

India's and Brazil's pharmaceutical sovereignty: Challenges and strategies for Active Pharmaceutical Ingredient (API) manufacturing independence

Abstract

The globalization of pharmaceutical supply chains has significantly improved access to affordable medicines worldwide. However, the concentration of active pharmaceutical ingredient (API) manufacturing in a limited number of countries has created strategic vulnerabilities for national health systems. Recent global disruptions, particularly the COVID-19 pandemic, exposed weaknesses in pharmaceutical supply chains and renewed interest in pharmaceutical sovereignty and local manufacturing capacity. This review examines the challenges and policy responses related to API manufacturing independence in India and Brazil, focusing on essential medicines. India has established itself as one of the world's largest suppliers of generic medicines, yet approximately 65–70% of its API requirements are met through imports, largely from China.¹ Brazil faces similar challenges, characterized by technological dependence, limited domestic API production, and reliance on imported pharmaceutical inputs.² Economic, technological, regulatory, and geopolitical factors influencing API manufacturing resilience are discussed, together with policy strategies aimed at strengthening domestic pharmaceutical industries and improving health security.

Keywords: active pharmaceutical ingredients, pharmaceutical sovereignty, essential medicines, India, Brazil, pharmaceutical manufacturing, health security

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Introduction

Active pharmaceutical ingredients (APIs) are the biologically active substances responsible for the therapeutic effects of medicines. The availability of APIs is a critical determinant of pharmaceutical manufacturing capacity, access to medicines, and national health security.¹

Over the last three decades, pharmaceutical manufacturing has undergone substantial globalization, with API production increasingly concentrated in Asia, particularly China and India. This shift was driven by lower production costs, economies of scale, favorable industrial policies, and expanding manufacturing infrastructure.^{1,3}

Although globalization has reduced medicine costs and improved market efficiency, it has simultaneously increased dependence on geographically concentrated supply sources. The COVID-19 pandemic highlighted these vulnerabilities when lockdowns, export restrictions, transportation bottlenecks, and manufacturing interruptions disrupted international pharmaceutical supply chains.³ These events prompted governments worldwide to reconsider industrial policies aimed at ensuring reliable access to critical medicines and pharmaceutical raw materials. This review analyzes the challenges associated with pharmaceutical sovereignty in India and Brazil and evaluates strategies designed to strengthen domestic API production and supply-chain resilience.

Global dependence on API supply chains

The modern pharmaceutical industry operates through highly interconnected and geographically dispersed supply chains that span multiple countries and continents. Active pharmaceutical ingredients (APIs), key starting materials (KSMs), chemical intermediates, excipients, and finished dosage forms are often produced in different locations before being assembled into final pharmaceutical products.⁴⁻⁶

While this globalized production model has substantially reduced manufacturing costs and improved access to affordable medicines, it has also increased dependence on a limited number of manufacturing hubs, particularly in Asia. China has become the world's leading supplier of numerous APIs, KSMs, and pharmaceutical intermediates, whereas India has established itself as a dominant producer of generic medicines and finished pharmaceutical formulations.⁷⁻⁸

The shift of pharmaceutical manufacturing to Asia was driven by several factors, including lower labor costs, favorable industrial policies, large-scale chemical manufacturing infrastructure, access to raw materials, and environmental cost advantages. Over time, this concentration generated highly efficient production networks capable of supplying global pharmaceutical markets at competitive prices. However, the same efficiencies have created significant structural dependencies. Current estimates suggest that a substantial proportion of global API production capacity is concentrated within a relatively small group of countries, creating vulnerabilities that can disrupt medicine availability worldwide when production interruptions occur.⁹⁻¹⁰

China occupies a particularly strategic position within global pharmaceutical supply chains because of its extensive upstream integration. Chinese manufacturers not only produce APIs but also dominate the production of essential intermediates, solvents, precursors, and KSMs required for pharmaceutical synthesis. This vertically integrated ecosystem provides significant cost and scale advantages that are difficult for competing regions to replicate. Consequently, pharmaceutical manufacturers in many countries, including India, the United States, and members of the European Union, rely heavily on Chinese suppliers for critical inputs.¹¹⁻¹²

The COVID-19 pandemic exposed the fragility of these global supply networks. Lockdowns, factory shutdowns, labor shortages, port congestion, and transportation restrictions disrupted the movement of

pharmaceutical raw materials across international markets. Temporary export controls imposed by several countries further amplified concerns regarding medicine availability. During the early stages of the pandemic, governments and healthcare systems became acutely aware that a disruption affecting a single manufacturing region could rapidly generate shortages of essential medicines worldwide. These events transformed pharmaceutical supply security from an economic issue into a matter of national security and public health preparedness.¹³

The concentration of manufacturing capacity has generated several important vulnerabilities:

I. Dependence on a limited number of manufacturing countries:

Particularly for critical APIs, KSMs, and intermediates. Supply disruptions in one major producing country can have global consequences.

