



Reviving India's API industry

From the viewpoint of the
COVID-19 outbreak



Executive summary (1/2)

- In the context of the recent coronavirus outbreak, PwC has undertaken an independent study to understand the challenges faced by the Indian active pharmaceutical ingredient (API) industry and interventions required to revive the industry.
- Dependence on China for APIs has been an ongoing concern for the industry and the outbreak of coronavirus disease (COVID-19) in China may disrupt India's pharmaceutical industry by impacting the supply of essential APIs.
- The percentage of API imports from China has spiked from around 1% in 1991 to about 70% in 2019. In the recent past, there has been a steep increase in the actual market price of some of the APIs imported from China.
- In the current context, if the situation aggravates, it can potentially lead to price volatility, impact exports for most pharma companies, and ultimately result in essential medicines becoming unaffordable and inaccessible to people.
- Our analysis based on critical APIs shows that:
 - 50% of the critical APIs are being imported and almost all the imports are from China.
 - Domestically produced APIs cover approximately 50% of the total quantity. However, key starting materials (KSMs) for most APIs are still sourced from China.
- The Chinese API industry has an inherent advantage because of economies of scale and support from the Chinese government in the form of financial incentives, infrastructure and regulatory policies:
 - lower capex requirements due to large Special Economic Zones (10–15 times the size of Indian SEZs)
 - lower borrowing costs: 5–7% vs 11–14% in India
 - lower logistics costs: 1% of total costs in China vs 3% for India
 - lower conversion costs as labour and electricity costs in China are relatively cheaper (an average of 11 US cents/kwh vs 19 US cents/kWh in India)
- Indian API manufacturers lost their competitive edge in the manufacture of APIs at the lower end of the spectrum and fermentation technologies to countries like China, largely on account of factors like:
 - stricter implementation of pollution control norms, leading to higher costs of manufacturing APIs in India
 - issues in interpretation of the Drug Price Control Order (DPCO), 2013
 - no financial incentives like lower tax, cheaper utilities and land subsidy to lower capex requirement
 - lack of large-scale mega parks to manufacture bulk drugs
 - collapse of the fermentation industry in India.



Executive summary (2/2)

India needs a holistic and conducive ecosystem to capitalise on the full potential of its API manufacturing capabilities which can include some immediate-term interventions and a few long-term ones:

Immediate:

- Provide faster environment clearance: The approval process could be brought down to 2 months from the current timeline of 4–6 months. Give total category capacity where additional clearance is not required as long as the pollution load is not exceeded. Deep sea discharge norms to be in line with global best practices.
- Encourage manufacturing by providing a fiscal stimulus:

API/intermediates

- Provide a 12% subsidy on the overall production value of these APIs/intermediates with the following criteria: minimum threshold on investment value (~INR 100 crore) in any greenfield or brownfield project and a minimum threshold on production value (~INR 250 crore) by the third year of operation.

Fermentation products

- Provide a 30% subsidy on overall production value with minimum threshold on both investment and production value. Additional subsidies can also be considered in line with fiscal incentives provided under electronics policy, such as wage reimbursement, capital subsidy and electricity at INR 2/kWh
- Accommodative pricing policy: Formulations under schedule I of DPCO, 2013, which are priced under INR 5/ unit could be excluded from price control. Immediate upward revision of price cap for impacted National List of Essential Medicines (NLEM) formulation because of significant API price increase.
- Financial incentives: Cost of electricity and water to be cut by 50% for 5 years, land to be provided at concessional rate, and infrastructure status to be provided to the industry

Long term:

- Develop 2–3 large clusters and provide plug-and-play infrastructural support in dedicated zones for manufacturing APIs.
- Encourage industry–academia initiatives.
- Facilitate alternative source of import by providing additional incentives.



