Why India's Pharmaceutical Industry Remains Poised for Growth in 2025

India's pharmaceutical industry, valued at around US$58 billion, is projected to reach US$120-130 billion by 2030 and US$400-450 billion by 2047. Growth is driven by rising lifestyle diseases, an aging population, increased focus on holistic health, and the growing consumerization of healthcare. India allows 100 percent FDI under automatic approval for greenfield investments and up to 74 percent for brownfield investments, with higher stakes requiring government approval, making it a prime destination for global investors seeking growth in the healthcare and life sciences domain.

India's pharmaceutical industry ranks third globally in pharmaceutical production by volume and 14th by value, supported by a well-established domestic sector comprising approximately 3,000 drug companies and over 10,000 custom manufacturing units. India is the world's largest provider of generic medicines, with a 20 percent global supply share by volume.

Often referred to as the "Pharmacy of the World," the Indian pharmaceutical industry encompasses a broad range of segments, including generic drugs, over-the-counter (OTC) medicines, bulk drugs, vaccines, contract research, biosimilars, and biologics.

Indian pharmaceutical companies have firmly established their presence in the prescription markets of the U.S. and EU, with over 650 U.S. Food and Drug Administration (FDA)-approved manufacturing facilities operating in India. Per a November 2024 report in *Forbes*, India supplies 40 percent of the U.S. generic drug market and 25 percent of all medicines in the UK.

The global pharmaceutical products market is projected to reach US$3,148.31 billion by 2032, growing at a compound annual growth rate (CAGR) of 7.5 percent from 2024 to 2032. This sustained expansion underlines India's critical role in the global pharmaceutical supply chain and presents significant investment opportunities for domestic and international stakeholders.

Fortune Business Insights estimates the global pharma market to be valued at US$1,763.9 billion in 2024, up from US$1,661.26 billion in 2023. Several factors contribute to this growth, including the rising prevalence of chronic conditions such as cancer, diabetes, and neurological disorders, an aging population driving increased healthcare demand, and higher healthcare spending in emerging markets. Additionally, new therapies for chronic diseases and the surge in GLP-1 obesity drugs—including Ozempic, Mounjaro, and Wegovy—are expected to drive prescription drug sales.

India's Pharmaceutical Market Size with Projections to 2047

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

Source: IBEF, Invest India

FDI policy for India's pharmaceutical industry

Greenfield pharmaceutical undertakings in India are allowed 100 percent FDI through the automatic route. For brownfield pharmaceutical investments, 100 percent FDI is permitted but with 74 percent under the automatic route and the remainder requiring approval from the Indian government.

In the greenfield category, companies establish their subsidiary and start their own production by constructing new plants or facilities from the ground up. Whereas, under brownfield investment, companies buy or lease existing facilities to begin a new production activity.

Key regulations

India's pharmaceutical sector operates within a comprehensive regulatory framework that is evolving to meet industry needs and innovation. These laws and quality standards seek to ensure product quality, safety, and affordability while fostering innovation. Businesses must align with key regulations and be compliant under quality norms to maintain competitiveness and operational success.

The Central Drugs Standard Control Organisation (CDSCO) is the premier regulatory authority in India's pharmaceutical sector. It operates under the aegis of the Ministry of Health and Family Welfare and plays a pivotal role in ensuring the safety, efficacy, and quality of drugs, cosmetics, and medical devices manufactured and marketed in India.

› Intellectual property and patent protection

The Patents Act, 1970, aligned with the TRIPS Agreement, defines patent eligibility and includes compulsory licensing provisions, ensuring access to essential medicines. Companies should proactively secure patents for innovations while factoring in potential licensing implications.

› Quality and compliance standards

The Drugs and Cosmetics Act, 1940, mandates strict adherence to product quality, labeling, and prescription guidelines. Additionally, Good Manufacturing Practices (GMP) under Schedule M set standards for facility operations, ensuring product consistency and compliance with WHO guidelines.

› Clinical trial and research compliance

Companies conducting clinical trials must follow stringent regulatory approvals to ensure ethical and safety standards for human subjects. With proposed Biomedical Research on Human Subjects regulations, firms should establish robust compliance mechanisms to mitigate regulatory risks.

