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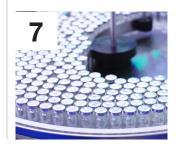


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Executive summary

The Government of India (GoI) recently launched a Production Linked Incentive (PLI) Scheme for the active pharmaceutical ingredient (API) industry, in line with the theme of building an Aatmanirbhar Bharat (selfreliant India). India's dependency on the import of APIs from a single source has increased substantially in the recent past and could pose a potential threat to national drug security.

The scheme is a step in the right direction towards making the API industry self-reliant over a period of time. The scheme should ensure that its benefits promote sustainable growth of the API industry by focusing on the industry's long-term survivability. For the scheme's success, key elements like scale of operations and backward integration need to be addressed.

The incentive package announced by the GoI includes the PLI Scheme worth INR 6,940 crore for API manufacturing and allocation of INR 3,000 crore for setting up three bulk drug parks.1 The PLI Scheme is applicable to 41 critical APIs/key starting materials (KSMs) and will help address the issue of supply of 53 identified critical APIs.² As per the PLI Scheme, incentives will be applicable only for domestic consumption and require backward integration in terms of domestic value add of 70% for chemical synthesis products and 90% for fermentation-based products.

Fermentation-based products need special attention because of the high capital requirement to set up manufacturing facilities. Many large Indian manufacturers stopped fermentation-based manufacturing because of cheaper imports.

After analysing the import data of APIs and KSMs³ of 53 identified critical APIs, we categorised them into four broad segments in order to determine the extent of dependency on imports and prioritise the list of molecules to generate actionable insights.4

We believe that the creation of a holistic ecosystem of strategic size is essential for the Indian API and bulk drugs industry to achieve economies of scale. This will enable India to become a global leader in the manufacturing of APIs.

Our recommendations are aimed at establishing a special scheme for fermentation-based products by protecting interested investors. We have recommended expanding the scope of the current scheme through inclusion of exports and existing facilities, backward integration, inclusion of some critical products and faster clearances. Strengthening bilateral trade and subsidising the cost of production of critical APIs for existing domestic manufacturers will prove to be beneficial for the industry. We have also recommended a few measures aimed at building a conducive ecosystem like granting infrastructure status to the API industry, promoting industryacademia initiatives and supporting research and development (R&D).



https://timesofindia.indiatimes.com/business/india-business/government-approves-a-package-of-rs-13760-crore-to-boost-manufacturing-of-apis medical-devices-in-country/articleshow/74749747.cms

Government Notification: File No. 3102611612020-Policy. Government of India, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals. 27 July, 2020.

Data from Export and Import Data Bank, Department of Commerce, Government of India

Data from industry experts, Indian Pharmaceutical Association (IPA) member companies, the Bulk Drug Manufacturers Association (BDMA) and the Indian Drug Manufacturers' Association (IDMA)

Setting the context

In the wake of the COVID-19 outbreak, upstream supply chains of most Indian pharma companies were completely disrupted as they were significantly dependent on a single source of import. This led to a substantial increase in the market price of some of the APIs that are imported from these countries, thereby impacting the input cost of the finished formulations. Research indicates that India's API imports have steadily increased from approximately 1% in 1991 to around 70% in 2019. For certain life-saving antibiotics like cephalosporin, azithromycin and penicillin, the import dependency is as high as 90%.⁵

A low-cost sourcing destination like China has certain advantages in terms of economies of scale, free land, availability of low-cost utilities like water, steam and power, along with support from the Government in the form of financial incentives, infrastructure and regulatory policies.⁶

The PLI Scheme will provide a much-needed impetus to the bulk drug industry and is a step in the right direction. However, the scope of the current scheme needs to expand to ensure that the current benefits lead to sustainable growth for the API industry and not just for a specified period. Based on our learnings from low-cost sourcing destinations, the core focus of the policy should be on long-term survivability of the industry, for which key elements like scale of operations and backward integration must be addressed. The entire pharma ecosystem is dominated by large players, from petrochemical companies on one end to large formulation players on the other. Hence, it's essential even for API players to achieve scale.

PwC conducted an independent study to understand the nuances of the recently announced PLI Scheme by talking to leading Indian API manufacturers. The purpose of the study was to come up with recommendations to ensure that the manufacturers are interested enough to invest in the scheme.



