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REVIEW ON IMPACT OF COVID-19 ON API IMPORT IN INDIA

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ABSTRACT

The coronavirus disease (COVID-19) pandemic, which originated in the city of Wuhan, China, has quickly spread to various countries, with many cases having been reported worldwide. Indian government implemented a lockdown throughout the country that started on March 24th, 2020, to reduce the transmission of the virus. This outbreak is inextricably linked to the economy of the nation, as it has dramatically impeded industrial sectors because people worldwide are currently cautious about engaging in business in the affected regions. India Pharmaceutical industry despite being a global market leader at generic drug formulations largely depends on imported API's from china. COVID-19 is wakeup call for Indian API Industry to reduce china dependence. The Indian government approved a plan in March 2020 aimed at increasing domestic API production in India. Under the plan, the government of India will provide grants-in-aid to states with a maximum limit of INR 1,000 crore ($131 million) for each bulk drug park.

KEYWORDS: Corona virus impact, Pharmaceutical industry, Active pharmaceutical ingredient, Bulk drug, china dependence, Government funding.

INTRODUCTION

In early December 2019, an outbreak of corona virus disease 2019 (COVID-19), caused by a novel severe acute respiratory syndrome corona virus 2 (SARS-CoV-2), occurred in Wuhan City, Hubei Province, China.[1] And Extremely soon corona virus disease spread worldwide this affects lives in many a ways like in health, industries, market, populations, safety concern, economy, etc.

The India Prime Minister Shri Narendra Modi called for the lockdown of entire nation on March 24, 2020 in an effort to contain the COVID-19 pandemic and the lockdown continued to 31 June 2020. Earlier (March 21, 2020) Modi meet with the leaders of the pharmaceutical industry via video conferencing to emphasize that the government is committed to helping the industry in maintaining the supply of active pharmaceutical ingredients (APIs) and stressing the importance of the manufacture of APIs. He said that in order to ensure production of critical drugs and medical equipment within the country, the government has approved schemes worth INR 10,000 crore ($1.3 billion) and INR 4,000 crore ($5.2 billion), respectively.[2]

In his meeting with members of the pharmaceutical industry, he added that it is imperative for the industry to work continuously and also ensure that there is not a shortage in the workforce in the pharma sector, which includes at the patient level.[2]

India supplies affordable and low-cost generic drugs to millions of people around the globe and operates more than 250 US Food and Drug Administration (FDA) and UK Medicine and Healthcare products Regulatory Agency (MHRA) approved plants. Furthermore, its active pharmaceutical ingredients (APIs) market is forecasted to attain revenue of $6 billion by the end of 2020.[3]

The active ingredient (AI) is the substance or substances that are biologically active within the drug and is the specific component responsible for the desired effect it has on the individual taking it. The purpose of APIs according to the FDA is to cause ‘pharmacological activity or other direct effects in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the human body.[4]

India and pharmaceuticals: longer term

According to a report on the Indian pharmaceutical industry, the source of APIs is a crucial part of the pharma industry’s strategic plan to combat the COVID-19 pandemic. The majority of APIs for generic drug manufacturing across the globe are sourced from India, which also supplies approximately 30 percent of the generic APIs used in the US. However, Indian manufacturers rely heavily on APIs from China for the production of their medicine formulations, procuring around 70 percent from China, the top global producer and exporter of APIs by volume.[3]

Indian pharmaceutical industries despite being a global market leader at generic drug formulations, Indian pharma players depend heavily for their bulk drugs and drug intermediates on China.

