

# Reduced Pharma Supply Chain in COVID-19: Measures to Reduce India's Reliance for Active Pharmaceutical Ingredients on China and other Countries

Narendra Vyas\*, Ankur Joshi, Sapna Malviya, Anil Kharia

Modern Institute of Pharmaceutical Sciences, Indore, Madhya Pradesh, INDIA.

## ABSTRACT

India, which is called the “world of pharmacy” for being a top supplier of medicines in several countries, can depend on other countries for Active Pharmaceutical Ingredients (API) and other raw materials. Although India is one of the major suppliers of high-quality medicines in several countries, the Indian pharmaceutical industry is highly dependent on China and other countries in terms of raw materials (including the production of essential medicines such as Crocin). These raw materials are called Active Pharmaceutical Ingredients (API), also known as loose drugs. Indian pharmaceutical manufacturers import medicines from China and other countries/regions to account for about 70% of total medicine demand. This article sheds light on the important question of how India depends on other countries to obtain API and other raw materials. Also, the effect of COVID-19 pandemic on the supply chain of bulk drugs, which indirectly affects the pharmaceutical manufacturers. The article concludes that this is the right time for India to remove the dependencies for bulk drugs on china and other countries and start producing their own API in the country itself. COVID-19 situation provides India an opportunity to become a preferred alternate hub for manufacturing APIs and intermediates.

**Key words:** Active Pharmaceutical Ingredients, Imports of API, Imports from China, COVID-19, Bulk drugs, Opportunity for India.

**Key Message:** India is mostly dependent on China for the import active pharmaceutical ingredients and other raw material because of their availability at cheaper price than other sources. In the present situation due to COVID-19 pandemic, all pharmaceutical sectors are facing a big problem related to unavailability of API and other raw material. This is the right time when India can develop its own API and crude drug market and remove the dependency of imports on China and other countries.

## INTRODUCTION

### Active Pharmaceutical Ingredients

API stands for “Active Pharmaceutical Ingredients”. It is a compound that is the most important raw material for making finished products. The API consists of any substance or combination of substances intentional to be used in the manufacture of medicines and when used in the manufacture of medicines, it becomes the active ingredient in the medicine. These substances are intended to provide pharmacological or other direct effects in the treatment, diagnosis, mitigation, prevention

or treatment of diseases, or to change the structure or any function of the human or animal body. In medicine, APIs produce the effects needed to cure diseases. For example, Acetaminophen is the raw material of Crocin and Acetaminophen can reduce body pain and fever.<sup>1</sup>

Each drug consists of two main components: a chemically active API and a chemically inert excipient, which are substances that provide API action on the system. Fixed-dose combination drugs use multiple APIs, while single-dose drugs (such as Crocin) use only one API.<sup>2</sup>

Submission Date: 26-04-2020;  
Revision Date: 20-07-2020;  
Accepted Date: 25-09-2020

DOI: 10.5530/ijper.54.4.175

### Correspondence:

**Dr. Narendra Vyas**

Professor, Modern Institute of Pharmaceutical Sciences, Alwasa, Behind Rewti Range, Sanwer Road, Indore-453111, Madhya Pradesh, INDIA.

Phone no: +91 9827526680

Email id: vyasji85@gmail.com



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## API manufacturing

API is not produced by a single reaction of raw materials, but is converted into an API through various chemical compounds reactions. The chemical compound that is about to become a raw material API is called an intermediate. From raw materials to APIs, some APIs undergo more than ten types of intermediaries during this process. The long production process continues until it is cleaned and a high degree of purity is obtained.<sup>2</sup>

API manufacturers first develop chemicals in the laboratory. The production department then uses large reactors to produce large amounts of APIs. Then check the purity before selling to the drug manufacturer. If the API is not ultrapure, the drug cannot meet strict quality standards. Therefore, the quality of the API plays a very important role.<sup>2,3</sup>

## MATERIALS AND METHODS

The review collected information through secondary means, namely the official websites of relevant regulatory agencies, news articles, research articles and knowledge gained through interaction with various industry departments and governments. Suggestions and guidance from experts of regulatory affairs department were taken.

