KIRTANE & PANDIT

Indian Pharmaceutical & Healthcare Industry

Transforming Global Healthcare Through Innovation and Scale

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Contents

1. EXECUTIVE SUMMARY

India's pharmaceutical and healthcare sector stands at a pivotal juncture, positioning itself as the backbone of global health security while transforming into a comprehensive healthcare solutions provider. Valued at USD 60 billion in 2024, the pharmaceutical market is projected to reach USD 174.31 billion by 2033, exhibiting a robust Compound Annual Growth Rate (CAGR) of 11.32%. The broader healthcare sector, valued at USD 372 billion in 2023, is expected to reach USD 638 billion by the end of 2025, representing unprecedented growth opportunities.

As the "pharmacy of the world," India supplies 20% of global generic medicines by volume and accounts for over 60% of global vaccine production, serving as a critical pillar in worldwide health access and affordability. The nation's pharmaceutical exports reached USD 30.47 billion in FY25, marking a strong 9.4% growth over the previous fiscal year. In the May 2025 monthly export snapshot, the USA accounted for 34.5% of India’s pharma exports, with a value of USD 1.71 billion for that single month.

The sector's transformation is underpinned by comprehensive government initiatives, including the world's largest health insurance scheme Ayushman Bharat covering 55 crore beneficiaries, Production-Linked Incentive (PLI) schemes with allocations of Rs. 15,000 crore for pharmaceuticals, and the ambitious target of achieving a USD 300 billion biotechnology sector by 2030. The industry directly and indirectly employs over 2.7 million people while contributing approximately 1.72% to India's GDP, positioning healthcare as a cornerstone of the nation's economic development strategy.

Digital transformation is reshaping healthcare delivery, with the Indian Digital Health Market valued at Rs. 75,658 crore (USD 8.79 billion) in 2024 and projected to reach Rs. 4,11,275 crore (USD 47.8 billion) by 2033 at a CAGR of 17.67%. This technological integration, combined with India's cost advantages and skilled workforce, creates a unique ecosystem for innovation and global competitiveness.

However, the sector faces significant challenges including heavy import dependence on APIs (72% from China), infrastructure gaps in rural healthcare delivery, and the need for enhanced R&D investment which currently stands at 0.7% of GDP compared to global averages of 2.5-3%. Despite these challenges, strategic government support, increasing private sector investment, and the global "China+1" diversification strategy present substantial growth opportunities.

Looking ahead, India's pharmaceutical and healthcare sector is poised to play a transformative role in achieving the nation's USD 5 trillion economy goal, with projections indicating pharmaceutical exports could reach USD 350 billion by 2047. The convergence of demographic trends, technological advancement, policy support, and global market positioning establishes India as a definitive leader in affordable, accessible, and innovative healthcare solutions for both domestic and international markets.

2. OVERVIEW OF THE INDIAN PHARMACEUTICAL & HEALTHCARE SECTOR

2.1 Economic Significance and Global Standing

The Indian pharmaceutical and healthcare sector represents one of the nation's most strategically important industries, functioning as both a domestic healthcare enabler and a global health security provider. The pharmaceutical industry, ranked as the world's third-largest by volume and 14th by value, encompasses over 3,000 drug companies and 10,500 manufacturing units, creating a comprehensive ecosystem for drug production and export.

India's pharmaceutical industry was valued at an estimated USD 55-58 billion in FY 2024-25, with domestic consumption accounting for USD 24-25 billion and exports contributing USD 30.5 billion. The sector's economic significance is further underscored by its contribution of approximately 1.72% to India's Gross Domestic Product and its role in supporting over 2.7 million direct and indirect jobs. The industry's export performance demonstrates remarkable consistency, with pharmaceutical exports growing from USD 17.27 billion in 2017-18 to USD 27.82 billion in FY24, representing a compound annual growth rate exceeding 8%.

The broader healthcare sector encompasses a more comprehensive ecosystem valued at USD 638 billion in 2023, including hospitals (USD 190+ billion), diagnostics (USD 65+ billion), medical devices, biotechnology, and digital health services. This integrated approach to healthcare delivery positions India uniquely in the global market, offering end-to-end solutions from drug discovery and manufacturing to healthcare delivery and medical tourism.

2.2 Global Market Position and Export Strength

India's global pharmaceutical footprint is characterized by its dominance in essential medicines and vaccines. The country serves as the world's largest supplier of generic medicines, contributing 20% of global pharmaceutical exports by volume. This position is particularly significant in vaccine manufacturing, where India produces over 60% of the world's vaccines, including critical immunizations for DPT, BCG, and measles. The nation's vaccine manufacturing capabilities gained international recognition during the COVID-19 pandemic, when India supplied vaccines to over 133 countries, demonstrating its capacity as a reliable global health partner.

The pharmaceutical export portfolio reflects India's manufacturing diversity, with products reaching over 200 countries worldwide. The United States remains the largest export market, accounting for more than 31% of India's pharmaceutical exports, followed by the United Kingdom and the Netherlands. This geographic diversification provides resilience against market-specific disruptions while establishing India as a trusted supplier across regulated markets including the US, UK, European Union, and Canada.

India's competitive advantages in global markets stem from multiple factors including cost-effective manufacturing, with production costs estimated at 20% of those in developed countries, a skilled workforce, and robust regulatory compliance. The country hosts the highest number of US FDA-approved pharmaceutical manufacturing facilities outside the United States, totaling 665 plants, which validates the quality and compliance standards of Indian pharmaceutical manufacturing.

2.3 Healthcare Infrastructure and Service Delivery

The healthcare delivery system in India operates through a mixed model combining public and private sector participation. Private hospitals contribute approximately 65% of treatment value, while government hospitals provide 35%, reflecting the growing reliance on private healthcare services driven by quality considerations and accessibility. The hospital market, valued at USD 136.6 billion in 2024, is projected to reach USD 264.8 billion by 2033, growing at a CAGR of 7.6%.

Healthcare workforce dynamics indicate both opportunities and challenges. The healthcare sector, as of FY24, is one of India's largest employers, employing a total of 7.5 million people. A recent research report predicts that the integration of Artificial Intelligence (AI) within the Indian healthcare sector will create nearly 3 million new jobs by 2028 & 6.3 million additional jobs are expected by CY30. However, the doctor-to-population ratio remains at 1:854, below the WHO-recommended standard, indicating significant scope for expansion in medical education and healthcare professional training.

