

# INDIA'S PHARMA SUPPLY CHAIN: PAVING THE PATH TO GLOBAL SUCCESS

**Dr. Sanjay Agrawal**

Over the past decade, the Indian pharmaceutical industry has experienced significant growth and is on a trajectory to become a global hub for low-cost manufacturing and research and development (R&D). This expansion has been fueled by increased revenue and exports, placing India among the leading players in the global pharmaceutical market. However, this growth has also brought forth a unique set of challenges, requiring a transformative approach to the supply chain. In collaboration with industry organizations, we conducted a study to assess the current state of India's pharma supply chain, identify challenges, and uncover opportunities for creating a competitive advantage.

**The Current State of the Supply Chain**

With projections estimating the Indian pharmaceutical industry is projected to reach \$65 billion by 2024 and is anticipated to double to \$130 billion by 2030. Indian pharma companies are diversifying their portfolios, investing in innovation, and focusing on manufacturing complex generics and biosimilars. However, the business differentiator is shifting from reverse-engineering expertise to improved operational performance metrics like service levels and cost efficiency. This necessitates a closer look at the supply chain to meet evolving demands and maintain a competitive edge.

**Challenges in the Supply Chain**

While Indian pharmaceutical companies have excelled in reverse engineering and generic drug manufacturing, operational aspects have received relatively less attention. Supply chain efficiency becomes paramount as the industry faces fierce competition and pressure to reduce drug costs. Fragmentation along the value chain, quality issues, price pressures, and regulatory scrutiny are some challenges that demand a strategic supply chain transformation.

**Quality and Regulatory Matters in India's Pharmaceutical Industry**

The Indian pharmaceutical industry has

witnessed tremendous growth over the past decade but has faced mounting scrutiny from global regulatory agencies regarding quality and safety standards. Export-related issues, especially concerning the US Food and Drug Administration (FDA), have garnered negative attention and affected large and small pharmaceutical companies. Plant shutdowns, import bans, and critical observations have impacted companies' revenue and credibility on the global stage. Additionally, the Central Drugs Standard Control Organization (CDSCO) has increased inspections to address the problem of low-quality drugs in the domestic market.

With nearly 600 FDA-approved sites in India, global regulatory agencies inspect these sites more frequently. The FDA has identified over 800 issues in the past eight years, leading to warning letters and increased scrutiny of Indian pharmaceutical firms. The observations typically point to data integrity, lack of adherence to standard operating procedures, weak documentation practices, and inadequate equipment validation.

**Quality issues span beyond the production floor and impact various stages of the value chain:**

**Procurement:** Poor-quality raw materials have led to batch failures, production delays, and resource shortages.

**Manufacturing:** Plant shutdowns and failure to obtain global regulatory certifications have resulted in significant unused capacity.

**Logistics:** Post-

market issues, such as complaints and product failures, directly affect storage, handling, and cost to discard rejected products.

**R&D:** Lack of quality control in R&D has resulted in failures of trial batches, causing delays in product launches.

**Pricing Regulation Impact:** The Drugs (Price Control) Order (DPCO) 2013 and DPCO 2016 have increased pressure on companies to manage stock recalls and shelf-life loss due to pricing changes and the addition and removal of drugs from the National List of Essential Medicines (NLEM). With these challenges, companies attribute quality and regulatory issues to internal and external factors. Internally, the lack of data checks, poor product testing, and equipment qualification contributes to quality challenges. Externally, factors related to sourcing and suppliers, such

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**Mr. Bharat:** 9819845676  
**Mr. Yash:** 9619497022, 8850374535

**Email:** toklabrothers@yahoo.com

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as unknown particles in raw materials or failures at vendor sites, and diverse regulatory requirements across countries pose challenges.

## Product Proliferation

The expansion of product portfolios, driven by new product development, varied dosage forms, enhanced formulations, and packaging changes to cater to new markets, has implications for the supply chain. It increases manufacturing and distribution costs, higher inventory levels, and a larger supplier base. Factors contributing to this proliferation include changing consumer demographics, increased competition, and varying regulatory requirements across export markets.