### India Loses its API Market

In the early 1990s, API production in India was self-sufficient. However, with the development of China as a raw material manufacturing country, it has occupied the Indian market with cheap products and eventually led to a higher economic level. When China entered the market, they started selling APIs, which were 40% cheaper than APIs in India. But as China's labor costs rise, China's APIs are now 20% cheaper than those of India.<sup>2,3</sup>

China has created a cheap API industry. Low-cost funds, active public funding models and tax incentives provide support for the industry. Its operating cost is a quarter of India's cost. China's financing costs are also between 6% and 7%, while India is 13% to 14%. As a result, Indian pharmaceutical companies have stopped producing APIs for many years due to low profit margins and non-profit sectors. Figure 1 shows various points, how china is producing API at cheaper price.<sup>4,5</sup> We started importing APIs (which is a cheaper option) and increased the profitability of our medicines. We import API, produce final formula and export it to other countries. India has stopped producing APIs of ascorbic acid (vitamin C supplements), aspartame

(artificial sweetener) and commonly used antibiotics (such as Rifampicin, Doxycycline, Tazobactam acid and even steroids).<sup>6-8</sup>

Not only has India started using imported APIs, it has even stopped producing materials used to create APIs (called intermediaries). The list of intermediaries includes Atorvastatin (cholesterol drug), Chloroquine (malaria drug), Gabapentin (anxiolytic drug), Ciprofloxacin and Cephalosporin (antibiotics).

In the globalized market economy, no country can avoid imports and India has been importing bulk medicines from abroad for some time. But the most alarming fact is that this dependence depends heavily on one source, namely China and this dependence on imports from a single country puts India in a strategically disadvantageous position. If China decides to suspend the supply of intermediate products and other raw materials in India, it will have a drastic impact on the Indian pharmaceutical industry and will stop it almost

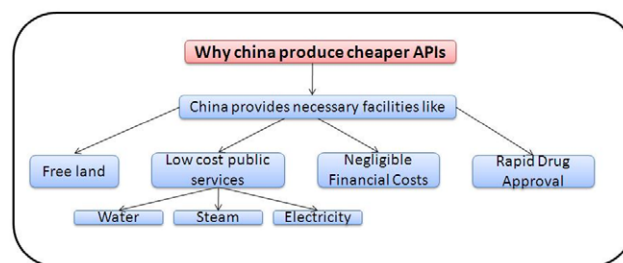


Figure 1: Facilities on API production given by China.

Table 1: Global distribution of Chinese API exports.<sup>8</sup>

Order	Country	Sum share (%)	Main products
	United States	20.22	Vitamins, amino acids, sweetening agents
	India	8.88	Antibiotics, hormones
	Germany	8.43	Antibiotic vitamins
	Japan	7.12	Enzymes, amino acids, activated carbon
	Netherlands	5.15	Vitamins, amino acids, antibiotics
	Korea	4.15	Antibiotics, Sulfamido, Natural extracts
	Belgium	3.61	Vitamins, amino acids, organic acids
	Spain	3.19	Vitamins, amino acids, antibiotics
	Italy	3.07	Antibiotic, hormones, citric acid
	UK	2.32	Vitamins, amino acids

(Source: www.pharmaexcil.com)

entirely. Table 1 shows the Global distribution of Chinese API exports.<sup>7,8</sup>

### Imports of Drugs from Other Countries

The Indian pharmaceutical industry is the third largest in the world by volume and the fourteenth in value. India exported medicines worth \$ 14389 million in the 2018-19 financial years. India also exported bulk / intermediate medicines worth \$ 3911 million in the 2018-19 financial years. However, the country also imports various bulk drugs/active pharmaceutical ingredients (API) to produce drugs. Two thirds of the total imports of bulk drugs/intermediate drugs come from China. Imports from China are mainly due to economic considerations. Table 2 shows the details of the imports of bulk products/drug intermediates by India from China and other countries.<sup>9,10</sup>

As far as intermediates are concerned, there is a 65 to 70% dependence on China, in particular Antibiotics, Cephalosporin, Vitamins, Aspirin, Paracetamol, Metformin, Ranitidine, Ibuprofen, Amoxicillin, Ciprofloxacin, Cefixime, Ofloxacin, Ampicillin. Figure 2 shows the imports percentage of API and crude drugs by India from China.<sup>9,10</sup>