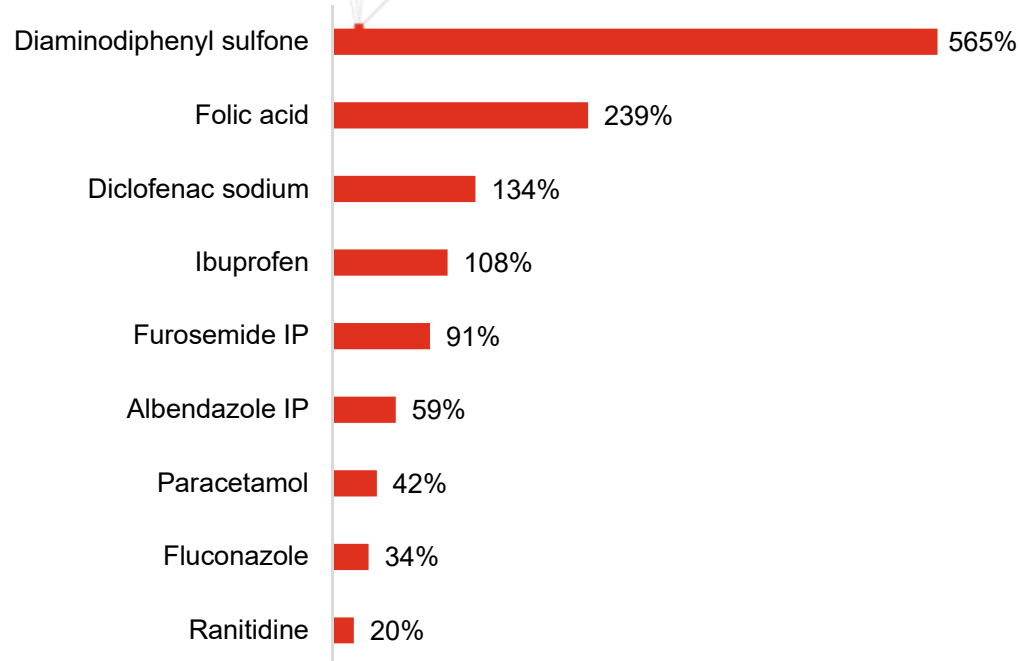
Setting the context

Dependence on China for APIs has been an ongoing concern for the industry

Background

- API is an important segment of the Indian pharma industry, contributing to around 35% of the market.
- On an average, the contribution of API to the overall cost is approximately 40%, but in certain cases, it may go up to 70–80% depending on the prevailing API prices.
- Due to the competitive pricing offered by Chinese suppliers, in the last few years, the Indian API industry has been dependent on China for imports of APIs and advanced API intermediates.
- It is significant to note that the percentage of API imports from China has spiked from around 1% in 1991 to around 70% in 2019, primarily backed by large-scale manufacturing incentives and state-driven subsidies offered in China to promote exports.
- In the recent past, the actual market price of some of the APIs which are imported from China has risen steeply, thereby raising the input cost.

Select examples of price increase of APIs (% , 2013–2019)



The recent outbreak of coronavirus (COVID-19) in China may disrupt the supply of essential APIs for the Indian pharma market and may impact price volatility.

Source: PwC's report on 'Taking stock: Rising prices of active pharmaceutical ingredients (APIs) and their impact on the Indian health sector'

Taking stock of the current situation

Key highlights

- 01** 50% of APIs are imported and the bulk of these imports are from China.
- 02** The Indian pharma industry is highly dependent on imports from China for some of the key APIs: penicillin G, levodopa, streptomycin, meropenem, carbidopa, vancomycin, gentamicin and progesterone.
- 03** Domestically produced APIs account for 50% of the total quantity; however, key starting material (KSMs) for some key APIs like caffeine, chloramphenicol, azithromycin, sulfadoxine, ciprofloxacin, metformin, ciprofloxacin, levofloxacin, ofloxacin, ampicillin, amoxicillin and cephalosporins are sourced from China.
- 04** All fermentation-based products like penicillin G, amoxicillin and tetracycline, which are used as base chemicals for most antibiotics, have a very high dependence on China. These products could be at the risk of going out of supply.

Source: PwC analysis

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Key Intermediates/ KSMs from China having high demand in India

S. no.	Name of intermediate	Name of API synthesised
1	Cyanoacetic Acid	Caffeine
2	L-aminodiol	Chloramphenicol
3	Azithromycin amine	Azithromycin
4	MCPSA and DCMP	Sulfadoxine
5	Cyclopropylamine	Ciprofloxacin
6	DCDA	Metformin
7	DCFA – 2, 4-Dichloro-5-flourobenzoyl chloride	Ciprofloxacin
8	2, 3, 4, 5-tetrafluoro benzoyl chloride	Levofloxacin ester Ofloxacin ester
9	L-Alaninol	Levofloxacin ester
10	DL-Alaninol	Ofloxacin ester
11	6 APA	Ampicillin and Amoxicillin
12	7 ACA	Cephalosporins

