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Analytical Overview of Internationalisation of India's Path to be a Global Pharma Leader

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Abstract

India's pharmaceutical sector has solidified its position as a foundational pillar of the global healthcare system, supported by a deep pool of scientific expertise, competitive manufacturing efficiencies, advanced process chemistry, and increasingly resilient supply-chain networks. With more than 3,000 pharmaceutical manufacturers and over 10,500 production facilities—including industry leaders such as Sun Pharmaceutical, Dr. Reddy's Laboratories, Cipla, Biocon, and the Serum Institute of India—the country stands as the world's foremost supplier of generic medicines and the third-largest pharmaceutical exporter by volume. Its diverse operational models, complex generics, biosimilars, contract research and manufacturing services, and a rapidly expanding range of specialty and innovative therapies, position India as a significant driver of global pharmaceutical advancement.

This research paper examines India's internationalization journey within the pharmaceutical sector and evaluates its growing influence in global health markets. It explores the nation's transition from a volume-centered generics manufacturing base to an emerging innovation-led biopharmaceutical ecosystem, supported by targeted policy interventions and industrial reforms. The study also identifies the top ten pharmaceutical products currently prominent in the Indian market and assesses the implications of global tariff increases and shifting trade policies on the industry's competitiveness, export capabilities, and operational performance.

Overall, the findings emphasize that India's pharmaceutical industry plays a pivotal role not only in achieving the country's long-term economic vision—such as the aspiration to become a \$30–35 trillion economy by 2047—but also in advancing global efforts to ensure the availability of affordable, effective, and high-quality healthcare.

Keywords: Indian pharmaceutical industry, global generics, internationalization, biopharma, complex generics, tariff hike

1. Introduction

India's pharmaceutical industry has emerged as a global powerhouse due to a distinctive blend of strengths: a large pool of scientific and technical talent, cost-efficient manufacturing capabilities, a mature process-chemistry ecosystem, and increasingly agile supply-chain management. These interconnected advantages have allowed India not only to produce medicines at scale but also to maintain high quality while keeping costs competitive.

Today, the sector includes more than 3,000 pharmaceutical manufacturers and over 10,500 production facilities. These range from major integrated companies such as Sun Pharmaceutical, Dr. Reddy's Laboratories, and Cipla—firms that manage the entire value chain from APIs to finished formulations—to specialized leaders like Biocon in biosimilars and the Serum Institute of India in vaccines. Together, these companies operate across a wide array of business models: domestic branded generics, complex generics for highly regulated markets, API production, contract research and manufacturing services (CRAMS), biosimilars, biologics, and, increasingly, innovation-driven specialty medicines.

India is currently the world's third-largest exporter of pharmaceuticals by volume. Its strong export orientation generates a significant trade surplus and supports millions of livelihoods, directly and indirectly. As the largest supplier of generic medicines globally, India accounts for nearly 20% of worldwide generic drug demand—playing a critical role in making healthcare affordable in both developed and developing markets.

Several transformative trends are shaping the next phase of the “Indian pharmaceuticals for the world” narrative. These include a global push for supply-chain resilience (often linked to reducing dependence on single-country sourcing), a sharper emphasis on R&D and quality

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systems, and a strategic shift toward higher-value services through CDMOs and CROs. Regulatory harmonization efforts across markets, increased availability of venture and private equity funding, rapid adoption of digital and AI-driven technologies, and a growing focus on sustainability are further propelling the industry's evolution.

Indian pharmaceutical companies now invest an estimated 8–11% of their revenues into research and development—an essential driver for strengthening pipelines in biopharma, vaccines, and emerging biotechnology platforms. Government initiatives such as the Production Linked Incentive (PLI) Scheme and the broader “Make in India” program are helping expand domestic manufacturing capacities while enhancing global competitiveness.