India has also more than doubled China's import of antibiotics in recent years and the trade is now

worth billions of dollars. There are now no domestic producers of penicillin and its derivatives. A public health crisis was always feared if China ever stopped supplying. This became reality after COVID-19 created a shortage of essential drugs, as India relied on China for many API. Pharmaceutical companies blame the government for stating that cheap imports forced many manufacturers to shut down. Some stopped producing ingredients for other drug manufacturers and produced more complex formulations, which they then export to developed markets in the United States and Europe. Bureaucracy and the lack of environmental permits in India have also made the production of raw materials uneconomical.<sup>10-12</sup>

However, returning to mass production of raw materials is not difficult or too late. If the government acts quickly, things can change in less than 10 years.

### Impact of COVID-19 on Pharmaceutical Industries

COVID-19 pandemic affected pharmaceutical industries across the globe. The corona virus outburst has started to strike India's pharmaceutical area by raising the prices of crude key ingredients and API. Now the prices for penicillin and vitamins are twice or thrice the price. Likewise the cost of Paracetamol has also gone up. Another major impact is that pharmaceutical company's faces disruptions due to total factory closures in China. If the pandemic continues then stocks of API, pharmaceuticals and other chemicals may reduce, resulting in shortages.<sup>13</sup>

According to Indian drug regulatory authority about 57 API of crucial importance like vitamins, antibiotics and steroids or hormones might go out of stock in case of a extended lockdown in China. The outburst of COVID-19 cause potential major disruptions to supply and shortages of critical medical products. Supply chain break could be truly serious for our access to the drugs.<sup>13</sup>

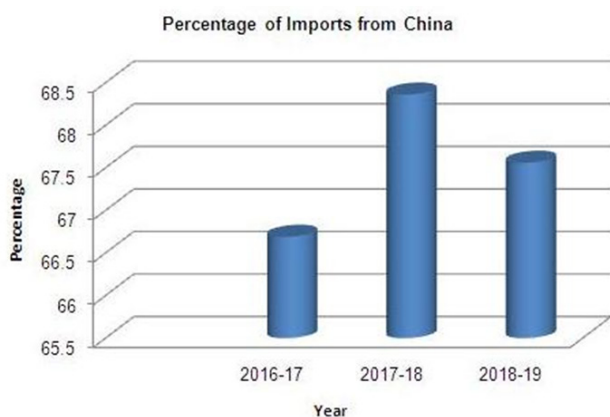
The government controlled the sale and distribution of Hydroxychloroquine stating it as an important drug to meet the necessities of any emergency arising due to COVID-19 pandemic. Since Hydroxychloroquine is found to be useful against corona virus in laboratory studies and *in-vivo* experimental studies. Its use in prophylaxis is resulting from the available evidence of benefit as treatment and supported by pre-clinical data.<sup>13,14</sup>

The government has also restricted the export of diagnostic kits with immediate effect and ensures that the manufacturers cannot increase the price of medical devices ahead of what is permitted under any circumstances. This is carried out to ensure that there is

**Table 2: Imports of bulk drugs from China and other countries to India.<sup>7,10</sup>**

Year	Total imports (in Crore)	Imports from China (in Crore)	% of imports from China
2016-17	19653	13106	66.69
2017-18	21481	14755	68.36
2018-19	25552	17263	67.56

(Source: Latest statistics from Director General of Commercial Intelligence and Statistics)



**Figure 2: Percentage of imports to bulk medicines from China**

no price increase, especially when the nation is fighting a pandemic.<sup>13,14</sup>

### Opportunity for India to Regrow Its API Market

We cannot increase API production as we end up equaling the economies of scale generated by the Chinese units. Our production cost for API will be higher, which in turn would hinder the competitiveness of product exports. We have to match the prices offered by Chinese companies. For this, we must invest in extraordinarily high API production to allow Chinese API buyers to move to India. The other alternatives to purchasing API, when China cannot supply, are the United States, Singapore, Italy and Hong Kong.<sup>15,16</sup>