The telemedicine and digital health segment has emerged as a critical component of healthcare delivery, particularly in addressing rural access challenges. The telemedicine market is expected to reach USD 5.4 billion by FY25, driven by increased adoption of remote healthcare solutions and government initiatives promoting digital health infrastructure. The Ayushman Bharat Digital Mission (ABDM) has created over 73 crore health accounts, establishing a foundation for integrated digital health services nationwide.

3. HISTORICAL EVOLUTION AND MARKET TRANSFORMATION

3.1 Foundation Era: Building Indigenous Capabilities (1970-1990)

The foundation of India's modern pharmaceutical industry was established through the Patent Act of 1970, which introduced a process patent regime that enabled Indian companies to reverse-engineer drugs and develop indigenous manufacturing capabilities. This legislative framework allowed domestic companies to focus on process innovation rather than product development, creating a competitive advantage in generic drug manufacturing that continues to define India's pharmaceutical identity today.

During this period, the government adopted an import substitution strategy aimed at reducing dependence on foreign pharmaceutical products. State-owned enterprises and emerging private companies invested heavily in building manufacturing infrastructure, particularly for essential medicines and bulk drugs. This era established companies like Ranbaxy, Dr. Reddy's Laboratories, and Cipla as pioneering forces in Indian pharmaceutical manufacturing.

The focus on essential medicines production during this period created a strong foundation in Active Pharmaceutical Ingredients (APIs) and formulations. By the 1980s, India had developed significant capabilities in producing antibiotics, cardiovascular drugs, and anti-diabetic medications, establishing the country as a reliable supplier of affordable medicines for both domestic and international markets.

3.2 Liberalization and Global Integration (1990-2010)

The economic liberalization policies introduced in the 1990s marked a transformative phase for the Indian pharmaceutical industry. The opening of the economy to Foreign Direct Investment (FDI) and the gradual alignment with international intellectual property norms under the World Trade Organization's TRIPS Agreement fundamentally altered the industry's strategic direction.

During the early phase of liberalization (1991-2008), the chemical and pharmaceutical sectors experienced substantial capital influx, accounting for approximately 70% of total investment in chemicals during this period, with about 85% directed toward petrochemicals and related sectors. This investment surge coincided with impressive growth in chemical exports, encompassing pharmaceuticals, which grew at a compound annual growth rate of 13% between 1998 and 2009.

The period witnessed significant consolidation and international expansion by Indian pharmaceutical companies. Strategic acquisitions, partnerships with multinational corporations, and investments in research and development capabilities transformed Indian companies from domestic generic manufacturers to globally competitive pharmaceutical enterprises. Companies like Sun Pharmaceutical, Lupin, and Aurobindo Pharma established international subsidiaries and manufacturing facilities, particularly in regulated markets.

Regulatory harmonization with international standards became a key focus during this period. Indian pharmaceutical companies invested heavily in achieving compliance with US FDA, European Medicines Agency, and other international regulatory requirements. This investment in quality systems and regulatory compliance established the foundation for India's current position as a leading supplier to regulated markets.

3.3 Modern Era: From Volume to Value Creation (2010-Present)

Since 2010, the Indian pharmaceutical industry has experienced a strategic transformation from volume-based generic manufacturing to value-driven innovation and specialized therapeutics. This shift reflects the industry's maturation and its response to evolving global healthcare needs and competitive dynamics.

The post-2010 era has been characterized by significant advancements in biotechnology, biosimilars, and complex generics. Indian companies have invested substantially in developing capabilities for biologics manufacturing, with companies like Biocon, Dr. Reddy's, and Cipla establishing world-class biotechnology facilities. The biosimilars market in India has emerged as a significant growth driver, with Indian companies developing affordable alternatives to expensive biologic drugs. Contract Research and Manufacturing Services (CRAMS) has evolved as a major segment, with the industry expected to reach USD 22-23 billion by FY2026, growing at a CAGR of 12%. This growth reflects India's emergence as a preferred destination for global pharmaceutical companies seeking cost-effective manufacturing and research services. Major international pharmaceutical companies including Pfizer, Novartis, and GSK have established significant manufacturing and R&D operations in India.

The digital transformation of healthcare delivery has accelerated significantly in recent years, particularly following the COVID-19 pandemic. The integration of artificial intelligence, machine learning, and digital health platforms has created new opportunities for pharmaceutical companies to engage with healthcare providers and patients directly. The Indian Digital Health Market's projected growth to USD 47.8 billion by 2033 reflects this digital transformation's scale and potential.

3.4 Post-COVID Paradigm Shift: Resilience and Self-Reliance

The COVID-19 pandemic catalyzed a fundamental shift in global pharmaceutical supply chain strategies, positioning India as a beneficiary of the "China+1" diversification approach adopted by multinational pharmaceutical companies. This strategic realignment has created unprecedented opportunities for Indian manufacturers to expand their global footprint and establish long-term partnerships with international companies.

India's vaccine manufacturing capabilities gained global recognition during the pandemic, with the Serum Institute of India and Bharat Biotech playing crucial roles in global vaccine supply. The development and manufacturing of Covaxin, India's indigenous COVID-19 vaccine, demonstrated the country's capabilities in end-to-end vaccine development and large-scale manufacturing.

Government initiatives launched during and after the pandemic have focused on building supply chain resilience and reducing import dependencies. The Production-Linked Incentive schemes for pharmaceuticals and medical devices, with allocated funding exceeding Rs. 5,000 crore, aim to strengthen domestic manufacturing capabilities and attract global investment in critical healthcare technologies.

The pandemic also accelerated the adoption of telemedicine and digital health solutions, with over 17.6 million calls handled through the Tele MANAS mental health services platform, demonstrating the scalability and acceptance of digital healthcare delivery models. This digital health infrastructure development has created a foundation for integrated healthcare services that combine pharmaceutical products with digital health solutions.

