

A Study on Review of Pharmaceutical Market in Indian Context

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ABSTRACT

The Indian Pharmaceutical Industry has undergone significant evolution since the country's independence, transforming from a largely import-dependent sector to one of the largest and most dynamic in the world. This evolution has been shaped by various factors, including changes in patent laws, government regulations, and global market dynamics. Today, India stands as a global leader in generic drug manufacturing and exports, with a robust domestic market and a growing presence in international markets. This article provides a comprehensive overview of the historical background, evolution, current scenario, and future prospects of the Indian pharmaceutical industry. It examines key trends, challenges, and opportunities facing the industry, along with the major players driving its growth and innovation. The Researchers aim to study the dynamics of Indian Pharmaceutical market. The study further aims to review the current scenario of Indian Pharma market and to understand the future prospects. The study encompasses the general review of the Pharmaceutical Industry in Indian context. The inferences gathered are indicative in nature rather than exhaustive.

Keywords: pharmaceutical market, pharmacy, pharma industry

I. INTRODUCTION

The Indian pharmaceutical industry has a rich history dating back to the country's post-independence era. Initially dominated by multinational corporations (MNCs), the industry underwent a significant transformation in the 1970s with the introduction of the Indian Patent Act, which shifted focus towards process patents and encouraged domestic manufacturing of bulk drugs. Subsequent changes in patent laws and government regulations further fuelled the growth of the industry, leading to the emergence of Indian pharmaceutical companies as global players. Today, India's pharmaceutical industry is characterized by its strength in generic drug manufacturing, research and development capabilities, and a growing focus on innovation and specialty medicines. The industry has become a key driver of economic growth and exports, contributing significantly to India's GDP and foreign exchange earnings. However, the sector also faces challenges such as regulatory complexities, pricing pressures, and increasing competition. Despite these challenges, the future prospects for the Indian pharmaceutical industry remain promising, driven by factors such as demographic trends, increasing healthcare spending, and rising demand for affordable medicines. With its strong foundation and dynamic ecosystem, the Indian pharmaceutical industry is poised for continued growth and innovation in the years to come.

II. THEORETICAL REVIEW

A comprehensive literature review on the pharmaceutical market in India encompasses an analysis of various scholarly works, research articles, reports, and publications addressing key aspects of the industry. This review delves into the industry's overview, including its size, growth rate, major players, and economic contribution. It also scrutinizes the regulatory framework governing drug approval, pricing, marketing, and intellectual property rights. Market dynamics are explored, including trends such as the demand for generic drugs, emergence of specialty pharmaceuticals, and healthcare reforms, alongside opportunities such as increased healthcare spending and expansion into international markets. The impact of the COVID-19 pandemic on the pharmaceutical market, Finally, the review offers insights into future trends, market growth projections, innovation opportunities, and strategies for sustainable development.

III. RESEARCH METHODOLOGY

The paper "A review study on Pharmaceutical Market in Indian Context" is a conceptual study extensively based on secondary data analysis. Its primary objective is to study and review the dynamics and the current scenario of Indian Pharma market and to understand the future prospects. Furthermore, it seeks to examine the current body of literature on pharmaceutical industry and draw conclusions from it. The conclusions drawn from this study reflect the insights gained through reviewing existing literature and are representative of the pharmaceutical industry as a whole. It's important to note that the selection of papers and literature for review was based on the author's discretion, which may introduce limitations to the study. Consequently, the inferences presented should be considered indicative rather than exhaustive, highlighting a potential limitation of the research.



Figure 1: Research Process Adopted for the Study

Source: Authors' Study

IV. OBJECTIVES OF THE STUDY

1. To study the dynamics of Indian Pharmaceutical market.
2. To review the current scenario of Indian Pharma market and to understand the future prospects.

V. INDIAN PHARMACEUTICAL INDUSTRY

Historical Background

Following India's independence from British Power in 1947, multinational corporations (MNCs) were initially permitted to export drugs, primarily consisting of low-priced generics and a few high-priced specialty items. However, as the Indian government intensified pressure against the importation of finished products, MNCs established formulation units within India and began exporting only bulk drugs to the country.

