Pharmaceuticals Industry Primer

FINANCE AND INVESTMENT CELL
SHRI RAM COLLEGE OF COMMERCE

TABLE OF CONTENTS

ABSTRACT

The Indian pharmaceutical industry has evolved from an import-dependent market into a global leader in generic drug manufacturing. This shift has been driven by policy reforms, cost-efficient production and strong export capabilities. This report examines the industry's historical development, value chain, demand and supply drivers, and emerging trends shaping its future. Key growth drivers include rising chronic diseases, an aging population, increased healthcare access, and government-led initiatives like PLI schemes. These have supported research, manufacturing and biopharmaceutical innovation in the industry. On the other hand, the sector faces challenges like import dependence for raw materials, heavy price controls, workforce skill gaps and regulatory and environmental constraints. The study argues that India must transition towards an innovation-led growth focused on complex generics, biosimilars and specialty medicines. The industry's ability to address structural vulnerabilities while also leveraging government support and global trade opportunities will determine its long-term position in the changing global healthcare landscape.

INTRODUCTION

The current pharmaceutical industry across the globe is experiencing an intense shift due to growing aging populations and an upsurge in chronic illnesses and a marked shift towards high-value biosimilars and personalized medicine. As of 2025, the current market across the globe is estimated at $1.77 trillion and set to grow at a CAGR of 6.15%, which has made it possible for it to reach an estimated $3.22 trillion as of 2035. North America continues to remain at the forefront of this industry as its market shares range between 36% and 42%. The other fastest-growing route for this industry is across the Asia-Pacific market. The current industry across this globe is spearheaded by giants F. Hoffmann-La Roche, Novartis, AbbVie, Johnson & Johnson, and Pfizer.

Against this backdrop of a global scenario, India has ably converted from a volume-based manufacturing powerhouse to a dredged cornerstone of the global chain of value. Popularly termed the "Pharmacy of the World," the Indian pharmaceutical market is pegged at $55-65 billion, and is expected to reach $130 billion by 2030 with a CAGR of 8% to 11%. The global position of India is quite intimidating; India is ranked 3rd globally in terms of production volume.

Company	Market Cap (Est. 2025)	Key Focus Areas	FY25 Revenue (Est.)
Sun Pharma	₹4.0 Lakh Cr+	Specialty, Oncology, Dermatology	₹48,000 Cr+
Divi's Labs	₹1.7 Lakh Cr+	API Manufacturing, Custom Synthesis	₹9,360 Cr
Cipla	₹1.1 Lakh Cr+	Respiratory, Anti-retroviral, Urology	₹26,000 Cr+
Dr. Reddy's	₹1.0 Lakh Cr+	Generics, Biosimilars, Chronic Care	₹28,000 Cr+
Torrent Pharma	₹1.3 Lakh Cr+	Cardiovascular, CNS, GI	₹11,500 Cr

An Overview of Key Indian Pharmaceutical Companies: Estimated Market Cap, Key Focus Areas and FY25 Revenue

HISTORIC PERFORMANCE

India's pharmaceutical industry has transformed from an import-dependent, MNC-dominated market (80-90% share post-1947) into the "Pharmacy of the World," ranking 3rd globally by volume. Government CPSEs like HAL (1954) and IDPL (1961) built domestic capacity, while the Patents Act 1970 (process patents only) enabled reverse engineering, cutting MNC share from 70% to 23% (1970-2004). India now supplies nearly 20% of global generics, with exports surging from $600M (1995) to $30.47B (FY25) across 200+ countries. Stronger CDSCO-led regulation, USFDA-compliant sites (262+), and TRIPS-compliant 2005 product patents (with Section 3(d)) continue shaping growth.

Post-independence growth and development

The number of producers expanded from 30 (1947) to 2,257 units (1970) and around 16,000 (1990), later consolidating to about 3,000 companies with around 10,500 units (2025). Market size rose from ₹10 crore (1948) to $55 billion (2025), while exports jumped from $600 million (1995) to $30.47 billion (FY25). Foreign MNC dominance of 80-90% post-independence steadily declined as domestic firms captured more than 90% market share by 1995.