Prior to 1991, the Indian pharmaceutical industry only imported 0.3 percent of its APIs from China; however, the globalization of Indian pharmaceutical companies and the rise in large-scale formulation manufacturing prompted the increase in API procurement from China. The primary driver being the low cost of production.[3]

The details of India's import of bulk drugs/ drug intermediates are as under[5]

Year	Total imports (US $ mn)	Import from China (US $ mn)	Percent of import from China
2018-2019	3560.35	2405.42	67.56%

The impact of the corona virus COVID-19 outbreak has exposed the dependence of India on China for its active pharmaceutical ingredient (API) requirements. For India's pharma industry, which is staring at a probable supply chain disruption of APIs, this is a 'wake-up call' to reduce dependence on China.[6]

India is considerably dependent on Chinese imports for many APIs that are required to manufacture essential drugs listed in the National List of Essential Medicines (NLEM) 2015. Data analysis reveals that the value share of China in India's import of a few key bulk drugs — such as 6-APA, DCDA, PAP and Pen-G— is between 98 and 100 per cent. Reasons for that much dependence on china are.[2],[7]

1) Production cost of API in China is about 20-30% less than that in India.
2) High volume ingredients[8]
3) China exports API globally which provides huge economies of scale in manufacturing.
4) They have several government funding options as well as tax incentive schemes unlike we have it here in India.[7]

Where India is lacking behind[2]

1) Scale and cost competitiveness
2) High working capital costs, rising capital costs for setting up and expansion
3) Restriction of foreign investment in the sector
4) Unfavorable excise duty structure
5) Power and utility costs, which are much higher than in China

6) Lack of sufficient common effluent treatment plants

7) Constantly changing environmental policies adopted by states

Advantages for India[2]

1) Recent thrust by the US and European regulators for quality and adherence to GMP norms, gives India a significant advantage in competing with Chinese suppliers.

2) Having broad and deep knowledge of science associated with API and formulations

3) India has better quality complaint bulk drug manufacturing facilities in the country in comparison to those in China.

4) In the case of wage or labor cost, India still has an advantage as the GDP in China is about 5-10 times higher than ours. This automatically makes their labor more expensive

5) High labour pool.

Safety concerns

The pharma industries basically focus on manufacturing of quality product. The quality for pharmaceuticals is defined as the product having Quality, Safety, Efficacy, Identity, Purity, strength. In that one of the important factors is safety.

From this corona virus outbreak the safety and quality of APIs/ Bulk drug imported from china is trust issue. We can't put our patient's life in danger. So that Indian government completely stops the import from china.

What would be a future of India in API Production?

India imports almost 70% of active pharmaceutical ingredients (APIs) and intermediates from China, which is huge and needs be reduced.[2]

With China facing quality issues, India can become self dependent and can take a lead and plan big for exports.[9]

Generic drug market

The most attractive markets for API manufacturers are the US and Europe. Partly because they are the most lucrative markets – drug sales generated revenues of $4bn in the US in 2017 according to EFPIA. However, government support for generic pharmaceuticals in the US and Europe – as part of an effort to combat rising drug costs and healthcare spending – has further increased their attractiveness for API firms, US FDA [generic drug] approvals have accelerated, and the shift to more complex products that can capture a higher price is

more prevalent in the western markets. As health agencies in the Western markets continue to push generic utilization, the pricing for generic products, especially in Europe, exerts pressure throughout the supply chain. Despite the dominance of the US and Europe, markets elsewhere are becoming increasingly important for the API industry. Again this is partly due to growing pharmaceutical sales. However, shifting epidemiology is also a factor; rising healthcare spending in Asia continues to drive the attractiveness of the market, as well as the increasing prevalence of lifestyle diseases.[8]

Indian government regulations[7][2][10][11][12]

If China takes about six months to set up the factory and produce raw materials, India, on the other hand, takes about six years to build a factory for the production of raw materials. Indian API industry has a complex license renewal system. They need to approach various authorities for the renewal of application.[7]

The government should think of how to reduce this dependency on import of APIs and how to encourage manufacturing of API within the country. Tax incentives, subsidies, less compliance, ease of doing business and creating such an atmosphere can reduce the dependency in over 5-10 years down the line to 50%,"[12]

The Indian government approved a plan in March 2020 aimed at increasing domestic API production in India. The approved plan would provide financing of INR 3,000 crore ($394 million) for common infrastructure facilities for three bulk drug parks in India over the next five years. Under the plan, the government of India will provide grants-in-aid to states with a maximum limit of INR 1,000 crore ($131 million) for each bulk drug park. Parks will have common facilities such as solvent recovery plant, distillation plant, power and steam units, and common effluent treatment plants.