These developments align with India's broader economic ambition. The government aims to transform India into a \$30–35 trillion economy by 2047, positioning it as the world's third-largest economy, surpassing Japan and Germany. The pharmaceutical industry—given its export strength, innovation momentum, and deep talent base—is poised to play a critical role in driving this unprecedented growth.

2. Literature Review

The existing body of research on India's pharmaceutical sector underscores that the country's global success is rooted not merely in cost competitiveness but in its ability to maintain consistent, high-quality production standards. Studies emphasize that quality frameworks such as Six Sigma, Lean Manufacturing, and Total Quality Management (TQM) play a vital role in strengthening operational efficiency, reducing variability, and enhancing international credibility. The adoption of these systems allows Indian manufacturers to meet stringent global regulatory requirements, thereby supporting their sustained expansion in international markets.

Research on the biopharmaceutical industry highlights its strategic importance in fostering resilient healthcare systems and driving innovation. The literature points out that this sector significantly contributes to global economic development by generating high-skilled employment, advancing scientific research, and integrating cutting-edge technological solutions. Collectively, these studies reinforce that biopharmaceuticals hold a pivotal position in improving public health outcomes and shaping the future of medical innovation worldwide.

The report “*Global Pharma Winners – Focus and Efficiency Matter*” by Roland Berger further offers insights into the managerial and strategic dimensions of global pharma leadership. It stresses that success in the international pharmaceutical arena hinges on strong business acumen, including effective leadership, strategic alignment, sound financial management, and the capability to execute long-term plans. These factors are identified as essential pillars for building a sustainable and competitive global pharmaceutical powerhouse.

Together, the reviewed literature emphasizes that India's ascent in the global pharmaceutical landscape is driven by a combination of operational excellence, scientific innovation, strategic leadership, and commitment to high-quality standards. This multidimensional foundation is crucial for strengthening India's position as a global healthcare contributor.

3. Objectives of the Research Paper

The key objectives of this research paper are as follows:

1. To examine and analyze the structure, evolution, and current dynamics of the Indian pharmaceutical industry, with a specific focus on India's internationalization journey and its emergence as a significant contributor to global pharmaceutical growth.
2. To identify and evaluate the top ten pharmaceutical products in India in the present market landscape, based on recent data and industry performance.
3. To assess the impact of recent global tariff hikes on the operational performance, export competitiveness, and overall growth trajectory of the Indian pharmaceutical industry.

4. Research Methodology

This study uses a descriptive and analytical research approach based entirely on secondary data. All information has been collected from reliable internet sources, academic journals, research reports, government websites, industry publications, and credible articles related to the Indian pharmaceutical sector.

The data gathered from these sources was reviewed and analyzed to identify key trends, major product categories, internationalization patterns, and the impact of tariff changes on the industry. No primary data—such as surveys, interviews, or field research—was used. The study relies solely on published and publicly available secondary information.

5. Analysis & Findings

How Pharmaceutical Products from India Are Reaching Global Markets?

Robust Supply Chains

Recent global disruptions—including U.S.–China trade tensions, rising import tariffs, the COVID-19 pandemic, regional conflicts, and persistent geopolitical instability—have revealed the fragility of global pharmaceutical supply networks. These events caused shortages of Active Pharmaceutical Ingredients (APIs), delays in raw material transportation, and interruptions in manufacturing activities worldwide.

To address these vulnerabilities and strengthen long-term supply-chain resilience, India introduced two major strategic measures:

Production Linked Incentive (PLI) Scheme

The PLI scheme incentivizes domestic manufacturing of essential APIs and Key Starting Materials (KSMs) by offering financial benefits on incremental sales. This initiative aims to reduce dependence on imports, enhance domestic production capacity, improve self-reliance, and increase India's global export competitiveness.

Bulk Drug Parks

Bulk Drug Parks are specialized industrial clusters offering subsidized shared infrastructure—including reliable power supply, common testing laboratories, and effluent treatment facilities. By lowering production costs and enabling economies of scale, these parks help Indian bulk drug manufacturers remain globally competitive in both pricing and supply capabilities.