Impact of Patents Act 1970

The Indian Patents Act 1970 removed product patents and allowed only process patents, enabling large-scale reverse engineering and competition. Before the Act, drug prices were among the highest globally, but by 2004 there were sharp price declines. Before the Act, foreign MNCs had 80-90% market share, which reduced to about 23% by 2004. Patent ownership also shifted over time, from foreigners holding 80-90% of patents pre-1970 to rising Indian global filings (56 in 1995-99 to 246 in 2000-04), with 8,926 mailbox applications filed after product patents returned in 2005.

Rise of generic manufacturing in India

India's global pharma leadership was built on scaling low-cost generics, rapidly expanding domestic dominance and exports to become a major supplier to regulated markets like the US. India is supplying nearly 20% of global generics by volume. Post-1970, domestic firms rose from around 20% share (1970) to more than 90% (1995), with generics forming about 70% of industry revenue (2015). Generic exports surged from $600M (1995) to $30.47B (FY25), meeting nearly 40% of US generic demand.

Export growth and global market presence

India's pharma exports scaled rapidly after the 1990s, rising from around $1B (1990) and $600M (1995) to $5.2B (2005), $11.4B (2010), $17.27B (FY18), $27.85B (FY24) and a record $30.47B (FY25). India ranks 3rd globally by volume, but 11th-14th by value, and contributes nearly 3% of global pharma exports (2023). It has maintained a pharma trade surplus since 1987-88, reaching about $19B in FY25, while pharma forms around 6% of India's total merchandise exports.

Evolution of regulatory framework and compliance

India's pharma regulation evolved from the Drugs Act (1940) and Drugs Rules (1945) into a modern CDSCO-state framework aligned with global quality norms. Manufacturing expanded from 2,257 units (1970) to 16,000

(1990) and peaked at 23,000+ (2005), later consolidating to 10,500 units across 3,000 companies (2025) as GMP standards tightened (Schedule M, 1987; revised 2023). Compliance scaled with global accreditation, with USFDA-approved plants rising from 1 (1990) to 670+ (2025), but oversight remains stretched with around 2,000 officials supervising 10,000+ factories and as much as 1 million pharmacies.

Key milestones (TRIPS agreement and beyond)

The WTO's TRIPS Agreement set minimum global intellectual property standards and required India to restore 20-year product patents for pharmaceuticals, reshaping the industry's shift from reverse engineering to innovation. Post-TRIPS, India's pharma industry saw sharp growth in innovation and global integration. Indian firms' global patent filings rose from 56 (1995-99) to 246 (2000-04), while 8,926 mailbox applications were filed by foreign companies by 2005. Industry R&D spend jumped from $30M (1995) to $495.2M (2005-06). Exports expanded from $600M (1995) to $3.7B (2005) and $30.47B (FY25). FDI inflows increased from $12M (1994) to $342M (2004), with $24.62B cumulative (2000-2025).

VALUE CHAIN

Spending on Research and Development by Corporates

The Indian pharmaceutical sector is moving away from producing generic drugs to developing new drugs through government support for research and development and innovation according to the National Policy on R&D and Innovation in Pharma-MedTech. Sun Pharma and Dr. Reddy's main Indian competitors invest between 6.5 and 9 percent of their revenue into research and development while companies that drive global innovation will spend more than 25 percent of their budget during 2024 to 2025.

- **Patent Filings:** India achieved its first 110375 patent applications during fiscal year 2024 to 2025 which represents a 197 percent increase from the previous year. Indian residents now make domestic filings which represent 618 percent of the total filings.

- **Average R&D Cost per Drug:** The worldwide cost to develop a New Chemical Entity (NCE) reaches approximately 26 billion dollars while Indian companies that create advanced generics and biosimilars maintain operational budgets between 50 million and 150 million dollars.

Raw Material Sourcing (API)

India is the world's 3rd largest producer of Active Pharmaceutical Ingredients (APIs) by volume, though it remains strategically dependent on imports for critical intermediates.

- API import share in India amounts to approximately ₹392 billion which equals $4.7 billion while this amount fulfills about 35 percent of India's total API demand.

