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Case Report

India's pharmaceutical industry: Some evidence

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Abstract

An aging population, an increase in lifestyle diseases, and rising consumer demand for healthcare are expected to propel India's pharmaceutical industry, currently valued at about \$58 billion, to grow to \$120-130 billion by 2030 and \$400-450 billion by 2047. With up to 74% of FDI permitted and green field venture procedures made simpler, India is establishing itself as a major location for international investors wishing to grow in the life sciences and healthcare industries.

Keywords: India; Pharmaceutical industry, Growth, Global supply

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1. Introduction

In addition to boasting the world's third largest pharmaceutical industry (by volume and 14th largest by value), India's pharmaceutical sector has approximately 3,000 companies and over 10,000 manufacturing units. India is the largest supplier of generic drugs in the world (with a 20% market share) and is also one of the largest manufacturers in the US and EU with more than 650 facilities currently registered under FDA's program.¹ This business is well-established and diversified across generics, over-the-counter (OTC) drugs, vaccines, etc. The market for pharmaceuticals in India, which is estimated to be worth about \$58 billion, is rapidly evolving and offers attractive investment opportunities due to recent progress in biotechnology, continued healthcare needs in domestic Tier 2 & Tier 3 cities.²

India is the world's largest manufacturer of generic drugs and a major producer of low-cost vaccines and generic medicines. Indian pharmaceutical industry is the third largest drug producer by volume having emerged as a rapidly growing industry (with growth rate of 9.43% CAGR) during the last nine years. Here are few of the main sectors of Indian

pharmacy industry which include generic medicines, over-the-counter medicines, bulk medicines, vaccines, contract manufacturing and research, and biologics. This sector supplies over 50% of the global demand for various vaccines, 40% of generic demand in the US and 25% of total medicine supply in the UK. The pharmacy sector of the country consists of a network of 3,000 pharmaceutical companies and 10,500 production units. Today, more than 80% of the antiretroviral drug medication consumed globally to treat AIDS (Acquired Immune Deficiency Syndrome) is supplied by Indian pharmaceutical firms. According to the recent report, Indian pharmaceutical market is expected to grow to US\$ 130 billion by the end of 2030.⁵

There is a prediction that the Indian pharmaceutical industry will grow to an estimated US\$ 65 billion in 2024, and is expected to double in size to about US\$ 130 billion by 2030 and soar up to a staggering US\$ 450 billion by the year 2047. As stated by the government, the present valuation of the industry is around US\$ 50 billion, with exports constituting more than US\$ 25 billion. Discussing the market for hospitals, in FY 23, it was valued at US\$ 98.98 billion and expected to grow at a steady rate of 8% CAGR to reach approximately US\$ 193.59 billion by FY 32.³ India ranks

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among the top 12 global destinations for biotechnology and stands third in the Asia Pacific region. The country holds a share of 3-5% of the global biotechnology market. The bio economy of India in 2022 was valued at US\$ 137 billion with the target to touch US\$ 300 billion by 2030. The target of the pharmaceutical sector is Rs. 11,08,380 crore (around US\$ 130 billion) by 2030 while for the biotechnology sector it is Rs. 25,57,800 crore (approximately US\$ 300 billion) during the same year.⁴ The biosimilars market is expected to grow at an astonishing growth rate of about 22% and can reach nearly US\$ 12 billion by the year 2025, which is almost 20% of India's total pharmaceutical market. India has emerged as the third-largest producer of Active Pharmaceutical Ingredients (APIs) having an 8% share of the global API market. The country manufactures over 500 different APIs and accounts for 57% of APIs on the WHO's prequalified list.

1.1. Recent developments

The Indian pharmaceuticals industry is a key player on the global stage, ranking third in production volume and 14th in value.⁵ Recently, this sector has witnessed significant investments and developments.