II. Susceptibility to trade restrictions and geopolitical tensions:

Export controls, sanctions, trade disputes, and diplomatic conflicts can interrupt access to essential pharmaceutical ingredients.

III. Exposure to logistics and transportation disruptions:

Global pharmaceutical production depends on reliable shipping networks, ports, air freight services, and customs procedures. Disruptions in transportation systems can delay the delivery of critical inputs.

IV. Environmental and industrial risks:

API manufacturing involves chemical-intensive processes that are vulnerable to environmental regulations, industrial accidents, energy shortages, and wastewater treatment constraints. Any disruption affecting major manufacturing regions can influence global medicine supplies.

V. Potential shortages of essential medicines during emergencies:

Public health crises, pandemics, natural disasters, and geopolitical conflicts can rapidly expose weaknesses in internationally fragmented pharmaceutical supply chains.

An additional concern involves the growing concentration of fermentation-based API production. Products such as antibiotics, vitamins, amino acids, and specialized biologically derived compounds often require complex production infrastructure and substantial operational investments. Over recent decades, many countries reduced domestic manufacturing of these products because imported alternatives were more economically attractive. As a result, dependence on a small number of suppliers increased, creating significant strategic risks when supply disruptions occur.¹³

The pharmaceutical sector also faces increasing pressure related to sustainability and environmental compliance. Regulatory agencies and governments are demanding stricter environmental standards for chemical manufacturing, wastewater disposal, and emissions control. While these measures are essential for sustainable industrial development, they may also contribute to production cost increases and capacity constraints, particularly in countries seeking to rebuild domestic API manufacturing capabilities. Balancing competitiveness, sustainability, and supply-chain resilience has therefore become a major policy challenge.¹³

In response to these vulnerabilities, many countries have introduced initiatives aimed at strengthening pharmaceutical sovereignty and supply-chain resilience. The United States, European Union, India, Brazil, Japan, and several other emerging economies have launched

policies supporting local manufacturing, strategic stockpiles, supplier diversification, and investment in domestic API production. These initiatives reflect a growing consensus that complete dependence on globalized pharmaceutical supply chains may compromise health security during periods of crisis. Rather than pursuing complete self-sufficiency, policymakers increasingly advocate a balanced strategy that combines domestic manufacturing capacity, international cooperation, and diversified sourcing networks.¹³

Ultimately, pharmaceutical supply chains must reconcile two competing objectives: economic efficiency and strategic resilience. While globalization has significantly reduced medicine costs and expanded access to healthcare products, recent events have demonstrated that excessive concentration of manufacturing capacity can undermine health-system security. Strengthening API production capabilities, broadening supplier networks, promoting technological innovation, and encouraging regional manufacturing partnerships are therefore becoming central components of pharmaceutical industrial policy worldwide.¹³ (Figure 1)