The approved plan also creates a Production-Lined Incentive (PLI) Scheme for promotion of domestic manufacturing of critical key starting materials, drug intermediates, and APIs in the country with financing of INR 6,940 crore ($910 million) for the next eight years. Under the PLI Scheme, financial incentives will be given to eligible manufacturers of 53 critical bulk drugs on their incremental sales over the base year (2019-20) for a period of six years. Out of 53 identified bulk drugs, 26 are fermentation-based bulk drugs, and 27 are chemically synthesized-based bulk drugs. The rate of incentive will be 20% (of incremental sales value) for fermentation-based bulk drugs and 10% for chemically synthesized-based bulk drugs.[2]

The goal of India's government is clear, namely, to reduce the company's dependence on imported APIs, which the government estimates for some specific bulk drugs can be as high as 80% to 100%. The Indian government said the plan is expected to reduce manufacturing costs of bulk drugs in the country and dependency on other countries for bulk drugs. The bulk drug park plan will be implemented by State Implementing Agencies (SIA) to be set up by the respective state governments in India.[2]

The PLI scheme intends to boost domestic manufacturing of critical key starting materials, drug intermediates, and APIs by attracting large investments in the sector to ensure sustainable domestic supply and thereby reduce India's import dependence on other countries. The scheme will be implemented through a Project Management Agency (PMA) to be nominated by the Department of Pharmaceuticals. The PLI plan will be applicable only for manufacturing of the 53 identified critical bulk drugs (i.e., key starting materials, drug intermediates and APIs).[2]

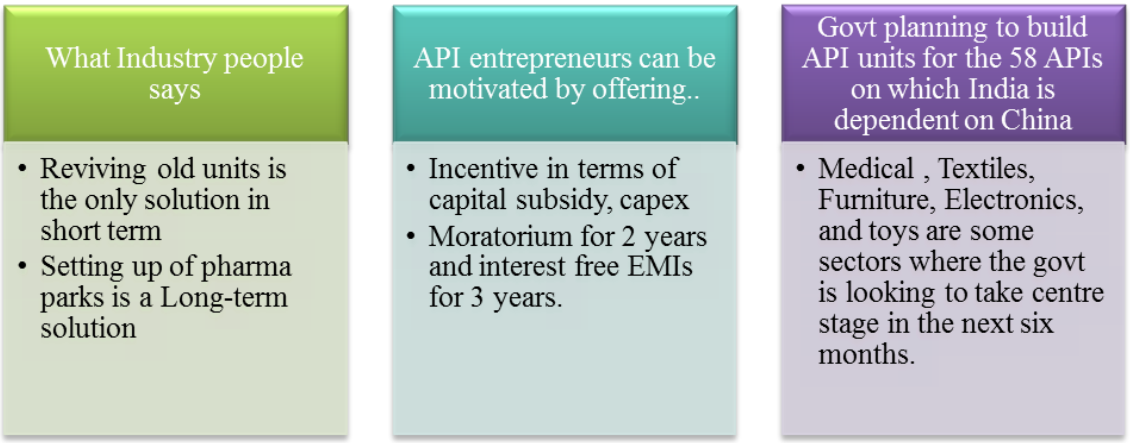

Fig.: Overview from different sectors about empowerment of API Industry.

WHO Plan For Covid-19[15]

The World Health Organization (WHO) has released a detailed plan on late April 2020 that seeks $31.3 billion in funding to support the Access to COVID-19 Tools (ACT) Accelerator, a global collaboration launched by the WHO and others to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines.

The WHO's plan calls for $31.3 billion in overall funding with funding targets in specific areas: vaccines ($18.1 billion), therapeutics ($7.2 billion), and diagnostics ($6 billion).

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