



# Active Pharmaceutical Ingredients (API) Shortages

Addressing the Challenges of API Shortages through Real-Time Insights and Data Intelligence



# Drug Shortages

## What is a drug shortage?

Without a standard definition, the concept of drug shortages is multifaceted, **with more than 56 definitions worldwide**. These definitions may focus either on the supply side or on the demand side of the pharmaceutical industry, and they take into account factors like the level in the drug supply chain or the duration of the shortage.

**However, there is a generally accepted understanding of what a drug shortage represents and the common elements include:**



**Insufficient Supply:** This can result from various factors, such as production issues, regulatory problems, or disruptions in the supply chain.



**Impact on Patient Care:** If patients cannot access necessary medications due to a shortage, it can have serious health implications.



**Duration:** Drug shortages can be of varying durations, ranging from short-term disruptions to prolonged, ongoing shortages.



**Scope:** The scope of the shortage can range from a single drug to multiple drugs or even broader categories of medications.



A drug shortage can be defined as a situation in which the supply of a pharmaceutical product is insufficient to meet the current or anticipated demand.

Drug shortages can vary in terms of severity and duration and can impact the availability of essential medications, potentially leading to challenges in patient care and public health.

# First drug shortage

## The insulin crisis

The first recorded drug crisis was the insulin shortage in 1920s that became a pivotal moment in the history of drug manufacturing.

The insulin shortage highlighted both the challenges of ensuring a consistent supply of vital medications and also the need for sustainable production methods, quality control, and a strong supply chain in the pharmaceutical industry.

This event can be seen as a precursor to the more frequent and complex drug shortages that have become a concern in recent decades.



# Drug Shortages

## Why do drug shortages occur?

The US Food and Drug Administration (FDA) primarily attributes shortages to quality/manufacturing issues but also points to production delays, some caused by not receiving raw materials and components from suppliers, and drug discontinuations.

Drug shortages can be attributed to a variety of causes, and these causes can be broadly categorized into **three main groups**:



Supply issues



Demand issues



Regulatory issues

***An estimated 70% of shortages are caused by manufacturing and quality problems.” - Healthcare Supply Chain Association.***

There were identified at least **four key factors** as driving medicine shortages:

- ➔ Low Manufacturer Profit Margins
- ➔ Quality Issues
- ➔ Geographic Concentration
- ➔ Manufacturing Complexities





**The multifactorial nature of drug shortages means that multiple factors can contribute to a shortage.**

**Let's deep dive into some of the main causes of drug shortages:**



- ➔ **Manufacturing Problems:** Manufacturing issues can disrupt the production of medications. These problems may include equipment failures, quality control issues, contamination, or other factors that prevent the smooth and consistent manufacturing of drugs.
- ➔ **Just-in-Time Inventory:** The use of just-in-time inventory management, a strategy to reduce inventory carrying costs, can make pharmaceutical supply chains more vulnerable to disruptions. With this approach, companies keep minimal stockpiles of medications, leaving little room for error in the event of supply chain interruptions.
- ➔ **Financial Pressures:** Financial challenges faced by pharmaceutical companies can impact their ability to produce certain drugs. Factors such as increased production costs, reduced profit margins, or the high cost of complying with regulatory standards can influence a company's decision to continue producing a particular medication.
- ➔ **Shortage of Active Pharmaceutical Ingredients (API):** Many drugs rely on specific raw materials or active pharmaceutical ingredients (APIs). Shortages or disruptions in the supply chain for these raw materials can directly affect drug production, leading to shortages of finished pharmaceutical products.

# Active Pharmaceutical ingredients (API) Shortages

Starting with the pandemic context, the pharmaceutical industry has been facing a paradox: while global demand for medications has surged, the supply chains responsible for delivering these vital products have grown increasingly fragile.

Central to this vulnerability is the production of Active Pharmaceutical Ingredients (APIs) – the critical components that give medicines their efficacy.