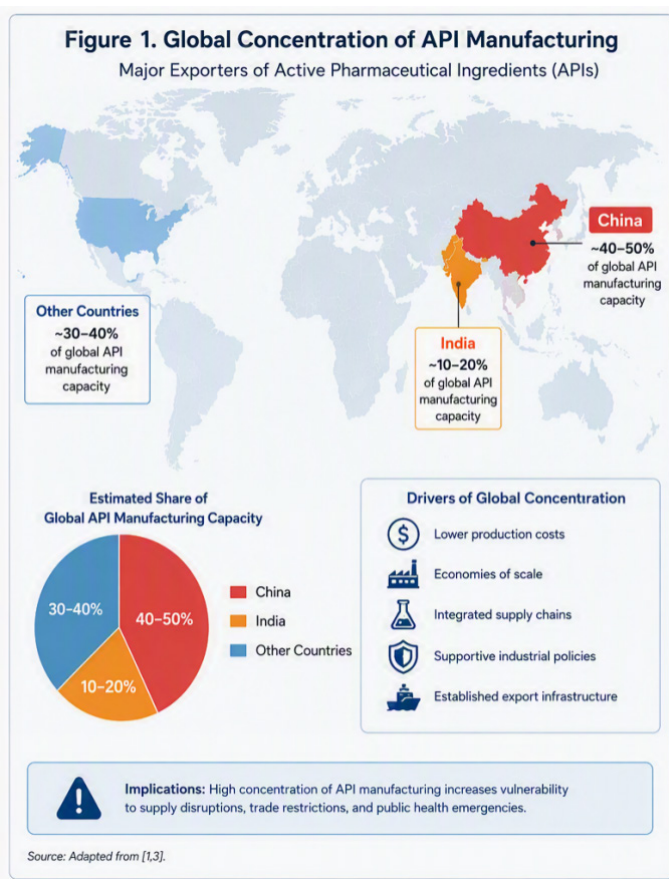


Figure 1 Global concentration of active pharmaceutical ingredient (API) manufacturing capacity and key factors contributing to supply-chain dependence.

India's journey toward API manufacturing independence

India is widely recognized as the “pharmacy of the world” due to its significant contribution to global generic medicine production. The country supplies approximately 20% of global generic medicines by volume and is one of the largest exporters of pharmaceutical products worldwide.¹

Despite this success, India's pharmaceutical industry remains substantially dependent on imported APIs. Cherian et al. reported that approximately 68% of India's API demand is fulfilled through imports, with China representing the dominant supplier for several essential medicines.¹

Factors contributing to import dependence

Several factors contributed to the decline of domestic API manufacturing competitiveness:

- I. Lower production costs in China.
- II. Larger manufacturing scales and integrated supply chains.
- III. Rising environmental compliance costs in India.
- IV. Limited investment in advanced process technologies.
- V. Dependence on imported intermediates and key starting materials.¹

Between 1991 and 2020, many Indian API manufacturers shifted their focus toward higher-value formulation manufacturing rather than basic chemical synthesis, further increasing reliance on imported inputs.¹

The COVID-19 pandemic exposed these vulnerabilities when temporary disruptions in Chinese manufacturing affected global pharmaceutical supply chains and raised concerns regarding the availability of essential medicines.

Government policy initiatives

In response, India implemented several policy measures to rebuild domestic API manufacturing capacity.

Production Linked Incentive (PLI) scheme

The Indian government launched the PLI scheme to encourage domestic production of critical APIs, drug intermediates, and key starting materials. The program provides financial incentives linked to manufacturing output and aims to reduce import dependence.¹

Bulk drug parks program

India established a bulk drug parks initiative to improve manufacturing infrastructure and reduce production costs through shared utilities, waste-management systems, and industrial clustering.¹

Research and innovation support

Government programs have increased funding for:

- I. Process innovation.
- II. Fermentation technologies.
- III. Green chemistry approaches.
- IV. Pharmaceutical process engineering.
- V. Advanced manufacturing platforms.¹

Remaining challenges

Despite substantial policy support, key challenges persist:

- I. Cost disadvantages relative to Chinese manufacturers.
- II. Dependence on imported intermediates.
- III. Regulatory complexity.

IV. Limited domestic fermentation-based API capacity.

V. Need for continuous technological modernization.¹

Consequently, complete pharmaceutical self-sufficiency remains unlikely in the near term, although enhanced domestic capacity can significantly improve resilience and reduce strategic vulnerability.

Brazil's pharmaceutical industry and technological dependence

Brazil possesses the largest pharmaceutical market in Latin America, accounting for approximately 40% of regional pharmaceutical sales. Nevertheless, domestic API production remains limited, and the country continues to rely extensively on imported pharmaceutical inputs.²

According to Rodrigues, Costa, and Kiss, the historical evolution of the Brazilian pharmaceutical sector led to an industrial structure centered primarily on formulation and packaging activities while upstream pharmaceutical chemistry and API production remained comparatively underdeveloped.²

This structure has contributed to a long-standing dependence on foreign technologies, multinational corporations, and imported raw materials.