- China remains the primary supplier, providing approximately ~74% of India's total API imports.

- About 65% of India's API production is consumed domestically. The PLI scheme has approved 27 projects which will establish 41881 MT of capacity to increase self-reliance.

- **Price Trends:** API realisations were relatively flat in 2024 due to global overcapacity but are projected to grow 6-8% in 2025-26 as market pricing stabilizes.

Manufacturing and Production

India holds the top position in global generic drug production because it offers low-cost manufacturing services.

RECENT TRENDS

The India-EU Free Trade Agreement

The India-EU Free Trade Agreement is going to change the pharmaceutical industry in a big way. This agreement was finalized in 2026. It removed a hurdle. An 11% tariff on Indian pharmaceutical exports. The India-EU Free Trade Agreement is not about saving money. It also sets up a "Working Group on Conformity Assessment" that helps India and the European Union recognize each other's manufacturing standards. This group works with India's CDSCO and the European Medicines Agency. It has reduced the time it takes for generics and biosimilars to get to the market. Now Indian companies have access to a huge market worth $572 billion. Many European companies are moving their high-quality API imports from China to India.

"Biopharma SHAKTI" and the ₹10,000 Crore Mission

The Indian government has started the Biopharma SHAKTI initiative. It has allocated ₹10,000 crore for this mission over the five years. The Biopharma SHAKTI mission wants to change the pharmaceutical industry. It wants to move from a volume-driven industry to a value-driven biopharma industry. The goal is to get a 5% global market share in biopharmaceuticals by 2030. The government is using the ₹10,000 crore to develop ecosystems for "living drugs" like monoclonal antibodies and cell therapies. This will help Indian companies make biologics that were earlier imported at a high cost.

The "Bio-RIDE" Framework and National Biofoundries

The Indian government has started the Bio-RIDE scheme. It has allocated ₹9,000 crore for this scheme. The Bio-RIDE scheme wants to launch the "Bio-Economy" which is worth $140 billion. A key part of this scheme is the development of National Biofoundries. These biofoundries will give startups access to fermenters. They will help develop 1,000 bio-products. The scheme will use AI-powered modeling to reduce drug discovery time by 50%. This will make the sector less dependent on imported materials. It will also meet "Green Chemistry" standards for sustainability.

Foray into High-Tech Medical Devices

The Indian medical device sector is becoming a high-tech manufacturing base. Exports have risen from $2.5 billion in FY21 to $4.1 billion in 2025. They are expected to reach $50 billion by 2030. The Production Linked Incentive scheme for devices has established 13 new facilities. These facilities make devices like MRI machines and CT scanners. The sector has seen 71 deals worth $2.6 billion in one quarter. Many multinational companies like Siemens and Philips are setting up Research & Development centers in India.

Clinical Trial Boom

India has become a destination for clinical trials. In 2024 18,000 new clinical trials were registered. This is a 50% increase from the year. India's patient base provides a genetic diversity for complex therapies. Most of these trials are focused on -communicable diseases like oncology and cardiovascular diseases. The government has accredited over 1,000 trial sites. The ICMR has set up a network for Phase 1 Clinical Trials. This network focuses on value indigenous molecules and CAR-T cell therapies.

R&D Paradigm Shift

The PRIP scheme is changing the way Indian companies do R&D. It is allocating ₹5,000 crore for this scheme. The scheme provides assistance for downstream R&D. This has increased R&D expenditure in companies. They are now focusing on "Complex Generics" like inhalers and biosimilars. Seven Centers of Excellence have been set up in NIPERs. They have been allocated ₹90-110 crore each. This is bridging the gap between research and drug innovation. The PRIP scheme is a step forward for the Indian pharmaceutical industry. It will help Indian companies make innovative drugs.