Government Support

Strong policy support has been fundamental in helping Indian pharmaceutical products penetrate international markets. Government schemes and financial incentives have strengthened manufacturing ecosystems, improved export readiness, and enabled firms to comply with global standards.

PLI Scheme

With a budget allocation of ₹15,000 crore (US\$ 2.04 billion) for the period 2020–21 to 2028–29, the PLI scheme encourages large-scale manufacturing, new investments, and diversification into high-value pharmaceutical categories. By H1 FY25, ₹604 crore (US\$ 69.76 million) had already been disbursed to beneficiary firms.

Strengthening of Pharmaceutical Industry (SPI)

The SPI scheme, with an outlay of ₹500 crore (US\$ 60.6 million), provides support to MSMEs and pharmaceutical clusters to improve quality, productivity, regulatory compliance, and environmental sustainability.

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)

As of June 30, 2025, a total of 16,912 Jan Aushadhi Kendras are operational across India, offering 2,110 medicines and 315 medical devices/consumables at affordable prices. The government aims to increase this network to 25,000 outlets by March 2027, thereby expanding access to low-cost, high-quality generic medicines.

Additionally, export incentives, bilateral trade agreements, and continuous regulatory reforms further enhance India's global market competitiveness.

Market Alignment and Compliance Adaptation

To successfully enter and sustain a presence in international markets, Indian pharmaceutical manufacturers adapt their products to meet diverse regulatory, packaging, and compliance requirements worldwide.

Adaptation to Local Requirements

Manufacturers integrate anti-counterfeiting features—such as holographic seals and tamper-evident packaging—to ensure product security. Packaging formats are tailored to meet country-specific regulations, including child-resistant closures for the U.S. and Braille labeling for the European Union.

Serialization and Traceability

To comply with global directives such as the EU Falsified Medicines Directive (FMD), exporters deploy end-to-end track-and-trace systems. QR codes and unique serial numbers are printed on every saleable unit, ensuring complete product authenticity and supply-chain transparency.

Neutral Labels under Rule 94

Indian CDMO facilities often use neutral or unbranded packaging as allowed under Rule 94, enabling foreign clients to apply their own branding and marketing elements after import. This flexibility is especially important for private-label brands and contract manufacturing partnerships.

Strategic Partnerships

Collaborations with international companies help Indian pharmaceutical firms ease market entry, navigate regulatory landscapes, and strengthen global supply chains.

Example

PolyPeptide Group AG & Lupin Manufacturing Solutions (LMS)

- **Partnership Type:** Long-term strategic collaboration for peptide-based APIs
- **Impact:** Enhances peptide production capabilities, strengthens global supply-chain resilience, and improves operational efficiency.

This partnership demonstrates how Indian pharmaceutical companies are integrating into advanced global biopharmaceutical value chains.

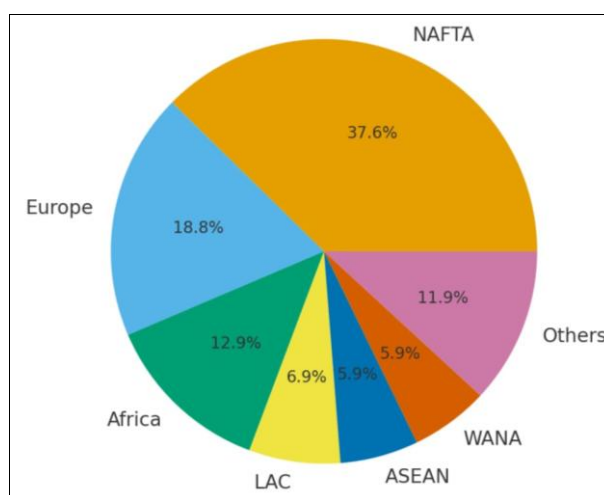


Fig 1: Major export destinations in India's pharma export (FY25)

