Reviving the idea of API in Indian market

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APIs or Active Pharmaceutical Ingredients industry has been in the headlines after the outbreak of Covid 19. In this recent outbreak, many companies are up on the updates to challenge the issue that Indian society may face in recent times. Is India strong enough to manufacture and build its products and end to end means! A matter of question has hindered the mindful of scholars who time and again believed that India is never smart with the complete processing of the API in the country. Therefore, an independent study took place to understand the challenges that the API industry may face and interventions that require a revival in the industry.

Dependency on China for APIs has been an ongoing concern for the Indian Industry

Depending on a country like China for API has been an ongoing concern for the industry. The outbreak has impacted at large. APIs have built an important segment in Indian pharma industry, contributes to 35% of the market share. The differences have disrupted the Indian pharmaceutical industry, impacting the large supply of APIs in the market. The percentage of API imports from China has spiked from around 1% in 1991 to around 70% in 2019. In the recent past study, a steep increase in the actual market price of some of the APIs has been imported from China.

Currently, the situation has aggravated its potential lead, which is the price of volatility and impacts on the export for most pharma companies. It has ultimately resulted in essential medicine, which has become unaffordable and often considered inaccessible to the people. The analysis on the critical aspects of the API shows that;

- There is an increase of 50% of the APIs which are now being imported. All these imports are made from China.
- Domestically produced, the API tends to cover around 50% of the total quantity. Hence the key to start the materials for the majority of the APIs are sourced from China.

The Chinese API industry has an advantageous position because of the economics of scale and support from China. The Chinese Government, in the form of financial incentives and infrastructure, has regulated policies. It includes;

- It has lowered the Capex requirement due to the large special economic zones (10-15 times of the Indian SEZs).
- It lowers the borrowing costs, which is 5-7 % compared to 11- 14% in India.
- It lowers the conversion costs like labour and electricity costs in China which are relatively cheaper in comparison to India.

The manufacturers of the Indian APIs have lost the competitive edge at the lower end of the spectrum. It is the fermentation technology for the countries like China.

- The strict implementation of the pollution control norms leads to a higher cost of manufacturing APIs in the Indian market.
- The issue of the interpretation of the Drug Price Control Order (DPCO) in the year 2013
- No financial incentives are present like lower tax, land subsidy, and even cheaper utility to the lower Capex requirements.
- There is a lack of large scale mega parks for the manufacture of bulk drugs.
- The collapse of the fermentation industry in India.

What does India need to revive the Indian API Industry?

The Indian market needs a holistic and conducive ecosystem. This will capitalise the fullest of the potential of the APIs to manufacture the capabilities, which includes some sort of immediate term intervention and long term costs as well.

As an immediate effect, providing a faster environment clearance is important. The approval of the process comes down to two months from the current process timelines that of 4-6 months.

It gives a total category capacity, an additional clearance that is not required as long as the pollution load is not exceeded. In the deep sea, discharge norms that it is to be in line with unsurpassed global practices.

It is important to encourage manufacturing by the fiscal stimulus. The APIs intermediates provide 12% of the subsidy on the overall production value, including a minimum of the investment value and production value by the third year of the operation.

Offering 30% of the subsidy has an overall production value that has a minimum threshold for both investment and production value. The fiscal incentives offer under electronic policies like wage reimbursements, capital subsidy and even electricity.

The accommodative formulations are priced under the different units, which could be excluded from the price control. The immediate upward revision of the price cap has impacted the formulations at a significant API price increase.

On a long term plan:

- There is a development of 2-3 large range of clusters and offering plug-play infrastructural support in the dedicated zones to manufacture the APIs in India.
- It is encouraging industry-academia initiatives.
- It also facilitates the alternative source to import by offering additional incentives.

Facilitating alternative sources of import is crucial for India

For the APIs and the intermediates of the higher strategic importance, the manufacturers are domestic, and the lack of raw material is a concern. Therefore, the Government of India must adopt alternative ways of success. It helps in initiating the promotion of import of the intermediate. The APIs are multiple sourced to reduce the monopoly in the imports. An additional 10% of the subsidy can be provided if the imports are sourced from China.

Conclusion

The Indian API industry has been struggling for the long term. It is because of the high dependency on China. The accounts for the bulk of total imports made from China were noteworthy. The price of API price has been volatile and seen prices of APIs, which is going to 100% in the recent past time. The higher dependence on a single source is of a significant adverse effect.

If India wishes to be completely free, then a lot many changes are to be brought in the system. To revive our domestic API industry, it should deeply affect the policies like the strict implementation of pollution control, Implementing DPCO, lowering the cost of import duties and a complete collapse of the indigenous fermentation industry. In the longer term, the Indian Government may look at work as per the Chinese Model to develop the clusters for the APIs and fermentation that needs to be encouraged; otherwise, India will fall massively on producing APIs all alone, which is impossible.

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