⁶ PwC analysis of data from industrial research

Key highlights of the PLI Scheme for the API industry

The Gol's INR 9,940 crore package to boost the domestic API manufacturing industry is divided into two parts – INR 6,940 crore has been allocated for the PLI Scheme and INR 3,000 crore will be spent on setting up three bulk drug parks. The PLI scheme is applicable to 41 critical KSMs/APIs and aims to address the supply issue of 53 identified critical APIs. The list has been classified into two broad categories – chemical synthesis products (n=27) and fermentation-based products (n=14).

The PLI Scheme is open only for manufacturers of critical KSMs/drug intermediates (DIs)/APIs in India and the eligibility shall be subject to a threshold of incremental investment for manufacturing of identified KSMs/APIs and drug intermediates. The scheme is valid from FY 2020–21 to FY 2029–30.

For chemical synthesis products, the incentive would be 10% on incremental sales for five years, i.e. from FY 2022–23 to FY 2027–28. For fermentation-based products, the incentive would be 20% on incremental sales for four years, 15% for the fifth year and 5% for the sixth year, i.e. up to 2028–29.⁷

Out of the total allocation of INR 6,940 crore for the PLI Scheme, INR 4,600 crore will be earmarked for fermentation-based products and INR 2,340 crore for chemical synthesis products. Under the fermentation-based category, two companies per product will benefit from the incentives, while four companies per product will benefit under the chemical synthesis category.

However, the scheme is applicable only for domestic consumption and incremental investment needs to be done in a greenfield facility or through expansion of an existing facility, along with ensuring 70% domestic value add for chemical synthesis products and 90% for fermentation-based products. Products eligible for the PLI Scheme account for almost 50% of the total imports.



⁷ Government Notification: File No. 3102611612020-Policy. Government of India, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals. 27 July, 2020.

⁸ Ibid

Fermentation industry – need for special attention

Setting up a fermentation plant requires very high capital investments and since this industry has been highly marginalised by an import onslaught from a single source, it needs special attention. Initially, huge capacity was created by both the public and the private sector to cater to the growing demand. However, because of the cheap rates, a substantial quantity was being imported from China, forcing local manufacturers to shut down operations as production became commercially unviable. Today, India does not have any manufacturing facility for fermentation-based products and is completely dependent on a single source.

As India lacks a foothold in the manufacturing of fermentationbased products and considering the fact that large Indian manufacturers have already failed once, the GoI may need to treat fermentation-based products differently in order to restore investor confidence. This segment may require some sort of guarantee from the GoI to ensure long-term survivability of the local fermentation industry and draw investor attention.



Detailed analysis of eligible APIs/ KSMs

It will take India at least 2-3 years to strengthen its domestic API manufacturing capacity and hence the sector needs a bridging strategy until the country becomes self-reliant.

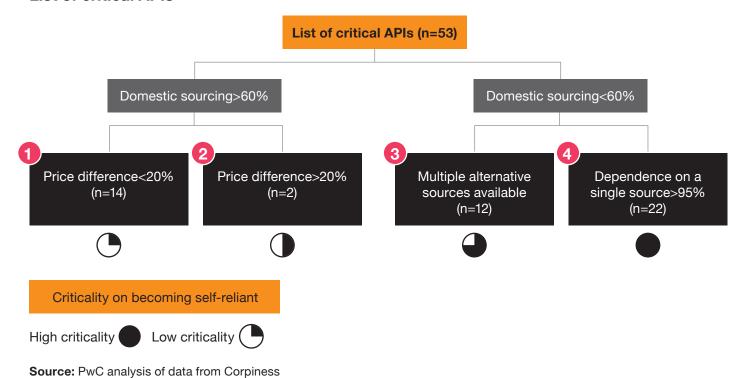
In order to find the extent of import dependence for the 53 identified critical APIs, we adopted the following methodology:

