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Can India Reclaim API Throne from China?

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Despite having the third-largest pharmaceutical industry by volume in the world and being the largest manufacturer of generic medicines globally, India is heavily dependent on China for imports of raw materials, Key Starting Materials (KSMs), and Active Pharmaceutical Ingredients (APIs). India is the source of around 60,000 generic brands across 60 therapeutic categories and manufactures more than 500 different APIs. However, India imports about 70 per cent of its APIs from China as itâ??s a cheaper option than manufacturing them domestically. There were 58 APIs in which India was heavily dependent on China. In the case of 45 APIs, India was dependent on China for 100 per cent of imports. Out of these 58 APIs, 29 APIs are manufactured through fermentation and 29 APIs are manufactured through chemical synthesis. The Department of Pharmaceuticals has drawn up a list of 56 APIs to prioritise them for the Make-in-India initiative. These include APIs or bulk drugs that go into the making of essential drugs, such as antibiotics, anti-HIV medicines, and the humble but indispensable paracetamol. The plan to make APIs in India has been in the works for some time but the Council of Scientific and Industrial Research (CSIR) was engaged only recently. Letâ??s see how these steps taken by the government help to promote the production of KSMs and APIs in India in the coming years.



India imported APIs and bulk drugs worth ~Rs 377 billion in 2023-24, accounting for ~35 per cent of its total API requirement, of which China accounted for ~70 per cent. Moreover, dependence on Chinese imports of APIs for certain essential medicines is as high as 80-100 per cent. Almost the entire requirement of certain fermentation-based APIs like ciprofloxacin and norfloxacin is sourced from China. The cost advantages with the Chinese API industry and the volatility in the prices of APIs have made domestic production of certain APIs unviable for Indian manufacturers, resulting in continued dependence on China. Even where APIs are manufactured locally, KSMs are primarily sourced from China. The Chinese API industry, which accounts for ~40 per cent of the global requirement, is supported by higher economies of scale, subsidies, and fiscal incentives offered by the Chinese Government, along with lower power, fuel, and borrowing costs.

The rating agency ICRA noted that the overall API market in the country is about Rs 1100 billion with domestic sales at Rs 725 billion and exports touching Rs 375 billion to both semi-regulated and regulated markets (comprising trade supply and contract manufacturing). API exports from India have grown at a CAGR of 7.7 per cent over 2018-19 to 2023-24. Region-wise, exports are fairly diversified with Europe being the highest contributor with ~19 per cent share, followed by USA at 9 per cent.

India, one of the major producers of APIs or bulk drugs in the world, has imported Rs 353 billion worth APIs and bulk drugs in 2021-22 and also exported bulk drugs/Drug Intermediates (DIs) worth Rs 333 billion in 2021-22. The imports of APIs for 2022-23 touched Rs 362 billion.

The Centre for Market Research & Social Development in its report pointed out that in the global API market, China is the undisputed leader, as volume wise China produces approximately 20 per cent of the world's API production. China manufactures over 2000 APIs and exports them. The percentage of API imports from China has spiked from around 1 per cent in 1991 to about 70 per cent in 2019. A study conducted by PwC shows that 50 per cent of the critical APIs are being imported and almost all the imports are from China. Domestically produced APIs cover approximately 50 per cent of the total quantity. However, KSMs for most APIs are still sourced from China.

It may be noted that in the early 90's, India was among the leading producers in API category. However, over a period of time due to many changes in the manufacturing policies and regulations and with decreasing margins and stringent environmental norms, the Indian pharmaceutical manufacturers cornered themselves from the API manufacturing and it resulted in the closure of many pharmaceutical companies. During the same period, China strengthened itself in the API sector. Today, India, which was among the leading manufacturers in the API once upon a time, now imports more than 70 per cent of the API and intermediates from China and this is truly a matter of great concern.

Government's support

To make the country Atmanirbhar in APIs and bulk drugs, drug intermediates, the government has declared "2015 as Year of API". The Department of Pharmaceuticals is implementing three schemes by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries.

