

India's Pharmaceutical Sector

Context:

A senior executive from **Novartis** has stressed the need for stronger **IP rules and regulatory data protection (RDP)** to attract pharma R&D investment to India. The debate highlights India's challenge of moving beyond **generics towards innovation-led R&D** while ensuring **affordable medicines**.

How Do Drug-Quality Concerns Threaten India's Global Pharmaceutical Leadership?

- **Patient Safety:** Substandard or contaminated medicines can cause treatment failure and serious health consequences.
 - e.g., Indian-made cough syrups were linked to child deaths in **Gambia and Uzbekistan** due to contamination with diethylene glycol and ethylene glycol.
- **Regulatory Action:** Quality failures can trigger inspections, recalls, warning letters and import restrictions in major markets.
 - e.g., Compliance with **USFDA and European Medicines Agency** standards has become a competitive requirement for exporters.
- **Export Competitiveness:** Repeated violations raise compliance costs and can disrupt access to tightly regulated markets.
 - e.g., Plant-level compliance failures can disrupt exports from an entire manufacturing facility.
- **Global Reputation:** Persistent quality concerns weaken India's credibility as the **"Pharmacy of the World"**, affecting trust in Indian medicines.

Why Has India Struggled to Move from Generic Manufacturing to Original Drug Discovery?

- **Generic-Centric Model:** India's strength in generic formulations and process chemistry has not translated sufficiently into original drug discovery.
 - e.g., India continues to lag in globally successful **new chemical entities, patented biologics and first-in-class therapies**.
- **Weak Research Linkages:** Fragmented collaboration between academia and industry limits movement from laboratory research to commercial products.
- **Risk-Capital Constraint:** Long development periods and high failure rates make discovery research difficult to finance.
- **Weak Translation Capacity:** Gaps in clinical research and commercialisation reduce the conversion of promising research into marketable therapies.
 - e.g., The **Biopharma SHAKTI Mission** seeks to strengthen biologics, biosimilars and clinical-trial capacity.

How Can India Leverage Global Supply-Chain Shifts to Strengthen Its Pharmaceutical Competitiveness?

- **Capture China+1 Demand:** Diversification away from concentrated supply chains can create new manufacturing opportunities for India.
 - e.g., India can expand production of critical **APIs and KSMs**, where dependence on China remains high.
- **Enter Higher-Value Segments:** India can use its established manufacturing base to capture growing demand beyond ordinary generics.
 - e.g., **Biosimilars, recombinant products, cell-based therapies and advanced vaccines** offer higher-value opportunities.
- **Expand CRDMO Services:** Global firms can increasingly use India for research, development and manufacturing rather than only finished-drug production.
 - e.g., **Syngene, Piramal Pharma Solutions and Divi's Laboratories** illustrate India's expansion into CRDMO.
- **Deepen Global Value-Chain Integration:** Stronger integration can bring technology, capital, specialised skills and access to international markets.
- **Diversify Markets:** Expanding beyond concentrated export destinations can reduce exposure to regulatory and commercial shocks.
 - e.g., Greater penetration into **Europe, Latin America, Africa and Asia** can reduce excessive dependence on the US market.

Way Forward

- **Secure Critical APIs and KSMs:** Adopt a targeted strategy for vulnerable inputs, supported by domestic capacity and long-term offtake.
- **Create Patient Capital:** Support high-risk discovery through milestone-based public funding and stronger private investment.
- **Strengthen Research Translation:** Connect **academia, startups, pharma firms and clinical-trial networks** to move discoveries into products.
- **Unify Quality Regulation:** Strengthen Central-State coordination, digital inspections, traceability and pharmacovigilance.
- **Move from Volume to Value:** Scale **biologics, biosimilars, complex generics, advanced vaccines and CRDMO** alongside conventional generics.
- **Balance Innovation with Access:** Combine stronger IP incentives with **price regulation, public procurement and affordable generics** so that innovation does not undermine healthcare equity.