Source: IDMA

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S. no.	Name of intermediate	Name of API synthesised
13	(S,S)-2, 8 Diazabicyclo [4, 3, 0] Nonane	Moxifloxacin
14	4-Cyanopyridine	Ethionamide Protionamide
15	4-Amino-5-(aminomethyl)-2-methyl pyrimidine	Vitamin B1 Hcl
16	4-Methyl-5-ethoxyloxazole	Vitamin B6 Hcl
17	2-isopropyl-4, 7-dihydro-(1,3)-dioxepin	Vitamin B6 Hcl
18	2-mercaptothiazoline	Cysteamine Hcl
19	3-Cyanopyridine	Niacin
20	Beta Picoline	Niacin
21	Ethyl 3-(N,N dimethyl amino) acrylate	Ciprofloxacin

**Import of Penicillin G
(Essential API for manufacturing
several antibiotics from China)**

Penicillin G

6000 ton

Challenges faced by the Indian API industry

Indian API manufacturers lost their competitive edge in the manufacture of APIs at the lower end of the spectrum and fermentation technologies.

01 **Stricter implementation of pollution control norms:**

This is leading to higher costs of manufacturing APIs in India. Under the current norms, companies have to go through a fresh approval process every time they want to make a change in the product mix, a process that can take as long as 4 months. For increase in production or addition of equipment, it could be 8 months or even more.

02 **Interpretation of DPCO, 2013**

In order to cope with decisions related to scheduled vs non-scheduled formulations, new drugs, demand notices for overcharging, etc., Indian pharma companies were forced to evolve business strategies to move up the value chain and focus on commercially attractive segments like finished formulations and complex-to-manufacture APIs. Local formulation players thus started sourcing raw materials and simple APIs from cost-competitive locations like China, which has led to increased dependence on a single source and huge fluctuations in API prices.

03 **No tax incentives, higher utilities and borrowing cost**

Non-availability of tax incentives to boost API parks, higher borrowing and utilities cost (e.g. electricity, water, steam) and low import duties have led to cheaper imports from giant plants in China, which enjoyed economies of scale.

04 **Lack of mega bulk drug parks**

Lack of large clusters for bulk drug manufacturing having common facilities for pollution control, effluent treatment and single environmental clearance leads to higher capex requirement.

05 **Issues faced by fermentation industry**

Initially, huge capacity was created by both the public and private sector to cater to growing demand. However, because of the cheap rates, substantial quantities were being imported from China which forced local manufacturers to shut down operations owing to commercial unviability.

As the sole manufacturer of penicillin, China has started manufacturing intermediates from penicillin G (6-APA, 7-ADCA and 7-ACCA) and therefore has strategically priced penicillin, which makes even the production of intermediates uneconomical in India.

Source: PwC report on 'Taking stock: Rising prices of active pharmaceutical ingredients (APIs) and their impact on the Indian health sector', industry sources

Inherent advantages of the Chinese API industry

Economies of scale and government support in the form of infrastructure and subsidies will be the key drivers.



15%

Y-o-Y growth of industry



20%

Global API output by volume



2,000+

API molecules



5x

Increase in number of manufacturers in 5 years

Economies of scale leading to lower set-up and production costs (15–20% lower cost)

- **10–15x larger** in size than Indian SEZs
- **Logistics costs: 1% of total costs in China vs 3% for India**
- Over 1,000 API manufacturers vs 300–400 in India

Supportive R&D ecosystem USD 1.6 billion invested by the government

Creation of a research ecosystem:

- 'Thousand Talents Plan' attracted over 50,000 PhDs through generous funding support (up to USD 75,000/year)
- Strong industry and academia partnerships

Financial assistance, ~13% tax incentives and soft loans

- **Borrowing costs: 5–7% vs 11–14% in India**
- **~13% tax incentives** for the export of APIs
- **Exemption from various taxes** and low to no import duties

Liberal policies and cheaper utilities

- **Electricity costs are half** of those in India
- **Steam is 40–50% cheaper** compared to India

Source: Industry sources

High dependence on a single source can have a cascading effect

High dependence on China

Chinese APIs account for around 70% of all imported APIs in volume terms.

Supply disruption and cost trends in China

Prices of most commonly used APIs have shot up anywhere between 50% and 200% due to increasing wages and other costs in China, scenarios like the coronavirus outbreak and impurity-related issues.