1. Due to robust performance in key markets such as the US, Europe, and emerging regions, Indian pharmaceutical companies are anticipated to see revenue growth of 9–11% in FY25.
2. In October 2024, the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) achieved a remarkable milestone by selling Rs. 1,000 crore (US\$119 million). Sanofi has made a big announcement: it intends to invest \$435 million over the next six years to expand its global capability center (GCC) in Hyderabad.
3. There were 24 mergers and acquisitions (M&A) in the Indian pharmaceutical sector in the first quarter of 2024, with a combined value of US\$ 456.3 million.
4. As of June 30, 2024, 2,127 of the 1,40,803 organizations recognized as startups by the Department for Promotion of Industry and Internal Trade (DPIIT) were in the pharmaceutical industry.
5. In a calculated move, MedGenome purchased a portion of GenX Diagnostics, an Odisha-based chain of diagnostic labs.
6. Cipla recently got approval from the Central Drugs Standard Control Organization (CDSCO) to introduce plazomicin, a new antibiotic, in India. This drug is intended to treat complicated urinary tract infections (cUTI), which affect approximately 150 million people each year.
7. 26 applicants were approved to manufacture medical devices between 2020–21 and 2027–28. As a result, 138 products under the PLI scheme were approved, requiring a total financial commitment of approximately US\$ 411.01 million (or Rs. 3,420 crores).
8. The automatic route has allowed up to 100% of foreign direct investment (FDI) in green field pharmaceutical projects. In contrast, FDI for brown field projects can automatically reach 74%; any further investment needs permission from the government.
9. The total amount of foreign direct investment (FDI) equity inflow into the drugs and pharmaceuticals sector between April 2000 and September 2024 was Rs. 2,01,347 crore, or roughly US\$ 23.04 billion.
10. Lupin Ltd. made headlines in November 2023 when it introduced the first fixed-dose triple combination medication for the treatment of chronic obstructive pulmonary disease (COPD). A month prior, in October 2023, Glenmark Pharmaceuticals introduced Zita, a reasonably priced triple combination medication designed to help people with Type 2 diabetes better control their blood sugar levels.
11. The Ministry of Health & Family Welfare of India, the Indian Pharmacopoeia Commission (IPC), and the Ministry of Health of Suriname signed a Memorandum of Understanding (MoU) on June 4, 2023, to recognize the Indian Pharmacopoeia (IP) in Suriname.
12. To promote the Unani System of Medicine in India, the Ministry of Minority Affairs and the Ministry of Ayush partnered in May 2023.
13. Increased the number of "Jan Aushadhi Kendras" from 10,000 to 25,000 in 2023. The Department of Pharmaceuticals is preparing to launch the Pharma MedTech Sector's Scheme for the Promotion of Research and Innovation (PRIP). The Union Cabinet has approved this initiative, which will have a massive budget of Rs. 5,000 crore (roughly US\$ 604.5 million) and run for five years, from 2023–2024 to 2027–2028.
14. Emcure Pharmaceuticals Limited (EPL) has made history by being the first to launch Orofer FCM 750, a cutting-edge addition to its parenteral iron brand that contains ferric carboxymaltose (FCM). The majority of Indian patients with iron deficiency and iron deficiency anemia are intended to use this new dosage.
15. In addition, Indian pharmaceutical and medical device companies are being invited to invest. It is anticipated that the partnership between the Japan Federation of Medical Devices Associations and the Pharmaceutical Traders Association will contribute to the stabilization of the global supply chain, specifically for medical devices and APIs.
16. In a noteworthy move, Sun Pharmaceutical Industries Limited declared that it had successfully acquired Concert Pharmaceuticals.
17. Known for its creative methods, Glenmark Pharmaceuticals Ltd. (Glenmark) has created history by introducing Akynzeo I.V., a novel intravenous injection formulation, in India. This product, which is under an exclusive licensing agreement with the Swiss biopharma group Helsinn, is intended to prevent chemotherapy-induced nausea and vomiting (CINV).
18. Entod Pharmaceuticals recently unveiled their new line of ocular cosmetics, which are intended to improve eye comfort and appearance.
19. In India, BDR Pharmaceutical unveiled Apatide, the first generic form of apalutamide. This drug will be accessible nationwide and is designed to treat both

metastatic castration-sensitive prostate cancer and non-metastatic castration-resistant prostate cancer.

20. With the introduction of its LYBER line, Anglo French Drugs & Industries Limited (AFDIL), a reputable company with 99 years of experience in the pharmaceutical sector, has made an intriguing entry into the fertility market.
21. The medical device market is expected to reach \$50 billion by 2030, with a 15% compound annual growth rate (CAGR).
22. A licensing agreement to market phenobarbital for injection in the United States was signed in November 2022 by Sun Pharma and SPARC. In October 2022, Glenmark made headlines as the first company in India to introduce a fixed-dose combination of dapagliflozin and teneligliptin.
23. Additionally, Lupin agreed to buy two inhalation brands from Sunovion Pharmaceuticals Inc. Two out of the six strengths of Lenalidomide Capsules are eligible for first-to-market, 180-day exclusivity in September 2022, according to Dr. Reddy's Laboratories.
24. Cipla and the Drugs for Neglected Diseases initiative (DNDi) launched a four-in-one antiretroviral treatment for HIV-positive children in South Africa in June 2022. Additionally, Glenmark was the first pharmaceutical company in India to market a fixed-dose combination medication for asthma that included indacaterol and mometasone.
25. To lower low-density lipoprotein (LDL) cholesterol, Sun Pharmaceutical Industries Limited announced in May 2022 that it would introduce Bempedoic Acid under the Brillo brand in India through one of its wholly owned subsidiaries.