- ➔ **Pharmaceutical raw materials** are the basic components or ingredients used to produce medications, such as tablets, capsules, injections, and other drugs. These raw materials can be of various types, including active pharmaceutical ingredients (APIs), excipients, and packaging materials.
- ➔ **Active pharmaceutical ingredients (APIs)** are the primary active component in a medication that provides its therapeutic effect. Excipients can include fillers, binders, lubricants, and preservatives. On the other hand, inactive substances are added to the medication to assist with the formulation, effectiveness, and stability.

## Geographic Concentration of API Manufacturing

### A leading factor for API shortages

Supply chain disruption has led to delays in raw material availability and shortages. The pandemic magnified the challenges of pharma companies' heavy reliance on foreign contract manufacturing organizations (CMOs).

**Delivery times for shipments from Chinese CMOs to the U.S. West Coast took less than 50 days till early 2019. In January 2022, these delivery times hit a record high of 113 days.**



**The U.S. imports nearly 70% of APIs. While China contributes ~15% to the U.S. API market, the European Union, which is currently involved in the Russia-Ukraine conflict, offers ~25% of the API manufacturing facilities.**

- ➔ Many pharmaceutical companies have centralized their active pharmaceutical ingredient (API) manufacturing in a few regions, particularly in countries like China and India where labor and production costs are lower, to cut expenses and improve efficiency.
- ➔ Labor in developing countries such as India and China saved companies up to 40% annually compared to U.S. labor wages.
- ➔ **This offshoring strategy**, while economically efficient, has made supply chains lengthier, more complex, and more susceptible to disruptions, whether from geopolitical tensions, trade wars, natural disasters, or pandemics.

# Geographic Concentration of API Manufacturing

## How to meet this challenge?

- ➔ **Diversifying production of active pharmaceutical ingredients (APIs)**
- ➔ **Mapping APIs and medicine supply to quantify risk:** To avoid unnecessary and life-threatening disruptions to the medicine supply chain, it's essential to know where and how many APIs are produced to better anticipate potential risks and take action.
- ➔ **Increasing speed and improving efficiency through continuous manufacturing,** which produce medicines more efficiently than traditional technology, with a smaller environmental footprint.  
  
Currently, most medicines are produced using batch manufacturing, which involves multiple steps – like blending, weighing, compressing, or coating – at multiple times, across multiple locations, with starts and stops throughout the process, including confirming the quality of the product.
- ➔ **Investing in manufacturing in low- and middle-income countries:** To improve equitable access to vaccines and medicines, some regions are expanding their manufacturing capacity to reduce reliance on external forces and markets. This includes Africa, where approximately 70-90 percent of medicines are imported from outside the continent.
- ➔ **Re-shoring API Manufacturing - A New Direction for the Pharmaceutical Industry:**  
While overseas manufacturing can offer cost benefits, the hidden costs of supply chain disruptions, coupled with potential incentives from governments, make the economic argument for offshoring less definitive. Reshoring can also lead to faster response times, better quality control, and increased intellectual property protection.



# Re-shoring API manufacturing by leveraging **intelligent data**

From strategic planning and location scouting to supply chain establishment and risk management, data-driven insights can guide and optimize the re-shoring process.

**Here are 10 essential areas where precise B2B data can empower an API manufacturer:**



## **Helps identify optimal locations**

for setting up new manufacturing units domestically.

## **Provides data on skill sets and**

**salary trends** can assist companies in workforce planning and talent acquisition.



## **Helps identify local suppliers for**

**raw materials**, intermediates, equipment, and technology.



## **Offers insights into cutting-edge**

**technologies** suitable for modern API production.



## **Provides insights into the comparative costs of domestic vs. overseas manufacturing,**

including hidden costs like transportation, tariffs, and potential supply chain disruptions.

## **Helps identify potential partners,**

ranging from local governments to academic institutions and technology providers to foster collaborations and joint ventures.

## **Provides knowledge of local regulations and standards,**

ensuring smooth and compliant establishment and operations.

## **Provides insights into potential**

**risks** associated with re-shoring, such as geopolitical factors, local economic conditions, or environmental concerns.