In the early 1960s, the Indian government actively encouraged domestic manufacturing of bulk drugs. Subsequently, in the ensuing decade, the Indian Patent Act prohibited the granting of product patents for substances used in foods and pharmaceuticals. Instead, only process patents were permitted, with a duration of five years from the date of patent granting or seven years from the filing date. During this period, the Drug Price Control Order (DPCO) was introduced to prevent excessive

profits from essential medicines. Additionally, MNCs were required to reduce their ownership holdings in Indian ventures to 40%.

The 1980s and 1990s marked a period of flourishing for domestic pharmaceutical companies. Consequently, the market share of MNCs decreased significantly, dropping from 75% in 1971 to the current level of 35%. (Ravishankar B, 2007)

Evolution of Indian Pharmaceutical Industry

The Indian pharmaceutical industry has undergone significant evolution over the years, transforming from a largely import-dependent sector to one of the largest and most dynamic in the world. The Indian Pharmaceutical industrial development can be categorized into following eras:

1) Post-Independence Era (Pre 1970s)

In its early stages, the pharmaceutical industry primarily revolved around Ayurvedic medicines and therapies. However, it was during the British rule that allopathic medicine gained traction in India. The industry remained relatively small due to the limited number of Indian firms, which restricted its growth. During this period, multinational companies (MNCs) dominated the market, aided by the Patent Act of 1911. This legislation prohibited both process and product patents for 16 years, with the possibility of extension for an additional 10 years. Consequently, indigenous firms were prohibited from manufacturing patented drugs, further consolidating the dominance of MNCs.

2) Expansion and Globalization (1970-1990)

During this period, the Indian Patent Act of 1970 played a significant role, shifting focus towards procedure patents rather than product patents, which were protected for seven years. This marked a golden era for the Indian pharmaceutical industry, characterized by the widespread adoption of the "reverse engineering process" by domestic companies to produce drugs without paying royalties to the patent holders. Additionally, the implementation of the Drug Price Control Order provided minimal incentive for multinational corporations (MNCs) to introduce new drugs in India. As a result, numerous Indian pharmaceutical companies emerged, leading to substantial growth in production infrastructure. Furthermore, the government actively promoted exports through various initiatives, further bolstering the industry's development. (Chitra M, 2020)

3) Emergence as a Global Player (2000s-2010s)

In 1991, India embarked on a path of globalization, liberalization, and privatization, impacting nearly every sector of the country. This shift towards liberalized markets encouraged multinational corporations (MNCs) to enter the domestic market, while many Indian companies expanded abroad by establishing operations in foreign markets. India gained recognition as a leading destination for the manufacturing of generic drugs. In 1995, India became a founding member of the World Trade Organization (WTO). As per WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, the government was compelled to amend its Patent Act, transitioning from process patents to product patents. The approval of the Patents Amendment Act in 2005, known as the Patent Act 2005, mandated the implementation of product patents in India for a period of 20 years. This change significantly heightened competition and completely transformed the production landscape. Companies wishing to manufacture patented drugs before the expiration of the patent term were required to obtain licenses by paying substantial fees. Consequently, Indian pharmaceutical companies underwent significant changes, shifting their focus from simply replicating drugs through re-processing to investing in research and development. (Chitra M, 2020)

Despite these changes, the pharmaceutical market experienced remarkable growth. This growth can be attributed to several factors, including the comparatively low cost of labor in India compared to overseas markets. Additionally, India's abundance of technical and management talent eliminated the need for overseas management skills. Furthermore, the availability of locally sourced equipment necessary for manufacturing contributed to the industry's expansion. (Festa G, 2021)

4) Current Trends and Future Prospects

In the early 2020s, the Indian pharmaceutical industry continues its dynamic evolution fueled by various factors. These include the uptick in healthcare spending, heightened demand for generic medications, advancements in technology and innovation, and a growing emphasis on specialty and biopharmaceuticals. The COVID-19 pandemic served as a stark reminder of the industry's resilience and capabilities, with numerous firms playing pivotal roles in producing and distributing essential medicines, vaccines, and medical supplies worldwide.