DEMAND-SIDE FACTORS

Increasing burden of chronic diseases in India

The rapid epidemiological transition from infectious diseases to non-communicable diseases (NCDs) has been a key factor leading to the transition of the Indian pharmaceuticals industry. NCDs have accounted for approximately 60-66% of all fatalities in the country. It has brought implications for pharmaceutical demand, as chronic therapeutic areas are currently growing at 9-10% annually, significantly surpassing acute therapies growing at around 6%. The number of individuals with diabetes in India increased from 32 million in 2000 to 63 million in 2012, reached 101 million recently, and is projected to hit 134 million by 2045. Concurrently, cardiovascular diseases (CVD) have become the leading cause of mortality, responsible for nearly 25-28.1% of all deaths, with an age-standardized death rate of 272 per 100,000 population, notably exceeding the global average. Oncology is also witnessing aggressive growth, as new cancer cases were estimated at 1.39 million in 2020, rising to approximately 1.5-1.7 million recently, and are projected to reach up to 2.5 million annual cases by 2030. As a result, therapies for cardiac, metabolic, neurological and oncological conditions have been dominating domestic market revenues. These further support the projections that the Indian pharma market will double from its current valuation of $65 billion to between $120 billion and $130 billion by 2030, and potentially $450 billion by 2047.

Growth in the aging and affluent middle-class population

India is experiencing a massive demographic and economic transition that is fundamentally reshaping healthcare consumption. Historically, the elderly (aged 60 and above) accounted for a steady 5-6% of the population between 1900 and 1950, but this cohort has now reached 10-11%. Driven by longevity gains, this group is projected to surge to 20-21% by 2050, totaling an estimated 347 million individuals and nearly 31% by 2100. Although seniors currently represent only a tenth of the total

population, their reliance on long-term treatments means they already account for 17% of the total pharmaceutical market. Industry analysts forecast that this "silver generation" will drive 25-33% of total pharma demand within the next two to three decades. Amplifying this age-driven demand is the rapid expansion of the affluent middle class, as middle-income households are expected to expand from 50% in 2019 to nearly 80% by 2030. This upward economic mobility is a crucial catalyst for the healthcare sector, as households entering high-income brackets increase their expenditure on services like healthcare by 3-4 times. Ultimately, this expanding middle class is projected to drive 75% of total consumer spending by 2030, accelerating the transition from basic generic medicines to high-value specialty therapies, preventive healthcare and premium medical devices.

Increased accessibility of public and private health insurance

The Indian health insurance market is expanding rapidly, projected to reach $39.5 billion by 2032 at a 13.1% CAGR. Public schemes like Ayushman Bharat (PM-JAY) have issued over 41 crore cards, covering 55 crore vulnerable beneficiaries. This expanding financial coverage, including outpatient insurance growing at 18.34% CAGR, directly increases the consumption base for essential and chronic drugs.

High out-of-pocket expenditure

A strong reliance on self-funded healthcare drives demand for affordable options, with middle and lower-income demographics relying heavily on generic options and government schemes. To mitigate high out-of-pocket costs, the National Pharmaceutical Pricing Authority (NPPA) actively enforces price caps, reducing the prices of essential chronic combination therapies by up to 90%. This intense price sensitivity cements India's reliance on low-cost generic drugs, which are up to 33% cheaper than US equivalents.

Increase in the demand of vaccines as a preventative measure

India is a global manufacturing powerhouse for preventative care, currently supplying over 60% of the world's vaccines by volume. Domestically, the vaccine segment generated ₹1,767 crore in recent annual sales. Vaccines also form a critical component of India's international trade, capturing a 2.47% share of the country's total drug and pharmaceutical exports.

Shift of consumer preference to branded generic drugs and specialty drugs

The Indian formulation market is heavily skewed, with branded generics holding a massive 96.6% market share compared to just 3.4% for patented innovator drugs. The branded generics segment is projected to grow from ₹2.1 trillion in 2023 to ₹3.71 trillion by 2030. Concurrently, market leaders are aggressively pivoting to high-margin specialty drugs, with companies like Sun Pharma now deriving approximately 18% of their total revenue from specialty therapies.

Greater public awareness on preventive and prophylactic care

Rising disposable incomes are shifting consumption from basic necessities to everyday preventive health. The Indian nutraceuticals market exemplifies this trend, projected to expand from $8–$9 billion to between $20–$30 billion by 2030. Growing at an aggressive CAGR of 15-20%, this sector is expanding potentially 10 times

faster than traditional pharmaceuticals, driven by demand for scientifically validated, clean-label functional foods.

