



# Pharma's Second Wind: Can India Remain the World's Pharmacy?

WEALTH BULLETIN SEPTEMBER, 2025





## Chairman's Message:

As we enter a new quarter of FY2025, it is increasingly evident that the Indian pharmaceutical industry stands at the cusp of a new structural upcycle – a “Second Wind.” The confluence of three transformative forces – a favourable regulatory backdrop from the U.S. FDA, the global diversification of supply chains under the “China Plus One” strategy, and the Indian government’s proactive push through Production Linked Incentive (PLI) schemes – has positioned India’s pharma and Active Pharmaceutical Ingredient (API) ecosystem for accelerated growth.

Our competitive advantage, built on decades of process chemistry expertise, a skilled scientific workforce, and regulatory familiarity with advanced markets, is being complemented by a new strategic mindset: self-reliance in key starting materials, compliance excellence, and diversification into high-value therapies. However, sustaining this momentum requires continued vigilance in quality systems, faster execution of backward integration, and a deeper investment in innovation.

This month's newsletter examines the key trends, data, and dynamics defining this "Second Wind" – and what they mean for India's ambition to remain, and redefine, its role as the Pharmacy of the World.

I hope readers will find this month's newsletter insightful.

*CA DR Rajesh Khandol*

# Introduction: The Global Pharmaceutical Landscape is Reshaping

The global pharmaceutical landscape is undergoing a fundamental reshaping in the post-pandemic era. While COVID-19 initially disrupted supply chains and exposed global dependence on a few production hubs, it has since catalysed a decisive reorientation toward resilience, regulatory trust, and geographic diversification.

For India, this represents a generational opportunity. The country already accounts for nearly **20% of global generic exports by volume**, and over **60% of global vaccine demand**. Yet, what differentiates the present moment from past growth cycles is that the structural tailwinds are now externally validated and policy-supported – rather than purely cost-driven.

However, optimism must be tempered with realism. Compliance remains a critical differentiator, as evidenced by recent regulatory actions against a few major sites. Input-cost pressures and lingering dependence on China for key starting materials (KSMs) remain strategic vulnerabilities. Nonetheless, the direction is clear – India is not merely expanding capacity; it is repositioning its role in global pharma value chains.

In the last twelve months, multiple global and domestic indicators have aligned to confirm this shift. U.S. FDA approvals for Indian manufacturers have continued at a steady pace, global drugmakers are increasingly awarding API contracts to Indian firms under the "China Plus One" strategy, and government-backed initiatives under the PLI scheme are materially expanding India's domestic API base. Simultaneously, the capital markets have taken note – with a visible uptick in mergers, acquisitions, and new investments in both manufacturing and R&D capabilities.



# U.S. FDA Regulatory Tailwinds: The Quality Comeback

One of the clearest indicators of structural strength in Indian pharma is the sustained pace of **Abbreviated New Drug Application (ANDA)** approvals from the U.S. FDA. According to the FDA's official monthly approval data and corroborated by corporate filings, Indian companies such as **Aurobindo Pharma**, **Sun Pharma**, **Dr Reddy's**, and **Lupin** collectively account for a significant share of total ANDA clearances issued over the past 12 months.

For instance, **Aurobindo Pharma** reported over **540 cumulative ANDA approvals** as of FY2025, while Sun Pharma and Dr Reddy's maintain robust pipelines with dozens of pending submissions. Industry tracker Pharmabiz reports that monthly approvals for Indian companies have held firm through 2024-25, demonstrating sustained regulatory confidence.

Equally important is the improvement in compliance outcomes. Publications such as Mint and Business Standard note that the number of U.S. FDA observations and Form 483s issued to Indian sites has declined over the past two years, reflecting the industry's renewed focus on quality culture, data integrity, and risk-based monitoring. While isolated incidents, such as the FDA's June 2024 warning letter to Sun Pharma's Gujarat facility, highlight ongoing challenges, the broader trajectory is positive.

This combination of **regulatory tailwinds** and **compliance maturity** has restored trust in Indian pharmaceutical exports to regulated markets – a foundation on which the "Second Wind" is being built.



# The China Plus One Catalyst: De-risking the Global Supply Chain

The geopolitical realignment of pharmaceutical supply chains is another major driver of India's renewed prominence. For decades, global drugmakers relied heavily on Chinese intermediates and APIs due to cost efficiency and scale. However, post-pandemic supply shocks, coupled with tightening environmental norms in China, have compelled multinational corporations to diversify sourcing.



Reports from Reuters and The Wall Street Journal confirm that large global players, including Pfizer, Merck, and Novartis, have begun increasing procurement from Indian manufacturers under long-term sourcing agreements. Industry leaders, such as Aurobindo Pharma's MD, have also publicly noted a surge in export inquiries from the U.S. and Europe, attributing it directly to the China+1 realignment.

Consulting analyses from Bain and Goldman Sachs estimate that India could capture up to 20-25% of the incremental global API outsourcing opportunity over the next five years, provided it sustains its compliance trajectory and cost competitiveness.