1.The Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical KSMs/ DIs and APIs in India, with a financial outlay of Rs 6,940 crore and the tenure from FY 2020-2021 to FY 2029-30, provides for financial incentive for 41 identified products. A total of 48 applications have been selected under the scheme. Out of these, 27 projects

have already been commissioned with the installed capacity of 41,881 metric tonnes.

The government has received a total 249 applications across all four categories of products. Out of these applications, 48 applications have been approved with committed investment of Rs 3,938.57 crore and expected employment generation of around 9,618 persons. With the successful implementation of this Scheme, it is expected that in the coming years, the import dependence in the notified bulk drugs will get reduced over the implementation period of the scheme.

The scheme provides for financial incentive for six years to eligible manufacturers of 41 bulk drugs on their incremental sales over the base year. For fermentation based eligible products, rate of incentive for the first four years (2023-2024 to 2026-2027) is 20 per cent, for the fifth year (2027-28) it is 15 per cent and for the sixth year (2028-2029) it is 5 per cent. For chemical synthesis products, rate of incentive for entire six years (2022-2023 to 2027-2028) is 10 per cent. Industrial Finance Corporation of India (IFCI) Ltd is the Project Management Agency (PMA) for the scheme.

2.Production Linked Incentive Scheme for Pharmaceuticals, with a financial outlay Rs 15,000 crore and the tenure from 2020-21 to 2028-29, provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years. The product category two covers the APIs/KSMs/DIs except for the 41 eligible products already covered under the PLI Scheme for promotion of domestic manufacturing of critical KSMs /DIs/ APIs in India.

3. The Scheme for Promotion of Bulk Drug Parks, approved during March 2020, with a financial outlay of Rs 3,000 crore and the tenure from FY 2020-2021 to FY 2024-25, provides for financial assistance to three States for establishing Bulk Drug Parks. The Department had received proposals from 13 states namely (i) Uttar Pradesh (ii) Tamil Nadu (iii) Telangana (iv) Karnataka (v) Maharashtra (vi) Gujarat (vii) Madhya Pradesh (viii) Rajasthan (ix) Punjab (x) Haryana (xi) Himachal Pradesh (xii) Andhra Pradesh and (xiii) Odisha.

After evaluation of the proposals, Andhra Pradesh, Gujarat and Himachal Pradesh were conveyed final approval in October-November 2022 for creation of common infrastructure facilities (CIF) in the proposed Bulk Drug Parks in these three states, under the scheme. The respective State Implementing agencies (SIA) have indicated completion of these projects within next 24-28 months. An amount of Rs 900 crore has been allocated under the scheme in BE 2022-23 to release the first instalment of Rs 300 crore per state. As on December 16, 2022, first installment of Rs 300 crore were released to the SIA of Gujarat. The Ministry of Chemicals noted that first installment to the SIAs of Himachal Pradesh and Andhra Pradesh will be released, after the receipt of corresponding state shares to the SIA accounts.

In a bid to permanently address India’s dependence on China for APIs, the Council of Scientific and Industrial Research (CSIR) is working with the coal and petroleum industries to generate chemicals that form the main therapeutic components in various medicines. The Department of Pharmaceuticals has drawn up a list of 56 APIs to prioritise them for the Make-in-India initiative. These include APIs or bulk drugs that go into the making of essential drugs, such as antibiotics, anti-HIV medicines, and the humble but indispensable paracetamol. In the first phase, the focus is on about 30 ingredients. The plan to make APIs in India has been in the works for some time but the CSIR was engaged only recently. Manufacturing of 35 APIs, which have been imported earlier, has started production in India. These 35 APIs are among the 53 APIs for which India has 90 per cent import dependence. These 35 APIs are being manufactured from 32 different manufacturing plants.

Besides, the CSIR with other laboratories has developed cost-effective 25 technologies using locally available chemicals for the production of APIs under COVID API Mission and in the process of transferring the technologies to API industries. Mostly processes synthesis are completed for all. Technology transfer is yet to be done. Industries need to come forward. Lack of GMP facility in CSIR is also a gap area.