4. GOVERNMENT POLICIES AND STRATEGIC INITIATIVES

4.1 Healthcare Access and Universal Coverage

The Indian government's commitment to universal healthcare access is exemplified through the Ayushman Bharat scheme, recognized as the world's largest government-funded health insurance program. Launched in 2018, this comprehensive initiative provides healthcare coverage to over 55 crore beneficiaries across 12+ crore families, offering insurance coverage of Rs. 5 lakh per family per year for secondary and tertiary care hospitalization.

The scheme's implementation has been supported by substantial budget allocations, with Rs. 9,406 crore (USD 1.08 billion) allocated for FY26, representing a 28.8% increase from the previous year. As of January 2025, over 73 crore Ayushman Bharat Health Accounts (ABHA) have been created, with more than 5 lakh health professionals registered on the platform, establishing a comprehensive digital health infrastructure.

The Health and Wellness Centers (HWCs) component of Ayushman Bharat aims to establish 150,000 centers across the country to provide comprehensive primary healthcare services A total of 1,77,906 Ayushman Arogya Mandirs (AAMs), formerly Ayushman Bharat Health and Wellness Centres (AB-HWCs), are operational as of June 30, 2025, offering free essential medicines, diagnostic services, and teleconsultation services. These centers focus on maternal and child health, non-communicable diseases, communicable diseases, and palliative care while providing essential drugs and diagnostic services.

The National Health Mission (NHM), complements Ayushman Bharat by strengthening primary healthcare infrastructure and services. The mission focuses on upgrading existing facilities, building new healthcare infrastructure, and improving the availability of medical equipment and supplies, particularly in rural and underserved areas. According to government sources, the latest budget allocation for the NHM in FY 2025-26 is ₹39,435 crore (approximately USD 4.77 billion). This allocation represents a 7% increase over the revised estimates for FY 2024-25 and a 5% increase over the previous year's budget estimates.

4.2 Manufacturing Excellence and Self-Reliance Initiatives

The Production-Linked Incentive (PLI) schemes represent the government's strategic approach to building domestic manufacturing capabilities and reducing import dependencies in critical healthcare sectors. The pharmaceutical PLI scheme, with an estimated allocation of Rs. 15,000 crore for FY25, aims to enhance domestic manufacturing capabilities and foster innovation in high-value pharmaceutical products.

The scheme has attracted significant investment commitments, with cumulative pledges exceeding Rs. 1.46 lakh crore across 11 bulk drug lines. This investment is expected to strengthen India's API manufacturing capabilities, addressing the critical dependency on imports, particularly from China, which currently accounts for 72% of India's bulk drug and intermediates imports.

The medical devices PLI scheme, with an outlay of Rs. 3,420 crore covering 138 products across 26 applicants, aims to transform India into a global medical device manufacturing hub. The government has set an ambitious target to elevate the medical devices industry from its current USD 11 billion valuation to USD 50 billion by 2030.

Bulk Drug Parks development represents a strategic initiative to create integrated manufacturing ecosystems. Three bulk drug parks have been approved with Rs. 3,000 crore investment, designed to provide shared infrastructure including common effluent treatment plants, quality testing laboratories, and research and development facilities. These parks aim to reduce manufacturing costs and enhance global competitiveness of Indian pharmaceutical manufacturers.

The establishment of Centers of Excellence (CoEs) under government initiatives promotes research and development across the pharmaceutical value chain. Eighteen CoEs have been established, providing grant-in-aid to educational and research institutions for developing new molecules and technologies, improving existing manufacturing processes, and enhancing product quality. The government provides financial support up to 50% of the total project cost, with an upper limit of Rs. 5 crores per CoE.

4.3 Digital Health Transformation and Innovation

The Ayushman Bharat Digital Mission (ABDM) represents India's comprehensive approach to creating an integrated digital health ecosystem. The mission aims to develop the necessary digital infrastructure to support healthcare delivery, enhance efficiency, and improve access to quality healthcare services across the country.

Key components of ABDM include the creation of unique Health IDs for all citizens, digitization of health records, and establishment of interoperable health information systems. The mission facilitates seamless exchange of health information between healthcare providers, insurance companies, and patients, promoting coordinated and effective healthcare delivery. The implementation of digital health initiatives has shown significant results. The Tele MANAS program, focused on mental health services, has handled over 17.6 million calls across 53 cells established in 36 states and union territories, demonstrating the scale and impact of digital health interventions. The U-WIN platform, launched for digitizing vaccination records, represents another significant milestone in creating comprehensive digital health infrastructure.

MedTech Mitra, a platform launched by the Ministry of Health and Family Welfare, supports young Indian innovators in the medical technology sector by providing assistance in research, development, and regulatory approvals. This initiative aligns with the vision of transforming India into a leading USD 50 billion MedTech industry by 2030 while fostering indigenous development of affordable, quality medical devices and diagnostics.

4.4 Biotechnology and Innovation Ecosystem Development

The Department of Biotechnology (DBT) plays a pivotal role in India's biotechnology development, with budget allocations reaching Rs. 2,251.52 crore (USD 271 million) in the Interim Budget 2024-25. A budget of ₹3,446.64 crore (USD 417 million) for FY 2025-26, marks a significant increase from the budget allocated in FY 2024-25. The BioE3 Policy (Biotechnology for Economy, Environment, and Employment), introduced in August 2024, promotes high-performance biomanufacturing aimed at driving green growth by enhancing R&D, fostering innovation, and creating employment across sectors.

The Bio-RIDE (Biotechnology Research Innovation and Entrepreneurship Development) scheme consolidates various biotechnology initiatives with a budget allocation of Rs. 9,197 crore (USD 1.1 billion) for 2021-22 to 2025-26. This comprehensive program includes a new Biomanufacturing and Biofoundry component designed to strengthen India's biotechnology infrastructure and capabilities.

The Biotechnology Industry Research Assistance Council (BIRAC) has established 60 successful bio-incubation centers, providing infrastructure and support for biotechnology startups. BIRAC offers funding assistance through initiatives including the Biotechnology Ignition Grant (BIG), Sustainable Entrepreneurship and Enterprise Development (SEED), and Launching Entrepreneurial Driven Affordable Products (LEAP) schemes, with funding ranging from Rs. 30 lakh to Rs. 100 lakh per startup.