Rise in formulation prices and drop in margins

Prices of drugs to shoot up to meet high API costs

Increasing healthcare costs and decrease in capex

- Cost of treatment for patients to shoot up
- Pharma firms reduce capex

Drug shortages

High cost

Job cuts

Increased healthcare burden

Shutdown of companies

Source: PwC analysis, industry sources

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Recommendations to revive the Indian API industry

India needs a holistic and conducive ecosystem to capitalise on the full potential of its API manufacturing capabilities.

A favourable financial and regulatory ecosystem and policies are likely to enable the API industry to ensure health security in India by making it self-reliant.



Recommendations

Immediate

- Faster environment clearance
- Encourage manufacturing of key APIs/intermediates and fermentation products by providing a fiscal stimulus
- Accommodative pricing policy under DPCO 13
- Financial incentives

Long term

- Develop large clusters and provide plug-and-play infrastructural support in dedicated zones for manufacturing APIs
- Industry-academia initiatives
- Facilitate alternative sources of import

Source: Industry sources, IPA paper, Katoch Committee Report



Recommendations – immediate

1. Faster environment clearance

- The approval process could be brought down to 2 months as delays adversely impact industry competitiveness both domestically and in export markets.
- Changes in the product mix (API and intermediates) should be freely permitted if the chemical effluents approved to be processed in effluent treatment plants are all covered. Environmental clearances should be given for categories (broader baskets) and not for individual drugs.
- There should be no restrictions on quantity produced as long as the overall pollution load is not breached.
- Deep sea discharge norms for fermentation products to be rationalised as per global best practices.

2. Encourage manufacturing by providing a fiscal stimulus

For APIs and intermediates

- Incentivise production of key identified APIs and intermediates where dependence on China is very high.
- Provide a 12% subsidy on the overall production value of these APIs/intermediates with the following criteria: a minimum threshold on investment value (~INR 100 crore) in any greenfield or brownfield project and a minimum threshold on production value (~INR 250 crore) by the third year of operation.
- Tariff on currently imported products to ensure viability of greenfield projects.

For fermentation products

- China has overtaken India with respect to fermentation products because of cheaper imports. Moreover, setting up a fermentation plant also requires very high capital investments and hence needs special attention.
- Provide a 30% subsidy on overall production value with a minimum threshold on both investment and production value.
- Provide a few other subsidies in line with fiscal incentives provided under the electronics policy like wage reimbursement, capital subsidy and electricity at INR 2/kWh.

Source: Industry sources, IPA paper, Katoch Committee Report, Electronics Policy 2014-20