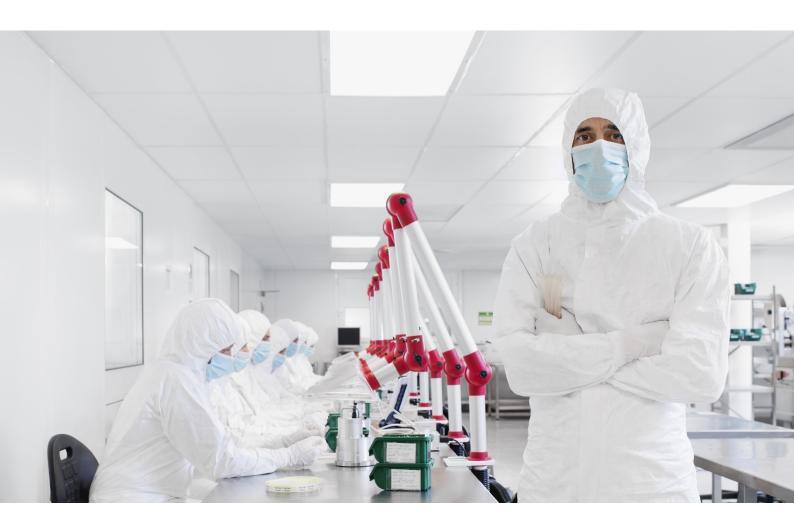
- Our research team mapped each of the essential APIs and KSMs against its respective Harmonized System (HS) Code using primary and secondary sources.
- Data for 50 out of the 53 identified APIs was analysed. The APIs ornidazole, tinidazole and lopinavir were not analysed because of limited data availability. We also analysed six out of eight KSMs listed as a part of the PLI Scheme. The data analysed is from APIs which make up for approximately 50% of the total imports.
- The HS Codes were then used to find out the import value and volume of respective APIs and KSMs (for AY 2019) from the official import-export data repository of the Department of Commerce, Government of India.
- Additionally, the research team also mapped the domestic production price and domestic and global suppliers against the respective APIs and KSMs identified via primary and secondary sources of data.
- Overall import and domestic data has been used to identify key insights related to import reliance and domestic capabilities.



To draw meaningful conclusions based on the available information, we created four broad categories for all the APIs.

List of critical APIs





Category I

1. More than 60% of the requirement is sourced domestically and the price difference is not more than 20% higher when compared to a leading import source.

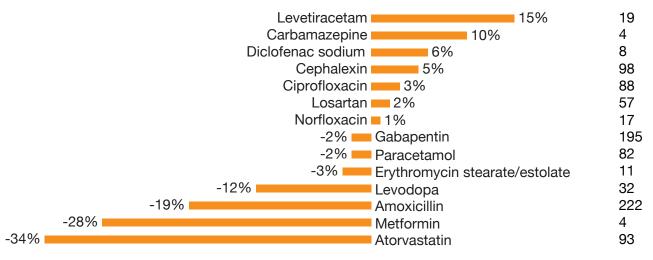
For 14 out of the 53 identified critical APIs, more than 60% of the total required quantity is sourced from domestic suppliers and hence, reliance on import is less for these APIs. Moreover, the average price difference for these 14 APIs supplied by Indian suppliers and the leading alternative source is less than 20%. Hence, this category can be qualified as a low-risk category as we

have domestic supplies of these APIs and the price difference is not very high. For this category, we can look at extending the scheme to the existing facilities of manufacturers if the minimum threshold of the domestic value add is fulfilled. This will ensure that we do not invest in building excess capacity.

Price difference for 14 APIs (comparison between Indian suppliers and the leading alternative source of import)

Price difference between India and the leading import source

Value of imports in INR crore



Source: PwC analysis of data from Corpiness and IPA member companies

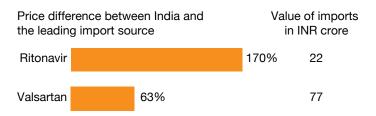
Category II

2. More than 60% of the requirement is sourced domestically but the price difference is more than 20% higher compared to a leading import source.

For only 2 out of the 53 identified critical APIs, 60% of the requirement is fulfilled by domestic suppliers. However, the price difference between the APIs supplied by Indian suppliers and those from the leading

source of import is very high. Hence, the Government could consider subsidising local suppliers to increase domestic consumption, along with taking measures to incentivise cost-reduction initiatives.

Price difference between Indian suppliers and the leading source of import



Source: PwC analysis of data from Corpiness and IPA member companies

Category III

3. Less than 60% of the requirement is sourced domestically. However, multiple alternative sources are available.

Out of the 53 identified critical APIs, 12 have domestic sourcing of less than 60%. However, they either have alternative import sources of supply or enough domestic suppliers. Some of the APIs in this category are critical and India's total import value is higher than

INR 100 crore for APIs like potassium clavulanate, prednisolone, telmisartan and doxycycline. The Gol may need to negotiate trade deals and engage in tie-ups with alternative sources to avoid any supply issues in the near term.