The National Speed Breeding Crop Facility at the National Agri-Food Biotechnology Institute (NABI) in Mohali represents India's commitment to agricultural biotechnology innovation. Such facilities support the development of climate-resilient crop varieties and advanced agricultural biotechnology solutions, contributing to food security and sustainable agriculture.

5. INVESTMENT LANDSCAPE AND CAPITAL MARKET DYNAMICS

5.1 Foreign Direct Investment Trends and Performance

India's pharmaceutical sector has emerged as a significant magnet for foreign investment, with the cumulative FDI equity inflow in the drugs and pharmaceuticals industry reaching Rs. 2,00,166 crore (USD 23.41 billion) during April 2000-March 2025. This sustained investment demonstrates long-term international confidence in India's pharmaceutical capabilities and growth potential.

Recent performance indicators show robust momentum, with the drugs and pharmaceuticals sector experiencing foreign direct investment equity inflow worth over one billion U.S. dollars in financial year 2024, representing a sharp increase compared to previous years and especially compared to FY2019 when investments were only USD 266 million. This growth trajectory, with further equity inflow of approximately ₹19,134.4 crore (USD 2.4 billion) during FY 2024-25, and approvals worth ₹7,246.4 crore for brownfield projects, reflects the sector's increasing attractiveness to international investors, particularly in the context of global supply chain diversification strategies.

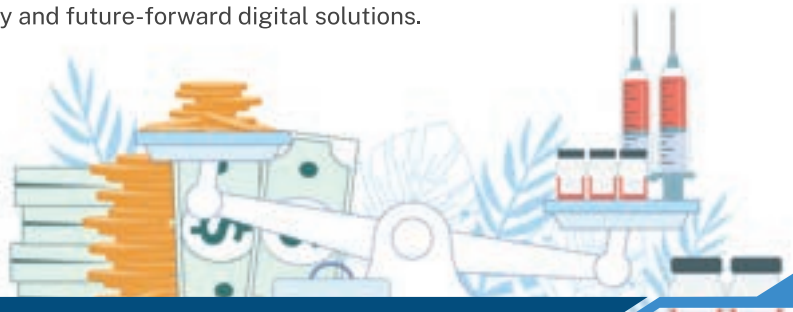
The regulatory environment remains highly conducive to foreign investment, with 100% FDI allowed through automatic route for Greenfield pharmaceuticals projects, while Brownfield pharmaceuticals projects permit up to 74% FDI through automatic route and higher percentages through government approval. This liberal FDI policy has facilitated significant international partnerships and technology transfer initiatives.

Major international investments have included strategic commitments from global pharmaceutical companies seeking to establish or expand their Indian operations. Sanofi announced plans to invest USD 435 million over six years to expand its global capability center in Hyderabad, while Amgen committed USD 200 million investment, demonstrating continued multinational engagement in India's pharmaceutical ecosystem.

5.2 Private Equity and Venture Capital Ecosystem

Private equity (PE) firms are demonstrating strong interest in Indian hospital chains, driven by the sheer size of the market, the existence of relatively underserved areas outside major urban centers, a high incidence of disease burden, and the continuous growth in both public and private insurance coverage. Notable deals exemplify this trend, such as Temasek's US 2 billion acquisition of an additional 414.8 billion.

Concurrently, the healthtech startup ecosystem is attracting significant venture capital (VC) funding. In May 2025, healthtech-led startup funding, securing US$288.93 million across 9 deals. This included substantial rounds like PB Healthcare's US218 million seed round and Complement's US 16 million raise. The total funding in the healthtech sector between 2014 and 2024 amounted to approximately US$7.25 billion, with several unicorns, including PharmEasy, Cure. Fit, Innovaccer, and 1mg, emerging from this vibrant segment. The robust private equity interest in hospital chains and the surge in healthtech startup funding reflect a dual investment strategy. This approach capitalizes on the persistent demand for physical healthcare infrastructure (hospitals) while simultaneously betting on technological disruption in healthcare delivery (healthtech). This indicates a sophisticated understanding of India's evolving healthcare needs and the diverse avenues for value creation, addressing both traditional service delivery and future-forward digital solutions.



5.3 Mergers and Acquisitions Activity

Mergers and Acquisitions (M&A) activity in the Indian pharmaceutical and healthcare sector has shown some fluctuations. In the first quarter of calendar year 2025 (Q1 CY25), the sector experienced a 70% drop in deal values, reaching US$2.1 billion, compared to the previous quarter, with deal volumes also seeing a marginal 3% decline.

Despite these short-term dips in deal values, the underlying strategic drivers for consolidation and acquisition remain strong. Indian pharmaceutical companies are generally bullish on the M&A route, with local firms increasingly becoming aggressive acquirers of brands. Globally, M&A trends in health industries include a "string-of-pearls" approach in biopharma, where large-cap players acquire early- to mid-stage innovation to fill pipeline gaps and hedge against patent cliffs. There is also an increased preference for alternative deal structures, such as earn-outs, royalties, and licensing agreements, particularly in biotech and diagnostics, to finance innovation and platform builds. Recent notable M&A activities in India include KKR's acquisition of Healthium Medtech for Rs 7000 crore and the merger of Aster DM Healthcare and Quality Care India. While overall M&A deal values may experience short-term fluctuations, the underlying strategic imperatives for market expansion, pipeline enhancement, and technological integration remain robust. This indicates that M&A will continue to serve as a key mechanism for growth and competitive positioning within the Indian pharmaceutical and healthcare landscape.

6. MARKET DYNAMICS AND COMPETITIVE LANDSCAPE

6.1 Market Structure and Growth Dynamics

The Indian pharmaceutical market demonstrates remarkable diversity across therapeutic categories, formulation types, and distribution channels. The market stands at USD 66.66 billion in 2025 and is forecast to reach USD 88.86 billion by 2030, advancing at a 5.92% CAGR, driven by chronic diseases, policy incentives and steady export demand providing a balanced twin-engine of domestic consumption and international sales.

