

SELF-RELIANCE ON API

OPPORTUNITY FOR INDIAN PHARMACEUTICAL INDUSTRY AMID COVID-19 CRISIS

MAY 2020





Coronavirus has brought the entire world to a standstill having far reaching consequences beyond the spread of the disease. It may cause the largest global recession in history with nearly half the world in a lockdown situation affecting various business sectors, stock markets, supplies, logistics, etc. Major economies such as US, EU, China and UK have been badly affected. The economic fallout could be prolonged beyond the period of the pandemic. The effort to rebuild economies would be at an enormous scale across the world.

With probable rising geopolitical tensions of China with developed economies, India can leverage its role and capitalize on the opportunity to serve the world with API and intermediates products. It is certainly an opportune time for India to strategically evaluate on not only becoming self-reliant in API but also export largely across the globe in the next 5-10 years.



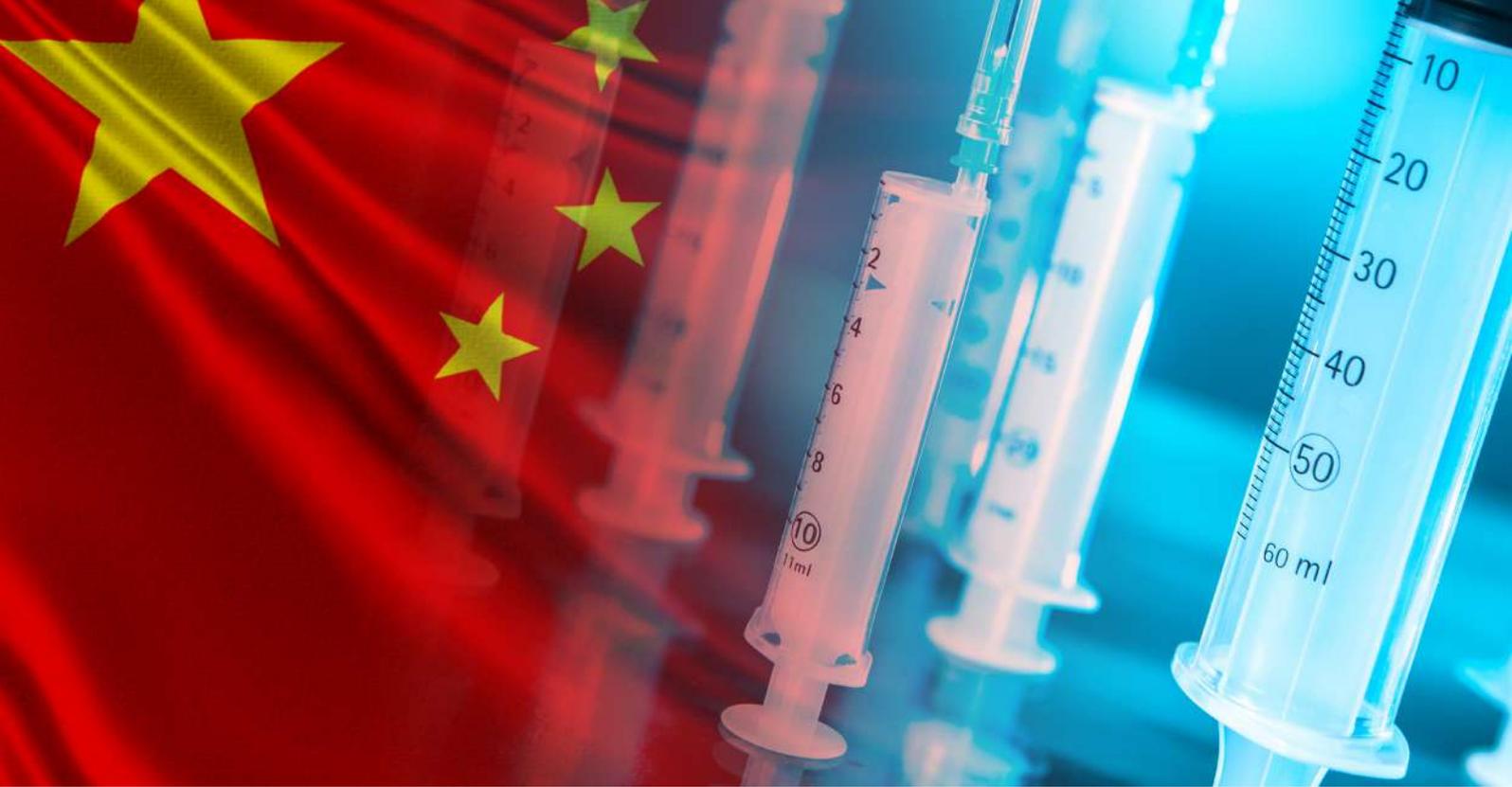
EFFECTS ON GLOBAL PHARMACEUTICAL INDUSTRY