## Supply Chain Fragmentation

India's pharmaceutical value chain is complex and fragmented, impacting product quality and safety. Numerous players at each stage, lack of integration, and poor visibility and traceability of products create multiple challenges. The presence of many vendors, multiple manufacturing facilities, decentralized R&D centers, and an under-equipped distribution network further complicate supply chain operation.

## Infrastructure Gaps

Infrastructure gaps in transportation, storage, and power supply present additional challenges for the pharmaceutical industry. Inadequate road and rail networks, insufficient air connectivity, and a lack of a robust cold chain network hinder timely and effective supply chain execution. These constraints pressure companies to ensure proper storage conditions and protect the integrity of their products during transit.

## Gaining a Competitive Edge:

Transforming India's Pharma Supply Chain Over the past five to 10 years, several markets, including China, Germany, Italy, and Brazil, have witnessed steady growth, posing serious competition for India in exports and imports. China's dominance in active pharmaceutical ingredients has impacted India's ability to cater to its domestic demand, with 75 percent of bulk drugs imported from China. Price increases and China's focus on exports further threaten the supply of raw materials. To maintain a competitive

edge in the global market, Indian pharma companies must design a supply chain that is more adaptive, flexible, and responsive to changes in supply and demand. This involves focusing on four dimensions:

## Reduce End-to-End Complexity:

- Consolidate and optimize the supply chain network, considering potential GST regime scenarios.
- Tailor supply chain segments are based on consumers' needs, product types, attributes, and markets.
- Address portfolio complexity upstream (R&D portfolio) and downstream (product SKU proliferation).

Create Agility and Visibility in the Supply Chain:

- The transition from a "planning for convenience" to a "planning for market" model.
- Tighten planning functions with clear long-term, medium-term, and short-term plans across plants, products, and markets.
- Define a clear inventory strategy with replenishment norms across all nodes of the supply chain network.

Build a Robust Quality and Compliance System:

- View quality as a vital internal governance body rather than just a support function.
- Establish a strong quality organization with visibility across all good manufacturing practices in the supply chain.
- Take structured initiatives to improve quality standards to meet growing regulatory requirements and scrutiny.

## Use Technology Across the Supply Chain:

- Integrate enterprise software to increase transparency and operational efficiency.
- Focus on automation to streamline workflows and gain end-to-end costs and business value transparency.
- Improve tracking and visibility throughout the value chain to optimize distribution and inventory levels.

By embracing these strategies and transforming their supply chains, Indian pharma companies can overcome challenges, enhance competitiveness, and maintain a significant global market share, especially in high-margin businesses like specialty and complex generics and biosimilars. Adopting new technologies and process

enhancements will enable companies to respond effectively to market dynamics and achieve best-in-class performance levels, ensuring sustained growth and success in the pharmaceutical industry.

## Revamping the Pharma Supply Chain

A comprehensive transformation is required to unlock India's pharma supply chain's full potential. This transformation demands commitment from top management and a capable execution team to sustain the benefits. Consumer goods companies that have built world-class supply chains have emerged as market leaders. Pharma companies must follow suit to prepare for the future and gain a competitive advantage.

## Steps to a Successful Supply Chain Transformation

- **Embrace the Vision:** Leadership must embrace the vision of a transformed supply chain and communicate its importance across the organization.
- **Build Capabilities:** Build the necessary capabilities to adapt to evolving market demands and enhance operational performance.
- **Focus on Operational Excellence:** Strive for operational excellence by optimizing processes and reducing inefficiencies.
- **Collaboration among supply chain partners and stakeholders is crucial for seamless operations and value creation.**
- **Implement Technology:** Leverage cutting-edge technologies like data analytics, AI, and blockchain to improve visibility and decision-making in the supply chain.
- **Continuous Improvement:** Foster a continuous improvement and innovation culture to stay ahead in a dynamic market.

India's pharmaceutical industry has demonstrated impressive growth, positioning itself as a global player. To maintain and enhance this success, a supply chain transformation is imperative.

By embracing new ways of working, investing in capabilities, and focusing on operational excellence, Indian pharma companies can achieve a competitive advantage, solidify their position in the global market, and continue to contribute significantly to the growth and development of the industry.

(The author is pharmaceutical consultant)