### Government actions to reduce the dependence

The Department of Pharmaceuticals (DoP) department of the Ministry of Chemicals and Fertilizers claimed that increased imports of API from China are due to fact that they are providing the same cheaper rates than others suppliers. It reflects that imports of API from China are cheaper and gives extra profit to pharmaceutical producers. Although India seeks other imports such as those from the United States, Italy, Singapore and Hong Kong for such imports, there is a fear of a sharp increase in the price of finished drugs when API are imported from countries other than China. And as far as dependence of India on imports is considered, the policies designed by the government authorities to minimize this and enhance indigenous production have remained only on paper.<sup>15,16</sup>

The Department of Pharmaceuticals (DoP) has a scheme: "Assistance to the Bulk Medicines Industry for a Common Service Center" to provide assistance to the Bulk Medicines Industry for a Common Services Center in any upcoming drug park promoted by state governments or state corporations.<sup>16</sup>

The government's main agency, the Central Drug Standards Control Organization (CDSCO), has prepared a list of 38 essential API in which India must be independent. The list is likely to contain drugs based on the fermentation process, such as crucial Antibiotics, Penicillin, Amoxicillin, Ampicillin, Tetracycline and essential hormonal vitamins and pills. It is a market that China dominates all over the world. However, there remains a suggestion from the government and not an imposition to start producing these selected API.<sup>16,17</sup>

India is taking several measures to reduce its dependence on imports of API, a raw material commonly used for medicines, by manufacturing it on the domestic market. Domestic drug manufacturers, which mainly import API from China, saw a sharp rise in the prices of these

raw materials after the Chinese government closed many API production plants due to environmental concerns. This prompted the pharmaceutical lobby to ask for an increase in the prices of drugs that are currently under price control. India wants to promote API production in India as part of the Make in India initiative. Many foreign investors have shown interest in creating such structures.<sup>17,18</sup>

The Directorate General for Foreign Trade (DGFT) has at present limited the export of 26 API: Paracetamol, Ornidazole, Erythromycin, Vitamins B1, B6 and B12, Metronidazole, Progesterone, Chloramphenicol, Clindamycin, Acyclovir, Neomycin and Tinidazole, with immediate effect. Since the COVID-19 epidemic in China has been shown to influence its supply. Companies that intend to export these products must obtain a certificate of opposition from the government. The government list of 26 API and medicines represents 10 percent of all Indian pharmaceutical exports.<sup>18,19</sup>

### Suggestive measures needed to solve the problem

China has offered many benefits, such as free land, low-cost public services such as water, steam and electricity and negligible financial costs. China has reformed its drug approval processes to shorten the overall process and fast production. It established a priority drug review process for critical conditions and reduced the time needed to approve changes to the clinical trial process. Medicines for anemia and intestinal cancer are produced in China and imported by India.<sup>20</sup>

To promote the API sector, the government must offer its producers free land, low-cost public services such as water, steam and electricity and negligible financial costs. It should also liberalize policies for clinical trials and the approval of drugs already approved in other countries. It should also liberalize the conditions for clinical trials. Figure 3 shows steps taken to improve APIs production in India.

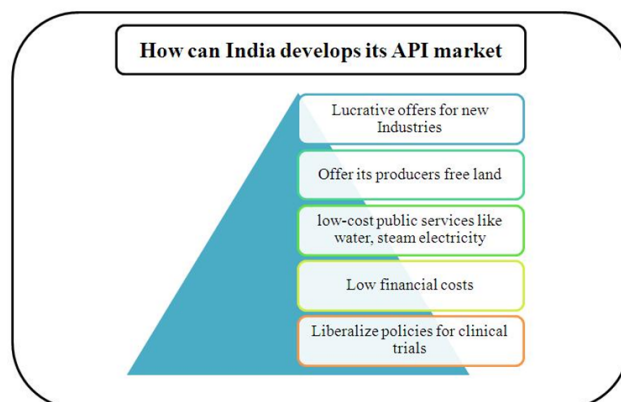


Figure 3: Steps taken to improve API production in India.