Therapeutic Segment Analysis

Anti-infectives represent the largest therapeutic segment with 19.6% market share in 2024, reflecting India's continued focus on addressing communicable diseases and infectious conditions. However, the oncology segment is projected to experience the fastest growth at 7.10% CAGR through 2030, driven by increasing cancer incidence, improved diagnostic capabilities, and expanding insurance coverage for targeted therapies.

The shift toward chronic disease management is evident in market dynamics, with chronic therapeutic drugs accounting for approximately 38% of the Indian pharmaceutical market in 2024. Cardiovascular drugs experienced 10.7% growth in early 2025, establishing them as the largest chronic disease segment by value, while anti-diabetic medications continued their steep rise with 6.9% growth.

Distribution Channel Evolution

Generic prescription drugs maintained market dominance with 69% of total market share in 2024, underscoring India's continued competitive advantage in cost-effective healthcare solutions. However, Over-The-Counter (OTC) medicines are forecast to expand at 6.70% CAGR to 2030, indicating growing consumer confidence in self-medication and preventive healthcare approaches.

Retail pharmacies retain the largest share at 75% of the market, supported by India's extensive network of approximately 850,000 pharmacies nationwide. Online pharmacies represent the faster-growing channel at 7.30% CAGR to 2030, driven by digital adoption, convenience, and direct-to-consumer delivery models, with e-pharmacies growing 7.3% a year thanks to easy ordering, flat-fee home delivery and bundled tele-consult services.

6.2 Leading Players and Market Concentration

Domestic Market Leaders

Sun Pharmaceutical Industries Limited maintains its position as India's largest pharmaceutical company with over 43,000 global employees, including more than 3,000 in R&D functions. The company's diverse portfolio spans over 50 nationalities, demonstrating the global scale of Indian pharmaceutical operations. Sun Pharma leads Indian pharmaceutical companies by market capitalization, reporting a market capitalization value of over 3.97 trillion Indian rupees as of September 2025.

Cipla Limited operates across 17 countries with 27,764 permanent employees, maintaining strong positions in respiratory and HIV drug segments. The company's commitment to diversity is reflected in its workforce composition, with females comprising 25% of top management positions and significant representation across all organizational levels.

Dr. Reddy's Laboratories has established itself as a leader in generics and biosimilars, with global operations and strategic focus on regulated markets. Lupin Limited specializes in cardiovascular and anti-diabetic medications, with over 1,400 R&D team members contributing to its innovation pipeline, while Cipla and Divis Laboratories ranked second and third respectively in market capitalization during 2024.

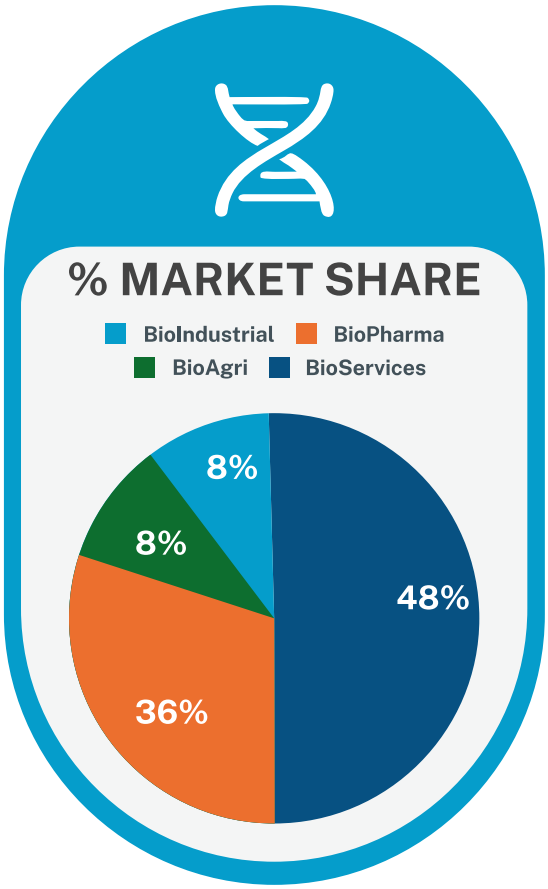
International Presence and Partnerships

The biosimilars and biologics segment is led by companies like Biocon, which has emerged as a significant player in affordable biologics manufacturing. Serum Institute of India maintains its position as the world's largest vaccine manufacturer by volume, while Bharat Biotech has demonstrated indigenous vaccine development capabilities through products like Covaxin.

International pharmaceutical companies, too, maintain a significant presence in India through local subsidiaries and manufacturing operations. Major global players including Pfizer, Novartis, and GSK have established significant manufacturing and R&D operations in India, contributing to technology transfer and capability development.

6.3 Biotechnology Sector Dynamics

India's biotechnology sector has experienced exponential growth, with the market valued at USD 101.5 billion in 2024 and projected to reach USD 297.2 billion by 2033, representing a CAGR of 11.09%. The sector comprises four main segments: BioIndustrial (48.09% market share), BioPharma (35.65%), BioAgri (8.24%), and BioServices (8.02%).



The biotechnology startup ecosystem has expanded dramatically from approximately 50 startups in 2014 to nearly 9,000 by the end of 2024, reflecting sustained growth in the bioeconomy. The Department for Promotion of Industry and Internal Trade (DPIIT) has recognized approximately 2,500 startups in the pharmaceutical and biotechnology sectors by mid-2025, showing growth from 2,127 startups recognized as of June 2024. The total number of DPIIT-recognized startups across all sectors has grown to over 150,000 by early FY 25-26, maintaining a steady pace of addition.

BioPharma Segment Leadership

BioPharma represents the largest value segment within biotechnology, valued at approximately USD 4.4 billion in 2020 and expected to reach USD 12.8 billion by end of 2025, representing a CAGR of 23%. India's strength in vaccine manufacturing is evident through its supply of around 60% of global demand for DPT, BCG, and measles vaccines, positioning the country as a critical component of global immunization programs.

The bioinformatics segment leverages India's IT infrastructure and skilled workforce, with the market valued at USD 510 million in 2020 and projected to surpass USD 1 billion by end of 2025. Government initiatives like the Biotechnology Information System Network facilitate collaborations between biotechnology and IT sectors, creating integrated solutions for healthcare and agricultural applications.