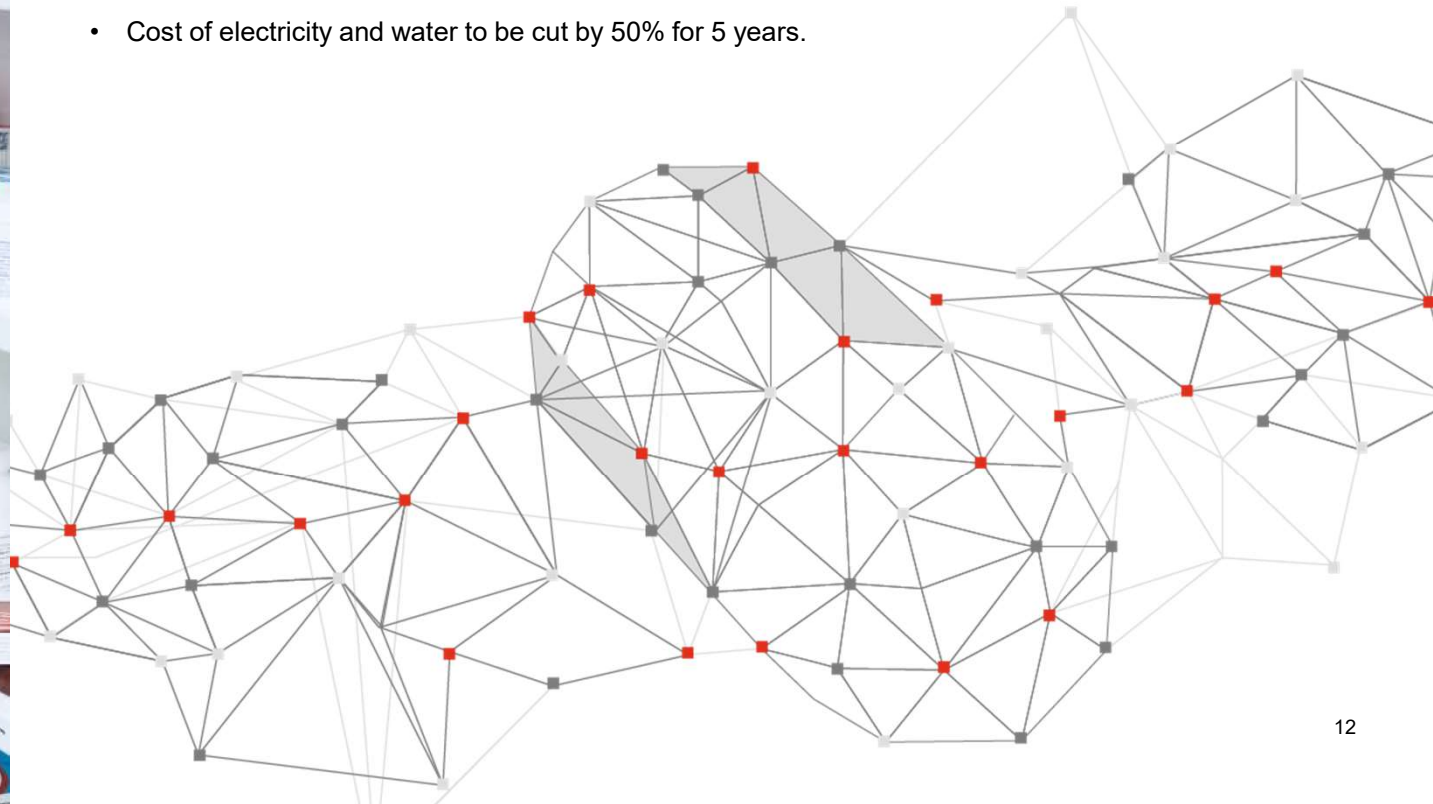
Recommendations – immediate

3. Accommodative pricing policy under DPCO, 2013

- While some of the policy changes may take time, we need to increase demand for domestic API by incentivising formulation manufacturers.
- The formulations under scheduled I of the DPCO, 2013, which are priced under INR 5 per unit, could be excluded from price control.
- Upward revision on price cap for all impacted formulations where API prices have increased substantially. Recently, there was an upward revision on price cap for 21 such formulations using Para 19.

4. Financial incentives

- Industry to be provided infrastructure status to enable ease of financing.
- Cost of electricity and water to be cut by 50% for 5 years.



Recommendations – long term

1. Develop large clusters and provide plug-and-play infrastructural support in dedicated zones for manufacturing APIs

- Construct 2–3 large-sized dedicated zones and lease them to private players for operating manufacturing plants.
- Set up common utilities such as solvent recovery and distillation plants, power and steam units, effluent treatment plants, common logistics centres, regulatory infrastructure and warehousing to make smaller units economically viable in these zones.
- The following support can be looked at to encourage investments in mega parks:
 - stamp duty waiver
 - 50% subsidy on water and electricity for 5 years
 - SGST reimbursement – 75% for 5 years
 - 50% subsidy on expenses incurred for quality certification/patent registration
 - waiver on development charges, which are currently at 9% of property cost.
- Evaluate strategic locations for these mega parks, e.g. union territories, where the center can play a larger role in controlling costs such as like cost of land and utilities.

2. Industry–academia initiatives

- Facilitate collaborations with institutions like National Institute of Pharmaceutical Education and Research (NIPER), Council of Scientific and Industrial Research (CSIR) labs and universities to improve process technologies (e.g. yield improvement).

3. Facilitate alternative sources of import

- For APIs and intermediates of high strategic importance that cannot be manufactured domestically, due to lack of either raw materials or concerns relating to environmental hazards, the government needs to adopt alternative sources.
- Initiatives to promote imports of intermediates and APIs from multiple sources to reduce monopoly in imports. An additional 10% subsidy can be provided if the imports are from sources other than China.

Source: Industry sources, IPA paper, Katoch Committee Report

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Conclusion

- 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% 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 we revive our 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.
- 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, suggested changes around 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.



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