Import of key raw materials for APIs from China: Challenges

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INTRODUCTION

India's main worry today is the dependence of the country's pharmaceutical sector on China for many of its Active Pharmaceutical Ingredients (APIs) and intermediates has only increased over the years with no serious efforts from government or industry to intensify production of APIs.

Currently, India is importing often 80 per cent of the country's annual requirements of APIs. Any action by China to prevent export of APIs and other raw materials to India on account of border conflict would be disastrous because the industry does not have any alternate sources to acquire these basic raw materials. This means that production of several essential and lifesaving drugs required within the country is going to be in trouble. Currently, India is importing even many common drugs like aspirin, paracetamol, metformin and erythromycin.

Companies have chosen India as a sourcing destination for several years, Thanks to India's lower cost structure for manufacturing, labour, materials and equipment. India possesses an outsized talent pool of chemical engineers and scientists and a large manufacturing capacity focussed on regulated markets. China also has talented scientists and engineers, a coffee cost base, far better infrastructure than India, an improving GMP and patent protection environment.

Further, China has quick access to good sort of intermediates and chemicals. For fermentation-based APIs, steroids, intermediates and lots of base chemicals, China leads and has overtaken India.

India has been producing most of the APIs required within the country but, the value of production of APIs accustomed to be quite high due to low scale of operations and high power and labour costs. Low returns and stringent environmental regulations had also discouraged API producers within the country. It's at this point; China emerged as a producer of APIs with huge capacities and lower cost of production. This example motivated Indian pharma industry to import APIs from China which led to the gradual decline of API sector within the country.

The Central government realised the danger of total dependence on China for all the country's requirements of APIs for a few time. Now, Pharmexcil has decided to line up an innovation desk with the target to market import substitution and help the pharmaceutical industry to avoid excess dependence on API imports. What's extremely urgent is to explore sources of essential APIs in other parts of the planet to satisfy any emergency situation.

Challenges

1. Quality

Some Chinese API companies are found guilty of not following established manufacturing processes also as data recording, as guided by the USFDA, from time to time. Thus there are frequent recalls by customers using Chinese APIs. Recent worldwide recall of vital sign drug Valsartan may be a case in point as one API sourcing from China led to US recalls by quite 10 formulation manufacturers.

In another incident, number of children's vaccines were revealed to be faulty, putting an unknown number of infants in danger. These kinds of lapses have led to frequent USFDA inspections and increased number of warning letters to Chinese plants with restriction on new approvals and rendering the plants unviable.

While the complexity of the pharmaceutical staple supply chain has increased in recent years and a greater percentage of staple production is now outsourced to companies in emerging markets, overall staple quality and reliability has increased. This news is substantial, because any variation within the quality of raw materials – whether chemical starting materials or glass vials for final product packaging – can have an immediate impact on product yields, costs, regulatory submissions, availability and most significantly , patient safety.

Specific requirements and expectations should be outlined in quality agreements and supported deep knowledge that the drug manufacturers have gained about their processes and therefore the staple properties which will influence critical quality attributes. Manufacturers should even have comprehensive staple management strategies in situ that include risk assessments, segregated receiving and handling areas, release testing protocols, supplier audits, communication systems and therefore the quality agreements mentioned above. One challenge is that the lack of any standard requirements for staple management. Industry groups just like the BioPhorum Operations Group (BPOG) are watching this issue.

2. Cost Factor

In the case of wage or labour cost, India still has a plus because the GDP in China is about 5-10 times more. This automatically makes their labour costlier. The cost of production in India for API is higher and so it hampers the export competitiveness of products. Because the price of products in China increases, this negatively affects profit margins for Indian companies.

3. Availability & rate fluctuation

The regulatory enforcement and factory closures in China have led to a rise in staple cost and inventory lead times. Regulatory enforcement had the most important impact on smaller players causing a shutdown for many of those players. This has effectively shifted supplies to a couple of select large producers with higher minimum order requirements. Likewise on the wages front, China gained a lot in its development at which demand for labour starts to grow faster than supply thus creating labour shortages and pushing up the worth of labour.

4. Government policy

It was a troublesome call when government decided to withdraw the Customs duty exemption on import of 73 bulk drugs as import of those low-cost key APIs/raw materials which were mostly from China, was helping Indian formulation companies, or may be the entities that make syrups, tablets, injections and so on remain competitive. A rise in medicine prices because of rise in input costs would be unpopular as imports included raw materials which were used to make life-saving medicines for critical illnesses like cancer and HIV/AIDS. Whilst India's dependence on imports is considerable, policies formulated by the government to attenuate an equivalent have remained only on paper.

Also China have several government funding options also as tax incentive schemes unlike we have it here in India. If China takes about six months to line up the factory and produce raw materials, India, on the opposite hand, takes about six years to create a factory for the assembly of raw materials. Indian API industry features a complex licence renewal system and wish to approach various authorities for the renewal of application.

5. Dumping duty

The authority considers it necessary to recommend imposition of a definitive protective tariff on imports of subject goods from the topic country for three years. India imports most of its raw materials for medicine from countries like China, Germany, the US, Italy and Singapore. A minimum of 41/100 Chinese goods are suffering from the protective tariff in India.

Obligation to pay anti-dumping duty on import of certain APIs is yet one more burden exporters need to bear with the abolition of advance licensing scheme. Also Commerce Ministry had imposed different rates of this duty on several APIs over the years to guard the domestic API sector.

6. Environment

An environmental overhaul initiated by the Chinese government against polluting industries has led to the closure of the many factories producing chemicals, intermediates and APIs. Many API companies are unable to suit the stricter regulations because their plants are old and upgrading is unjustified for low margin products. The value of creating a longtime API plant compliant with new regulations has also gone up significantly over the years.

The crackdown initiated at a specific factory can cause disturbance within the value chain that included intermediate and API players. The Chinese government has made it mandatory for chemical plants to work from only those chemical parks that have complied with stricter environmental norms. As of now, only ~45% of the entire parks are compliant, which means major plant shutdowns or relocations, going ahead.

Additionally, restrictions like prohibition of chemical production within a kilometre of the Chang Jiang (the world's third-longest river that flows through nine provinces of China), environmental tax (imposed in January 2018) and specific emission norms (implemented in July 2018) have added to the woes of API players in China.

7. Others

API Industry would not be enough to free the pharmaceutical industry from ongoing problems. Lack of research and development may be a larger problem than the absence of an API Industry. Ideally a world level drug company needs 15-20 acre of land to line up a factory. But no company has been allotted quite 10 acre of land at the under-construction tract.

As per the provisions of the Drugs & Cosmetics Act, API manufacturers supplying bulk drugs to Indian exporters need to register with Drugs Controller General of India. But, unregistered manufacturers of APIs supply their materials to exporters under the advance licensing scheme. Exporters thus stand to lose export orders worth several crores of rupees as they cannot procure raw materials from unregistered suppliers for export purpose.

Conclusion

There are reports from various quarters which suggest that China will take another 5-6 years to compete, if not overtake, Indian formulation business. We, therefore, got to be prepared and plan a roadmap to build up our pharma industry. But, given the historical unstable political relationship with China, is it risky to be overhooked in to China for API? With the present environmental issue aggravating things all across China, thousands of staple factories are forced to pack up. Besides, Chinese regulatory and economic relations with the US may sour further because of the US-China trade war. This might end in the embargo of Chinese products directly or indirectly. So, self-reliance for Indian pharma industry is completely the necessity to sustain and lead.

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