China has found itself facing global scrutiny due to the pandemic erupted in Wuhan and their delay in alerting the world community. Coronavirus has caused a host of problems in the global pharmaceutical supply chain especially China. China, being the epicenter of the Coronavirus outbreak is the world leader in manufacturing the building blocks of the drugs i.e. Active pharma ingredients (API). Logistics and transport have been severely affected. This has led to a high imbalance in the supply and demand of pharmaceuticals. Less availability of manpower has led to a decrease in productivity and capacity utilization in the pharmaceutical industry.

This has had a cascading effect on the pharma industry (formulations). Economies such as India, US, etc. who

are heavily dependent on China for a host of APIs, Key Starting Materials (KSM) & raw materials to develop their formulations for exports / domestic consumption have been affected.

However, China is on its way to recovery and closed factories are gradually resuming operations but other countries such as India, EU, US etc. are facing the heat in terms of supply shortages due to internal logistics issues and resulting in increasing prices. Countries would be a bit conservative in terms of importing larger requirements from China. India is the next biggest pharma market with major focus on formulations and manufacturing various API.



CHINESE PHARMACEUTICAL INDUSTRY – A LEADER IN GLOBAL API PHARMACEUTICAL MARKET

According to the UK regulator, the Chinese continue to dominate the API industry in the world with a share of 55%¹ of the global manufacturing output. Companies such as Nanjing, Zhejiang Hisun Pharmaceutical Co. Ltd are the largest manufacturers and exporters of APIs worldwide. Chinese are also keen on focusing on developing formulations & next generation drugs - Biosimilars, Biologics, etc. They are focusing on investing in cold processing and continuous processing technologies in manufacturing.

Initially, the Chinese pharma industry was not competitive as compared to other players, but the Chinese government has played a very strong role over the years. About 20 years back China was behind India in API manufacturing and currently, they are the global market leader in API segment

Key initiatives taken by China:²

- Chinese Government collaborated with private sector companies and provided acres of land for bulk drug parks (up to 10,000 acre), very low-cost utilities (water supply, electricity) initially for bulk drug manufacturing and many incentives
- Cheap cost of capital – Provision of various subsidies, incentives. Production cost is 20-30%³ less as compared to India

- Environmental regulations in China are not very stringent as compared to other countries
- Manpower availability and higher productivity
- China has worked very hard in terms of qualifying sources of raw materials for API manufacturing especially US, European Medicines Agency (EMA) which is time consuming with tough compliance measures. They have accordingly developed their manufacturing base
- China is a member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). Pharma regulatory procedures are streamlined as per international standards
- With time, they developed higher productivity resulting in economies of scale and hence provide highly competitive costs

KEY TAKEAWAYS

- **GOVERNMENT OF CHINA HAS PLAYED AN IMPORTANT ROLE IN ENSURING ITS CURRENT STATUS AS A WORLD LEADER IN MANUFACTURING API & RAW MATERIALS**
- **CHINA HAS PROVIDED CHEAP COST OF CAPITAL, INCENTIVES & SUBSIDIES TO MANUFACTURERS**
- **THEY ESTABLISHED A STRONG BASE OF QUALIFIED RAW MATERIAL SOURCES FOR MANUFACTURING AS PER US OR EUROPEAN GUIDELINES**

1 [Economic Times](#)

2 Primary research

3 [HA Asia India still depends on China](#)

INDIA'S DEPENDENCE ON CHINA AND ITS EFFECTS

India's pharma industry has been valued at ~USD 38 bn⁴ in 2019 and the domestic pharma market valued at ~USD 20 bn⁵. Currently, India is one of the largest exporters of generic formulations worldwide (especially to the US) accounting for 30%⁶ of the global export volumes. In terms of API, India is the third largest manufacturer in the Asia Pacific⁷.

