the Patents Act helped the sector develop into what it is today.

Some of the leading indian pharmaceutical companies are Zydus Life Sciences, Sun Pharmaceutical Industries Ltd., Dr. Reddy's Laboratories, Cipla Ltd., Lupin Ltd., Aurobindo Pharma Ltd., Glenmark Pharmaceuticals, Divi's Laboratories, Abbot India, Alkem Laboratories, etc. [1].

SWOT ANALYSIS

SWOT (strengths, weaknesses, opportunities, threats) analysis is used in businesses to identify its internal strengths and weakness, as well as its external opportunities and threats to remain proactive and change with changing times [1]. The aim of this study was to examine the drug formulation, manufacturing, packaging of medications using SWOT methodology.

A SWOT analysis of the pharmaceutical industries helps in figuring out by the upper management what the industries are excelling in, what developments need to be made, where the growth is possible, and what preemptive measures need to be taken to conserve their shareholders or company names [2].

Strengths

- The present domestic drug regulatory environment has been supportive to the growth of an evolving pharmaceutical industry [3].
- Global competitiveness enhanced by recent amendment to Schedule M (Good Manufacturing Practices) of Drugs and Cosmetics Act and Schedule Y (new drug discovery).
- Increasing usage of pro-competitive provisions such as Section 3D of the Indian Patent Act to fight against ever-growing strategies employed to promote monopoly by big players.
- Revamped regulatory regime.
- To boost the nation's drug regulatory system, the Central Government gives CDSCO (Central Drugs Standard Control Organization) a budget of Rs. 1750 crore. The monies will be used wisely to support the state and federal drug regulatory departments' capacity building initiatives.
- Compliance with international regulatory and Good Clinical Practices (GCP) standards [1].
- Take steps to create an integrated regulatory structure by creating a National Drug Authority so that the same organization is in charge of both quality regulation and pricing control.
- The network of Pharmacovigilance Centres helps to track adverse drug reactions at national, zonal, and regional levels in the country.
- A proposal to restrict trade margins and bring almost 374 bulk pharmaceuticals under price control.
- Clinical Trials Registry of India (CTRI), has improved monitoring of clinical trials in India
- First compulsory licence granted by the Indian Patent Office and its implication for the pharmaceutical industry.
- India is thought to have an advantage over China in terms of skilled, English-speaking labour and equitable protection of intellectual property rights backed by a strong legal system [1, 3].

Weaknesses

- The nation has demonstrated an insufficient regulatory structure, compliance, and enforcement regime, as evidenced by actions like the production of fake or subpar medications.
- Despite its significant evolution, the national drug regulatory system still needs to increase its people and system requirements.
- Insufficient experience to effectively exploit the new patent regime.
- A lack of international trade experience.
- Minimal level of future and technology forecasting planning strategically.
- Data protection issues.

- There is intense competition here.
- Capacity constraints for Competition Commission of India (CCI) to scan pharmaceutical mergers and takeovers.
- Non-tariff barriers imposed globally.
- High market barriers for small and medium-sized enterprises (SMEs) with limited financial and technical capacity constraints to enter the larger market due to lack of technical knowhow and inability to comply with GMP.
- Product patent regime does not favour the generic industry as much as process patent regime did.
- Linking regulatory issues with intellectual property rights (IPR) issues.
- Inadequate guidelines on regulation of biosimilars.
- Inadequate regulatory standards.
- Deficiency of reliable measures to safeguard the interests of illiterate and vulnerable patients in clinical trials.
- Coordination between multiple agencies.
- *Ethics committee:* Frequency of meetings, guidelines for approval, letter of approval, ethics approval time.
- Regulatory approval time [1, 4].