India's pharmaceutical market is expected to be worth USD 50 billion in FY 2023–2024, with USD 23.5 billion coming from domestic sales and USD 26.5 billion from exports. The industry is highly diversified, with products ranging from biologics to generic drugs, employing about 925,811 people, and contributing Rs. 1,75,583 crores in value added to an overall output of Rs. 4,56,246 crores for FY 2022-23.³ It is noteworthy that improvements in chronic disease treatments and the emergence of GLP-1 obesity medications like Ozempic and Wegovy are expected to propel pharmaceutical sales, highlighting the dynamic nature of the sector. (Table 1).

Table 1: India's projected pharmaceutical market size.

Year	Market value (US\$ in billion)
2021	42
2024	58
2030 (P)	120-130
2047 (P)	400-450

Source: IBEF, Invest India.

2. FDI policy for India's Pharmaceutical Industry

Green field pharmaceutical investments in India allow for 100% FDI via an automated process, allowing businesses to build new facilities from the ground up. On the other hand, 100% FDI is permitted for brown field investments as well; however, only 74% of these can be acquired automatically, with the remaining portion needing government approval.⁴ Companies that want to start new production activities buy or lease existing facilities as part of brown field investments.

2.1. Major regulations

The Central Drugs Standard Control Organization (CDSCO), which oversees the drug industry in India, has a strong regulatory framework that guarantees the efficacy, safety, and quality of pharmaceuticals, cosmetics, and medical equipment. The Drug Price Control Order (DPCO), 1995, which controls pricing, the Patent Act, 1970, which protects intellectual property rights while guaranteeing access to necessary medications, and the Drugs and Cosmetics Act, 1940, which requires adherence to quality standards, are important regulations. Strict compliance regulations also apply to clinical testing and medical devices, that in order to stay competitive and maintain operational success, businesses must set up efficient compliance systems and follow good manufacturing practices (GMP).⁵

2.2. Strategic ideas for businesses

To enhance business strategies, companies should prioritize regulatory compliance through frequent audits of relevant laws and manufacturing processes, ensuring adherence to clinical testing standards. Additionally, they must consider the implications of compulsory licensing in their intellectual property approaches. Adapting costs and prices in line with DPCO price controls while safeguarding profit margins by offering supplementary services is essential.⁶ Furthermore, leveraging India's robust R&D ecosystem to innovate, particularly in biologics and combination therapies, will position businesses to capture emerging market opportunities effectively.

3. Why India's Pharmaceutical Industry Outlook Remains Bright

Due to factors like an aging population and the rise in lifestyle-related diseases, India's pharmaceutical industry, which is currently valued at about \$58 billion, is expected to grow significantly, reaching \$120–130 billion by 2030 and possibly \$400–450 billion by 2047. With eight of the top 20 generic pharmaceutical companies in the world based in India, the nation has the most FDA-compliant drug manufacturing facilities outside of the United States. With more than 55% of its drug exports going to heavily regulated areas and 65–70% of the WHO's vaccine requirements being met, it plays a significant role in the global market. Furthermore, with 60,000 generic brands produced, India is a key supplier of generics worldwide, bolstered by substantial

investments from big pharmaceutical companies and a strong biotech workforce.⁷

4. PLI Schemes

Since its launch in 2020, India's Production Linked Incentive (PLI) program has greatly increased domestic production of medical equipment, drug intermediates (DIS), active pharmaceutical ingredients (API), and key starting materials (KSMS). India's production capabilities have significantly increased as a result of the recent focus on growing these sectors through the promotion of initiatives like Bulk Drugs on November 6, 2023, and Medical Equipment Manufacturing on November 25, 2024. As a result, 50% of total production is now exported, increasing India's competitiveness internationally and decreasing its dependency on imports, especially for necessary pharmaceuticals like Penicillin G.⁸

5. Export Performance

The United States was the biggest importer of India's pharmaceutical exports in FY24, making up 31.35% of total exports at US\$8.73 billion. The UK and South Africa came in second and third, respectively, with US\$784.32 million and US\$718.54 million, or 2.82% and 2.58% of the total. With exports of US\$699.16 million and US\$667.49 million, respectively, the Netherlands and France were two other noteworthy importers.⁹ **Table 2** ranks India's leading pharmaceutical companies based on their market capitalization.

Table 2: India's leading pharmaceutical companies based on their market capitalization.

