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Review Article

Impact of Covid-19 on the Active Pharmaceutical Ingredient Supply Chain

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Abstract: An increasing number of adverse events are raising concern in the pharmaceutical supply chain due to contaminated active pharmaceutical ingredients (APIs). Most of the active pharmaceutical ingredients are not currently under the scope of environmental regulations, despite their negative impact on human health and the environment. API's life cycle plays a significant role in identifying potential supply chain sources and determining their impact on the environment. The Covid-19 pandemic's intermittent manufacturing interruptions and the increase in the frequency of drug shortages over the past ten years have sparked worries about how resilient the world's drug supply chains are. Many clinical trials were conducted on patients with COVID-19 during the SARS-CoV-2 pandemic and resulted in millions of deaths globally by 2022.

Keywords: Active Pharmaceutical Ingredients, Supply chain, Covid-19, Drug shortage, Production

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1. Introduction

The pharmaceutical supply chain begins with primary manufacturing, which includes extracting herbal ingredients or synthesizing API chemically or biologically. Long cycle times are typically associated with primary manufacturing, which makes it less flexible to shifts in either demand or supply. In order to create the final products, secondary manufacturing adds excipients to the active ingredients made at the primary sites, then proceeds with additional processing and packaging. The importance of raw materials, excipients, and packaging materials as inputs into pharmaceutical manufacturing should be acknowledged when evaluating supply-chain vulnerability. Locations for secondary manufacturing are frequently situated apart from those for primary manufacturing. The location choices made by multinational corporations often take into account the optimization of transfer prices and taxes. Secondary production sites are more common than primary sites and typically cater to local and regional markets.

In the early 2020s, coronaviruses, especially severe acute respiratory syndrome (SARS)-CoV2, became a global concern. The world has witnessed an exogenous demand shock of APIs in the pharmaceutical industry as a result of the covid-19 pandemic [1]. Same time, global pharmaceutical industry faces huge challenges due to its dependence on China for APIs. A country's trade balance may suffer if it decides to impose export restrictions on generic medications in response to API supply chain issues. The Covid-19 pandemic has revealed weaknesses in logistics and supply chains. An export ban on API during Covid-19 restricts the prices that are rising as a result of the increased supply of drugs in the domestic market, but the unexpected demand for these drugs will also raise their costs domestically. However, the ultimate impact of the export ban on API prices may be uncertain due to the rise in demand brought on by preventive and curative measures. The circumstances surrounding the lifting of the export ban were fascinating.

As an alternative, it is imperative to assess domestic drug API supply capacities to prevent over-reliance on any one nation by the global pharmaceutical industries. The pandemic additionally offered an opportunity to reduce the dominance of China in API production [2]. There are several steps involved in the drug-development process. Typically, drugs are made up of two main parts: the substance known as an excipient and the API, or active pharmaceutical ingredient. APIs, sometimes referred to as intermediate drugs, are chemical compounds that are essential as raw materials to make pharmaceuticals. The API supply chain is made up of a number of interconnected processes that come together to manufacture the pharmaceutical drugs that US for patients. APIs are supplied by vendors to manufacturers, and further manufacturers ship them to wholesalers, distributors, and retail, specialty, and mail-order pharmacies; they are also sent to hospitals, clinics, nursing homes, jails, and other care facilities. While initial reports about API shortages have concentrated on foreign manufacturing, there is also reason for concern regarding the impact of the COVID pandemic on API distribution in the United States. According to reports, the pandemic, widespread illness, quarantines, and social distancing measures may make it harder for manufacturers to source the APIs. Furthermore, a rise in the need for specific drugs will result in a greater demand for a variety of APIs, including those used to treat critical illnesses and respiratory diseases during the COVID-19 pandemic. The COVID-19 pandemic has also put pharmaceutical supply chains through an exceptionally severe stress test. This has given forward-thinking businesses a chance to evaluate how they can improve capacity across the board, from patient delivery to manufacturing [3]. Pharmaceutical companies should be working closely with legal counsel to proactively review supply contracts in the near term. to identify potential cross-border issues, force majeure terms and implications, and indemnity provisions likely to be involved in contractual breaches due to COVID-19 disruptions or to assess tax implications associated with potential changes. Pharmaceutical executives can also maintain the focus of their organization on issues besides the pandemic by pointing out how novel innovations and strategies, like enhanced production capacity, can mitigate COVID-19. Some of the factors affecting the pharmaceutical industries in emerging markets are likely to intensify competition between current market leaders and increase growing risks related to climate-related disruptions, changing domestic regulatory environments in emerging markets that could affect existing API manufacturers, and more restrictive international trade [4].