SUPPLY-SIDE FACTORS

Favourable government policies (PLI schemes) and manufacturing in India (Aatmanirbhar Bharat)

The turnover before the introduction of PLI schemes was $15.5 billion (FY15), and after the schemes came into effect it increased to around $52-55 billion (FY25), with exports touching figures of $30.47 billion. The 'Bulk Drugs PLI' achieved realized investments of ₹4,814 crores, where ₹4,330 crores were committed, leading to generation of ₹2,720 crores in sales, which further led to avoidance of ₹2,192 crores in imports, and also the localization of 26 APIs. The 'Pharma Drugs PLI' realized ₹41,920 crores, very different from the committed figures which were ₹17,275 crores. China's import share remains 71.72% by value, but on the other hand, import growth decelerated from 19.95% in FY22 to 5.89% in FY24. It can be concluded that these policy rollouts correlate heavily with FDI, which hit $2.06 billion in FY23 and $1.27 billion in H1 FY26, representing a 144% YoY increase.

Growth of contract research and manufacturing services (CRAMS)

The CRAMS sector in India is expected to have 11.8-14.67% CAGR, heavily outpacing the global average of 7.2-7.3%, leading to it reaching $44.63 billion by 2029. The CRDMO segment, which is $3-3.5 billion at present, is projected to touch figures of $22-25 billion by 2035 at 15%-16% CAGR. The US and Europe hold 70% of global CRDMO value, but India leads volume, with 48% of active API DMFs over the globe in 2024. CRAMS employment reflects this shift in value, as scientific personnel are now being 65-90% of the workforce at leading CRDMOs like Syngene and Aragen.

Increased drug patent expiries in the US

A patent cliff of around $300 billion is lurking on the US, between 2025 and 2030, expected to impact roughly 190 drugs, which also include around 70 blockbusters. Major targets include Keytruda and Eliquis, with $29.5 billion expiring in 2028 and $18-20 billion expiring between 2026 and 2028, respectively. Indian exports have been mapped closely to these openings. FY25 US-bound exports increased by 20.43% to $10.51 billion, claiming a share of nearly 34.5% in total exports. Strategically, manufacturers in India are targeting the $300 billion oncology and $100 billion GLP-1 markets to capture volume, as an entry in the generics segment forces them to do 45-60% price reductions.

Growing emphasis on developing complex generic drugs, biosimilars and specialty pharmaceuticals

Presently, less than 3% of India's exports consist of complex products and biosimilars, capturing only around 1.5-2% in NAFTA and 1-1.5% in Europe. Roadmaps which have been developed, target a 10-15% share by 2030. The biosimilars sector in our country expects 14.2% CAGR from 2024 to 2034, and high-value biologics sector aims for 22% CAGR. In the global landscape, specialty generics are forecasted to grow at 15.5% CAGR, with the Asia-Pacific region having growth rate of around 10.5%.

Reduction in taxes on various drugs

The GST 2.0 reforms which rolled out in

September 2025, unified layered taxes, which were effectively 9-13%, down to 5% or Nil for essential drugs. Essential therapeutics had been displaying strict price inelasticity, showing resilient demand after the reforms. On the other hand, lifestyle and non-essential drugs had high price elasticity. The anti-obesity market, spurred by price reductions of drugs like semaglutide, expanded rapidly from ₹133 crores in 2021 to over ₹628 crores by 2025. Nutraceuticals being now levied 5% GST as compared to 18% earlier, witnessed immediate volume surges due to flat 11% MRP reduction. Consequently, the Indian Pharma Market defied transitional shocks to post figures of around 7.3% as its growth rate in September 2025.

CHALLENGES

Heavy dependence on China for importing APIs and KSMs

In FY 2024-25, India had imported bulk drugs which were valued globally at $4.35 billion. China had a significant 73.71% share in the total imports. India's import dependence is the most evident in essential therapeutic areas, being as high as 87%-97% for antibiotics and 90%-98% for vitamins. During China's environmental crisis in 2016-18, the price index for Indian Paracetamol increased by 45%. Presently, India has not been able to counter this challenge effectively, because Chinese production costs remain 20-30% lower, further supported by nearly 5 to 10 times larger fermenter sizes and highly centralized industrial clusters.