Looking ahead, the industry is poised for further transformation marked by consolidation, innovation, and expansion. Opportunities are anticipated to emerge from burgeoning markets, digital health solutions, personalized medicine approaches, and ongoing healthcare reforms. Nonetheless, the landscape remains fraught with challenges, including regulatory complexities, pricing pressures, intellectual property disputes, and intensified competition. Navigating these hurdles demands strategic agility and resilience from industry participants.

Types of Drug Systems in India

India boasts a diverse array of medical and pharmaceutical systems rooted in ancient civilizations. These include Ayurveda, Siddha, Unani, Homeopathy, Yoga, and Naturopathy.

Ayurveda, translating to "science of life," encompasses principles and philosophies on health, disease, and medicine. It is documented in texts like Charak Samhita and Sushruta Samhita and emphasizes treatment through drugs, diet, and lifestyle.

The Siddha system, one of India's oldest medical systems, focuses on holistic healing and considers various factors such as age, sex, environment, and diet. Siddha medicines, derived from natural sources, have shown efficacy in treating certain diseases.

Unani medicine, originating from Greece and later developing in India, revolves around promoting positive health and preventing diseases. It is based on the humoral theory and uses remedies derived from plants, metals, minerals, and animals.

Homeopathy, which flourished in Germany, has gained popularity in India as a method of disease treatment. It operates on the principle of treating like with like and utilizes minimal doses of substances to stimulate the body's natural healing process.

Yoga and Naturopathy advocates for a holistic lifestyle, emphasizing proper eating habits, physical activity, and natural remedies such as hydrotherapy and massage. Yoga comprises eight components, including physical postures and breathing exercises, aimed at achieving mental and physical well-being.

The Indian government established the Department of Indian Systems of Medicines and Homeopathy to regulate and standardize traditional medicines. Efforts include setting standards for drug manufacturing and establishing a medicinal plant board to ensure the availability of quality raw materials. India's health statistics reflect its large population and growing healthcare needs. The country's life expectancy, though improving, remains lower than that of developed nations like the United States. The healthcare infrastructure includes numerous medical and pharmacy institutions, hospitals, registered doctors, and nurses, catering to the healthcare needs of its populace.

Products and Performance

India's pharmaceutical industry primarily comprises bulk drugs and formulations. The country produces approximately 70% of its bulk drug needs and 90% of its formulation requirements. Around 60% of total bulk drugs are exported, making them a significant source of foreign exchange. India ranks as the fourth largest bulk drug producer globally, following the United States, Western Europe, and Japan. While multinational companies have traditionally dominated the formulation manufacturing sector, Indian companies like Reddy's, Ranbaxy, Cipla, and Wockhardt are steadily gaining ground. These companies have solidified their position in the domestic market and are now poised for international expansion, particularly in the generics market.

The growth of the Indian pharmaceutical market has been hindered by price control measures. The Drug Price Control Order (DPCO) has undergone three amendments, with the latest version in 1995 reducing the number of products under price control to 76. It is expected that this number will further decrease significantly with the implementation of the New Drug Policy in 2002. In response to price controls, companies often withdraw certain products from the market and introduce others that are not subject to price regulation. However, this practice has led to shortages of essential medications, adversely affecting consumers and contributing to the proliferation of counterfeit drugs.

Value of Production of Indian Pharmaceutical Industry

The Indian pharmaceutical industry has been experiencing significant growth over the years, driven by factors such as increasing healthcare needs, rising incomes, a large population, and a growing demand for affordable medicines both domestically and internationally. The industry has been known for its strength in generic drug manufacturing, research and development, and a robust supply chain.

