



EXAMINING MACRO-ENVIRONMENTAL FACTORS OF PHARMACEUTICAL INDUSTRY

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ABSTRACT

The pharmaceutical sector is expected to change as a result of a number of factors, including technological advancements, new laws, rising drug production costs, and new consumer demands. The organisation that establishes the comprehensive framework on the performance of the pharmaceutical industries, dictating all aspects of the behaviour of the market actors, is indirectly influenced by macro-environmental elements such as Political, Economic, Social, Technological, Legal, and Environmental factors. In order to have a competitive advantage over other market participants, the purpose of this research is to comprehend the macroeconomic reasons responsible for the business model revolution. To provide a comprehensive picture of the current market environment internationally and in the context of India, the study's existing literature on macroeconomic factors influencing the pharmaceutical landscape has been studied.

KEYWORDS: *Pharmaceutical Industry, Macro-Environment Element, Competitive Advantage*

1. INTRODUCTION

The phrase "macro environment" refers to all external factors that significantly affect a company's performance, strategy, and decision-making. A wide range of external factors, such as societal, legal, economic, and technological conditions, make up the macro environment. Governments and businesses both struggle to totally control external factors. But deliberate decisions and methods can mitigate the impact on the economy. Understanding the key macroeconomic issues affecting the pharmaceutical sector globally and in India is the main objective of this study. The article goes on to analyse corporate-specific macro factors using Sun Pharmaceutical Industry Ltd. as an example.

Pharmaceuticals are a class of newly formed organic substances that have improved our quality of life. Branded and generic medications are developed, manufactured, and marketed by the pharmaceutical business (González et al., 2021). The market was worth over USD 1.25 trillion in 2019 as opposed to USD 390 billion in 2001. By 2023, it is anticipated that the global pharmaceutical market would reach USD 1.5 trillion. The US continues to dominate the pharmaceutical market, with North America accounting for 48.9% of global pharmaceutical revenue. However, recently, a number of emerging nations have begun to have significant influence. Emerging markets include nations with economies like Brazil, India, Russia, Colombia, and Egypt. Although Latin American nations participate in the expanding industry, their contribution to global earnings is still minimal. Comparatively, the Chinese pharmaceutical sector has experienced the fastest growth rates in recent years (Mikulic, 2020).

In addition to the pharmaceutical market, pharmaceutical consumption was also rising globally, in part due to changes in clinical practise and a rising demand for medications to address age-related and chronic disorders. It is certain that the COVID-19 pandemic in 2020 and the subsequent years will change the pharmaceutical industry in terms of income and investment in new chemical and biological entities as a result of the efforts to produce stronger and more potent vaccines against the SARS-CoV-2 virus. (CIHR, 2019).

In terms of volume and value, the Indian pharmaceutical sector is the third largest in the world. It is one of the markets with the fastest rate of growth and the biggest volume exporter of generic medications. India is the country with the most pharmaceutical production facilities that have received USFDA approval outside of the US. In terms of value and volume, the domestic pharmaceutical market makes up around 2% of the worldwide industry. In the years 2019 through 23, it is expected that India's pharmaceutical spending would increase by 8–11% CAGR and total between US\$28–32 billion. India is aptly known as the "Pharmacy of the World" due to the affordable prices and excellent quality of its pharmaceutical products. (Raveendran, 2022).

The purpose of this paper is to study the key geopolitical, economic and legal aspects of the pharmaceutical industry globally and in Indian context.



2. CRITICAL ANALYSIS OF KEY GLOBAL GEOPOLITICAL, ECONOMIC AND LEGAL ENVIRONMENTAL ASPECTS OF THE PHARMACEUTICAL INDUSTRY

2.1 Geopolitical Factors: Governments are the primary source of most political influences, while corporations have very few regulatory powers. The capacity of a business to service and retain consumers while turning a profit is mostly impacted by political considerations. Political factors that affect business include taxation, employment laws, and political stability. They have an effect on how businesses operate, which may be advantageous or disadvantageous. The pharmaceutical sector must adhere to tight regulations in practically every nation. A complicated regulatory framework, made up of various government bodies and drug-related laws, governs the pharmaceutical industry. This frequently relates to the potency and safety of medications.