Indian pharmaceutical companies are increasingly adopting strategic approaches to strengthen their presence in international markets. The export distribution for FY25 highlights the global footprint of India's pharmaceutical sector. NAFTA countries (the U.S., Canada, and Mexico)

remain the largest export destination, accounting for 37.6% of total pharma exports. Europe follows with 18.8%, while Africa contributes 12.9%, reflecting India's strong role in supplying affordable medicines to developing regions. Other markets such as LAC (Latin America & Caribbean),

ASEAN, and WANA (West Asia & North Africa) represent smaller yet significant shares. Additionally, 11.9% of

exports are directed to various other regions, underscoring the industry's broad global diversification.

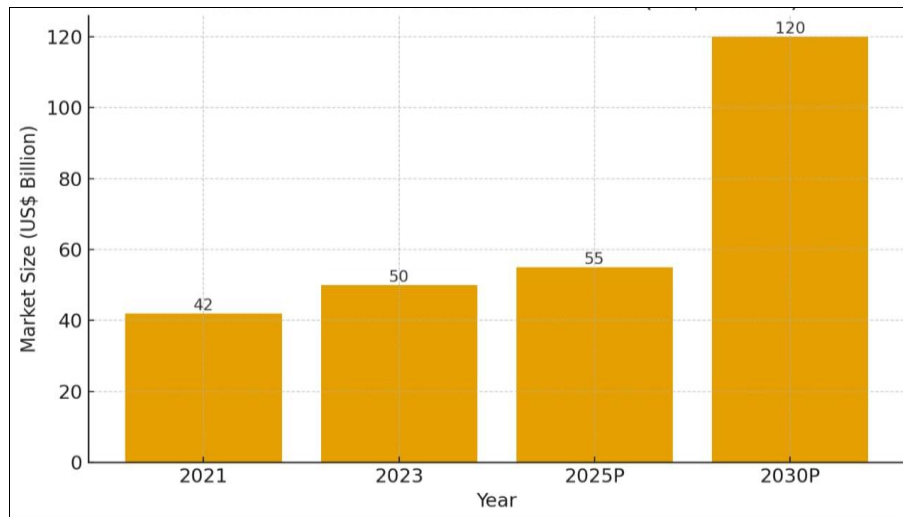


Fig 2: Indian pharmaceutical market size (US\$ billion)

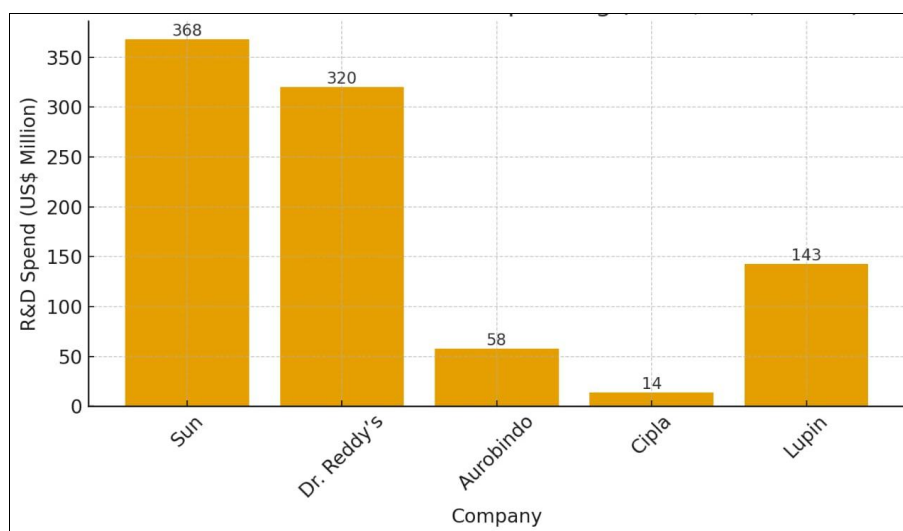


Fig 3: Indian pharmaceutical R&D spending (FY25, US\$ million)