The pharmaceutical industry in India reached an estimated value of \$42 billion in 2021 and is projected to grow to \$130 billion by 2030. India leads the world in the production of generic medicines, accounting for 20% of global pharmaceutical exports. Additionally, it is the largest supplier of vaccines globally, contributing over 60% of total vaccine production. Indian pharmaceutical products are exported to various regulated markets including the US, UK, European Union, and Canada.

According to the Economic Survey 2023, the turnover of the domestic pharmaceutical market was approximately \$41 billion. In fiscal year 2022–23, India's pharmaceutical exports revenue stood at \$25.3 billion, as reported by Pharmexcil. India ranks third globally in terms of the dollar value of drugs and medicines exports. (www.statista.com, 2024)

Key pharmaceutical hubs in India include cities such as Vadodara, Ahmedabad, Ankleshwar, Vapi, Baddi, Sikkim, Kolkata, Visakhapatnam, Hyderabad, Bangalore, Chennai, Margao, Navi Mumbai, Mumbai, Pune, Aurangabad, Pithampur, and Paonta Sahib.

Exports, and Imports

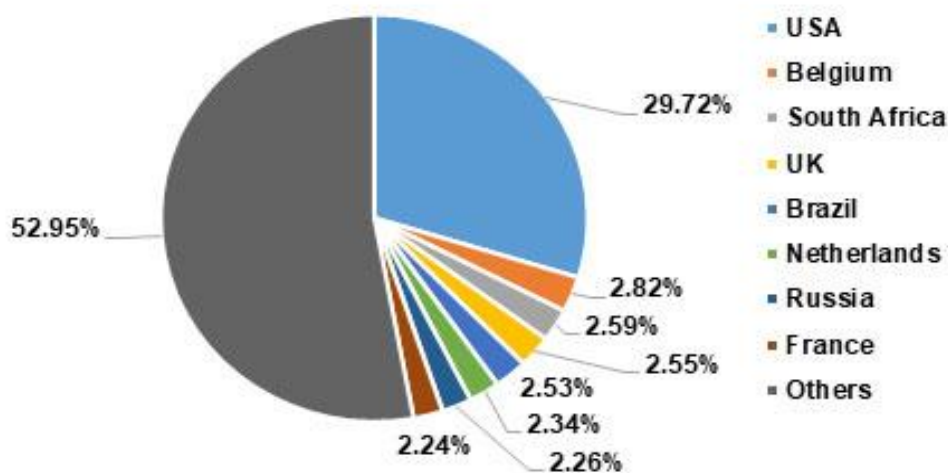
India has established itself as a significant global supplier of pharmaceutical products, having exported to over 200 nations worldwide, with the United States being a major recipient. The primary pharmaceutical exports include drug formulations, biological products, bulk drugs, and drug intermediates.

India exports pharmaceutical products to various regions globally, including North America, Africa, the European Union (EU), ASEAN countries, Latin America & the Caribbean (LAC), the Middle East, Asia, CIS countries, and other European regions. Approximately two-thirds of India's pharmaceutical exports are directed to NAFTA, Europe, and Africa. The top five export destinations for the Indian pharmaceutical industry in the fiscal year 2022-23 were the USA, Belgium, South Africa, the UK, and Brazil.

During the same period, the USA, Belgium, and South Africa emerged as major importers from India, with a share of 29.72%, 2.82%, and 2.59%, respectively. India's pharmaceutical exports to these countries in FY23 were as follows: USA (\$7.54 billion), Belgium (\$714.92 million), South Africa (\$657.0 million), the UK (\$647.68 million), and Brazil (\$642.67 million). Notably, India's pharmaceutical exports to the USA experienced a Compound Annual Growth Rate (CAGR) of 6.18% over the past year. Similarly, for Belgium and South Africa, the growth rates were 59.2% and 7.23%, respectively, over the same period. (www.statista.com, 2024)

As of April 2023, the number of USFDA-approved sites (both for bulk drugs and formulations) in India stood at 703. Additionally, Indian firms had filed 4,505 Drug Master Files (DMFs) of Type II Active with the USFDA by January 2023. USFDA inspections had been suspended for the past couple of years due to the COVID-19 pandemic; however, they have resumed, with expectations that these inspections will further bolster Indian exports to the USA.

