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India's Dependency on China for APIs: Why and How?

DR. SANJAY AGARWAL

INDIA is well-known for relying extensively on imports of API (active pharmaceutical ingredients) to manufacture pharmaceutical products. There has been growing pressure to minimize this reliance by focusing more on indigenous production. China is currently the world leader in API production and export, accounting for over 20% of worldwide API production. This is due to lower utility costs and more government backing, and India imports some of the most potent APIs from China, such as paracetamol.

India is the most reliant on China for API imports of any country, while national initiatives to boost indigenous production methods remain on paper. The most fundamental component or building block of a drug is the API. For example, the main medicinal ingredient in Aspirin or Crocin is acetaminophen or paracetamol.

The list of 38 notable APIs is likely to include pharmaceuticals produced through fermentation. It consists of the antibiotics penicillin, amoxicillin, ampicillin, tetracycline, and vital vitamin and hormone supplements. China leads this market all over the world.

"It's fascinating to see how the Indian pharmaceutical business has progressed." If we follow our path back to the early 1990s, India was self-sufficient in formulations and API production. However, we have undergone a dramatic transformation in the last two decades. And, take a look at the change; currently, China provides the majority of our API,"

Most API manufacturing plants are only operating at 30% of their capacity in India, compared to 70% in China. It is now widely acknowledged that India has already lost its API production base to China.

Complex API market

Due to the low-profit margin on APIs, Indian pharma makers see importing APIs, preparing formulation medications, and exporting them as viable options. "The three variables responsible for over-dependence on Chinese imports are wage cost, infrastructure facilities, and tax incentives.In terms of wages and labor costs, India still has an advantage because China's GDP is around 5-10 times ours. "This automatically raises the cost of their labor." says experts.

According to the latest numbers from the Directorate General of Commercial Intelligence and Statistics, China accounted for 66.69 percent ($1826.34 million or 13,107 crores) of all bulk medicines and drug intermediates imported in 2016-17, out of a total of $2,738.46 million (19,653.25 crores).

In 2017-18, India imported $2,993.25 million worth of bulk pharmaceuticals and intermediates, amounting to Rs 21 481 crores, with China accounting for 68.36% ($2,055.94 million or Rs 14, 755 crores). In 2018-19, Chinese imports remained at 67.56 percent ($2,405.42 million or Rs 17, 263 crore), accounting for $3,560.35 million or Rs 25, 552 crore of total Indian imports. In addition, from 2016-17 to 2018-19, India's reliance on imports increased by 23%.

The Ministry of Chemicals and Fertilizers' Department of Pharmaceuticals (DoP) stated that Chinese imports are due to economic factors, indicating that Chinese imports are cheaper and more cost-effective for pharma makers.

In the event of a contingency, such as the most recent one, lakhs of Chinese facilities remained closed for up to two years to improve their environmental compliance. Uncertainty loomed large over whether smaller Chinese units unable to comply with stricter norms would reopen; India looked to other sources for import, such as the United States, Italy, Singapore, and Hong Kong. However, when APIs are imported from countries, there is always the risk of a sudden increase in completed pharmaceuticals.

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Chinese API market and India's over-dependence

With China's pharmaceutical industry becoming more competitive, Chinese pharmaceutical products are making quick progress in the global market, propelling China to become the world's largest manufacturer and exporter of active pharmaceutical ingredients (API). Industry experts estimate that China and India produce more than two-thirds of all active pharmaceutical components, with China accounting for the lion's share.

According to a recent analysis issued by commerce minister Suresh Prabhu, India imports almost 80% of APIs from China. This is even though the cost of producing APIs in India and China is comparable. India presently imports roughly $3 billion worth of APIs, intermediates, and other chemicals from China. This represents over 80% of the country's annual API requirements.

"The cost of doing business in India and China is highly competitive, with only a 3% differential in labour costs; the remainder is competitive with the Indian market." According to the study, even though material, depreciation, and indirect human costs are the same as in India, imports (of APIs) from China are on the rise.

According to the study, the increase in imports attributes to the following factors: "They (Chinese enterprises) have tremendous capacities built up by the government and are now handled by the private sector." There is also significant bank assistance in the form of low-interest loans. Compared to our plants, they also have more freedom regarding pollution standards and effluent treatment."

"The majority of the reliance is on drug intermediaries, and the Chinese have an advantage in capacity. Another critical concern is India's lenient approach to granting Chinese product registrations. Approval of Indian products takes two to five years in China, and acceptance of Chinese items takes two to five months in India. All of this adds up to a cost difference.