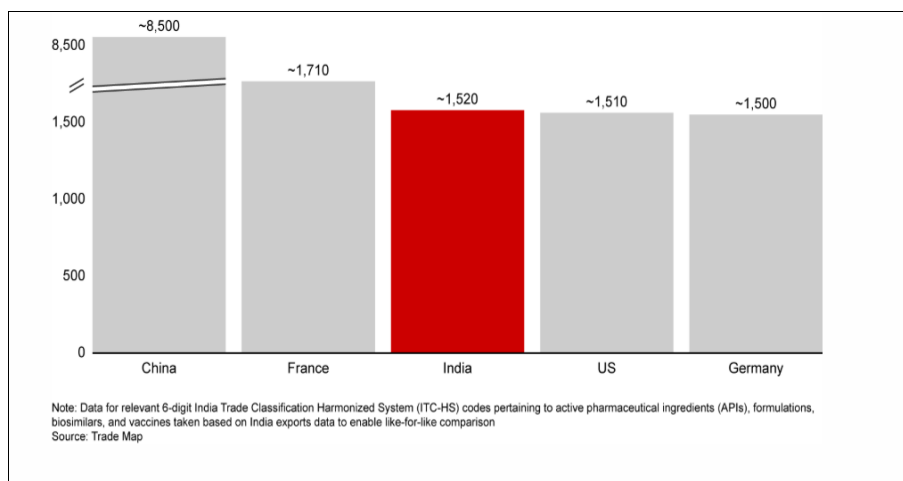


Fig 4: Pharmaceutical exports (2023) thousands of tons

Top 10 Pharma Products in India

1. Paracetamol – Reliable Fever & Pain Relief: Paracetamol is one of the most widely used global medicines. Known for its safety and effectiveness, it

remains a top choice for treating fever and mild-to-moderate pain, making it one of India's highest-demand pharmaceutical products.

2. Azithromycin – Powerful Broad-Spectrum

Antibiotic: Widely prescribed for respiratory, skin, and soft-tissue infections, azithromycin continues to see steady demand. Its convenient dosing and strong clinical results make it a preferred antibiotic across India.

3. **Rabies Vaccine – Critical for Human & Animal Health:** Due to frequent animal bite cases and growing awareness of zoonotic diseases, the rabies vaccine is in high demand in both the human healthcare sector and the veterinary segment.
4. **Vitamin D3 – Essential for Bone Health:** Vitamin D3 supports calcium and phosphorus absorption, helping maintain strong bones and prevent deficiencies such as osteoporosis. Its high usage in supplements and fortified products keeps it a major export item.
5. **Iron Supplements – Key Solution for Anemia:** Iron deficiency anemia remains common in India and many developing countries. WHO-GMP-compliant iron supplements enjoy strong domestic and international demand due to their essential role in managing anemia.
6. **Hepatitis B Vaccine – Important Immunization Product:** With expanding global vaccination programs, the Hepatitis B vaccine continues to see rising demand. Indian manufacturers supply high-quality, GMP-certified vaccines to numerous countries.
7. **Amoxicillin + Clavulanic Acid – Widely Used Antibiotic Combo:** This combination is one of the most prescribed antibiotics for bacterial infections. It is a staple in pharmacies and remains in high demand in both domestic and export pharmaceutical markets.
8. **Veterinary Vaccines – Growing Segment in Pharma:** Increasing emphasis on livestock health and disease prevention boosts demand for veterinary products such as Ivermectin, Rabies vaccine, and Enrofloxacin injections. This segment is rapidly expanding in India.
9. **Oral Rehydration Salts (ORS) – Essential for Rehydration:** ORS is vital for treating dehydration caused by diarrhea, heat exposure, and illness. Its affordability and effectiveness make it a widely used product across rural and urban India.
10. **COVID-19 Related Formulations – Sustained Post-Pandemic Demand:** Even with fewer active cases, medicines like Favipiravir, Zinc, and Vitamin C remain in demand for immunity building and post-COVID recovery care.