6.4 Contract Development and Manufacturing Services (CDMO)

Contract development and manufacturing services generate USD 15.63 billion today and are set to triple by 2029. The Innovative Pharmaceutical Services Organization (IPSO) created in March 2025 maps standards for quality, data integrity and digital tech transfer, welcomed by US and EU sponsors.

India is emerging as a key player in the global pharmaceutical supply chain, with its CRDMO industry set to double to Rs. 1,21,282 crore (USD 14 billion) by 2028, according to Macquarie. This growth reflects increasing global outsourcing trends and India's competitive advantages in cost-effective manufacturing and skilled workforce.

Hybrid models, such as Shilpa Medicare's development-plus-manufacturing platform, accelerate molecule progression from laboratory to commercial batches. Over USD 7 billion already funnels into global capability centers handling discovery analytics, clinical biostatistics and regulatory affairs.

6.5 Hospital and Healthcare Services Market

The Indian hospital market demonstrates strong growth momentum, valued at USD 136.6 billion in 2024 and projected to reach USD 264.8 billion by 2033, exhibiting a CAGR of 7.6%. Private hospitals contribute approximately 65% of treatment value, reflecting consumer preferences for quality healthcare services and advanced medical technologies.

Major hospital chains are implementing expansion strategies to capture growing healthcare demand. Apollo Hospitals completed a significant merger between Apollo 24/7 and Keimed worth Rs. 2,475 crore (USD 296 million), creating a comprehensive digital healthcare platform valued at Rs. 22,481 crore (USD 2.69 billion). Aster DM Healthcare announced plans for Rs. 900 crore (USD 120.97 million) capital expenditure over three years, targeting 40% revenue contribution from India by 2025.

Public-Private Partnerships (PPP) in healthcare have gained prominence as a mechanism for expanding healthcare infrastructure. The government's plan to build major hospitals in all 761 districts through PPP models addresses critical healthcare access gaps, particularly in rural and underserved areas.

The medical tourism segment contributes approximately 10-12% to overall hospital revenue, with the market valued at USD 7.69 billion in 2024 and projected to reach USD 14.31 billion by 2029. India attracts medical tourists through its combination of high-quality healthcare services, skilled medical professionals, and cost advantages, with major surgeries costing approximately 20% of developed country prices.

7. REGULATORY FRAMEWORK & QUALITY ASSURANCE

India's pharmaceutical and healthcare sectors operate within a comprehensive and evolving regulatory framework designed to ensure product safety, efficacy, affordability, and ethical practice. Several key regulatory bodies as discussed below oversee different facets of the industry.

7.1 Central Drugs Standard Control Organisation (CDSCO) Framework

Organizational Structure and Mandate

The Central Drugs Standard Control Organisation (CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India serves as the National Regulatory Authority (NRA) of India. Its headquarters is located at FDA Bhawan, Kotla Road, New Delhi, with six zonal offices, four sub-zonal offices, thirteen port offices and seven laboratories spread across the country.

The Drugs & Cosmetics Act, 1940 and rules 1945 have entrusted various responsibilities to central & state regulators for regulation of drugs & cosmetics, envisaging uniform implementation of provisions to ensure safety, rights and well-being of patients by regulating drugs and cosmetics. CDSCO is constantly striving to bring out transparency, accountability and uniformity in its services to ensure safety, efficacy and quality of medical products manufactured, imported and distributed in the country.

Core Regulatory Functions

Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of Drugs, Conduct of Clinical Trials, laying down standards for Drugs, control over quality of imported Drugs, and coordination of activities of State Drug Control Organizations by providing expert advice to bring about uniformity in enforcement of the Drugs and Cosmetics Act.

CDSCO along with state regulators is jointly responsible for grant of licenses of certain specialized categories of critical drugs such as blood and blood products, I.V. Fluids, Vaccines and Sera. The organization builds comprehensive databases of various permissions and licenses issued by State FDAs through the Sugam platform.

7.2 Drug Controller General of India (DCGI) Authority

Leadership and Decision-Making Framework

The Drug Controller General of India (DCGI) is the head of the Central Drugs Standard Control Organization, responsible for approval of licenses of specified categories of drugs such as blood and blood products, IV fluids, vaccines, and sera in India.

DCGI lays down standards and quality of manufacturing, selling, import and distribution of drugs in India, prepares and maintains national reference standards, and ensures uniformity in enforcement of the Drugs and Cosmetics Act. The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC).

Medical Device Regulation Authority

With the notification of Medical Device Rules 2017 by the Government of India, DCGI acts as Central Licensing Authority (CLA) for medical devices falling under the purview of these rules. Out of four Classes of medical devices from Class A to Class D, DCGI is the direct licensing authority for Class C and Class D devices, while coordinating licensing for Class A and B devices through State drug controllers as State Licensing Authority.

7.3 Clinical Trial Regulations and New Drug Approval

Updated Regulatory Framework

The New Drugs and Clinical Trials (Amendment) Rules, 2024, which went into effect on April 1, 2025, requires registration of Clinical Research Organizations (CROs) with the Central Licensing Authority, which is the Drugs Controller General of India (DCGI), prior to conducting clinical trials or bioavailability or bioequivalence studies of new drugs or investigational new drugs in humans.

The rules outline registration requirements and procedures for CROs and applicable forms, with the SUGAM Portal serving as the primary submission platform, though access is restricted to users within India.

Clinical Trial Approval Process

In accordance with the 2019-CTRules, sponsors must submit clinical trial applications to the Drugs Controller General of India (DCGI) to obtain authorization to conduct clinical trials in India. The investigator must also obtain ethics committee (EC) approval from a DCGI-registered EC prior to initiating a study.

According to regulatory guidelines, the DCGI review and approval process may be conducted in parallel with the EC review for each clinical trial site, though CDSCO must confirm EC approvals have been obtained per the protocol prior to approving study initiation.

7.4 Recent Regulatory Updates and Global Harmonization

Updated Guidelines and Standards

In May 2024, CDSCO published a revised guidance for the submission of clinical trial applications for biological products developed in conformity with the 2019 NDCT Rules and GCP Guidelines of India. This document comprises information on submission of Clinical Trial Applications for evaluating safety and efficacy (biologicals), requirements for permission of New Drug Approvals (biologicals), and preparation of quality information for drug submission.