Price controls lowering profit margins

The Drugs (Prices Control) Order has strictly implemented price ceilings for around 74 scheduled bulk drugs and their formulations in India. Approximately 10% of the domestic sales of the leading generic manufacturers in India fall directly under these rigid price controls. On the other hand, costs of importing raw materials have to be met alongside an additional premium of 25-30%, due to logistics and exchange risks. Intermediate costs increased to 13% after China removed its export tax rebates. EBITDA margins of companies fell from 28-30% historically to 19-20%, due to inability to adjust selling prices proportionately.

Skill and talent gaps leading to imbalance between demand and supply of workers

The pharma industry in India has been facing a critical mismatch of demand and supply of workers, despite fresher hiring intent being 73% across Indian sectors in early 2026. Universities across India produce thousands of graduates annually, but employers have been reporting massive practical skill deficits in areas like biosimilar manufacturing, AI-enabled analytics and advanced R&D, which are key drivers of demand. Global giants like Novo Nordisk recently announced 9,000 job cuts, which is around 11.5% of its workforce, to reduce its operational costs. But Indian firms on the other hand are actively seeking but failing to find workers having practical skills, as they rely more on proof-of-work portfolios rather than academic degrees, to fill specialized roles.

Heavy tariffs imposed on drugs exported from India

The recent geopolitical trade barriers have led to costs increasing rapidly. In 2025, a 20% tariff was imposed on Indian APIs, alongside a 25% tariff on Chinese APIs. Related inputs like glass used for packaging face tariffs of 15%, while container ocean freight increased

from $3,500 to $6,500. As of February 2026, the weighted average effective tariff rate levied on India's exports to the US was at 13.4%, which led to heavy decrease of profit margins of Indian generics in international markets.

Environmental challenges

Due to heavy ignorance of environmental consequences, a lot of challenges have arisen. The CPCB flagged 4,493 Grossly Polluting Industries, issuing 572 show-cause notices and ordering 29 immediate closures in late 2025. On the other hand, nearly 60% of India's 8,500 SME pharmaceutical units faced risks of shutting down as they failed to follow GMP standards. Pharmaceutical wastewater is highly hazardous, with COD concentrations being upto 20,000 mg/L in untreated effluents. Another challenge to be countered is that nearly 95% of specific antibiotic compounds can be released into sewage systems. To achieve environmental protection compliance, companies have to face heavy capital costs for advanced filtration.

THESIS

The pharmaceuticals industry in India has established itself globally as the 3rd largest producer in the world by mass-producing affordable generic medicines. However, the strategies that helped India earn the title of the "Pharmacy of the World" are becoming obsolete, leaving the future of the industry to be highly uncertain. India has to shift its perspective, from mass-manufacturing existing drugs, to creating high-value, life-saving biologics and complex treatments itself. The industry must leverage new government funding and international trade agreements to build and spark innovation. It also has to counter the major threat of 73% import reliance on China for basic raw materials. India has to fix its critical shortage of practical, in-demand skills within its workforce. Ultimately, it comes down to whether the Indian pharma sector can fix these vulnerabilities in due course of time, to successfully lead the upcoming era of global healthcare.

REFERENCES

1. **Bain & Company.** (n.d.). *Healing the world: A roadmap for making India a global pharma exports hub.* https://www.bain.com/insights/healing-the-world-a-roadmap-for-making-india-a-global-pharma-exports-hub/
2. **India Brand Equity Foundation.** (n.d.). *Indian pharmacy: Pharma companies in India.* https://www.ibef.org/industry/pharmaceutical-india
3. **Patil, R.** (2025, November 20). *Pharmaceutical market size, share and trends 2025 to 2034.* Precedence Research. https://www.precedenceresearch.com/pharmaceutical-market
4. **IQVIA Institute for Human Data Science.** (2025, August 27). *The global use of medicines 2025: Outlook to 2029* [Webinar presentation]. IQVIA. https://www.iqvia.com/-/media/iqvia/pdfs/events/presentation_global-meds-webinar_public.pdf
5. **Levy, V.** (2024, May 31). *2024 global life sciences sector outlook: Driving resiliency.* Deloitte. https://www.deloitte.com/cbc/en/Industries/life-sciences-health-care/analysis/global-life-sciences-sector-outlook.html