India's new efforts will also improve drug safety and quality. Last year, the FDA issued an alarm on a carcinogenic ingredient, NDMA, used in Losartan and Valsartan for blood pressure, produced by the Chinese company Zhejiang Huahai. This has resulted in the withdrawal of these drugs worldwide. In addition, last year, a scandal over the doses of contaminated vaccines sold in China led to the arrest of executives from Changsheng Biotech, who was also accused of falsifying the data during the production of a rabies vaccine given to children.<sup>20,21</sup>

In addition to the above problems, there is a disconnect between concerns expressed by official statistics about China's growing dependence on imports on business in the pharmaceutical division. Whereas representatives of the pharmaceutical sector express concern about China's growing dependence on imports, official statistics of trade does not reflect the same. None of the government agencies regularly provides data of imports for large quantities of drugs. The annual report of Department of Pharmaceuticals provides figures for full import only and not discretely for bulk formulations and drugs. Hence, it is very complicated to take on studies on the bulk pharmaceutical trade in the Indian pharmaceutical sector. Second, compared to the Indian pharmaceutical sector import data provided via Prowess (Center for Monitoring the Indian Economy) and WTO international business statistics, the import data reflected in the yearly reports come out to be mostly underestimated. So, it need an adequate experiential studies to obtain the truthful image.<sup>21,22</sup>

### Support from Indian API Manufacturers

Indian pharmaceutical manufacturers have many advantages, such as qualified employees, strong R&D potential, strong vertical integration of generic drug production and good R&D, innovation and design. However, there is room for improvement in the areas of GMP systems such as strengthening quality management systems, structures and equipment, materials control, documentation and laboratory systems etc. Necessary actions that can be taken by providing policies, resources, establishing regular protocols, necessary training for stakeholders and monitoring supply chains to ensure consistency by performing internal audits. Buyers of Indian drugs and importing countries must be assured of the quality of worldwide standards, as well as GMP. Despite the high quality of Indian medicines, some of the latest regulatory measures for some Indian manufacturing plants still require more detailed analysis. The domestic manufacturing industry should also consider the transition from the current

import-dependent scenario to the self-sufficiency of active pharmaceutical ingredients. The government is actively responding to this situation and is developing strategies to allow domestic pharmaceutical companies to produce high-quality and cost-effective APIs. It is necessary to classify SMEs better according to WHO-GMP, USFDA/EDQM/PIC and other international standards. The requirement of CGMP is the main legal protection in the production of medicines. The company must follow the requirements of CGMP to ensure the quality of production. Encourage the pharmaceutical industry to increase R&D expenditures and reduce taxes and fees on essential medicines and APIs to stimulate growth. However, more attention should be paid to public-private cooperation and industry-academia collaboration. Figure 4 shows some important points highlighting areas to work for improving opportunities for India.<sup>23,24</sup>

Therefore, it is time for India to become self-sufficient in API to avoid another deficiency such as that caused by the COVID-19

### Import Substitution Industrialization (ISI)

ISI's industrial policy is based on the understanding that economic development, especially industrialization, can be achieved only by increasing local capabilities that can replace imports to reduce or possibly eliminate economic leakage. Import substitution is the procedure of reducing or stopping the import of some goods by their substitution from domestic goods market of the country with similar domestic adequate and with superior consumer characteristics of price that is not higher than imported ones. Thus, import substitution



Figure 4: Opportunities for India.

strategy conforms to the goal of improvement of the pharmaceutical market.

The policy of import substitution in different time periods in more or less obvious form was adopted by the huge majority of the world.<sup>25</sup>

Positive practice in solving the troubles of import substitution in the pharmaceutical field was shown in India. Even 50 years before, a private pharmaceutical industry in this country was almost absent; the Indian market was occupied by multinational companies that have accumulated 85% of the pharmaceutical market in money equivalent. In 1970, India has taken patent law, there was established a state control over the prices on drugs, the program of preferences was implemented in public procurement for national producers if they produce medicines of the same quality as imported. This led to the fast growth of the Indian pharmaceutical industries; drugs of local production were considerably more profitable than imported drugs.<sup>26</sup>

The industry is now actively making efforts to work towards import substitution through a task force constituting various stakeholders that include government officials, Pharmexcil, manufacturers, CSIR (Council of Scientific and Industrial Research) labs and others. The task force is identifying top 100 imported raw materials and products. These products could be individually or jointly developed.<sup>27</sup>

Therefore, the policy of import substitution should be strictly followed in order to improve domestic production of APIs and their substitutes.