› Drug pricing and market access

The Drug Price Control Order (DPCO), 1995, regulates the prices of essential medicines, setting ceiling prices and monitoring cost fluctuations. Companies must integrate pricing compliance into their market strategies to avoid violations and optimize profitability.

› Regulation of medical devices

India's medical devices are regulated under the Medical Devices Rules, 2017, which classify devices into four risk-based categories and ensure their quality, safety, and efficacy. The CDSCO oversees regulation, requiring manufacturers to appoint an authorized representative, submit an application, pay fees, and compile a dossier for registration, with Class A and B devices needing a license from the State Licensing Authority.

Strategic considerations for businesses:

- Ensure regulatory compliance with evolving laws and regular audits of manufacturing and clinical trial practices.
- Factor in compulsory licensing risks when developing intellectual property strategies.
- Adapt to DPCO price controls while maintaining profit margins through cost optimization and value-added services.
- Leverage India's R&D ecosystem to innovate and capitalize on growth segments like biologics and combination therapies.

Why India's pharmaceutical industry outlook remains bright

India's pharmaceutical industry is currently valued at approximately US$58 billion, with projections indicating growth to US$120-130 billion by 2030 and US$400-450 billion by 2047. Key factors driving this expansion include the rising prevalence of lifestyle-related diseases, an aging population, increased focus on holistic health and well-being, and the growing consumerization of healthcare.

India hosts the largest number of U.S. FDA-compliant pharmaceutical manufacturing facilities outside the United States. Eight of the world's top 20 generic drug companies originate from India, and more than 55 percent of the country's pharmaceutical exports are directed to highly regulated markets. Additionally, India is the world's leading vaccine exporter, supplying approximately 65-70 percent of the World Health Organization's (WHO) vaccine requirements, particularly for DPT, BCG, and measles. The country's significant role in affordable HIV treatment further reinforces its position as a key global pharmaceutical supplier.

India produces 60,000 generic brands across 60 therapeutic categories, accounting for 20 percent of the global generics supply. Major investors in the Indian pharmaceutical sector include AstraZeneca, Dr. Reddy's, GSK, Divi's, Zydus, Novartis, Pfizer, Sun Pharma, Teva, Mylan, and Johnson & Johnson.

Furthermore, India is the second-largest contributor to the global biotech and pharmaceutical workforce, highlighting its critical role in the industry's future growth and innovation.

PLI schemes

In 2020, India announced the Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs), the Scheme on Promotion of Bulk Drug Parks, and the PLI Scheme for Promoting Domestic Manufacturing of Medical Devices.

For a list of applicants approved under the respective pharmaceutical industry PLI schemes, see the official links here:

- Promotion of Domestic Manufacturing of Critical Key Starting Materials (KSMs) / Drug Intermediates (DIs)/ Active Pharmaceutical Ingredients (APIs) in India – PLI Bulk Drugs – as on November 6, 2023.
- Promoting Domestic Manufacturing of Medical Devices – as on November 25, 2024.

In terms of their impact, the PLI schemes are enhancing India's pharmaceutical and medical device manufacturing capabilities. Exports now constitute 50 percent of total production, reflecting strengthened global competitiveness. India's dependence on imports has decreased with the domestic production of key bulk drugs such as Penicillin G. Furthermore, technology transfers from global companies have facilitated the local manufacturing of advanced medical devices, including CT scanners and MRI machines, reinforcing India's potential to become a hub for high-value healthcare innovation.

Also Read: India's Medical Devices Industry: Investor Outlook

Export performance

In 2023-24, the U.S., UK, and South Africa were among the largest importers of Indian pharmaceutical products, accounting for 31.35 percent, 2.82 percent, and 2.58 percent of total exports, respectively. India's pharma exports in FY24 stood at US$8.73 billion to the U.S., US$784.32 million to the UK, US$718.54 million to South Africa, US$699.16 million to the Netherlands, and US$667.49 million to France.

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, accounting for 3 percent of the total FDI inflow across all sectors.