APIs which source less than 60% of their requirements domestically

S.no.	API name	Total import value (in INR crore)
1	Potassium clavunalate	933
2	Prednisolone	145
3	Telmisartan	128
4	Doxycycline	127
5	Dexamethasone	54
6	Carbidopa	39
7	Olmesartan	38
8	Piperacillin tazobactam	9
9	Aspirin	7
10	Oxcarbazepine	4
11	Cefixime	1
12	Artesunate	1

Source: PwC analysis of data from Corpiness and IPA member companies

Category IV

4. Less than 60% of the requirement is sourced domestically and there is a very high dependency on a single source.

For 22 out of 53 critical APIs, domestic sourcing is less than 60% and dependency on a single source is more than 95%. This becomes a high-risk category and quick measures are required to build domestic capacity for

this particular set of APIs. Concentrated efforts are required to remove dependencies for APIs for which domestic sourcing is less than 10%.

APIs highly dependent on a single source

S. no.	API	Total import value (in INR crore)	Percentage of dependency on a single source (of total import)	Domestic sourcing
1	Azithromycin	727	100%	20–40%
2	Ceftriaxone	572	99%	<10%
3	Meropenem	320	97%	20–40%
4	Vitamin B12	304	99%	<10%
5	Rifampicin	273	98%	<10%
6	Acyclovir	222	100%	<10%
7	Clarithromycin	143	100%	<10%
8	Sulbactam	132	100%	20–40%
9	Betamethasone	126	98%	20–40%
10	Levofloxacin	122	100%	40–60%
11	Cefoperazone	65	100%	20–40%
12	Vitamin B1	55	94%	<10%
13	Tetracycline	48	99%	<10%
14	Metronidazole	45	100%	40–60%
15	Ofloxacin	42	100%	20–40%
16	Clindamycin phosphate	42	99%	<10%
17	Oxytetracycline	32	100%	<10%
18	Sulfadiazine	27	98%	<10%
19	Clindamycin HCL	24	100%	<10%
20	Neomycin	19	96%	<10%
21	Streptomycin	16	100%	<10%
22	Gentamycin	7	100%	<10%

Source: PwC analysis of data from Corpiness and IPA member companies

Additional analysis of critical KSMs listed under the PLI Scheme

Apart from the identified critical APIs, we also analysed data for six out of the eight KSMs listed under the PLI Scheme. We are almost 100% dependent on a single

source of import for all the analysed KSMs and hence, it becomes critical to build domestic capacity for manufacturing all the listed KSMs.

KSMs covered under the PLI Scheme

S.no.	KSMs	Total import value (in INR crore)	Largest source of import	Percentage of dependency on a single source (out of total import)
1	Penicillin G/ 6-APA	1,146	China	94%
2	TIOC	1,052	China	63%
3	CDA (1,1-cyclohexane-diacetic acid)	738	China	68%
4	7-ACA (7-amino-cehalosporonic acid)	732	China	83%
5	DCDA (dicyandiamide [2-cyanoguanidine])	510	China	95%
6	PAP (para-amino phenol)	692	China	100%



Recommendations

India needs to rebuild its API industry so that it can lead to economies of scale and remain competitive. Keeping these objectives in mind, we would like to offer the following suggestions for consideration. Our suggestions are based on a detailed analysis of eligible products and our conversations with leading Indian manufacturers who are also the potential investors for the PLI Scheme.

Suggestions for fermentation-based products:

- Relook at selling price as a selection criteria: Since fermentation-based products like Pen-G and few others are not manufactured domestically, it will be difficult to arrive at the actual cost of production and quote a selling price. For fermentation-based products, manufacturers will need time to discover the price and hence the selection criteria and weightage on selling price should not be considered for fermentation-based products.
- Downside protection on capital investment: Given the high capital investment required to build capacity at scale for fermentation-based products, the Government should look at providing some minimum guarantee on the return of investment for a limited timeframe to manufacturers willing to invest in this category. This will ensure sustainability of the project for a manufacturer for the initial period, until the model becomes selfsustaining.
- Use import duties to control import price: Import duty should be used as an instrument to control import prices and ensure that domestic manufacturing costs remains cheaper.

