

# MAKE IN INDIA TO TRANSFORM

## INDIA'S PHARMACEUTICAL SECTOR

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The Indian pharmaceutical industry is widely regarded as a successful example of industrial policy in action. Once marked by heavy dependence, scarcity of essential medicines despite their availability in the global market, and extremely high prices, the sector has undergone a dramatic transformation. By the early 1990s, Indian pharma firms began proving their capability in the manufacture of generic medicines, forcing MNCs to collaborate with them. Today, it exports to more than 150 countries, making it a net earner of foreign exchange. Medicines supplied by Indian firms are among the most affordable in the world, and the country supplies around 70 percent of the World Health Organization's vaccine requirements for global immunization programmes. These achievements have earned India the moniker, 'pharmacy of the world'.

Indian pharma is now deeply integrated into global value chains (GVCs), both in manufacturing and R&D. It accounts for 4 percent of global export of active pharmaceutical ingredients (APIs), which is the key ingredient for finished dosage forms (formulations) and is a major destination for offshore corporate pharmaceutical R&D. Given this global footprint and the sector's strong performance, one might ask: what relevance does the *Make in India* initiative hold for an industry that already appears to be thriving?

Recent policy initiatives by the Government of India point to two critical areas where *Make in India* can play a transformative role.

### Reducing Import Dependence on Critical Raw Materials

A key vulnerability in the Indian pharmaceutical

sector is its excessive reliance on China for the import of key starting materials (KSMs), drug intermediates (DIs), and certain APIs. India currently meets 75% of import of KSMs/DIs/APIs (pharmaceutical raw materials) from China. Importing cheaper inputs from China and converting them into more profitable finished dosage forms in India makes good business model. However, overdependence on a single country poses strategic and supply chain risks in a crucial industry like pharmaceuticals especially in a world where supply chain dependencies are increasingly weaponised. Although this vulnerability was exposed on a few occasions, it manifested most severely during the COVID-19 pandemic. When the virus was spreading rapidly and global demand for COVID-related medicines surged, India emerged as a key supplier of such treatments. All the countries were striving to procure medicines for treating covid conditions, India emerged as a key supplier of such medicines. However, with China severely affected by the pandemic, the disruption in supply from that country raised serious concerns in India over the continued availability of essential medicines.



In an environment of growing uncertainty and panic the Indian govt. imposed temporary export restrictions on several medicines, including those used to treat COVID-19. On 3 March 2020, India restricted the export of 13 APIs including Paracetamol and formulations made of these APIs. In the following week, on 25 March 2020, India prohibited the export of Hydroxychloroquine (both API and formulations), a drug initially used in the treatment of COVID conditions in some countries but later found to be not effective. These restrictions on exports triggered concern among countries reliant on Indian pharmaceutical exports and drew strong criticism from then US President Donald Trump. This episode underscored the vulnerability of India's pharmaceutical industry due to its excessive reliance on a scheme in the pharmaceutical sector in 2020

on aimed at incentivising domestic production of those KSMs/DIs/APIs in which India is heavily import dependent. This scheme covers 41 Products which were identified by a Committee (Drug Security Committee) appointed by the Government in February 2020. Under this scheme, eligible firms are entitled for incentives worth ₹6940 crore over a period from 2022-23 to 2028-29. According to a press release by the Government of India, the response to the scheme has "exceeded expectations" in terms of new investments in manufacturing facilities. As against the committed investment of ₹3938.5 crore until 2028-29, an investment of ₹4254 crore has already been made in December 2024. And the creation of new facilities has resulted in import substitution worth ₹1144 crore. However, the impact of the scheme, in terms of reducing import dependence has been mixed. Imports of some products have declined, while others have seen increased import levels. Moreover, there are several products for which there were no or very few applicants, prompting the Department of Pharmaceuticals to reopen applications for 11 out of the 41 products as recently as May 2025. In those cases where private sector enterprises are not keen to get into the production of certain APIs or their KSMs and DIs, the public sector enterprises needs to be engaged strategically. A major challenge in import substitution is lack of

cost competitiveness. Chinese imports are on average 40 percent cheaper. Achieving viable domestic production would require substantial investments in R&D for process development and achieving economies of scale - both are difficult to achieve in the Indian contexts, where most API producers (accounting for 80% of API production in India) are small or medium-sized enterprises.