## **Provides data to understand the**

**competition** - this can guide manufacturers in defining their strategies to stay competitive.



## **Provides insights into how competitors are approaching**

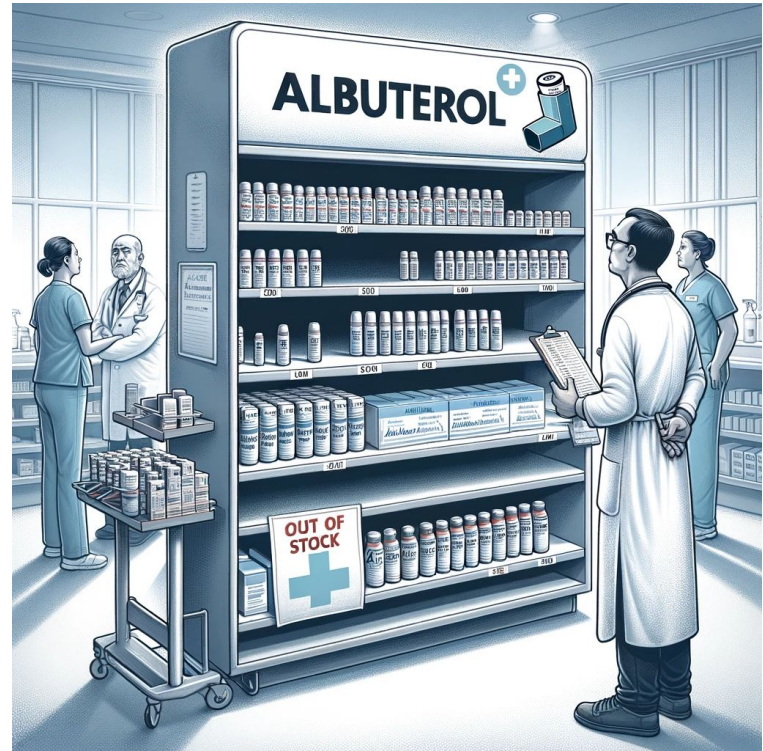
**re-shoring**, allowing companies to benchmark their strategies and find competitive advantages.

# The Albuterol Shortage:

## A Fast-Growing Crisis

Whether caused by a virus or a chronic disease like asthma, respiratory issues are very common nowadays and chances are that at some point in your life you or someone you know has used an inhaler to treat them.

**The most common generic drug prescribed with inhalers is liquid albuterol.**



## What is Albuterol and how does it work?

Albuterol is a common asthma medication. It relaxes and opens the airways to treat asthma symptoms, such as coughing, wheezing, chest tightness and shortness of breath.

Liquid albuterol is used in nebulizers to treat asthma. The nebulizer converts the liquid into a fine mist that is then inhaled. Many people with asthma and hospitals rely on liquid albuterol for quick-relief breathing treatments.

**Yet despite its essential status, this drug is one of the latest medications to suffer a shortage in the United States.**

# The Albuterol Shortage:

## A Fast-Growing Crisis

The shortage of albuterol sulfate inhalation solution has been a cause for concern in the healthcare and pharmaceutical industries. The Food and Drug Administration (FDA) officially recognized the shortage in October 2022, marking it as a national health crisis. Since then, the situation has only worsened, leaving pediatric hospitals scrambling to find alternative solutions.



*“When there are only one or two big factories making a drug, that is where you run into problems.”*

The shortage took a devastating turn when one of the primary suppliers of albuterol sulfate inhalation solution, Akorn Pharmaceuticals, filed for bankruptcy in February 2023. This unfortunate development led to the closure of major manufacturing plants in New Jersey, New York, and Illinois, compounding the already critical shortage of this vital medication.

Three other pharmaceutical companies supply albuterol to the U.S. — Nephron, Mylan (now part of Viatris) and Sun.

Only Nephron commented on the shortage, saying it has been unable to meet demand due to **manufacturing issues**. Nephron is the only remaining domestic albuterol manufacturer, and though it has since resumed shipping across the country, the climb to normal supply levels continues to be slow.