However, the paradox of the Indian pharma industry is that it imports majority of API / Raw materials & KSM from other countries majorly in China. **In 1991, India imported only around 0.3%⁸ of their pharma imports from China. Chinese imports accounted for at ~68% (USD 2.4 bn) in 2018-19⁹ of their import requirements. India is heavily dependent on imports from China for certain raw materials, majorly Fermentation based API formulations such as crucial antibiotics penicillin, amoxicillin, ampicillin, tetracycline Ofloxacin, Levofloxacin, Metronidazole, etc. Many of these are listed** under India's National List of Essential Medicines (NLEM) which are priority health needs of the country's population and addressing major disease burden.

Coronavirus pandemic has hit India's pharmaceutical

4 IPA - Indian Pharmaceutical Industry - The Way Forward

5 IBEF, February 2020

6 Pharmexcil

7 [Pharmabiz - API largest Segment of Indian pharma market](#)

8 [European Pharmaceutical Review](#)

9 [PIB.Gov.in](#)

sector due to a rise in API prices (doubling or even tripling of prices) for Vitamins, Penicillin G, Paracetamol intermediates etc. According to Pharmexcil, the cost of paracetamol escalated from Rs 250-300 kg to 400-450 kg and there was a 70% increase in the cost of antibiotic Azithromycin etc.

Price rises are attributed to the closure of certain API factories /set-ups in China, supply chain disruptions due to lockdown, inter-state transport challenges, unavailability of workers, etc. Manufacturing units of various companies are operating at lower capacity utilization (average of 40%)¹⁰ and some units are not operational due to low attendance owing to lockdown.

This disruption has had some cascading effects on India's pharma exports and has affected the countries dependent on India. Fearing decreased supplies from China, In March, DGFT had restricted exports of 26 bulk drugs & its formulations¹¹ for a temporary period leading to a lot of inconvenience for exporters in the form of penalties, blacklisting, all order cancellations, etc.

Even though the situation is now improving following resumption of manufacturing in China and relaxation of production guidelines in India, inter state movement restriction is causing bottlenecks resulting in price rise.

10 Primary Research

11 [Economic Times Article](#)





IMPORT DEPENDENCY ON CHINA

Dependency on China for imports of API has been mainly due to economic considerations and lack of govt. support. India like EU and the USA is dependent on China for supply of basic raw materials, Key Starting Materials (KSM) and certain APIs. It is not just India even the US and EU are also heavily dependent on China and are currently affected by the overdependence.

Chinese Expertise in chemistry

- Largest manufacturers of basic raw materials and KSM
- China developed proficiency in API development over the years. They manufacture over 2,000 types of API and supply globally (India lacks large-scale fermentation capacity)

High cost of manufacturing in India

- Cost of API manufacturing is high in India due to inadequate government support
- Higher cost of capital and consumables resulting in lower margins for API

Tougher norms & approval delays

- Delay in environmental clearance (tighter environmental regulations in India as compared to China). In India, the API sector is identified as one of the top 18 industries as highly polluting¹²
- Land acquisition is not easy in India and takes 1-2 years as compared to 6 months in China
- Multiple complex approvals for plant set-up and environmental clearances(2-3 years for API set-up in India as compared to 1 year in China)

12 [Express Pharma](#)

Key factors for comparison (India vs China)¹³

Factors	India	China
Overall Set-up & Production cost	India is cheaper by 15-20%	
Borrowing Costs	11-14%	5-7%
Logistics costs	3% of total cost	1% of the total cost
Labor cost	India is cheaper by 40-50%	
Land acquisition	1-2 years	6 months
Setting up a plant for API	2-3 years	1 year
Environmental clearance	1 year	6 months
Ease of doing business ranking (2019)	63	31

¹³ Indian Pharmaceutical Alliance – Way Forward, World Bank, Primary Interviews

In the last 5 years, many Chinese API manufacturers have been shut down due to their failure to adhere to pollution norms which led to supply disruptions and cost escalations. If China restricts its API supply to India in order to focus on formulations, it may adversely affect

Indian pharma players. High dependency on a single supplier for certain APIs, raw materials or KSM is a threat to national security. This has proven to be a wakeup call for India's pharma industry for its excessive dependence on China on many occasions.