Meanwhile, continuing to support the growth of the API and bulk drugs sector the government has opened 27 greenfield bulk drug park projects on March 2 this year. Investment of Rs 3,063 crore has been grounded and employment for 2,777 persons has been generated. The sales made by the commissioned projects is worth Rs 817.33 crore which includes exports of Rs 252.62 crore.

Steady growth

ICRA noted that the Indian API industry is expected to see 7-8 per cent CAGR over CY2023–CY2029 driven by steady growth in the formulations industry, which in turn will be aided by an increasingly geriatric population, growing prevalence of chronic

diseases, and rising contract manufacturing opportunities due to initiatives by export customers to diversify supply chain dependence on China to alternative destinations. At present the Indian API industry is highly fragmented with ~1,500 manufacturing facilities and several small and unorganised players in the field owing to low entry barriers. The Indian API industry contributes ~25 per cent to the Indian Pharma Industry by value. India is the third largest API manufacturer globally in terms of volume, after the US and China.

Sharing his views about the role of Foreign Direct Investment (FDI) in API sector **RK Agarwal, National President of the Bulk Drugs Manufacturing Association (BDMA)**, said “The API sector in India is experiencing a surge in investments from both domestic and international players, reflecting the growing confidence in the country's pharmaceutical industry. FDI plays a significant role in this context, as it is permitted under the automatic route in the pharmaceutical sector up to a specified limit. This has led to several overseas investment companies acquiring substantial stakes in fast-growing Indian pharma companies, signaling their increased interest in the market.”

Agarwal further pointed out that the trend is not one-sided. Indian companies are also actively acquiring stakes from overseas investors, showcasing a reciprocal interest in global collaboration. A notable example is Mankind Pharma, which has been involved in acquiring reputed brands from multinational corporations. Similarly, Dr. Reddy’s Laboratories has made strategic acquisitions of brands from global giants like Novartis and Sanofi. These investments highlight the dynamic nature of the API sector, where both domestic and international players are keen to capitalise on the opportunities presented by India's growing pharmaceutical market. The influx of FDI, along with strategic acquisitions, is helping to strengthen the sector's global competitiveness and fostering innovation and growth in the industry.

“We are very much positive that the Indian API sector will definitely become self-reliant and slowly will reduce its dependence on China for its KSMs and APIs. The central government had also initiated various steps and even announced to provide incentives to manufacture more than 55 APIs and KSMs under the PLI scheme. Though we are still at the nescient stage to take advantage of all these initiatives, but I am confident that with the infrastructure, talent pool, new advancements and technology, Indian industry will definitely reach to the level of a major API global supplier in the coming days,” said **Raja Bhanu, Director General of Pharmaceutical Export Promotion Council of India (Pharmexcil)**

Outlook

The Indian API industry has been struggling for a long time because of high dependence on China, which accounts for the bulk of the total imports. Because of this, API prices have been very volatile and we have seen prices of APIs going up by more than 100 per cent in the recent past. High dependence on a single source can have a significant adverse impact in emergency-like situations. In the context of the recent coronavirus outbreak, it has the potential of disrupting supplies of essential medicines, resulting in price volatility and ultimately leading to a situation where medicines are not available for patients. It is time for India to revive its domestic API industry, which has been deeply affected because of policies such as stricter implementation of pollution control norms, implementation of DPCO, 2013, lower import duties, and complete collapse of the indigenous fermentation industry.

As pointed out by PwC, India needs a holistic and conducive ecosystem to rebuild its API manufacturing capabilities, which would require favourable policies from the government and a supportive financial ecosystem to boost private and foreign investment. In the immediate term, pricing policy, along with some financial incentives and faster approvals on environmental clearances, can give a required boost to the API industry. In the slightly longer term, the government may look at the Chinese model and work on developing clusters for API and fermentation, along with looking at ways to encourage alternative sources. The Indian API market is on a promising trajectory, driven by government support, increased domestic production, and a growing demand for pharmaceutical products.

However, the stringent regulations for drug approvals, various drug price policies in the country, and high competition among API manufacturers are expected to hinder India's API market growth.