# The reason behind Albuterol Shortage:

## A Fragile Pharmaceutical Supply Chain

The shortage of albuterol sulfate inhalation solution is not an isolated incident but rather part of a broader issue related to the fragile domestic supply of vital generic drugs. This problem has been exacerbated by the COVID-19 pandemic and continues to affect various types of medicines.

There are several key factors that contribute to this problem:

- ➔ **Limited Profit Margins:** Many generic drugs have low profit margins, which can make them less attractive for pharmaceutical companies to manufacture. These drugs are typically cheaper for consumers and healthcare providers, but they also offer less potential for substantial profits compared to brand-name drugs or newer, patented medications.
- ➔ **Few Manufacturers:** Because of the low profitability of some generic drugs, there are often only a few manufacturers producing these medications. If one of these manufacturers encounters a problem, such as bankruptcy or manufacturing issues, it can lead to a significant shortage.
- ➔ **Supply Chain Disruptions:** The COVID-19 pandemic exposed vulnerabilities in the pharmaceutical supply chain. Lockdowns, restrictions, and disruptions in global transportation and manufacturing have disrupted the production and distribution of various medications, including generic drugs.
- ➔ **Regulatory and Quality Control Challenges:** Regulatory agencies like the FDA play a critical role in this process. However, challenges related to regulatory compliance and quality control can lead to production delays or even shutdowns of manufacturing facilities.
- ➔ **Market Forces:** Market dynamics, including mergers and acquisitions in the pharmaceutical industry, can also impact the supply of generic drugs. When larger pharmaceutical companies acquire smaller manufacturers, they may choose to discontinue certain generic medications or alter production plans, which can affect the availability of these drugs.



# Addressing Albuterol Shortage

## Using Veridion's Data Intelligence Tools

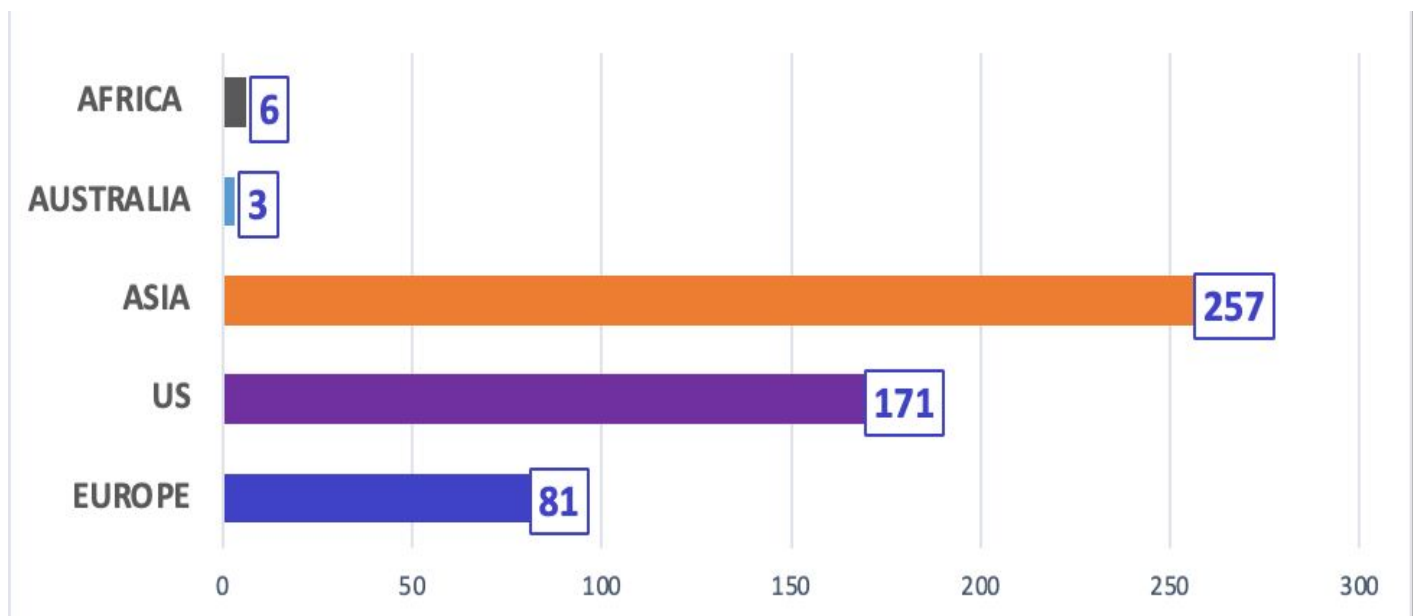
### Analyzing Albuterol distribution across continents using Veridion API Search technology

Veridion used its API search tool to conduct a simple analysis of global Albuterol manufacturers.

