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Review Article

Current Risk in the Supply Chain for the Active Pharmaceutical Ingredients Business

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Abstract: The active pharmaceutical ingredients (API) are very critical substances for generic drugs. Any issue in the global supply chain for sourcing APIs heavily impacts generic drugs demands in the market. It is imperative to keep a close eye on the API supply in order to spot possible priorities for domestic manufacturing as well as bottlenecks in the US pharmaceutical supply chain. Most of the API's are manufactured in countries like India and China, and any issue in the manufacturing or supply of the API's may critically impact generic drug production globally. The Government and regulatory agencies must take initiatives to mitigate the risk of supply chain interruptions in the API business.

Keywords: Active Pharmaceutical Ingredients, Supply chain, Generic Drugs, Business Intelligence System

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1. Introduction

The term "active pharmaceutical ingredient" (API) refers to any material or combination of materials that are used to make pharmaceuticals. These drugs are designed to alter the structure or any function of the human body, or to have pharmacological or other direct impacts in the diagnosis, therapy, mitigation, prevention, or treatment of disorders. They are used as the active ingredient in the finished product. These drugs are designed to alter the structure or any function of the human body, or to have pharmacological or other direct impacts in the diagnosis, therapy, mitigation, prevention, or treatment of disorders. The production of an API involves multiple chemical compound reactions rather than a single reaction involving raw materials. An intermediate is the name for the chemical substance that is going to be an API raw material. There are around 10 different sorts of intermediates involved in the process of turning raw materials into APIs. It is cleansed and brought to a high level of purity by a protracted production procedure. Globally, 90 percent of patients consumed generic drugs only. It is widely acknowledged that a healthy competition in the generic drug industry is essential to bringing down costs and averting medication shortages. Different generics marketplaces have different levels of competition; generics with four or more manufacturers often have larger discounts than those with three or fewer, increasing the risk of a drug shortage in the supply chain. Producing active pharmaceutical ingredients (APIs), which are needed for manufacturing generic medications, is a vital part of the global supply chain that is overlooked when only completed products are the focus. The majority of manufacturers of generic medications depend on other businesses to provide the active pharmaceutical ingredients (APIs) for their medicines. There is a possible high degree of competition for sourcing APIs, which may contribute to a lack of supply and the failure of the generic medication market. Whatever the number of manufacturers supplying a generic drug in the global supply chain, if there is only one API supplier, that

drug will be at a significant risk of shortage. Furthermore, if an API only has one supplier, it may raise the cost of that API, at least until a different supplier joins the market. For almost a decade, the global supply chain has been plagued by drug shortages, which primarily affect inexpensive and injectable generic drugs. The COVID-19 pandemic has caused supply-chain disruptions that have made shortages worse and made it more important to comprehend where medications marketed in the US come from elsewhere [1]. It was impossible to determine the frequency of usage of the APIs in the US or the cost of the equivalent finished pharmaceutical products [2]. Analysing the global API sales information would enhance the capacity to gauge the level of rivalry and supply risk of the different API marketplaces and offer a viable path for further investigation. When compared to medications with a high sales volume, drugs with a single API producer may not be as concerning if their sales volume is low. It's possible that factors like sales volume and the number of manufacturers won't be enough to accurately predict the possible effects of critical drug product shortages. Additionally, it is crucial to evaluate the therapeutic value that each API represents. One way to do this is by looking at the therapeutic classes that were used in this study. Certain markets may be crucial for which manufacturing variety would be advantageous, even if these markets were smaller. There are numerous medications in short supply in the United States at any given time. prescription shortages are a persistent issue that have detrimental effects on patients' health as well as the health care system, including higher prices and dangers associated with prescription replacements. The Government Accountability Office has conducted an analysis of FDA data and found a direct correlation between the unavailability of APIs and roughly one in ten drug shortages that occurred between 2011 and 2013. Thirty percent of drug shortages were caused by production delays, while an additional forty percent were caused by quality issues. Since the quality of the API plays a significant role in determining the quality of finished generic medications, both of these scenarios may also be related to API difficulties. It is also challenging for regulatory bodies and producers of generic drugs to oversee and enforce API production quality when APIs are manufactured abroad. It also complicates the process of managing operations across the supply chain. The ability to protect vulnerable people's health depends mainly on the actions and goals of other nations when the supply of generic medications is dependent on foreign sources for APIs. This puts the global pharmaceutical supply chain's capacity to anticipate and address public health emergencies in jeopardy. Additionally, if nations create incentives or impediments to API production, global suppliers may shift over time. Figure 1 shows the key issues of the supply chain for API business.