The report says that if an intermediate product is offered at a cheaper cost, the producer will accept it. Concerned about the country's reliance on Chinese APIs, the Centre intends to promote API manufacture in India. Indian pharma companies, on the other hand, continue to find API imports from China to be more cost-effective.

According to an expert, the Chinese government has taken decisive action against several of its API manufacturing plants due to pollution issues in the recent 4-5 months. "As a result, the price has gone up." However, Indian industries remain reliant on China for API imports."

While India's medicine manufacturing sector has a 75 percent or higher utilization rate, API manufacturing facilities have a lower rate. "The majority of regions have a rate of less than 50%. Lower capacity utilization means lower profit margins, and most facilities in India that cater to local markets operate at 30-40% capacity utilization on average, according to the report.

China has built a system for supplying raw materials to small-scale producers from within the industrial estate, the capacity utilization of Chinese API facilities is over 70%. "In the United States, it takes at least one year to establish an estate and manufacture raw materials, however in India, it takes three years or more to build an estate/factory for raw materials," according to the report.

The API market in China

Due to technological solid capability and fermentation, China enjoys a leading position in the worldwide API market due to its large-scale manufacturing capabilities, cost-effectiveness, and abundant availability of commodity bulk medicines and intermediates. The country's bulk medicines market has grown dramatically and is now fully diversified, with over 7,000 API manufacturers.

China is the world's second-largest pharmaceutical market, with sales expected to increase

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China produces about 2000 API items

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by 9.1% annually from $108 billion in 2015 to $167 billion by 2020. China's API market is expanding quicker than the rest of Asia, and it is predicted to grow at a 17 percent yearly rate from now through 2018. By 2018, China's API market, which is currently worth $7 billion, will be worth over $18 billion. According to the China Chamber of Commerce for Import & Export of Medicines and Health Products (CCCMHPIE), some MNCs use a vertically integrated strategy for their essential goods, from APIs through formulations. In contrast, others choose to buy APIs from outside.

Shortly, the Chinese API industry will grow faster and continue to transform. Latecomer advantages are gradually establishing new competitiveness, with peaceful environment variables outweighing production costs and policy benefits. The industry is more oriented toward mid-to-high-end market expansion than mid-to-high speed growth; Low-lying land for innovation is progressively taking shape, as is an Open Innovation System. Changes in the disease spectrum, public medical needs, and the new round of health reform; Internet plus and reshaping of the value chain; and Implementation of the "Belt and Road Initiative'' Health-related policy reform driven by both industry needs and external pressure; Changes in the disease spectrum, general medical conditions, and the new round of health reform.

GMP certifications are becoming increasingly common among Chinese API manufacturers. However, many Chinese API manufacturing plants continue to have significant quality issues. Independent audit organizations have investigated hundreds of API production sites in China for misrepresentation or fraud. The quality and safety of the products are essential concerns. Many APIs are synthesized in the United States using unregulated bulk chemicals, some of which are not pharmaceutical quality.

China is now the world's largest producer and exporter of APIs. China produces about 2,000 API medicinal items, with a capacity of over 2 million tonnes per year. It appears to have surpassed India as the world's top API exporter, with Chinese API makers supplying a significant portion of the Indian market. Like their Indian counterparts, Chinese manufacturers are shifting away from API production and toward FPPs (Finished Pharmaceutical Products), owing to the low-profit margins associated with APIs. China also imports a significant amount of APIs for domestic formulation.

China's government is cracking down.

The Chinese government's assault on polluting industries, particularly API makers, has left the Indian pharmaceutical business in the lurch, with API prices skyrocketing in recent months. The Indian pharmaceutical industry is reeling from the sudden increase in API prices, as the country is primarily reliant on APIs imported from China to manufacture medicine formulations.

According to media sources, the costs of several APIs in India have risen by 45 percent in the last four months. API prices have increased significantly in many situations, increasing even more if the scenario continues.

Despite repeated requests from the industry over several years to correct severe flaws in the regulatory framework that threaten the sector's ability to manufacture APIs in India, the Indian government has shown no haste to act. Given India and China's highly fragile geopolitical relationship, the country now faces a more dangerous scenario. If a problem escalates to the point where China decides to stop exporting APIs to India as a punitive action, the impact would be terrible for the country. The industry would be unable to obtain these essential raw materials from other sources, which could lead to a significant scarcity of life-saving pharmaceuticals in the country. ❍

(The author is leading pharma consultant)