### **Use of pharmaceutical alternatives to reduce dependence on imports**

The import of drugs can also be controlled by drugs containing the same drug ingredients but in different forms of salts, esters or complexes. For instance, tetracycline phosphate or tetracycline hydrochloride equal to 250 mg of tetracycline base salt is considered substitute drugs. Different dosage forms and concentrations in a single manufacturer's product line are alternatives to drugs (for example, sustained-release dosage forms and standard immediate-release dosage forms of the similar active component). The FDA is currently considering a tablet and capsule containing the same active ingredients as the replacement drug at the same dose.<sup>28</sup>

So, if there are possibilities of pharmaceutical alterations due to the use of different salts of the same therapeutic residue available in the country. We are able to reduce the dependence on imports of numerous groups of bulk drugs.

## **CONCLUSION**

The COVID 19 outbreak also provided an opportunity for Indian pharmaceutical companies to manufacture API and alternatives as preferred alternative centers. India's dependence on Indian medicines has been regarded as a threat to national security and the central government has approved many measures to promote the production and bulk production of API and bulk drugs in the country. This includes the approval of a plan of Rupees 3 crore to establish three bulk drug fleets in three states and provide 20% financial incentives over the next six years to provide manufacturers with 53 leading drugs. The plan is expected to reduce the cost of producing bulk drugs in the country and its dependence on other countries. The lessons from COVID-19 pandemic conditions and incentive policy of central government are big expectation to change the global influence of Indian pharmaceutical companies. More importantly, it will reduce relies of the domestic pharmaceutical companies on a sole provider like China. The government must revitalize public sector companies so that they can produce large quantities of medicines in India without having to rely too much on market forces. In addition, the main problem affecting the department is that different government departments/departments deal with different aspects in the case of insufficient coordination; the Ministry of Health is responsible for managing regulations and health issues, the Ministry of Pharmacy is responsible for formulating drug policies and the School of Science and Technology is responsible for innovation. The Ministry of Finance is responsible for taxation and the Ministry of Commerce is responsible for trade-related issues. Everyone must act in a coordinated and consistent manner to solve current problems.

India also needs to take measures to revitalize the innovation of the domestic pharmaceutical industry in order to gain lasting leadership in this field. Financial and institutional incentives should be provided. It also includes other collaborations between industry, academia and research institutions to promote the discovery of open source medicines in neglected diseases and the establishment of incubation centers. If India will consider and implement the above steps along with consequent efforts, it will be possible to attain the desired results.

So, from the overall facts we conclude that India is able to eradicate the dependencies on other countries for bulk drugs if government takes some necessary steps as discussed earlier and some new industries may started for production of API and bulk drugs in India.

## ACKNOWLEDGEMENT

The authors express deep thanks to all the regulatory authorities, Industrial and Govt. professionals who helped us in completion of this article. A special thanks to Shri Arun Kharia, Managing Director, Nandani Medical Laboratories Pvt. Ltd, Indore for providing help and facilities throughout the work.

## CONFLICT OF INTEREST

The authors declare no Conflict of interest.

