

Analysis of the Indian Pharmaceutical Sector: Current Status, Challenges and Opportunities

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Abstract

An essential component of society is business enterprise. A corporate firm's motivation will immediately influence society, including the environment, customers, employees, suppliers, and other stakeholders. The Indian pharmaceutical market is in a good position because there are a lot of medications that have recently lost their patents. Pharmaceutical manufacturers are focusing on manufacturing, and this trend is anticipated to continue as pharmaceuticals' share of the Indian and global pharmaceutical markets rises. The pharmaceutical regulatory environment is becoming increasingly strict on a global scale. The inability of pharmaceutical companies in India to actively participate in international markets was hampered by several additional problems, including uncertainty over the market's maturity level, the importance of investing in this industry, and differences in regulatory rigour. This article aims to describe the pharmaceutical market environment in India and throughout the world. Additionally, it covers the important difficulties that are present. It also considers a few indicators that show the pharmaceutical sector in India has a promising future.

Keywords: Pharmaceutical products, Pharma Market; Indian Companies, Challenges

Introduction

The need for health care services has expanded as health has emerged as one of the most important problems in many societies. Most nations have seen a rise in health spending due to these high needs. The pharmaceutical business is not an exception in this respect, and it is one of the sectors that has significantly contributed to rising healthcare costs [1,2]. On the other hand, medicine is recognized as the key and most efficient factor in enhancing public health and controlling specific diseases among individuals [3].

Furthermore, the two biggest issues that nations confront globally are enhancing public health and growing the pharmaceutical business. Governments closely monitor and regulate the pharmaceutical business since it is one of the most important components of any health system. Pharmaceutical firms' development and expansion have been significantly impacted by the implementation of some severe regulations and the government's microscopic oversight. A poor choice of laws or policies might end the existence of several pharmaceutical businesses, endangering the general public's health in the process. On the other hand, applying appropriate rules will aid in the growth and development of this business and ensure that pharmaceuticals are available where they should be, at the correct price, and of the highest possible quality, eventually improving community health. Meanwhile, pharmaceutical firms should work to adapt to these regulations to, first, retain their existing state and, second, spur expansion and growth by utilizing current opportunities or by converting threats into opportunities [4,5]. India's highly specialized pharmaceutical business has shown tremendous potential in recent decades. In terms of value, the sector came in at number ten, but volume rankings put it at number three. By 2023, the Indian pharmaceutical industry will reach USD 55 billion; under a future development scenario, it might even reach USD 70 billion. [6].

Indian Pharmaceutical Industry

Over the last 50 years, the Indian pharmaceutical sector has experienced a substantial expansion in the domestic and international markets. As a result, the proportion of "Made in India" medications in the Indian pharma sector increased to 80% in 2020 from providing just 5% of the world's medicine consumption in 1969 (95% share with global pharma). More significantly, over the same time, the nation also gained a dominant position in the worldwide generic drugs market and is today referred to as the "Pharmacy of the world" [7]. More than 20% of the volume of the worldwide generics market and 62% of the global demand for vaccines are contributed by the Indian pharmaceutical sector. As a result, the sector sometimes called the "archetype of affordable healthcare," has significantly improved public health outcomes in India and worldwide [8].

One of the top 10 industries for lowering the trade imbalance and luring in Foreign Direct Investment (FDI), the pharmaceutical industry has been a key contributor to India's economic growth. Between April 2000 and June 2020, the medicines and pharmaceuticals industry received cumulative FDI inflows totalling US\$16.54 billion [9]. Additionally, the trade surplus it has been producing, US\$20.7 billion in pharmaceutical exports and US\$2.31 billion in imports in FY20, makes it of utmost significance [10]. The industry is third in volume and 14th in value globally, employing about 2.7 million people directly or indirectly [11,12].

In their article titled "Opportunities and challenges for Indian pharmaceutical companies in overseas markets and need of digital tools for sustainable success," Reddy and Rao noted that Indian pharmaceutical companies are finding it difficult to survive in international markets as a result of competition, a lack of market knowledge, a convoluted regulatory pathway, and a failure to adopt the most recent digital technologies. The major goal of the study is to determine how various digital technologies may be used by various pharma sector disciplines to succeed in international markets. They discover a definite demand for domain-based digital tools for Indian pharmaceutical businesses to compete and survive in international markets [13].

The challenges, opportunities, and performance of the Indian pharmaceutical industry post-TRIPS noted that the country's patent law was changed to be compatible with the agreement on trade-related aspects of intellectual property rights (TRIPS), but that this change has created many difficulties for India's generic pharmaceutical producers. They learn that the industry's top generic businesses have inconsistent performance [14]

Objectives

This study aims to examine the Indian pharmaceutical industry's development possibilities. The report discusses its present situation, development pattern, several difficulties, and its outlook for the future. The study also focuses on stringent regulatory requirements in existing and developing economies that prevent the entry of new players and prevent this sector from expanding. This process entails thoroughly assessing the literature from secondary databases, reports, and research papers on the pharmaceutical business, IBEF, EY, McKinsey and Company studies, etc.