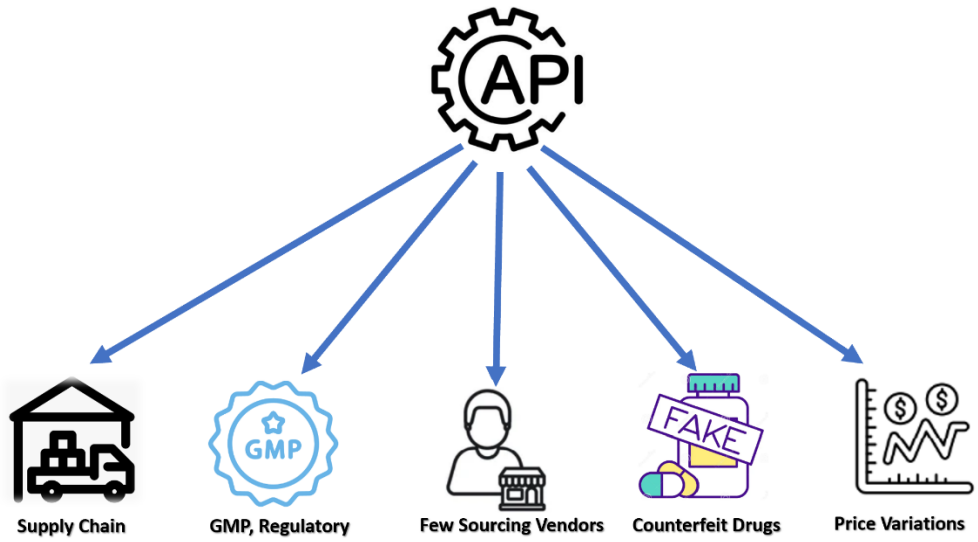

Figure 1. API distribution issues in the global supply chain

2. Dependability on limited sources

Dependence on a single or a small number of API sources is one of the major issues facing global API supply chains. The supply chain is susceptible to disruptions in multiple countries because of the heavy reliance on just a few of crucial suppliers for essential APIs [3]. The pricing and availability of critical drugs may be impacted by factors including price variations or shortages caused by trade disputes, geopolitical tensions, and changes in regulations in important production countries.

3. GMP and Regulatory compliance

It is crucial to guarantee the safety and quality of APIs in order to safeguard patient health. It can be difficult to maintain uniform quality control throughout international API supply chains, though. Variations in regulatory regulations, inspection processes, and manufacturing standards within nations might result in disparities in API quality [4]. It is imperative that the government unify regulatory standards and enhance cooperation among regulatory agencies. Mutual recognition agreements, Good Manufacture Practices (GMP) observance, and the creation of international norms for API manufacture can all contribute to ensuring regulatory compliance and uniform quality control along the whole supply chain.