Rank	Company	Market Cap (Rs Lakh Crore)	Headquarter
1	Sun Pharma	4.19	Mumbai, Maharashtra
2	Divi's Laboratories	1.49	Hyderabad, Telangana
3	Cipla	1.16	Mumbai, Maharashtra
4	Torrent Pharmaceuticals	1.08	Ahmedabad, Gujarat
5	Mankind Pharma	1.02	Delhi
6	Dr. Reddy's Laboratories	1.00	Hyderabad, Telangana
7	Zydus Lifesciences	0.98	Ahmedabad, Gujarat
8	Lupin	0.93	Mumbai, Maharashtra
9	Aurobindo Pharma	0.66	Hyderabad, Telangana
10	Alkem Laboratories	0.60	Mumbai, Maharashtra

Source: <https://medicinman.net/2025/03/top-10-indian-pharma-2025/>

6. FDI inflow

The cumulative FDI equity inflow into the drugs and pharmaceuticals industry in India from April 2000 to September 2024 was US\$23,048 million.⁸ accounting for 3 percent of the total FDI inflow across all sectors (**Table 3**)

Table 3: FDI Inflow into India's drugs and pharmaceutical industry

Financial year	FDI inflow (US\$ in million)
2018-19	266
2019-20	518
2020-21	1,490
2021-22	1,414
2022-23	2,058
2023-24	1,064

Source: DPIIT FDI Statistics

7. Indian and Foreign Pharmacy Firms Strike Strategic Partnerships

India's pharmaceutical industry has undergone a significant transformation thanks to strategic alliances between domestic and international pharmaceutical companies, which have improved patient access to cutting-edge treatments and spurred rapid innovation. Cooperative ventures to commercialize new molecular entities (NMEs) have become more prevalent in recent years. Notable partnerships include Glenmark Pharmaceuticals with Pfizer and Cipla with Eli Lilly, and they target diseases ranging from metabolic disorders to oncology. Due in large part to rising healthcare costs and the prevalence of chronic diseases, these partnerships give foreign businesses a stronger foothold in India's changing healthcare landscape while enabling Indian businesses to take advantage of global resources and expertise.⁹ The focus on both high-value NMEs and reasonably priced treatment options demonstrates a dynamic shift in the direction of tackling the nation's urgent health issues.

8. Incentives for R&D, Product Development and High-Value Production

Initiatives like the Production Linked Incentive (PLI) scheme, which encourages domestic production of cutting-edge goods like biologics and in vitro diagnostic devices, have a significant impact on India's pharmaceutical industry. The program aims to support the development of biotechnology and improve the supply chain for Active Pharmaceutical Ingredients (API) in partnership with the Council of Scientific and Industrial Research.¹⁰ Although Indian companies have historically concentrated on generic medications, there is a trend toward the study and creation of novel compounds, which is aided by R&D incentives. India is still a major player in the global pharmaceutical market thanks to its ability to produce high-quality vaccines, APIs, and generics.

9. Conclusion

India's pharmaceutical sector contributes significantly to the nation's international trade and offers investors appealing potential. India, which operates numerous plants that adhere to the good production practices (GMP) guidelines established by the US Food and Drug Administration (USFDA) and the World Health Organization (WHO), provides generic medications that are inexpensive and accessible to millions of people worldwide. India has long been the leading country in drug production. Over the next five years, medical costs in India are predicted to rise by 9–12%. Better domestic sales growth in the future will also rely on the company's ability to align its product portfolio with chronic agents like anti-cancer, anti-diabetic, antidepressant, and cardiovascular drugs. To lower expenses and lower the cost of health care, the Indian government has taken a number of actions. The aging of the population, the rise in chronic illnesses, the national health care program, which aims to provide universal health care, and other government initiatives, such as the establishment of pharmacies that sell reasonably priced generic medications, should all support the growth of the Indian pharmaceutical sector. It is anticipated that Indian pharmaceutical companies will profit from the early release of generic medications into the market. Additionally, pharmaceutical companies benefit from the increased focus on lifestyle medications, health programs, and preventive vaccinations. With the impending expiration of patents for popular biologics, which offers huge prospects in the global biosimilar market, the Indian pharmaceutical industry is well-positioned for major growth, especially in cutting-edge fields like CAR-T cell therapy, mRNA vaccines, and complex molecule development. Due to growing global market access and the capabilities of contract development and manufacturing organizations (CDMOs), the industry, which is currently valued at \$50 billion, is expected to grow to \$130 billion by 2030, making it the largest supplier of vaccines and a leading provider of generic drugs. India

needs to improve its innovation pipeline, maintain strict regulatory compliance, and increase its global footprint in order to take full advantage of these opportunities.

10. Source of Funding

None.

11. Conflict of Interest

None.

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