Key suggestions:

Increase the DVA to 90% for all categories: The import element under the PLI Scheme should be limited to 10% instead of 30%. The proposed domestic value add (DVA) should be 90% in case of both fermentation and chemical synthesis based products, since the objective of the scheme is to reduce dependency on import for critical APIs/KSMs/DIs. Further, in the case of synthesis-based products, manufacturers must aim to reach a production capacity of 20% vis-à-vis the world market to ensure competitiveness within the industry.



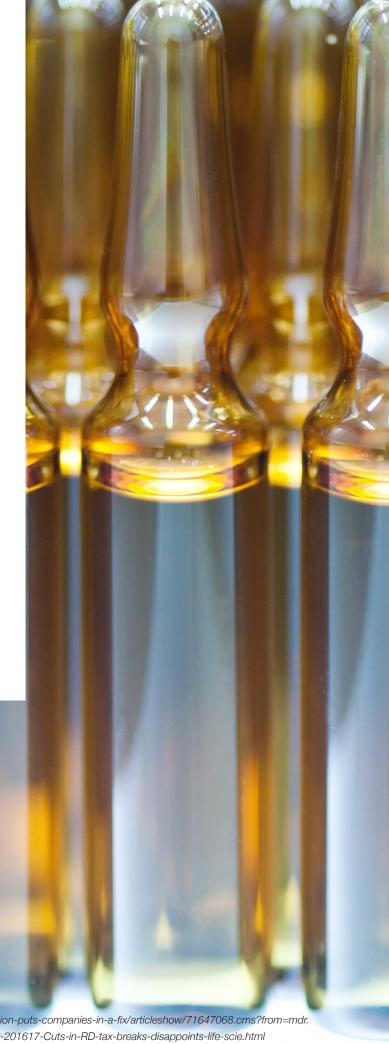
- Extend the PLI Scheme benefits to existing manufacturing facilities: The PLI Scheme only considers greenfield projects or a new production facility on the premises of an existing production facility. If the objective is to increase domestic production of APIs, then the scheme should also consider including brownfield projects as they can commence production faster. The scheme could also be extended to existing manufacturing facilities to encourage backward integration, subject to meeting the domestic value-addition criteria. This change may provide the industry with an opportunity to reduce production timelines and ensure early availability of indigenous KSMs.
- **Include exports:** The scheme should also include exports for all indigenously manufactured products as economies of scale is a crucial factor to become competitive. Hence, manufacturing plants may have to install capacity that exceeds the domestic demand and could be exported. Also, incentive calculation in the case of in-house or captive consumption should not be on the actual cost of production but the actual sales price or comparable sales price.
- Infrastructure status: The API industry should be given infrastructure status and offered soft loans with lower interest rates and longer repayment periods. This will help API manufacturers to:
 - Borrow money from various sources such as international lenders, domestic insurance organisations and pension funds for a reasonably longer tenure (around 15 years) and lower interest rates of approximately 4%.
 - Explore the possibility of external commercial borrowing methods such as foreign currency funding. Such loans are more economical due to lower rates of interest.
- Include a few other products: The current scheme covers products contributing to almost 50% of the total imports. A few other critical APIs/KSMs that are import dependent, like betamethasone, dexamethasone, prednisolone, progesterone, levonorgesterone, mifepristine and other fermentation-based corticosteroid APIs should be considered as a part of the scheme. KSMs are of critical importance for APIs and thus all critical KSMs should be an important focus of the policy.
- Extend incentive timeline: Considering the complexity of the manufacturing process involved and the requirement of regulatory approvals, especially in the case of fermentation-based products, starting production could take more than three years and hence we may need to look at extending the current incentive timeline.