Additionally, it can affect the way and places that medicines are distributed. Regardless, the complex regulatory framework that exists creates a considerable barrier to entry for new competitors in the pharmaceutical industry, making life considerably easier for the established drug producers and distributors. In the US, pharmaceutical companies are free to establish whatever price for their goods. Many pharmaceutical companies choose to mark up the prices at which they sell their goods, which has recently caused a great deal of resentment. When medications, like those used to treat diabetes, are vital to someone else's survival, it seems horribly unfair to charge such high prices for them. As a result, governments are starting to express interest in controlling the prices at which drugs can be sold. This would ultimately lead to less profit for pharmaceutical corporations when everything is said and done.

2.2 Economic Factors: Business operations are significantly impacted by the economy. Major economic factors that affects pharmaceutical industry in India include consumer spending, inflation rate, economic policy of government and prices of products. Due to sedentary lifestyle and increase in chronic diseases the healthcare spending on an individual in India is increasing considerable. The increased awareness on insurance and government incentives for below poverty line made people to spend more healthcare. Whatever the causes, this can only mean more money for the pharmaceutical sector.

2.3 Legal Factors- Federal rules, state laws, and norms imposed by custom are only a few types of laws that have an impact on enterprises. Frauds are rather frequent in the pharmaceutical and healthcare industries. This is why most governments have imposed tight restrictions that audit the growth of these corporations. Pharmaceutical businesses must therefore take care to operate in compliance with all legal obligations. Today's pharmaceutical firms rely heavily on data. They must therefore ensure that they are protected from online attacks. Customers could lose faith in a company's goods and services if they are vulnerable to cyber threats.

3. CRITICAL ANALYSIS OF KEY GEOPOLITICAL, ECONOMIC AND LEGAL ENVIRONMENTAL ASPECTS OF THE PHARMACEUTICAL INDUSTRY IN INDIA

3.1 Geopolitical Factors: The government's inability to create a clear regulatory framework and the lack of incentives at first caused the Indian pharmaceutical industry to grow at a relatively slow rate from 1947 to 1970. Currently, the industry is characterised by a plethora of governmental restrictions and policy changes, strict price controls, strict formulation rules, and a lack of global patent protection. The Drug Price Control Order (DPCO) and the Indian Patents Act (IPA) were both passed in 1970. Although DPCO served as a barrier to pharmaceutical companies' attempts to make free pricing unlawful, it achieved the objective of offering high-quality medications to the general people at affordable prices. The introduction of the IPA, which only recognised process patents and did not recognise product patents, gave the industry and businesses a tremendous boost and allowed them to start manufacturing bulk medications and formulations at reduced costs through reverse engineering. Due to the proliferation of several small businesses, this caused the sector to become highly fragmented.

3.2 Economic Factors: Health care costs represent a very modest fraction of Indians' income. As a result, the industry's growth has been inhibited and the demand has decreased. Spending on healthcare has a low priority because the average Indian has a low per capita income. Only in cases of emergency does an Indian seek medical attention. This has caused the number of unqualified doctors to soar and the use of non-standard medications to proliferate. Tax incidences are quite high. There are a number of taxes and fees that must be paid, including Excise Duty (State & Central), Custom Duty, Service Tax, Profession Tax, License Fees, Royalty, Pollution Clearance Tax, Hazardous Substance (Storage & Handling) License, Income Tax, Stamp Duty, and a plethora of other levies and charges. Specialty medications don't have adequate transportation or storage options. According to studies, around 60% of retail pharmacies lack proper refrigeration and store their medications in less-than-ideal settings. As a result, the pharmaceuticals given out will be of worse quality, which naturally raises the price. India's train system and roadways are both inadequate. As a result, transportation takes longer. Longer delivery times and higher inventory carrying expenses are required. All of this raises the unaccounted-for costs. Good highways have only recently been built, within the last couple of years.

3.3 Legal Environment: Today's pharmaceutical sector is heavily regulated and enforces compliance. As a result, the industry must bear significant legal, regulatory, and compliance costs. This tends to limit its dynamism, although in recent years, the government has started to ask the industry for recommendations on regulatory overheads in an effort to spur innovation in response to growing



threats from external markets. There is a sizable PSU section in the pharmaceutical industry that is extremely ineffective. The government improperly subsidises inefficient units by transferring surpluses from efficient units to the price equalisation account of inefficient units. Long term, this has rendered almost everyone ineffective. With effect from January 2005, the government switched from basing excise duty on manufacturing costs to MRP (Maximum Retail Price), raising the price of finished goods. The present administration has made several essential medicines unaffordable to the poor for a small profit.