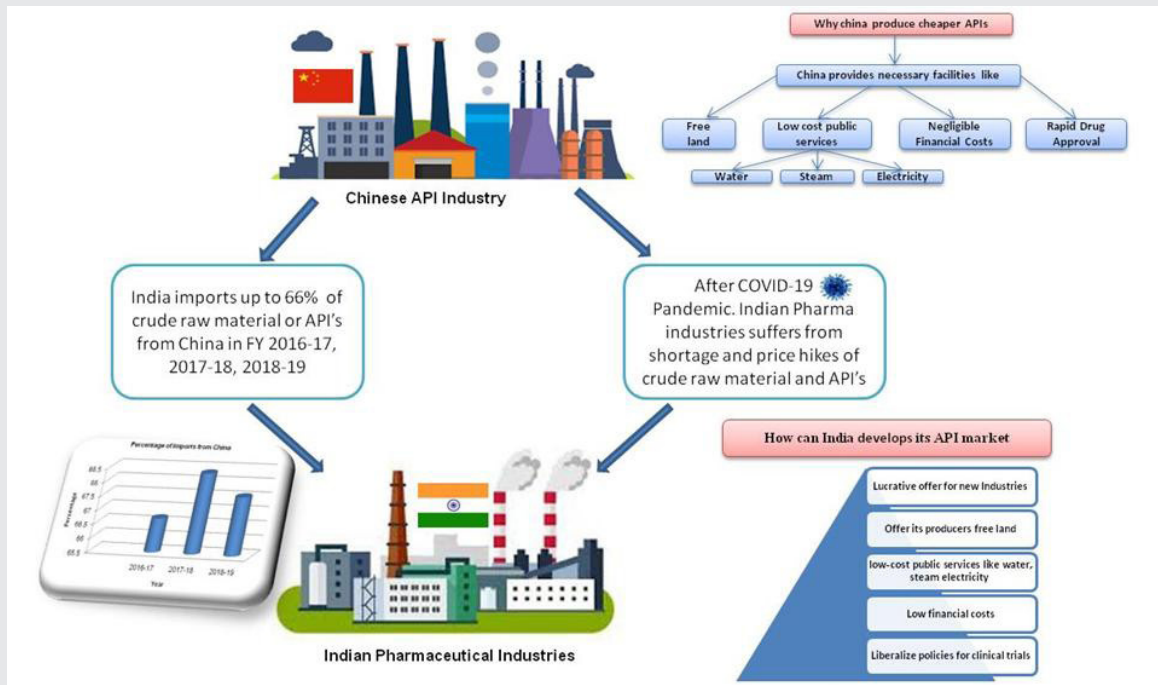
## ABBREVIATIONS

**API:** Active Pharmaceutical Ingredients; **COVID-19:** Corona virus disease 2019; **FDA:** Food and Drug Administration; **NDMA:** National Disaster Management Authority; **WTO:** World Trade Organization; **GMP:** Good Manufacturing Practices; **SMEs:** Small and Medium Sized Enterprises; **WHO-GMP:** World Health Organization - Good Manufacturing Practices; **CGMP:** Current Good Manufacturing Practices; **USFDA:** United States Food and Drug Administration; **EDQM:** European Directorate for the Quality of Medicines; **PICs:** Pharmaceutical Inspection Co-operation Scheme.

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## GRAPHICAL ABSTRACT



## About Authors



**Dr. Narendra Vyas** is presently working as Professor at Modern Institute of Pharmaceutical Sciences, Indore. He has done his B.Pharm and M.Pharm (Pharmacognosy) from Department of Pharmacy, Barkatullah University, Bhopal. He has completed his Ph.D from Bhagwant University, Ajmer in the year 2014. He has more than 12 years of teaching experience in the field of Pharmacy and many publications in National and International Journals of repute.



**Mr. Ankur Joshi** is presently working as Associate Professor at Modern Institute of Pharmaceutical Sciences, Indore. He has done his B.Pharm from Sun Institute of Pharmaceutical Sciences, Lahar and M.Pharm (Pharmacology) from B. R. Nahata College of Pharmacy, Mandsaur (M.P.). He has more than 12 years of teaching experience in the field of Pharmacy and many publications in National and International Journals of repute.



**Dr. Sapna Malviya** is presently designated as Head, Department of Pharmacy in Modern Institute of Pharmaceutical Sciences, Indore. She has received her pharmaceutical education from B. R. Nahata College of Pharmacy, Mandsaur (M.P.). She is Qualified ZED Consultant to Pharmaceutical Industries. Dr. Malviya achievements are recognized by her publications in various reputed peer-reviewed National and International journals, written articles and columns in newspapers on pharmacy education.



**Mr. Anil Kharia** is designated as Principal at Modern Institute of Pharmaceutical Sciences, Indore. He has done his B.Pharm and M.Pharm (Pharmaceutical Chemistry) from Dr. H S Gour University, Sagar. He is also a President of Indian Pharmaceutical Association, MP State Branch. He has more than 28 years of teaching and Industrial experience in the field of Pharmacy and many publications in National and International Journals of repute.

**Cite this article:** Vyas N, Joshi A, Malviya S, Kharia A. Reduced Pharma Supply Chain in COVID-19: Measures to Reduce India's Reliance for Active Pharmaceutical Ingredients on China and other Countries. Indian J of Pharmaceutical Education and Research. 2020;54(4):835-42.