- Quarterly incentive payout: Tax incentives should be claimed on a quarterly basis in line with the income tax refund rules. The incentive disbursement claims should have a provision for payment of interest if incentives are delayed beyond the agreed period. This will bring in accountability with respect to timely disbursal of claims. In case of a delay in disbursal, the interest should become payable to the applicant.
- **Incentive cap:** There should not be any limit on the incentives earned by individual items as scale is fundamental to build a competitive advantage.
- Production capacity threshold: The guidelines currently allow an applicant to commit to an annual production capacity in whole number multiples of the minimum annual production capacity. There should be a provision allowing an applicant to produce a fractional multiple of the minimum annual capacity.
- Faster environmental clearance: It usually takes intermediate manufacturing plants nearly a year to get the approval of the Central Pollution Control Board (CPCB). The CPCB does not provide immediate approval to manufacturers who adopt the zero liquid discharge (ZLD) process of wastewater treatment. Additionally, the volume of production by such manufacturing plants is restricted. It will take around 3-4 years to secure permission for land acquisition, construct a manufacturing plant and finally begin production. Therefore, the following recommendations could be considered:
 - Green clearances for pollution and effluent discharge should be provided to API manufacturing units by the Central Government and the state governments within 90 days from the date of application.
 - A fresh environmental clearance need not be taken if the pollution load of the API manufacturer remains constant and the existing API manufacturers are allowed to modify their product portfolio.
- Strengthen bilateral trade: India should look to strengthen bilateral trade relationships with other countries and encourage API manufacturing companies to import from them to reduce dependency on a single source.
- Incentivise domestic consumption: Domestic suppliers should be incentivised for local consumption of APIs/KSMs where import dependence is very high.
- **Faster refund:** The processes to enable refunds to reduce working capital cost should be improved. Almost 30-40% of a manufacturer's working capital is unusable as it is in the form of taxes, rebate claims and other subsidies. These collectively add about 3-4% to the additional costs.9

 Enable technology transfer: Technology transfer from alternative sources should be facilitated so that we can build domestic capacity in the short term and invest in experimental technology in the long term.

Additional suggestions:

- Industry-academia linkages: The Government should support industry-academia collaboration and facilitate public-private partnerships (PPPs) with research institutes of national importance such as the Indian Institutes of Science Education and Research (IISERs), the Council of Scientific and Industrial Research (CSIR), the National Institute of Pharmaceutical Education and Research (NIPER), the Indian Institutes of Science (IIScs)and the Indian Institutes of Technology (IITs) to develop substitutes/ alternatives for imported APIs/KSMs/DIs.
- FDI policy: The current foreign direct investment (FDI) policy for the pharma sector should be continued. Specific modifications can be made in the case of FDI approval in brownfield investments. The GoI needs to address concerns around approvals by the Foreign Investment Promotion Board (FIPB), the time frame for obtaining such approvals, etc., and issue reasonable, uniform and transparent guidelines.
- Support R&D: The pharma industry can be encouraged to set up a milestone-based funding mechanism for R&D in the API sector. The GoI may support the sector with a seed capital of INR 1,500 crore to facilitate R&D and start-ups in key technologies such as fermentation, chiral chemistry and biocatalysis. The weighted tax deduction of 200% on R&D expenditure can be reinstated. This was reduced from 200% to 150% from 2017 onwards and as per Union Budget 2019, the GoI plans to reduce it further in the near future.¹⁰



⁹ https://economictimes.indiatimes.com/news/economy/policy/gst-regulation-puts-companies-in-a-fix/articleshow/71647068.cms?from=mdr.

¹⁰ https://www.livemint.com/Industry/PLKYkBUiTBbS3E6SM93IAP/Budget-201617-Cuts-in-RD-tax-breaks-disappoints-life-scie.html

Conclusion

It is critical for India to boost its domestic capacity to manufacture APIs/KSMs/DIs in order to become a global leader in pharmaceuticals.

For the API sector to become self-reliant, we need to expand the scope of the current PLI Scheme and recognise alternative sources of import for the identified critical APIs/KSMs/DIs.

India needs to create an ecosystem that is conducive to increasing the domestic production of critical APIs/KSMs/DIs. Such an ecosystem will require the API industry to comply with the processes and policies created by the Government. Therefore, the GoI should ensure that such policies can be complied with easily by domestic manufacturers.

Improving the manufacturing standards of the domestic API industry, abiding by good manufacturing practices and investing in technology development will enable Indian API manufacturers to meet the high quality standards prescribed in most regulated countries and become preferred partners for pharmaceutical companies in the global market.