CDSCO invited comments on Revised Guidelines on Similar Biologics - Regulatory requirements for Marketing Authorization in India 2025, demonstrating ongoing efforts to align with international standards and enhance the regulatory framework for biological products.

Quality Surveillance and Market Monitoring

The CDSCO has issued new guidelines to enhance surveillance of quality and efficacy of drugs and cosmetics in the market through standardized drug sampling methodology. Standards for manufacturing, sale, import, and distribution are established under the Drugs and Cosmetics Act, 1940 and monitored stringently.

Monthly testing of 2,000 to 3,000 drug samples from the market is conducted, with medicines failing any quality parameter being flagged and listed on the official website, ensuring transparency and accountability. India's contribution as the world's largest supplier of generic drugs and vaccines reflects adherence to these quality standards.

7.5 Dual Regulatory Structure and Enforcement

Central-State Coordination Framework

India's drug regulatory framework operates through a dual structure: the CDSCO and 36 state-level regulatory agencies. The CDSCO primarily handles new drug approvals, clinical trials, and regulation of imported medicines, while state authorities oversee licensing for manufacturing, sale, and distribution of drugs.

A critical role of state bodies is conducting regular inspections to prevent production and distribution of spurious or adulterated drugs. This two-tiered system ensures checks and balances across the pharmaceutical supply chain, with efforts underway to enhance collaboration between central and state agencies.

Enforcement and Compliance Mechanisms

When manufacturers fail to meet quality and regulatory parameters established by the CDSCO, immediate corrective actions are implemented including recalling substandard drugs from the market, conducting comprehensive mapping of the supply chain to trace affected products, and initiating show-cause notices to manufacturers.

Depending on severity of non-compliance, regulatory authorities may recommend further punitive measures. Such proactive interventions aim to uphold public trust in the pharmaceutical system while ensuring patient safety, with commitment to enforcing quality standards underscoring regulators' dedication to maintaining integrity of the Indian pharmaceutical industry.

8. CHALLENGES & OPPORTUNITIES

The Indian pharmaceutical and healthcare sectors, while poised for significant growth, face a unique set of challenges that simultaneously present substantial opportunities for strategic intervention and investment.

8.1. Challenges

Infrastructure Gaps

A critical challenge is the significant shortfall in healthcare infrastructure. India requires an additional 2.4 million hospital beds to bridge the current bed-to-population ratio of 1.3 beds per 1,000 people. By end of 2025, 3 million beds are needed to meet the target of 3 beds per 1,000. This deficit particularly impacts access to quality care in rural areas.

Shortage of Healthcare Professionals

India faces a critical shortage of skilled healthcare professionals. An estimated 1.54 million doctors and 2.4 million nurses are required to meet the rising demand. The low doctor-patient ratio compromises the quality of care and increases the burden on existing medical staff.

High Cost of Advanced Technologies

The substantial price tag associated with the initial setup, ongoing maintenance, and necessary upgrades of state-of-the-art connected systems can be prohibitive for many healthcare institutions, especially those operating in rural areas with limited funding.

Pricing Pressures and Affordability Concerns

While the National Pharmaceutical Pricing Authority's (NPPA) price controls aim to ensure the affordability of essential medicines, they can compress profit margins for pharmaceutical companies. High out-of-pocket expenditure (OOPE), which stood at 54.8% of current healthcare expenditure in India, remains a significant concern for patients, pushing many into financial hardship.

Data Security and Privacy in Digital Health

With the increasing adoption of digital health solutions, concerns regarding patient data security and privacy are becoming more prevalent. The fragmented legal framework and lack of specific penalties for data breaches pose risks.

Supply Chain Dependencies

India continues to exhibit significant reliance on imports for a substantial portion of its Active Pharmaceutical Ingredients (APIs), historically importing 90% from China. Similarly, nearly 70% of medical devices are imported, creating vulnerabilities in the supply chain.

Regulatory Hurdles

Despite ongoing reforms, regulatory processes for new drugs, devices, and clinical trials can still be lengthy and complex, potentially delaying market entry for innovative products.

In contrast to above, India's pharmaceutical and healthcare sector is also positioned for unprecedented growth, with validated projections from multiple authoritative sources indicating transformational expansion.

8.2 Strategic Opportunities

Artificial Intelligence and Advanced Technologies

Advanced technologies like AI, machine learning, IoT, and blockchain are reshaping pharmaceutical manufacturing, drug discovery, and healthcare. The digital health market is projected to grow from USD 8.79 billion in 2024 to USD 47.8 billion by 2033 (CAGR 17.67%). Precision medicine, supported by genomics, biomarkers, and analytics, is a growing focus for Indian pharmaceutical and biotechnology firms. Industry 4.0 enables automation, real-time monitoring, and predictive analytics for improved efficiency and compliance in pharmaceutical manufacturing. Smart facilities using AI and advanced sensors are becoming standard. Telemedicine is expected to reach USD 5.4 billion by FY25, and combining digital health services with pharmaceutical products offers integrated care solutions.

Global Market Opportunities and Export Growth

The global "China+1" strategy is driving multinational pharmaceutical companies to diversify supply chains, making India a top alternative for manufacturing due to its infrastructure, regulatory standards, and cost advantages. India saw new project capital expenditures rise 28% to USD 110 billion, notably in large-scale supply chain and semiconductor investments. Of the ten largest greenfield projects globally in 2024, four were semiconductor-related — including one in India.

India's strong reputation for quality and compliance supports entry into regulated pharmaceutical markets, backed by 665 US FDA-approved facilities. In emerging markets, India's affordable manufacturing and reliability make it a preferred supplier for countries in Africa, Latin America, and Southeast Asia.

R&D Transformation and Capability Building

India is shifting from a generics-based to an innovation-driven pharmaceutical industry, investing in research facilities, international partnerships, and emerging therapies. The country's strengths in biotechnology — especially in vaccine development, biosimilars, and biologics — were highlighted by its indigenous COVID-19 vaccines. Drug discovery is progressing through collaborations, government, and private investment, with companies like Dr. Reddy's and Glenmark leading efforts on novel therapeutics and delivery systems. By 2030, innovative exports could reach $2 billion and may grow to $13–$15 billion by 2047 with comprehensive in-house development.