4. CONCLUSION

Global geopolitical pressure, the economic downturn, legal issues, technological innovation, and social concerns are the main influences on the pharmaceutical sector today. While there are many elements influencing its rise, including increased purchasing power and technology advancements, others, including rigorous rules and health-conscious lifestyles, are causing it to fail. The pharmaceutical sector has undergone significant upheaval during the past few years, and this phase of change is still ongoing. The market players must discover alternatives due to the decline in drug approvals. The market is dominated by greater understanding among the various stakeholders, new market participants, excessively rising R&D costs, and rising demand for generic drugs. To be competitive over the coming years, pharmaceutical businesses will need to modify their business models, engage in mergers and acquisitions, work with venture capital, and partner with various market players.

5. REFERENCES

1. González Peña OI, López Zavala MÁ, Cabral Ruelas H. *Pharmaceuticals Market, Consumption Trends and Disease Incidence Are Not Driving the Pharmaceutical Research on Water and Wastewater*. *Int J Environ Res Public Health*. 2021 Mar 4;18(5):2532. doi: 10.3390/ijerph18052532. PMID: 33806343; PMCID: PMC7967517.
2. CIHR. *Drug Bank Database*. Canadian Institute of Health Research; Ottawa, ON, USA: 2019. Version 5.1.3.
3. Mikulic M. *Statistics & Facts, Global Pharmaceutical Industry*. Statista; Hamburg, Germany: 2020.
4. Sun Pharma (2021), "Sun Pharma Annual Report", Published in 2021. Available at: www.sunpharma.com
5. Euromonitor (2018), "Healthcare Sector Analysis ", Published in 2018.
6. D. Chandler, *Strategy and Structure* (Cambridge, Mass.: MIT Press, 1962)
7. L. Wrigley, *Divisional Autonomy and Diversification* (PhD, Harvard Business School, 1970)
8. M. E. Porter, *Competitive Strategy* (New York: Free Press, 1980)
9. O. E. Williamson, *Markets and Hierarchies* (New York: Free Press, 1975)
10. R. E. White, *Generic Business Strategies, Organizational Context and Performance: An Empirical Investigation*, *Strategic Management Journal* 7 (1986)
11. UKEssays. November 2018. *PESTLE analysis of the pharmaceutical industry*. [online]. Available from:

- <https://www.ukessays.com/essays/economics/pestle-analysis-of-the-pharmaceutical-industry-economics-essay.php?vref=1> [Accessed 28 November 2022].
12. Gupta, R., 2022. *India's Economic Ambitions in the Pharmaceutical Industry*. [Online] Available at: <https://www.wilsoncenter.org/blog-post/indias-economic-ambitions-pharmaceutical-industry> [Accessed 28 November 2022].
13. KS, B., 2022. *Analysis: Sun Pharma and its Prospects*. [Online] Available at: <https://groww.in/blog/analysis-sun-pharma-prospects> [Accessed November 28 2022].
14. Koji Takahashi. " COVID- 19 Pandemic and Non- Standard Employees in Japan ", *International Journal of Japanese Sociology*, 2022
15. Narsana, B. & Mishra, S., 2020. *Recent legal developments in Indian pharmaceutical sector*. [Online] Available at: <https://www.lexology.com/library/detail.aspx?g=51950483-f37d-44fa-ab1f-f009c359f12c> [Accessed 28 November 2022].
16. Sarma, K., n.d. *India: Pharmaceutical Legal & Regulatory Environment*. [Online] Available at: <https://www.fldi.org/2017/10/india-pharmaceutical-legal-regulatory-environment/> [Accessed 28 November 2022].
17. Sendyona S, Odeyemi I, Maman K. *Perceptions and factors affecting pharmaceutical market access: results from a literature review and survey of stakeholders in different settings*. *J Mark Access Health Policy*. 2016 Sep 27;4. doi: 10.3402/jmahp.v4.31660. PMID: 27857827; PMCID: PMC5040822.