Indian Pharmaceutical Industry's Challenges

The regulatory environment for pharmacies across the world is becoming increasingly restrictive. To compete in the global market, the Indian pharmaceutical sector needs a strong regulatory framework. However, the industry is now dealing with several difficulties, including:

Lack of a consistent environment for pricing and policy- This problem is brought on by India's frequent and unforeseen domestic pricing policy changes. For investments and inventions, it has produced a hazy atmosphere. IPA recommends that the government and stakeholders collaborate to create a strategy for making pharmaceuticals for Indian patients that are reasonably priced.

Lack of competencies in the innovation sector- Despite India's abundant talent and labour. The government must invest in research projects and people to boost India's innovation. The subjectivity in some regulatory decision-making processes should be eliminated, and the government should encourage clinical research.

Impact of outside markets- According to reports, India depends largely on other nations for its active pharmaceutical ingredients (API) and other intermediates. For example, China is the source of imports for 80% of APIs. India is thus at the mercy of erratic price changes and supply interruptions. To stabilize supply, it is required to implement infrastructure improvements in the area of internal facilities.

Quality compliance investigation: Since 2009, India has received the most FDA inspections; as a result, ongoing investments in raising quality standards will divert funds away from other areas of development and growth.

Clinical trials: These are the industry's gold standard procedures for assessing the efficacy and safety of medications, and they must be validated before receiving regulatory clearance. India is evolving as a pharmacy, R&D, and clinical trial knowledge centre. To promote the development of affordable treatments for various illnesses, including diarrhoea, TB, malaria, meningitis, etc., the pharmaceutical sector must expand. Additionally, clinical trial regulatory delays are seriously impeding this prospect. As a result, the rate of innovation and the expansion of the clinical trial sector have been hampered. Additionally, issues including inadequate regulatory monitoring, the requirement for protections for informed consent for vulnerable groups, and compensation standards for patients for trial-related fatalities have come to light as major worries. As a result, our nation is losing out on many potentials because of the abovementioned restrictions during clinical trials.

Consistent code on sales and marketing: To organize marketing activities and avoid corruption, the Department of Pharma has provided rules on a consistent code of sales and marketing practices that apply to all pharmaceutical enterprises. However, the tax authorities utilize the Central Board of Direct Taxes (CBDT) circular based on MCI recommendations to decide what sales and marketing costs are allowed. The Department of Pharma rules differ from the MCI guidelines on sales and marketing methods. Therefore, the Department of Pharma's and MCI's standards have distinct benchmarks. Clarity is increasingly desired from the viewpoints of the tax authorities and the pharmaceutical business.

Mandatory licensing: The pharmaceutical sector currently adheres to tight laws and regulations on manufacturing and good manufacturing practices for developing drugs in domestic and foreign markets. Both Indian and international pharmaceutical enterprises will

become unstable due to the widespread practice of forced licensing. However, drug affordability and the need to preserve intellectual property should coexist harmoniously.

Producing high-quality medications: The Indian pharmaceutical sector effectively produces reasonably priced medications for the domestic market and export. Overseas markets must have growing faith in Indian-made medicines. To achieve this, the authorities must establish quality standards on par with international norms through suitable legislation and guarantee that these requirements are strictly upheld.

It would boost the Indian pharmaceutical sector, which makes up a significant portion of the Indian economy, by holistically concentrating on the abovementioned issues [15].

Conclusion

COVID-19 has well demonstrated the necessity of a good healthcare system, and a country's economy and society may be at risk if one does not exist. Applying lessons from the difficulties and best practices that arose throughout the pandemic is appropriate as India continues to combat COVID-19 and stabilize its economic growth trajectory. The infrastructure for providing healthcare must be quickly built and made available to the whole population. The healthcare and economic results of the nation have greatly benefited from the contributions of the Indian pharmaceutical sector. The epidemic has increased the industry's potential and problems in many ways. India has a chance because of the widening trust gap with China, but Vietnam and Malaysia are becoming increasingly competitive. Two-thirds of India's bulk pharmaceuticals or drug intermediates are imports from China.

The sector must leverage its advantages while taking a major step toward innovation to succeed in the post-pandemic future. New capabilities must be implemented across all business processes to improve efficiency and aid the industry in moving up the value chain. The government must provide enablers and a business climate that promotes growth. The report's following chapters go through the chances and obstacles the nation has in achieving its goal of fair and long-term access to healthcare and the best course of action. Additionally, it gives the sector insight into realising its goal of being the go-to source for cutting-edge pharmaceuticals worldwide. The Indian pharmaceutical sector has the chance to build on its strengths and implement significant reforms to rekindle innovation-led industrial growth and achieve the goal of US\$130 billion by 2030.

The pharmaceutical market is growing due to a variety of factors, including increasing pressure to reduce healthcare costs, an increase in the prevalence of several chronic diseases, encouraging findings from numerous clinical trials, and rising demand for a variety of medicinal treatments, such as for rheumatoid arthritis, blood disorders, and other ailments. In addition, an increasing number of drugs are also going off-patent, which is driving up drug demand. But obstacles, including high production costs and complexity, as well as strict regulatory requirements in both developed and emerging nations, limit the entry of new competitors and inhibit the growth of this industry. Therefore, it is important to foster a dynamic business environment to provide all participants with the knowledge and precise inventory needed to compete in business encounters at the market entry stage and get access to local and foreign markets.

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