Country	Approvals time (weeks)
USA	4–6
Western Europe	8–12
Eastern Europe	10
Estonia	8–10
Russia	10
India	*12–16*
Hong Kong	12
Taiwan	12

Opportunities

- Product-based patents will lead to the discovery of newer drugs thus pharmaceutical companies need to increase their spending on research for better gain in long term.
- Indian companies can become a global outsourcing and contract research hub for pharmaceuticals.
- TRIPS (Trade Related Aspects of Intellectual Property Rights) flexibilities.
- Rising opportunities for Contract Research and Manufacturing Services (CRAMS) are especially beneficial for SMEs with limited options to grow in a product patent regime.
- Growing bio-similar industry considering a large chunk of biotech pharmaceuticals going off patent by 2015.
- Significant investment from multinational companies (MNCs).
- Growing incomes.
- Growing attention to health.
- Market saturation is yet far away.
- Globalization.
- Facilitated international trade.
- Markets are rising.
- Significant export potential.
- In the interests of public health, countries are now able to import less expensive generic copies of proprietary medications thanks to mandatory licencing requirements negotiated during the Doha Round. Such programmes have already been launched in Thailand and South Africa, and Indian businesses have profited from them.

- The low-cost research, manufacturing and wide pool for clinical trials attract MNCs. Once such a corporation establishes a foundation in India, it would stay there for at least one and a half to two decades. This is typical of the industry, which requires certification of production facilities by various drug regulatory bodies of the world, incurring a very high cost [5, 6].

Threats

- The presence of foreign players introducing efficient technology-based products into the Indian market.
- Stricter registration procedures.
- Government regulations changing and becoming stricter.
- Counterfeiting threat.
- Regarding the patent regime's current structure, there are certain worries. It is probable that the new administration will alter some of the sections of the Patent Act that were created by the outgoing administration.
- The uncertainty surrounding the implementation of the value added tax (VAT) poses a short-term threat to the pharmaceutical business. The short-term effects are probably going to be bad, but the long-term effects are going to be good for the industry.
- Global pressure for data exclusivity, TRIPS-plus provision that hampers generic competition.
- Need for a strong centralized regulatory regime to effectively monitor GCP guidelines [7].
- Commercialization of clinical research.
- Competition from other developing countries.
- Particular non-tariff and para-tariff barriers, such as lengthy registration processes even when drugs have already undergone the most stringent, such as those used by the US Food and Drug Administration, and insistence on allowing the import of only medicines that have been registered in some developed nations, are being increasingly adopted by other countries.
- Foreign enterprises, especially multinational corporations, may totally alter the course of India's pharmaceutical movement by neutralising its emphasis on generics and cost competitiveness through mergers and acquisitions of a few Indian generic leaders [8].
- More intense rivalry as a result of recent East European and Chinese producers (e.g., there has been huge state-level investment by China in the biotechnology sector – albeit now India still has the edge due to IP rules) [7, 8].

Let us understand the pharmaceutical industry using some examples both in product-based and service-based sectors. Products by Dr. Reddy's Laboratories include pharmaceuticals, genetic drugs**,** vaccines, diagnostics**,** biologics**,** over-the-counter drugs and many more. Figure 1 shows the SWOT analysis of Dr. Reddy's Laboratories.

Figure 1. SWOT analysis of Dr. Reddy's Laboratories [6].

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Torrent Pharmaceuticals products range from over-the-counter drugs, generic drugs, vaccines, contact lenses, to animal health, and others. Figure 2 shows the SWOT analysis of Torrent Pharmaceuticals.

Figure 2. SWOT analysis of Torrent Pharmaceuticals.

Products and services by PharmEasy, which caters as online pharmacy chain, are devices and lab tests, personal care , nutrition and fitness supplements , ayurvedic care , homecare, baby & mom care. Figure 3 presents the SWOT analysis of PharmEasy.

Figure 3. SWOT analysis of PharmEasy.

SWOT analysis is important to decide the plan of action so that an industry can capitalize on its strengths, curtail weaknesses, take advantage of newer opportunities and respond to threats aggressively and optimally.

CONCLUSION

Indian pharmaceutical industry has gained a significant market stand universally. The SWOT analysis concludes that the Indian pharmaceutical industry enjoys a global share of the market and has a series of successful acquisitions. This review will help us to analyse the pharma industry with its strength in terms of resources and threats in terms of competition as well as changing regulatory structure to take necessary steps to improve its standing in the business sector. For higher growth in the marketing sector, a better understanding of the SWOT analysis of the industry or company is necessary.

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