Structural constraints

Several factors have limited the development of domestic API manufacturing in Brazil:

- I. Limited investment in pharmaceutical chemistry.
- II. Insufficient integration between universities and industry.
- III. Dependence on imported technologies.
- IV. High production and operational costs.
- V. Limited economies of scale.
- VI. Strong international competition from established producers.²

In addition, Brazil's trade deficit in pharmaceutical products has grown substantially over recent decades, reflecting continued dependence on imported APIs and advanced pharmaceutical technologies.²

Public health and strategic implications

Dependence on imported APIs can directly affect:

- I. Medicine availability.
- II. Supply continuity.
- III. Pricing stability.
- IV. Emergency preparedness.
- V. National health sovereignty.²

The COVID-19 pandemic further emphasized these concerns, particularly during periods of supply-chain disruption that affected access to vaccines, pharmaceutical intermediates, and essential medicines worldwide.

The Brazilian experience demonstrated that pharmaceutical manufacturing capacity should be viewed not only as an industrial asset but also as a strategic public-health infrastructure component.

Comparative analysis of India and Brazil

Factor	India	Brazil
Generic medicine production	Very strong	Moderate
API manufacturing base	Developed but import-dependent	Limited
Dependence on imported inputs	High	High
Industrial policy support	Extensive	Increasing
Technological capability	Advanced	More limited
Global export participation	Major exporter	Primarily domestic market
Primary challenge	Dependence on Chinese APIs	Structural technological dependence

India’s pharmaceutical sector possesses stronger industrial capabilities and greater international competitiveness. However, it remains vulnerable because of dependence on imported APIs and intermediates.¹

Brazil faces broader structural challenges associated with technological dependence and a comparatively weaker domestic API manufacturing ecosystem.²

Both countries therefore confront the common challenge of balancing economic efficiency with pharmaceutical security and strategic autonomy (Figure 2).



Figure 2 Comparative assessment of pharmaceutical sovereignty challenges, API manufacturing capabilities, and policy responses in India and Brazil.

Strategies for strengthening API independence

Industrial policy and financial incentives

Governments can encourage domestic production through:

- I. Tax incentives.
- II. Capital subsidies.
- III. Manufacturing grants.
- IV. Public procurement policies.
- V. Infrastructure investments.¹

Such measures can improve competitiveness and attract long-term investment.

Research and development

Sustained investment in R&D is essential for developing:

- I. Novel synthesis routes.
- II. Continuous manufacturing technologies.
- III. Biotechnological production platforms.
- IV. Green chemistry processes.
- V. Advanced analytical capabilities.¹

Technological innovation can reduce production costs and improve environmental sustainability.

Supply chain diversification

Total self-sufficiency is neither realistic nor economically optimal. Instead, countries should diversify supplier networks while simultaneously strengthening domestic manufacturing capacity.³

Diversified sourcing reduces exposure to regional disruptions and geopolitical risks.

Public-private partnerships

Collaboration among governments, academia, and industry can accelerate:

- I. Technology transfer.
- II. Workforce training.
- III. Process innovation.

IV. Industrial scale-up.

V. Commercialization of research outcomes.²

These partnerships are particularly relevant for emerging economies seeking to develop competitive API industries.

Regional pharmaceutical cooperation

Regional manufacturing networks may offer an intermediate solution between complete import reliance and full domestic self-sufficiency.

Potential benefits include:

I. Shared production infrastructure.

II. Technology sharing.

III. Expanded manufacturing scale.

IV. Enhanced bargaining power.

V. Reduced supply-chain risks.

Such approaches may be particularly valuable within Latin America and other developing regions.

Conclusion

The COVID-19 pandemic exposed critical vulnerabilities in global pharmaceutical supply chains and reinforced the strategic importance of domestic API manufacturing capacity. Pharmaceutical sovereignty has consequently emerged as a major policy objective for both developed and emerging economies.

India demonstrates how a globally competitive pharmaceutical industry can still remain vulnerable through dependence on imported APIs and intermediates. Recent government initiatives, including PLI incentives and bulk-drug manufacturing programs, represent important steps toward strengthening supply-chain resilience and manufacturing independence.¹

Brazil faces additional challenges associated with technological dependence, limited API manufacturing infrastructure, and reduced integration between industrial and scientific capabilities. Addressing these issues will require long-term investments in innovation, industrial development, and institutional collaboration.²

Although complete pharmaceutical self-sufficiency is unlikely to be economically feasible in an interconnected global economy, strategic investments in domestic manufacturing, technological innovation, and diversified supply chains can substantially improve access to essential medicines, strengthen public-health preparedness, and enhance national health security.

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Conflicts of interest

The authors declare to have no conflict of interest.

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