India's country-wise share of drugs, pharmaceutical and fine-chemicals exports (2022-23)



Source: DGCI&S, Pharmaceuticals Export Promotion Council

Major Players in the Pharmaceutical Industry in India

The pharmaceutical industry in India stands as a beacon of innovation, affordability, and global competitiveness. With a rich legacy dating back decades, it has emerged as a powerhouse in the global pharmaceutical arena.

India's pharmaceutical industry has witnessed remarkable strides, propelled by a conducive regulatory environment, robust infrastructure, skilled workforce, and a culture of innovation. Today, it stands as the world's third-largest producer of pharmaceuticals by volume and ranks among the top suppliers of generic drugs worldwide.

At the heart of this vibrant ecosystem lie the major pharmaceutical players, which have played a pivotal role in shaping the industry's trajectory. These companies exhibit a diverse portfolio, ranging from generic medicines to innovative therapies, biosimilars, active pharmaceutical ingredients (APIs), and research-driven initiatives. This below mentioned are the major players driving the growth and evolution of the pharmaceutical sector in India.

Top 10 public pharmaceutical companies in India by market capitalization as of December 2023

Rank	Company	Market capitalization (December 2023)
1	Sun Pharma	295,466 crore (US\$37 billion)
2	Cipla	100,787 crore (US\$13 billion)
3	Dr. Reddy's Laboratories	98,218 crore (US\$12 billion)
4	Divi's Laboratories	96,242 crore (US\$12 billion)
5	Mankind Pharma	76,792 crore (US\$9.6 billion)
6	Torrent Pharmaceuticals	72,168 crore (US\$9.0 billion)
7	Zydus Lifesciences	64,305 crore (US\$8.1 billion)
8	Aurobindo Pharma	61,154 crore (US\$7.7 billion)
9	Lupin	57,530 crore (US\$7.2 billion)
10	Alkem Laboratories	55,064 crore (US\$6.9 billion)

Source: Moneycontrol

Top 5 private pharmaceutical companies in India by reported valuation in 2022

Rank	Company	Valuation (2022)
1	Serum Institute of India	219,700 crore (US\$28 billion)
2	Intas Pharmaceuticals	59,300 crore (US\$7.4 billion)
3	Macleods Pharmaceuticals	43,200 crore (US\$5.4 billion)
4	Hetero Labs	24,000 crore (US\$3.0 billion)
5	USV	23,200 crore (US\$2.9 billion)

Source Moneycontrol

Indian Pharma Industry: Current Scenario

India's leading pharmaceutical companies are emerging as global players by employing both organic growth, through gradual business development, and mergers and acquisitions (M&A) to enhance their presence in existing markets and explore new ones. The domestic industry's established reputation as a world leader in producing high-quality generic medicines is poised to yield significant benefits as patents for several blockbuster drugs are set to expire in the coming years. Moreover, India's established status as a preferred manufacturing hub for multinational pharmaceutical companies is extending into other outsourcing activities. Escalating costs of research and development (R&D) and administration are prompting pharmaceutical firms to shift more of their discovery research and clinical trial operations to India or establish administrative centre there, leveraging the country's abundant scientific expertise and low labour costs.

A content analysis was conducted to identify key issues in the pharmaceutical sector, drawing from authoritative reports and institutional and corporate-level concerns. This analysis was performed manually due to the sensitive nature of the data, utilizing standard office software for searching, retrieving, organizing, cataloging, and processing relevant textual elements. The focus was on identifying strengths, weaknesses, opportunities, and threats (SWOT) using specific words and general concepts. The investigation yielded seven main areas, identified through manual content analysis and the affinity diagram technique. These areas include:

Pharmaceutical Research Hub: India's potential in pharmaceutical research and development is underutilized, with a focus on generic drugs. However, the country boasts a skilled workforce and numerous educational institutions in pharmaceutical sciences, making it an attractive location for global pharmaceutical companies to conduct research.