FDI Inflow into India's Drugs and Pharmaceutical Industry

Financial year	FDI inflow
FY 2018-19	US$266 million
FY 2019-20	US$518 million
FY 2020-21	US$1,490 million
FY 2021-22	US$1,414 million
FY 2022-23	US$2,058 million
FY 2023-24	US$1,064 million
FY 2025 (April-September 2024)	US$520 million

Source: DPIIT FDI Statistics

Indian and foreign pharma firms strike strategic partnerships

Strategic partnerships between Indian and foreign pharmaceutical firms are reshaping how the industry caters to the domestic market, ensuring faster innovation, better patient access to advanced therapies, and stronger market penetration. This trend is set to grow, making collaboration essential for successfully navigating India's evolving pharma landscape.

Below we mention a few trends observed across India's pharmaceutical market in recent years:

- **Growing collaboration:** The Indian pharmaceutical sector is witnessing a rise in strategic alliances with global big pharma companies, primarily to accelerate commercialization and expand market reach for new molecular entities (NMEs).
- **Deal activity and co-marketing agreements:** Between January 2019 and February 2024, 32 strategic alliances (excluding co-development deals) took place for NMEs in India, per reporting in the *Indian Express*, with six involving co-marketing agreements. Key partnerships include:
  - Glenmark Pharmaceuticals & Pfizer Inc. (2024) – Abrocitinib
  - Torrent Pharmaceuticals & Boehringer Ingelheim (2022) – Empagliflozin and its combinations
  - Cipla & Eli Lilly (2021) – Dulaglutide and Humalog
  - Cipla & F. Hoffmann-La Roche (2020) – Bevacizumab, Trastuzumab, and Rituximab

- **Mutual benefits:** Indian pharma firms find appeal among global investors and drugmakers as they can leverage their strong sales force and local market expertise to enhance distribution and adoption. Global pharma giants bring innovative therapies, marketing expertise, and ready-to-use promotional materials to strengthen commercialization efforts. Collaborations allow Indian firms to strengthen product portfolios with high-value NMEs, improving profit margins over generics. Meanwhile, global pharma companies gain accelerated market access and an expanded commercial presence in India.
- **Key therapeutic areas:** Initially driven by infectious disease treatments (COVID-19), partnerships now focus on oncology, cardiovascular diseases, and metabolic disorders, reflecting India's growing healthcare challenges.
- **Market expansion and growth potential:** India's rising healthcare expenditure, increasing chronic disease burden, and demand for innovative therapies make it an attractive market for foreign pharma companies, ensuring long-term partnership opportunities.
  Recent industry developments include:

› New drug launches by leading Indian firms signal growth in specialized therapies (e.g., Cipla's plazomicin approval, Lupin's COPD combination drug).
› Expansion in affordable treatment solutions, such as Glenmark's Zita for diabetes, highlights opportunities for cost-effective innovation.

Pharma industry view 2025: Opportunities for high-value products, R&D, biosimilars

Expressing his views on *CNBC*, Sudarshan Jain, Secretary General of the Indian Pharmaceutical Alliance, notes that leading Indian pharmaceutical companies are shifting focus onto specialty portfolios and expanding into higher-value drugs. Discovery products such as Nafithromycin and Saroglitazar are expected to drive a new wave of research from India. Additionally, committees have been established to streamline regulatory reforms, creating a more supportive ecosystem for R&D and innovation.

Jain highlights that the Indian pharma industry is poised to make significant advancements in cutting-edge areas, including CAR-T cell therapy, mRNA vaccines, and complex molecule development, all of which have strong growth potential. Furthermore, the patent expirations of blockbuster biologics by 2025 present a major opportunity for India in the global biosimilars market.

India's Contract Development and Manufacturing Organizations (CDMOs) are also emerging as preferred partners for biologics manufacturing, leveraging their cost efficiencies, regulatory compliance, and technical expertise. To fully capitalize on these opportunities, the Indian pharmaceutical industry must strengthen its innovation pipeline, maintain stringent regulatory compliance, and expand its global market presence.