Sustainability and Environmental Leadership

Environmental sustainability is increasingly vital in pharmaceutical manufacturing, with stricter regulations driving Indian companies to invest in green chemistry, waste reduction, and renewable energy. Circular economy practices — such as resource optimization and by-product use — are being adopted alongside effluent treatment and solvent recovery systems for compliance and cost savings. Pharmaceutical firms are also committing to carbon neutrality, implementing solar power, energy efficiency, and sustainable transport in their decarbonization strategies.

Universal Health Coverage and Access Enhancement

India's pharmaceutical industry can expand global healthcare access by developing affordable medicines, cementing its status as the "pharmacy of the world" and serving underserved populations. Ayushman Bharat and similar programs offer scalable models and have provided insurance to over 550 million people, strengthening India's leadership in health access. Medical tourism is forecasted to hit USD 14.31 billion by 2029, driven by advanced treatments, cost efficiency, and strong hospitality, boosting foreign exchange and job creation.

Strategic Vision 2047: Global Healthcare Leadership

India aims to become a global healthcare leader by 2047, targeting a USD 450 billion pharmaceutical sector and establishing itself as a top supplier. Strategic partnerships between industry, academia, and government will drive innovation in areas like AI, biotechnology, and digital health. Expanding global partnerships through alliances and acquisitions will help Indian firms enter new markets and enhance capabilities. By aligning cost advantages with global standards, India seeks competitive strength across market segments. Active participation in international regulatory initiatives will position India as a major voice in pharmaceutical regulation.

9. FUTURE OUTLOOK & CONCLUSION

As discussed in detail above, the Indian pharmaceutical and healthcare sector is poised for a transformative decade, driven by strong foundational growth drivers and emerging technological shifts. Navigating this complex landscape requires a strategic outlook that capitalizes on opportunities while mitigating inherent challenges.

The expected growth is primarily propelled by India's unique demographic dividend, a burgeoning burden of chronic diseases, and proactive government initiatives aimed at enhancing healthcare access, affordability, and domestic manufacturing capabilities. The rapid adoption of advanced technologies like Artificial Intelligence (AI) and telemedicine is further revolutionizing healthcare delivery. However, the sector navigates significant challenges, including persistent infrastructure gaps, a shortage of skilled healthcare professionals, and pricing pressures that balance affordability with industry profitability. These challenges, paradoxically, present substantial opportunities for strategic investment and innovative solutions, particularly through public-private partnerships and technological integration. Several key trends and disruptors will shape the future trajectory of the Indian healthcare sector:

Personalized Medicine: There is a growing emphasis on targeted therapies and diagnostics, with genomics and precision medicine gaining increasing traction. This shift will necessitate significant investment in advanced research and development capabilities and specialized talent.

AI-driven Healthcare: The continued expansion of Artificial Intelligence (AI) and Machine Learning (ML) applications will revolutionize drug discovery, data analysis, and patient outcomes. AI will play a critical role in enhancing diagnostic accuracy, optimizing treatment protocols, and streamlining administrative processes.

Sustainable Practices: A growing focus on sustainable and green manufacturing practices is emerging within the pharmaceutical industry, driven by increasing regulatory pressures and heightened environmental awareness. This will require industry players to invest in environmentally friendly production methods and supply chains.

Global Collaborations: Increased partnerships between Indian and international players are anticipated across various segments, including R&D, manufacturing, and market access, particularly in high-value areas like biologics. These collaborations will facilitate technology transfer and expand market reach.

The convergence of personalized medicine, AI, and sustainable practices represents the next frontier for the Indian healthcare sector. This shift will require significant investment in advanced research and development, specialized talent, and robust ethical frameworks. This progression is expected to move the industry beyond its established generic manufacturing prowess towards global leadership in cutting-edge healthcare solutions, enhancing its competitive position on the world stage.

To capitalize on this dynamic landscape, a multi-faceted strategic approach need to be implemented. This involves continued policy support for domestic manufacturing and R&D, targeted investments in infrastructure and workforce development, and accelerated adoption of digital health solutions. Industry players also need to prioritize innovation in high-value segments and strengthen supply chain resilience. Investors, in turn, should focus on high-growth areas and explore long-term strategies that align with India's evolving healthcare needs.

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KIRTANE & PANDIT

Pune

5th Floor, Wing A, Gopal House, S.No. 127/1B/ 11, Plot A1, Kothrud,
Pune – 411 038, India
Contact no : +91 20 67295100 / 25433104
E -mail : kpca@kirtanepandit.com

Mumbai

601, 6th Floor, Earth Vintage, Senapati Bapat Marg, Dadar West,
Mumbai- 400 028, India
Contact no : 022 69328846 / 47
E -mail : kpcamumbai@kirtanepandit.com

New Delhi

272, Rajdhani Enclave, Pitampura,
Delhi-110034, India
Contact no : +91-96438 74488
E -mail : kpcadelhi@kirtanepandit.com

Bengaluru

No. 63/1, I Floor, Makam Plaza, III Main Road, 18th Cross, Malleshwaram, Bengaluru – 560 055, India
Contact no : 080 23443548 / 23461455
E -mail : kpcabengaluru@kirtanepandit.com

Nashik

Gajra Chambers, Second Floor,
Kamod Nagar, Indira Nagar,
Nashik – 422009, India
Contact no. : +91 253-2386644
E - mail : kpcanashik@kirtanepandit.com

Hyderabad

401 to 405, 4th Floor, Sanatana Eternal,
3-6-108/1, Liberty Road, Himayatnagar,
Hyderabad - 500 029, India
Contact no : +91 99127 41089 / 94400 55917 / 98480 44743 / 98480 46106
E -mail : kpcahyderabad@kirtanepandit.com

Chennai

No. 128, Old No. 34, Unit No. 1, 6th Floor,
Crown Court, Cathedral Road Gopalapuram
Chennai 600086
Contact no : 044 47990259
E -mail : kpcachennai@kirtanepandit.com

Follow Us On:

kpca@kirtanepandit.com
www.kirtanepandit.com