4. Counterfeit Active Pharmaceutical Ingredients.

Worldwide API supply networks are susceptible to various security risks, such as the possibility of counterfeit pharmaceuticals. Due to the possibility of inferior or hazardous components, counterfeit APIs seriously jeopardize patient safety [5]. Counterfeit APIs may enter the market to flaws in supply chain security, including poor tracking mechanisms, improper access, and a lack of transparency. The risk of counterfeit pharmaceuticals must be reduced by putting strong supply chain security measures in place. API verification and authenticity can be improved by technologies like blockchain and barcoding systems, which allow partners to monitor drugs movement and spot possible counterfeits drugs. To successfully tackle counterfeit medications, cooperation between producers, authorities, and law enforcement organizations is also required.

5. Price Variations

One major issue facing international API supply networks is fluctuations in prices. The selling price of APIs can be impacted by changes in market conditions, currency valuations, and the cost of ingredients, which can ultimately affect the cost of pharmaceuticals [6]. Cost variations have the potential to put pressure on the API supply chain, restrict patient access to life-saving drugs, and raise healthcare expenditures. A number of measures can be used to reduce price volatility and increase accessibility. Stabilizing prices can be achieved through aggressive competition evaluation, long-term agreements with suppliers, and strategic collaborations among manufacturers. More ways to make APIs more affordable include fostering competition for generic drugs, supporting the growth of regional production capacities, and looking at economical sourcing choices.

6. Secure global supply chain

There are unique difficulties associated with the transportation and logistical components of global API distribution networks. Since APIs are frequently sent across geographical locations, interruptions or other problems with logistics may affect the drug's availability to patients [7]. Lack of facilities, convoluted customs processes, and transportation obstacles can cause delays, destroyed APIs, and higher expenses. To overcome these obstacles, effective supply chain management and logistics for transportation efficiency are necessary. API flow may be ensured and delays can be

minimized by working with dependable logistical partners, utilizing technology for real-time tracking and monitoring, and expediting customs clearance processes.

7. Data interoperability

Data interoperability amongst stakeholders across global API supply chains is crucial to effectively managing the challenges. To improve openness, exchange best practices, and share knowledge about new hazards and mitigation techniques, manufacturers, regulators, healthcare providers, and international organizations must collaborate. Conversation, information exchange, and the creation of shared standards can be facilitated by the establishment of forums for collaboration, such as international projects and industry groups. Improving partner collaboration and interaction can result in better risk management, increased transparency in the supply chain, and quicker interruption response times.

It would be especially important for medications whose APIs are currently in restricted supply or for drug classes where redundant or excess supply is specifically needed. It takes time and money for generic drug manufacturers to find and connect with API providers throughout the global supply chain on their own [8]. Governments can provide incentives to support the pharmaceutical production of APIs, including tax credits, grants, and state-led investment, along with a focus on finished drug production. However, encouraging local API manufacturing is primarily difficult when it comes to offering incentives to local generic medicine makers to choose domestic APIs, as they cost more than those imported from abroad. There is likely a need for additional incentives for local manufacturers to establish a market for domestically made APIs due to intense price competition in the generic medicine industry [9]. The government must provide its producers with free land, inexpensive public utilities like power, steam, and water, and minimal financial charges in order to support the API industry. Clinical trial regulations and the approval of medications that have already received approval in other nations ought to be liberalized as well.

8. Conclusion

The majority of generic medication manufacturers outsource the development and production of the active pharmaceutical ingredients (APIs) needed for the final pharmaceutical products they sell, rather than developing or producing these in-house. While generic manufacturers can gain from economies of scale and reduced production costs when APIs are produced externally, the US pharmaceutical supply chain is left more vulnerable as a result. It might be possible to find generic medications with covert supply-chain vulnerabilities by keeping an eye on API sources. This would be especially important for medications whose APIs are currently in restricted supply or for drug classes where redundant or excess supply is specifically needed. To ensure that the US pharmaceutical supply chain is prepared to meet the needs of vulnerable populations and strengthen its resilience in times of crisis and beyond, it is imperative to monitor global sources of API supply, broaden the definition of generics markets at risk for shortage to include markets with few API manufacturers, and diversify the supply chain, including through increased incentives for the domestic production of key APIs.

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