Nonetheless, India's current import dependence on China for key starting materials remains high — estimated at over 60% for select KSMs (Key Starting Materials). Bridging this gap is critical to realising the full benefits of China+1. Encouragingly, this is precisely where domestic policy interventions are gaining traction.

# The Tariff Angle: What Happened, Who Was Affected, and Why It Matters

## Timeline & Policy Noise

In late September 2025, U.S. tariff rhetoric escalated with announcements (and social-media proclamations) proposing punitive tariffs on certain pharmaceutical imports, including an initially publicised 100% tariff on branded/patented pharmaceuticals. That announcement created immediate market jitters and widespread headlines. Subsequently, reports indicated the White House shelved or clarified some of the initial proposals, generating a relief rally for the sector. This sequence of announcement → market shock → partial retreat explains much of the short-term price action in late September-early October.

## Economic Exposure: Generics vs Branded/Patented Drugs vs APIs

|   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | <p><b>Branded/Patented Drugs</b></p> <p>Proposed tariffs targeted mainly branded, on-patent medicines – a segment where certain Indian companies with branded US portfolios (or US branded subsidiaries) can have exposure. A 100% tariff on such products would be highly disruptive to revenues and would likely prompt rapid reshoring or local manufacturing requirements from multinational customers.</p>                                                                                                  |
| 2 | <p><b>Generics and APIs</b></p> <p>Analysts and industry bodies argue that the bulk of India's exports to the U.S. are generics and APIs, which are less likely to be directly hit by tariffs aimed at patented branded drugs. Several industry commentaries indicate limited direct impact on standard APIs and mass-market generics, though broad-based tariff measures (e.g., universal 10% tariffs applied to many imports earlier in 2025) can still raise costs for intermediates and compress demand.</p> |

# Stock-Price Correlation: Market Reactions

## (26-Sep-2025 → 08-Oct-2025)

Using the market price changes (26-Sep to 08-Oct 2025), we observe mixed short-term reactions consistent with tariff-related headlines and subsequent clarification:

| Sun Pharmaceutical Industries Ltd.                                                     | Divi's Laboratories Ltd.                                                                                                                            | Dr Reddy's Laboratories Ltd.                                                                                |
|----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| ₹1,587 → ₹1,632 (+2.8%)<br>Market cap Rs. 3,91,204 CR                                  | ₹5,689 → ₹6,113 (+7.4%)<br>Market cap Rs. 1,62,359 CR                                                                                               | ₹1,253 → ₹1,234 (-1.5%)<br>Market cap Rs. 1,02,971 CR                                                       |
| Modest recovery, reflecting diversified portfolio and partial insulation for generics. | Strong positive move; markets rewarded API exposure given China-Plus-One tailwinds and the view that Divi's is less exposed to branded-tariff risk. | Small dip; Dr Reddy's US exposure and branded/generics mix likely factored in nuanced investor positioning. |

Aurobindo, Cipla, Lupin, Glenmark, Laurus Labs: mixed single-digit moves reflecting company-specific exposure to U.S. generics, branded portfolios, and API specialisation.

The immediate market reaction was volatility rather than a uniform sell-off – API-centric firms (e.g., Divi's) and clear generics exporters saw relative strength, while companies with material branded/patented exposure or higher U.S. product concentration experienced more muted or mixed moves. The subsequent shelving/clarification of tariffs provided relief to broader indices.



# Government Policy and the PLI Push: Building Self-Reliance in APIs

The Indian government's Production Linked Incentive (PLI) Scheme for bulk drugs and APIs has moved decisively from announcement to execution. As of July 2025, 48 projects have been approved, covering 33 key APIs and intermediates, with significant investments commissioned under the initiative. The scheme aims to reduce import dependence, promote backward integration, and strengthen domestic manufacturing of critical raw materials.

Parallel initiatives, including the Bulk Drug Parks Scheme and dedicated financing for Greenfield API plants, further underline India's strategic focus on pharmaceutical self-reliance. The projected import substitution value from the PLI projects exceeds ₹15,000 crore, according to the Ministry of Chemicals and Fertilisers' estimates.

This combination of public investment, private execution, and export market demand forms the backbone of India's structural repositioning in the global pharma landscape.

|                                                                                                                 |                                                                                                     |
|-----------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| 01                                                                                                              | 02                                                                                                  |
| <b>48 Projects Approved</b><br>Covering 33 key APIs and intermediates with significant investments commissioned | <b>Import Substitution</b><br>Projected value exceeds ₹15,000 crore according to Ministry estimates |
| 03                                                                                                              | 04                                                                                                  |
| <b>Backward Integration</b><br>Dedicated financing for Greenfield API plants and Bulk Drug Parks                | <b>Strategic Self-Reliance</b><br>Reducing dependence on China for key starting materials           |

# Capital Markets, M&A, and Innovation Momentum

Market behaviour often validates what data predicts. Over the past year, Indian pharma has witnessed a visible resurgence in capital flows and strategic transactions. Sun Pharma's acquisition of U.S.-based oncology biotech Checkpoint Therapeutics, Torrent's consolidation moves, and Mankind Pharma's acquisition of Bharat Serums are notable examples. These deals signal a deliberate push toward complex generics, speciality pharmaceuticals, and biologics – a clear move up the value chain.