“ Some 5-7 years back whenever we visited the CPHI exhibition in India, I could see some Chinese API players with their stalls. However, currently the situation is such that for API they have more stalls than us. Our focus has decreased in API and this is worrying aspect as we are totally dependent on them for some API and intermediates.”

- AGM R&D, Leading Indian Pharma Company

“ India is the third largest manufacturer of API in the world. However, we are lagging in terms of manufacturing raw materials, KSM and some API (Antibiotics) as we do not have the necessary set-up. It is not that we do not have capability and know-how. We are so used to getting low cost products from China, we are not manufacturing these products anymore. Without govt. support and relaxation of norms we cannot compete with China.”

- Global Business Head (API & Formulations), International Business, Leading Indian Pharma company

KEY TAKEAWAYS

- **COST OF MANUFACTURING API IN INDIA IS HIGHER AS COMPARED TO CHINA. GOVERNMENT SUPPORT IN TERMS OF INCENTIVES, SUBSIDIES, LAND, ETC. IS LOW**
- **MANUFACTURING FERMENTATION APIS IS TECHNOLOGY INTENSIVE AND THERE IS A LACK OF INFRASTRUCTURE FOR MANUFACTURING CERTAIN API OR RAW MATERIALS**
- **ENVIRONMENTAL REGULATIONS ARE VERY STRICT IN INDIA ESPECIALLY FOR MANUFACTURING API**





DOES INDIA HAVE THE NECESSARY INFRASTRUCTURE AND CAPABILITIES TO MANUFACTURE API AT LARGER SCALE?

Manufacturing capability – Indian pharma companies have strong manufacturing capabilities and the necessary infrastructure for the formulations as compared to API, KSM and intermediates. They are manufacturing APIs for captive use in formulation development and exporting API to regulated markets. They lack the necessary infrastructure to manufacture certain APIs and intermediates for domestic market (E.g. Fermentation API, Vitamins, etc.)

Quality products – Indian pharma industry has taken strong strides in ensuring high quality standards and high efficacy of medicines at affordable cost. India is largely exporting pharmaceuticals to regulated markets such as US, EU, etc. Over the years, India has successfully faced audits of foreign drug regulators and currently has highest number of USFDA approved plants 665¹⁴ outside of the US

Plant utilization – While the formulation drug manufacturing sector in India has high average capacity utilization, API production facilities have a lower rate. India finds it difficult to compete with China on cost effective local manufacturing of API for domestic market. Most of the API production units in India run

¹⁴ [Business Today Indian pharma industry: From cultural practices to quality intensive; what lies ahead?](#)

at 30%-40%¹⁵ of their capacity. India lacks the efficiency and mastery of Fermentation based API (Vitamins, Antibiotics) manufacturing and hence dependent on imports

Public sector – In the past, public sector pharma companies (IDPL, HAL,) were highly capable of manufacturing API. But following large scale imports of low cost API from China, PSUs have accumulated losses

Manpower – India has a strong pharma & chemical industry manpower with good technical knowhow. Cost of labor is low

KEY TAKEAWAYS

- **INDIA HAS BEEN APPRECIATED FOR ITS QUALITY ESPECIALLY IN PHARMA FORMULATION DEVELOPMENT**
- **FOCUS IS MORE ON FORMULATION AS COMPARED TO API DEVELOPMENT**
- **INDIA HAS THE MANPOWER WITH GOOD TECHNICAL KNOWHOW**
- **PUBLIC SECTOR PHARMA COMPANIES ARE OPERATING AT VERY LOW CAPACITIES AND HAVE INCURRED LOSSES OVER THE YEARS**

¹⁵ [TPCI - API Paradox of India's pharmaceutical Industry](#)

WHAT ARE THE MEASURES THOUGHT OF BY THE INDIAN GOVERNMENT?

In the past, the Government has provided recommendations and in-principle approvals for developing API clusters/parks with various facilities for manufacturing, effluent treatment, power consumption, etc.