2. Drug Shortage due to Covid-19

API shortages or abrupt drops in supply can result from disruptions in the drug supply chain. A drug shortage occurs when there is insufficient supply of an API, making drugs unavailable to patients in need of an equivalent substitute. The Covid-19 outbreak has brought attention to the precarious state of affairs, as has the unprecedented demand for pharmaceuticals across the United States. API shortages are now a major problem that impacts all healthcare systems due to COVID-19 [5]. Another significant definition of a shortage provided by the Food and Drug Administration (FDA) is "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." According to an analysis by the FDA, 62% of the disruptions that resulted in shortages between 2013 and 2017 were caused by quality issues. Additionally, this report indicates that the primary underlying cause of these drug shortages is economic in nature. Even though problems with API supply have reportedly been the source of multiple drug shortages, there isn't enough concrete evidence to conclude that outsourcing has played a significant role in this trend. Due to resource constraints, there is a deficiency in the reliable API supply required to decide how best to reduce the risk of dependence on foreign suppliers. Pharmaceutical companies recognize that global supply networks will be necessary to deliver for customers, but they can still take steps to lessen their exposure to operational risk. The severity of API shortages has increased significantly in the last ten

years. A number of factors, such as manufacturing issues and recalls, sole source agreements, and rising demand, can cause disruptions in the drug supply, which finally impact the API shortage. Shortage-causing supply-chain disruptions are a complicated global problem that can be impacted by trade, pandemics, weather, and politics. API shortages are concerning because they have a negative impact on drugs availability and they result in increased health care costs.

3. Covid-19 Impact on API Production

The initial supply chain management approach involves companies keeping an eye on the backward integrated activities involved in inventory procurement. This approach has allowed for a decrease in production due to factory closures and economic slowdown. In reality, the world's capacity to merely generate an additional source of APIs and drug manufacturers is an additional challenge. The regulatory machinery, which includes clinical trials and inspections, must be operated; this is not a task that is simple or quick to complete. Some concerns had been raised about China's and India's manufacturing standards during the coronavirus outbreak. Regulatory bodies conclude that outsourcing carries a higher risk to quality based on a sample of API manufacturing. The high concentration of API production in one area increases supply-chain vulnerability from a risk-management standpoint [6]. Many pharmaceutical companies receive deliveries from a single API supplier, so problems at this level could have a broad impact on the availability of drugs. Supply shortages are particularly problematic when there are few options for making up for the shortage when a primary or sole-source supplier of an API or finished drug delays or stops production [7]. There were serious concerns about a global drug shortage as a result of India's subsequent export restrictions on APIs and China's temporary shutdowns during the COVID-19 outbreak [8]. Many stakeholders and global authorities have begun to question the current supply-chain model due to this and the increasing frequency of API shortages over the past ten years. Political dependencies and weak supply chain resilience—which is the supply chain's capacity to withstand disruptions—are the two main causes of concern for the API shortage. (Lucker). Increasing the cost of generic medications, creating national drug reserves, and reshoring the production of APIs are commonly discussed strategies to prevent shortages and ensure drug supply. However, there is a good chance that any of these actions would raise healthcare expenses, either directly or indirectly. API supply chains need to examine their supply chains in the wake of the COVID-19 pandemic and increase their spending on risk-mitigation tools like risk inventory, agile capacity, and dual or multi-sourcing [9]. However, it doesn't seem likely that those initiatives alone will result in a significant change in the world's API supply chain. Consequently, among the strategies that have been discussed to encourage reshoring are tax incentives and possible reshoring subsidies. Additionally, such initiatives would seem more feasible if carried out at the transnational level given the scale effects and necessary capital expenditures involved. Those initiatives would, from a risk-management standpoint, strengthen supply-chain adaptability by expanding geographical diversity. Additionally, variety at the manufacturer level. Risk theory also recommends concentrating efforts on drug substances that have a higher supply risk and implementing a variety of mitigating strategies [10, 11].

4. Conclusion

COVID-19 pandemic has affected thousands of people worldwide; with significant economic changes in the past and to the changes to be made for future. Global pharmaceutical supply chains are now being put to the test by the Covid-19 outbreak, which has also confirmed how heavily these supply chains rely on APIs produced around the world. A growing proportion of biopharmaceutical APIs are being produced worldwide, which may alter the global manufacturing footprint somewhat, but

comparative cost advantages are the main driver of this region's high concentration of API manufacturing. API producers will probably increase their spending on risk-mitigation strategies like risk inventory, agile capacity, and multi-sourcing in the wake of the pandemic. However, it appears unlikely likely that this will result in a significant change in the world's API supply base of operations. Nevertheless, any of these actions would probably result in a direct or indirect increase in healthcare expenses. Furthermore, it would take years and a lot of work to reshoring a sizable portion of API production. Generic medications have become more popular during the pandemic, both for therapeutic and proactive uses. It is anticipated that this increasing demand will continue as people prepare to live with COVID-19. The unfavorable supply shock of APIs from China during COVID-19 significantly impacted generic medication supplies.

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