Meanwhile, sector analysts from CRISIL and ICRA forecast 6-8% revenue growth for FY2025, supported by volume recovery in the U.S. and Europe and steady domestic demand. While input-cost inflation and pricing pressures remain challenges, the strategic pivot toward higher-value products and speciality therapeutics promises to sustain earnings resilience.

# Conclusion: Tariffs, Markets, and the FY-End Outlook

## Tariffs, Markets, and the FY-End Outlook

Tariff headlines in late September 2025 provided a stress test of the industry's resilience. Short-term market moves confirm two durable lessons: (1) policy uncertainty begets volatility – investors repriced risk rapidly when tariffs were first mooted; and (2) economic impact depends on product mix – firms focused on APIs and mass-market generics are materially less exposed to tariffs aimed at branded, on-patent drugs. The market's favouring of API specialists (e.g., Divi's) during this episode underlines the structural narrative that scale plus upstream capability is being rewarded.

For the remainder of the financial year (FY2026), our baseline outlook remains cautiously constructive: mid-single-digit revenue growth at the sector level with selective upside for firms that (a) convert PLI approvals into commissioned KSM/API capacity, (b) sustain US FDA compliance momentum, and (c) expand higher-margin complex generics/biologics capabilities. Tariff risk remains a non-trivial tail risk – a material tariff on broad classes of imports would pressure volumes and margins and could accelerate on-shoring by global customers. However, current evidence suggests that blanket, permanent tariffs affecting India's core generic/API exports are improbable because of public-health and domestic-market cost considerations in importing countries, and also because recent pricing and policy clarifications have moderated the initial shock.

## Actionable Takeaways for Leaders and Investors

**Monitor Three KPIs Closely**

Over the next 6-12 months: (1) monthly ANDA approvals and resolved US FDA observations, (2) commissioning reports from PLI projects and domestic KSM output, and (3) trade/tariff policy statements from major importers (U.S./EU).

**Strategic Positioning**

Favour API specialists and compliance-led generics players in the near term; watch branded-heavy names for elevated sensitivity to any future tariff escalations.

In sum, tariffs have introduced a policy risk premium but have not overturned the structural case for India's pharmaceutical industry. The "Second Wind" remains intact – provided the sector turns policy noise into long-term advantage by accelerating backward integration, maintaining regulatory discipline, and moving up the value chain.

# Performances



## (1) Equity Market

| Indices        | 01-09-2025 | 30-09-2025 | High      | Low       |
|----------------|------------|------------|-----------|-----------|
| BSE S&P SENSEX | 79,828.99  | 80,267.62  | 83,141.21 | 79,818.38 |
| NIFTY 50       | 24,432.70  | 24,611.10  | 25,448.95 | 24,432.70 |

## (2) Mutual Fund

### AUM Data of Mutual Fund

(INR. In Lakh Crore)

| Particulars                                | AUM As On<br>31-08-2025 | Fresh Fund<br>Mobilize During<br>Sep-25 | Redemption<br>During<br>Sep-25 | AUM As On<br>30-09-2025 |
|--------------------------------------------|-------------------------|-----------------------------------------|--------------------------------|-------------------------|
| Total AUM of all mutual<br>funds scheme    | 75.79                   | 13.56                                   | 13.99                          | 75.36                   |
| AUM of equity oriented<br>(growth) schemes | 33.38                   | 0.66                                    | 0.36                           | 33.68                   |

Source: Association of Mutual Fund of India (AMFI)

### SIP Contribution

(INR. In Crore)

| Month    | SIP Contribution | SIP AUM   |
|----------|------------------|-----------|
| Sep-2025 | 29,361           | 15,12,303 |

### (3) FII & DII Inflow/Outflow Position – September 2025

FII's selling in the month is 0.35 Lakh.

DII's buying in the month is 0.65 Lakh

(INR. In Crore)

| FII /DII   | Gross Purchase | Gross Sale | Net         |
|------------|----------------|------------|-------------|
| <b>FII</b> | 2.79Lakh       | 3.14 Lakh  | (0.35 Lakh) |
| <b>DII</b> | 3.27Lakh       | 2.61 Lakh  | 0.65 Lakh   |

#### DISCLAIMER

All statistics, contents, comparisons, conclusive discussions, other data, etc provided in this bulletin are based on facts and figures available in the public domain. Capital Sprout does not favour any particular product, fund, securities, stocks, investment mode, strategy or fund manager, etc. Comparison of any products, strategies, etc does not intent to favour any particular product, strategy, etc. Investment is a matter of independence and subjectivity. Investors are kindly requested to use their judgment, and decision or consult your financial advisor before making an investment decision.