Annexure A¹¹

Details of identified critical APIs

API	Total import value (in INR crore)	Total import volume (MT)	Percentage of domestic sourcing (out of total consumption)	Average import cost (in INR)	Average domestic cost (in INR)	Largest source of import	Percentage of reliance on largest source (out of total import)
Potassium clavunalate	933	1,301	<10%	7,169	NA	China	59%
Azithromycin	727	1,013	20–40%	7,172	NA	China	100%
Ceftriaxone	572	1,229	<10%	4,650	NA	China	99%
Meropenem	320	58	20–40%	55,310	60,143	China	97%
Vitamin B12	304	16	<10%	195,895	NA	China	99%
Rifampicin	273	303	<10%	9,007	8,910	China	98%
Acyclovir	222	665	<10%	3,337	3,342	China	100%
Amoxicillin	222	956	>60%	2,317	1,600	China	81%
Gabapentin	195	697	>60%	2,795	2,800	China	99%
Prednisolone	145	31	<10%	46,372	32,299	China	88%
Clarithromycin	143	133	<10%	10,704	NA	China	100%
Sulbactam	132	164	20–40%	8,071	NA	China	100%
Telmisartan	128	64	40–60%	20,143	12,549	Germany	96%
Doxycycline	127	225	<10%	5,623	NA	China	80%
Betamethasone	126	19	20–40%	65,642	52,718	China	98%
Levofloxacin	122	583	40–60%	2,092	2,228	China	100%
Cephalexin	98	274	>60%	3,562	3,750	Spain	99%
Atorvastatin	93	34	>60%	27,727	14,256	Mexico	46%
Ciprofloxacin	88	522	>60%	1,688	1,715	China	97%
Paracetamol	82	2,522	>60%	357	300	China	91%
Valsartan	77	68	>60%	11,335	18,000	China	90%
Cefoperazone	65	75	20–40%	8,675	NA	China	100%
Losartan	57	77	>60%	7,394	7,500	China	97%
Vitamin B1	55	251	<10%	2,190	1,857	China	94%
Dexamethasone	54	8	<10%	6,905	38,833	China	55%

¹¹ Data from Corpiness and IPA member companies

¹⁷ PwC | Reducing dependency: Making India's API industry self-reliant

API	Total import value (in INR crore)		Percentage of domestic sourcing (out of total consumption)	Average import cost (in INR)	Average domestic cost (in INR)	Largest source of import	Percentage of reliance on largest source (out of total import)
Tetracycline	48	194	<10%	2,450	NA	CHINA	99%
Metronidazole	45	645	40 - 60%	698	750	CHINA	100%
Ofloxacin	42	196	20 - 40%	2,133	2,339	CHINA	100%
Clindamycin phosphate	42	31	<10%	13,263	NA	CHINA	99%
Carbidopa	38	14	20 - 40%	28,028	20,419	SWITZERLAND	71%
Olmesartan	38	7	40 - 60%	51,323	45,000	NA	NA
Levodopa	32	60	>60%	5,367	5,198	JAPAN	58%
Oxytetracycline	32	165	<10%	1,946	NA	CHINA	100%
Sulfadiazine	27	121	<10%	2,232	2,673	CHINA	98%
Clindamycin HCL	24	20	<10%	12,113	NA	CHINA	100%
Ritonavir	22	11	>60%	19,794	53,460	CHINA	100%
Neomycin	19	176	<10%	1,066	1,500	CHINA	96%
Levetiracetam	19	34	>60%	5,513	6,312	CHINA	95%
Norfloxacin	17	71	>60%	2,330	2,357	CHINA	100%
Streptomycin	16	109	<10%	1,436	2,599	CHINA	100%
Erythromycin stearate/esplate	11	30	>60%	3,621	3,500	THAILAND	99%
Piperacillin tazobactam	9	8	20 - 40%	10,517	NA	CHINA	69%
Diclofenac sodium	8	67	>60%	1,120	1,188	CHINA	96%
Aspirin	7	153	<10%	442	312	FRANCE	59%
Gentamycin	6	9	<10%	7,075	12,214	CHINA	100%
Oxcarbazepine	4	5	40 - 60%	7,828	NA	NA	NA
Metformin	4	129	>60%	286	200	NA	NA
Carbamazepine	3	12	>60%	2,808	3,081	CHINA	100%
Artesunate	1	0	<10%	35,710	NA	ITALY	100%
Cefixime	1	1	40 - 60%	12,656	10,250	NA	100%

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