6. **Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India.** (2025). *Annual report*. https://pharma-dept.gov.in/annual-report
7. **Pharmaceuticals Export Promotion Council of India.** (2025). *Hand book 2025.* https://pharmexcil.com/uploadfile/Hand_Book_14_06_2025_final.pdf
8. **India Brand Equity Foundation.** (2025). *Indian pharmaceuticals industry analysis presentation*. https://www.ibef.org/industry/indian-pharmaceuticals-industry-analysis-presentation
9. **Invest India.** (2023). *Pharmaceutical sector spotlight: Driving innovation in India.* https://www.investindia.gov.in/blogs/pharmaceutical-sector-spotlight-driving-innovation-india
10. **Office of the Controller General of Patents, Designs & Trade Marks, Department for Promotion of Industry and Internal Trade, Government of India.** (2015, March 11). *The Patents Act, 1970 (incorporating all amendments till 11-03-2015).* https://ipindia.gov.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf
11. **World Trade Organization.** (1994, April 15). *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)*. https://www.wto.org/english/docs_e/legal_e/27-trips.pdf
12. **Chaudhuri, S.** (2005). *The WTO and India's Pharmaceuticals Industry: Patent Protection TRIPS and Developing Countries*. Oxford University Press. https://www.researchgate.net/publication/283482893_The_WTO_and_India's_Pharmaceuticals_Industry_Patent_Protection_TRIPS_and_Developing_Countries
13. **Kale, D., & Little, S.** (2007). *From imitation to innovation: The evolution of R&D capabilities and learning processes in the Indian pharmaceutical industry. Technology analysis & strategic management, 19(5), 589-609.* https://www.tandfonline.com/doi/pdf/10.1080/09537320701521317?casa_token=Mt0_VVjOn2wAAAAA:lATlr-cjTbTuPL6kk8FmOppS6Gmmn2tWu451Mw05CQVt4wCKSoCHrH7jL9ehRDQopyhd26REJ-zvhg
14. **Central Drugs Standard Control Organization.** (n.d.). Home. Ministry of Health & Family Welfare, Government of India. https://cdsco.gov.in/opencms/opencms/en/Home/
15. **U.S. Food and Drug Administration.** (n.d.). *Drug establishments current registration site (DECRS).* https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site-decrs
16. **World Health Organization.** (n.d.). *Good manufacturing practices (GMP).* https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/norms-and-standards/gmp
17. **Office of the Controller General of Patents, Designs & Trade Marks.** (2025). *Annual report 2024–25.* https://ipindia.gov.in/writereaddata/Portal/Images/pdf/English_Annual_Report_2024-25.pdf
18. **Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India.** (2023, August 18). *Notification: R&D policy for pharmaceuticals and medical devices.* https://pharma-dept.gov.in/sites/default/files/Notification%20-%20R%26D%20Policy.pdf