U.S. Drug Storage and India's Strategic Role

India has firmly established itself as a global leader in the pharmaceutical supply chain, exporting a wide range of medicines to markets across the world. In 2022–2023 alone, India recorded pharmaceutical exports worth approximately USD 25.3 billion, and it now manufactures 10 of the top 25 generic medicines globally. This strong export performance highlights India's pivotal role as a primary source of affordable, high-quality generic drugs for international healthcare systems.

The United States—where more than 90% of all prescriptions dispensed are generics—relies heavily on India as a key pharmaceutical partner. A significant share of the generics consumed in the U.S. originate from Indian manufacturers, underscoring India's irreplaceable position in the American drug supply chain.

In recent years, tariff tensions escalated when the U.S., under the Trump administration, imposed a 25% tariff on

most Indian exports, citing trade imbalances. Tariffs on several Indian goods increased by nearly 50%. However, generic pharmaceuticals were deliberately exempted, reflecting India's critical importance to U.S. drug security and public health.

Today, India supplies over 40% of all generic medicines used in the U.S., including essential treatments for chronic illnesses, oncology, and infectious diseases. As noted by Namit Joshi, Chairman of Pharmexcil, imposing tariffs on Indian pharmaceuticals would ultimately raise healthcare costs for American consumers and further strain an already vulnerable drug supply system.

Drug shortages in the U.S. are largely driven by low profitability of older generics, limited manufacturing capacity, and recurring quality-related shutdowns. These issues discourage investment in facility upgrades and redundant production lines. The situation is further aggravated by dependence on a fragile global supply chain for critical active pharmaceutical ingredients (APIs), making the system vulnerable to disruptions, sudden demand spikes, and geopolitical uncertainties.

Overall, India's pharma industry remains a cornerstone of U.S. medicine availability, and maintaining stable trade relations is crucial for ensuring uninterrupted access to essential drugs.

5. Conclusion

India's pharmaceutical industry has evolved into a globally influential sector, strengthened by its manufacturing excellence, cost efficiencies, scientific capabilities, and continuous policy support. The nation plays an indispensable role in ensuring worldwide access to affordable, high-quality medicines, emerging as both a major producer and exporter of complex generics, vaccines, APIs, and specialty formulations. With more than 40% of generic medicines consumed in the United States sourced from India, and with India producing several of the world's top generic drugs, its contribution to global healthcare security is undeniable.

The study highlights how India's path toward internationalization is driven by robust supply-chain reforms—such as the PLI scheme, bulk drug parks, improved quality standards, and modernization of manufacturing infrastructure. These initiatives have reduced import dependency, strengthened API self-reliance, and enhanced global competitiveness. Moreover, strategic partnerships, regulatory alignment, and market-specific adaptations have further accelerated India's integration into global value chains.

The analysis of the top ten pharmaceutical products in India demonstrates a strong domestic and export demand for essential medicines, vaccines, antibiotics, nutritional supplements, and post-pandemic formulations. This product diversity reflects India's ability to respond to both global health priorities and evolving market needs.

Additionally, the study shows that geopolitical shifts, including tariff escalations by major economies, have tested the resilience of India's pharma sector. Yet, exemptions granted to pharmaceutical goods—especially by the United States—underscore India's irreplaceable role in maintaining global drug stability. Persistent challenges such as API dependency, supply-chain vulnerabilities, and international compliance demands remain, but India's policy measures and expanding innovation ecosystem continue to mitigate

these risks.

Overall, India stands at a defining moment in its pharmaceutical journey. With strong manufacturing capacity, expanding global partnerships, and a growing shift toward biopharmaceutical innovation, India is positioned not merely as a global generics supplier but as an emerging leader shaping the future of global healthcare. As the world's demand for safe, affordable, and reliable medicines intensifies, India's pharmaceutical industry will continue to be a critical force in ensuring health security and equitable access across continents.

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