Healthcare Special Economic Zones: India's competitive advantage in medical tourism due to lower healthcare costs presents an opportunity for establishing special economic zones (SEZs) near transportation hubs. These zones could incentivize pharmaceutical industry growth and investment.

Manufacturing Facilities for Medical Equipment: With a large pool of skilled graduates and improving business environment, India has the potential to become a manufacturing hub for medical equipment, leveraging its cost-effective production factors.

Land/Town Planning for Healthcare Facilities: Rapid population and economic growth in India necessitate better infrastructure planning, including allocation of land for healthcare facilities. Improving access to private healthcare facilities can spur industry growth and employment.

Food and Drug Administration (FDA) Regulations: Stringent FDA regulations pose challenges for Indian pharmaceutical companies seeking access to international markets, particularly in the USA. Government support is essential to help companies comply with FDA standards and facilitate market access.

Health Insurance Penetration: Low health insurance penetration affects the affordability of healthcare services in India. While awareness and uptake of health insurance are increasing, coverage remains inadequate for certain medical conditions, indicating room for growth in insurance services.

Drug Price Control Order (DPCO): DPCO regulations aim to control drug prices to make them more affordable. While this benefits consumers, it can hamper pharmaceutical companies' profitability and innovation. Effective management is needed to balance the positive and negative effects of price controls on the industry.

Indian Pharma Industry: Future Prospects

Future prospects for the Indian pharmaceutical industry are promising, with several key components contributing to anticipated growth:

Population Dynamics: India's large and growing population, projected to reach 1.5 billion by 2050, presents a significant market opportunity. Increasing life expectancy and a doubling geriatric population over the next 15 years further contribute to healthcare demand.

Increasing Capacity to Spend: With improving literacy rates and GDP growth expected to be sustained, India's middle class, currently comprising 450 million people, will have enhanced purchasing power. Additionally, the opening up of reimbursement avenues can facilitate greater access to healthcare services.

High Disease Prevalence: India accounts for a significant portion of worldwide mortality and morbidity, highlighting the substantial demand for healthcare solutions. However, low awareness, detection, and diagnosis remain challenges to be addressed.

Interest from Global Stakeholders: The Indian pharmaceutical market is attracting attention from multinational pharmaceutical and insurance companies, as well as from the medical tourism sector. This interest indicates confidence in India's potential as a lucrative market and a hub for healthcare services.

Overall, with favorable demographic trends, increasing affluence, high disease prevalence, and interest from global stakeholders, the Indian pharmaceutical industry is poised for steady growth in the coming years, with projected growth rates between 9 and 11 percent.

VI. CONCLUSION

The Indian pharmaceutical industry has traversed a remarkable journey since independence, evolving from a sector reliant on imports to one of the world's largest and most dynamic players. Through shifts in patent laws, government regulations, and global market dynamics, India has emerged as a global leader in generic drug manufacturing and exports, with a burgeoning domestic market and a growing presence internationally.

Despite facing challenges such as regulatory complexities, pricing pressures, and intense competition, the industry's future prospects remain promising. Demographic trends, increasing healthcare spending, and rising demand for affordable medicines all contribute to a favourable outlook. The COVID-19 pandemic further underscored the industry's resilience and capacity for innovation, highlighting its pivotal role in global healthcare.

Moving forward, strategic agility and resilience will be essential for navigating regulatory hurdles, addressing pricing pressures, and capitalizing on emerging opportunities. The Indian pharmaceutical industry stands poised for continued growth and innovation, driven by a robust ecosystem of research and development, manufacturing capabilities, and a skilled workforce. With favourable demographic trends, increasing affluence, and growing interest from global stakeholders, the industry is well-positioned to sustain its trajectory of steady growth and contribute significantly to India's economic prosperity and global healthcare landscape.

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