At the same time, it has been reported that Chinese suppliers are drastically reducing prices in certain APIs, especially in those products where India has been able to enhance production and reduce costs, to retain their market share. For example, as Manu Kaushik reports in Financial Express on 9 July 2025 that in the case of atorvastatin the cost of production in India during the last one year has declined by 17% to ₹10000 per kg while the price of this Chinese API declined by 33% to ₹8000 per kg. Similarly, the domestic cost of production of ofloxacin has declined by 16% to ₹2700 per kg during the last year while the cost of Chinese imports declined by 30% to ₹2100 per kg. The predatory pricing strategy of Chinese suppliers calls for timely application of trade remedies to protect Indian producers.

While the PLI scheme is a major step towards reducing import dependence, it needs to be complemented by other policy measures that would create a conducive ecosystem in India for cost competitive production of pharmaceutical raw materials.

### Facilitating the Transition to an Innovative Pharma Industry

Indian pharmaceutical firms account for nearly one-third of India's industrial R&D expenditure. While the ratio of R&D spending to sales has been rising, albeit with some fluctuations as shown in the figure, this investment is concentrated in a handful of large firms. The second PLI Scheme in this sector, launched in 2021, aims product diversification into high value goods and the Scheme for Promotion of Research and Innovation in Pharma MedTech Sector, launched in 2023, aims to transform this industry from cost-based to innovation-based growth.



Source: Compiled from CMIE Profess database

Pharmaceutical R&D is inherently risky, time-intensive (typically 12–16 years), and capital-heavy. Despite these barriers, some Indian firms such as Zydus Cadila and Wockhardt have successfully demonstrated capabilities in developing novel drugs. Many Indian pharma firms have established separate R&D enterprises in India and abroad, for example Sun Pharma Advanced Research Company of Sun Pharmaceutical Industries, Aurigene Oncology of Dr. Reddy's, New York based Ichnos Glenmark Innovation of Glenmark Pharmaceuticals, and New Jersey based Zydus Therapeutics of Zydus Lifesciences. And some of the Indian pharmaceutical firms have also established affiliate R&D enterprises for drug discovery and development. For instance, Alembic Pharmaceuticals funded Incozen (a biotech firm in Hyderabad) for discovery activities and Rhizen Pharmaceuticals (in Switzerland) for development and commercialization efforts. A report by GlobalData in December 2024 notes that foreign R&D enterprises of four Indian firms - Zydus Lifesciences, Glenmark Pharmaceuticals, Alembic Pharmaceuticals, and Suven Life Sciences - have 16 new chemical and biological entities in Phases I to III of clinical development.

While indicators show that Indian pharmaceutical firms are gradually placing their foot firm on innovation, in clinical trials front, which is the most critical part of drug development accounting for about 40% of pharma R&D budget and takes about 3-6 years, India's share in global clinical trials seems to be declining, which is very concerning. Siddharth Kumar Singh reports in The Hindu on 24 March 2025 that during the Bio Asia Summit 2025 held in

Hyderabad in 2025, experts pointed out that India's share in global clinical trials is less than 3%. In 2019, this share of India was 11%. A New Drugs and Clinical Trial Rules 2019 were introduced in 2019 with the objective of addressing malpractices involved in clinical trials in India. Studies have pointed out some critical lacuna in the implementation of these regulations and the Central Drugs Standard Control Organization (CDSCO) has acted upon these issues recently by introducing some reforms recently and also and fixing a 90 day timeframe for the final decision on the clinical trial application. It is expected that the approval process will be streamlined soon.

With artificial intelligence increasingly being applied in drug discovery to accelerate timelines and reduce costs, India needs to support the growth of AI-driven pharmaceutical start-ups. For this, a thriving deep-tech startup ecosystem needs to emerge in India.

### Conclusion

The Make in India initiative holds significant potential for redefining India's pharmaceutical strategy - not merely by supporting domestic manufacturing, but by ensuring long-term resilience and enabling innovation. Reducing import dependence for critical inputs and facilitating the rise of an innovative pharmaceutical ecosystem will require a coordinated policy framework, strategic public sector participation, and sustained investment in R&D and infrastructure.