**Veridion's cutting-edge technology has shed light on the distribution of Albuterol production facilities across continents, revealing a significant concentration of Active Pharmaceutical Ingredients (API) manufacturers in Asia.**

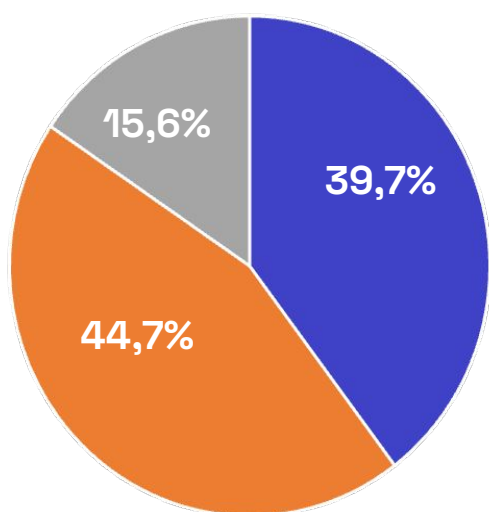
This insight is particularly crucial amidst the ongoing Albuterol crisis in the US, where supply chain challenges have been exacerbated by the heavy reliance on Asian manufacturers.

### Veridion API Search tool found 171 Albuterol manufacturers in US



The data curated by Veridion unveils that Asia is home to a staggering number of 257 Albuterol manufacturers, which is emphasizing the continent's dominant role in producing this active pharmaceutical ingredient.

Albuterol Manufacturers in Asia



■ China ■ India ■ Rest of Asia

- ➔ Within Asia, China and India emerge as pivotal players, boasting 102 and 115 Albuterol manufacturers, respectively.
- ➔ This geographical concentration highlights a critical dependency that could have far-reaching implications for global health, especially in times of medical urgency.

## The Solution: Continuous Manufacturing

Researchers are looking to develop a continuous manufacturing process for albuterol production, a flow that would eliminate transition times and create the final product much more quickly. Continuous manufacturing has been applied to pharmaceuticals before but never for liquid formations like albuterol.

Launched in October 2022, the albuterol manufacturing study will run for 36 months. See more details [here](#).

# Highlights: Addressing API Shortages

## Using Veridion's Data Intelligence Tools

Veridion's intelligent data can play a pivotal role in addressing API shortages by offering various solutions:



### Supplier Discovery & Verification:

Veridion Search API can offer extensive databases of suppliers to identify alternative suppliers quickly.

**Data on supplier reliability, quality, and compliance can help in ensuring that the APIs sourced meet the required standards.**



### Market Insights:

Veridion Search API can provide data on market trends and demands to help manufacturers understand the evolving landscape.

**Insights into emerging markets or alternative therapeutic solutions can guide R&D and strategic investment decisions.**



### Crisis Management:

In the event of a crisis, like a pandemic or geopolitical disruptions, Veridion's data can help in making swift decisions to **reroute suppliers, adjust production schedules, or find alternative sources.**



### Collaboration Opportunities:

Veridion's intelligent data can facilitate partnerships, joint ventures, or collaborations among manufacturers, researchers, and other stakeholders.

**Collaborative efforts can lead to shared resources, knowledge transfer, or the co-development of alternative sources for APIs.**



### Monitoring Competition:

Veridion can provide intelligence on competitors' activities.

**This information helps a manufacturer understand where they stand in the market and what innovative steps they might need to take to stay competitive.**

# Get in touch with us

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