Indian government has also developed a draft pharma policy focusing on the promotion of local manufacturing of API / Raw materials through price exemption for resulting formulations for a period of 5 years.

Indian Government has always considered over-dependence on China for API, a threat but most of the self-sufficiency measures have just remained on paper and unimplemented since then.

Following the COVID impact, the Indian government has taken some steps for the creation of a self-sufficient healthcare ecosystem. Government of India have approved the production-related schemes:

- Production linked Incentive scheme for API industry – Department of Pharmaceuticals has proposed to set aside INR 6,940 cr.¹⁶ for development of local API industry (26 fermentation-based drugs and 27 chemical synthesis based bulk drugs and local manufacturing of some medical devices)
- Bulk drug parks - Recently, the Indian government has focused on creating and enabling environment for manufacturing API in India by developing mega bulk drug parks (INR 3,000 cr.)¹⁷ having common facilities for fermentation capabilities, captive power plants, steam, pollution control, effluent treatment, single environmental clearance, etc.
- Department of Pharmaceuticals (DoP) has set-up a technical committee to discuss and provide recommendations for fermentation industry revival, technology development for API production, costing, and strategic business models

¹⁶ pib.gov.in

¹⁷ pib.gov.in

KEY TAKEAWAY

GOVERNMENT HAS ACTED AND ARE NOW FOCUSING ON REDUCING DEPENDENCE ON CRITICAL API & RAW MATERIAL IMPORTS BY INTRODUCING INCENTIVE SCHEMES AND SUBSIDIES FOR LOCAL MANUFACTURING OF API



CAN INDIA ACHIEVE SELF-RELIANCE IN API INDUSTRY?

COVID situation presents a golden opportunity for India to become self-reliant in the API industry.¹⁸

Government support:

- Indian govt. should learn from China that to compete strongly in the domain, continuous support and incentivizing is the key
- In India, it will be essential to provide support in the form of low land cost, a low cost of capital, low utility costs, interest subsidies, incentivized manufacturing, etc. for profitability. Old existing API entrepreneurs can be motivated through fiscal incentives (Capital subsidy, Capex support, Moratorium on loan repayment, etc.)
- Formulation Drugs manufactured with indigenous API should get price relaxations (exemption from Drug Price Control Order)
- Continuous supply of water & electricity
- Implementation of development of bulk drug parks and promoting these at national and international level aggressively

Faster Policy implementation

- Faster review & implementation of pharma policies to boost API production
- Evaluating the relaxation of certain pollution norms for critical API or raw materials if they can be manufactured in existing set-ups
- Increasing capacity of manufacturing plants if the pollution limit is met

Bulk Drug parks

- Identifying new clusters and expanding existing clusters with uninterrupted utility supply, incentives for manufacturing, tax holidays, moratorium period of 5 years, etc.
- Developing common facilities for pollution control, captive power consumption, effluent treatment, and single environmental clearance

Manufacturing select APIs:

- For the manufacture of API, there is a requirement of basic raw materials and KSM. It is essential to

identify these products and identify the critical API for manufacturing. It is essential to develop a manufacturing ecosystem for the same especially for fermentation-based API production

- There is a need to focus carefully on the strict qualification of raw material sources of APIs especially in India to develop robust base for manufacturing
- A technical committee of Department of pharmaceuticals should evaluate the cost of manufacturing certain critical APIs that are currently heavily imported (Fermentation API)

Revival of PSUs:

- Focus on reviving old PSU (provide financial support) to manufacture certain raw materials and API. Hindustan Antibiotics (HAL) has submitted a proposal for manufacturing of fermentation-based APIs which India is heavily dependent on China
- The government can evaluate Public-Private Partnerships for enabling capacity expansions and technical assistance in case of certain API or raw materials

Industry academia collaboration

- Industry player's focus on investment and expansion and research-oriented thinking of academia should be on the same page in order to bridge the gap and strengthen India's case for manufacturing
- Research and development for focusing on green chemistry to look at alternatives or processes for API or raw material manufacturing which have a lower carbon footprint. Focusing on developing technologies for fermentation
- Such efforts are already being undertaken by public sector institutions. For e.g. Production of Penicillin from waste fruits
- Fellowships or research grants can be considered, and focus should be on developing technical capabilities (green chemistry)

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¹⁸ Primary Research

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