19. **Organisation for Economic Co-operation and Development (OECD).** (2023, November 7). *Pharmaceutical research and development*. In *Health at a glance 2023: OECD indicators*. OECD Publishing. https://www.oecd.org/en/publications/2023/11/health-at-a-glance-2023_e04f8239/full-report/pharmaceutical-research-and-development_6eb5e4b8.html
20. **NITI Aayog.** (2025, October 29). *Reimagining manufacturing: India's roadmap to global leadership in advanced manufacturing*. https://niti.gov.in/sites/default/files/2025-10/Reimagining_Manufacturing_Indias_Roadmap_to_Global_Leadership_in_Advanced_Manufacturing.pdf
21. **KPMG India.** (2025, December). *The Indian pharma sector: Q2FY26*. https://assets.kpmg.com/content/dam/kpmgsites/in/pdf/2025/12/the-indian-pharma-sector-q2fy26.pdf
22. **Magliano, D. J., & Boyko, E. J. (Eds.).** (2021). *IDF diabetes atlas* (10th ed.). International Diabetes Federation. https://www.ncbi.nlm.nih.gov/books/NBK581934/
23. **World Health Organization.** (2023). *Noncommunicable diseases country profiles: India*. https://www.who.int/teams/noncommunicable-diseases/surveillance/data/profiles-ncd
24. **Institute for Health Metrics and Evaluation.** (2023). *Global burden of disease (GBD)*. https://www.healthdata.org/research-analysis/gbd
25. **United Nations, Department of Economic and Social Affairs, Population Division.** (2022). *World population prospects 2022: Ten key messages*. https://www.un.org/development/desa/pd/sites/www.un.org.development.desa.pd/files/undesa_pd_2022_wpp_key-messages.pdf
26. **Sathishkumar, K., Chaturvedi, M., Das, P., Stephen, S., & Mathur, P.** (2022). *Cancer incidence estimates for 2022 and projection for 2025: Result from National Cancer Registry Programme, India. Indian Journal of Medical Research, 156*(4–5), 598–607. https://pmc.ncbi.nlm.nih.gov/articles/PMC10231735/
27. **National Health Authority.** (2025). *Ayushman Bharat PM-JAY annual report*. https://nha.gov.in/PM-JAY
28. **Insurance Regulatory and Development Authority of India.** (2025, February 17). *Handbook on Indian insurance statistics 2023–24*. https://irdai.gov.in/handbook-of-indian-insurance
29. **National Pharmaceutical Pricing Authority.** (n.d.). *Circulars / orders*. https://nppa.gov.in/view_more?id=4
30. **Boston Consulting Group (BCG), & Indian Pharmaceutical Services Organization (IPSO).** (2025). *Unleashing the tiger: Indian CRDMO sector 2025*. https://web-assets.bcg.com/d7/ae/50563b1848029582e53496909f51/bcg-ipso-whitepaper-unleashing-the-tiger.pdf
31. **Popli, A. R., Zhang, F., Park, J., & De Leu, F.** (2026, January 7). *The emerging epicenter: Asia's role in biopharma's future*. McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/the-emerging-epicenter-asias-role-in-biopharmas-future

32. **Evaluate.** (2025, June 17). *2025 world preview: Pharma growth steady amid turbulent seas and rising China*. https://www.evaluate.com/thought-leadership/2025-world-preview/
33. **Greenwalt, L., Biggs, S., Fisher, J., & Pritchett, J.** (2025, October 29). *U.S. life sciences industry thrives with robust growth and innovation*. IQVIA. https://www.iqvia.com/locations/united-states/blogs/2025/10/us-life-sciences-industry-thrives-with-robust-growth-and-innovation
34. **Press Information Bureau, Government of India.** (2025, December 16). *Progress and implementation of the PLI scheme for medical devices*. https://www.pib.gov.in/PressReleasePage.aspx?PRID=2204598&reg=3&lang=1
35. **Press Information Bureau, Government of India.** (2025, February 24). *Policy to Practice: Harnessing biotechnology for a greener tomorrow*. https://www.pib.gov.in/PressReleasePage.aspx?PRID=2105774
36. **Press Information Bureau, Government of India.** (2026, February 2). *Transforming India into a Global Biopharma Hub (Budget 2026 -27 Series)*. https://static.pib.gov.in/WriteReadData/specificdocs/documents/2026/feb/doc202622776701.pdf
37. **Ministry of Environment, Forest and Climate Change, Government of India.** (2025). *Annual report 2024–25*. https://moef.gov.in/uploads/pdf-uploads/English_Annual_Report_2024-25.pdf
38. **United Nations Environment Programme.** (n.d.). *Pharmaceuticals in the Environment*. https://www.unep.org/topics/chemicals-and-pollution-action/chemicals-management/pollution-and-health/pharmaceuticals

CONTRIBUTORS

Research and Design Team

Ritwik Jaiswal
Atharva Nimbalkar
Priyanshu Agrawal

Directors

Rachit Jain
Aashray Zutshi