

Deciphering the industry drivers behind drug shortages

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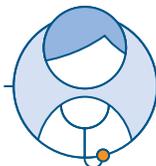
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Pharmaceutical distributors pride themselves on delivering their own brand of solutions to help customers enhance efficiencies while supporting quality care. Yet, when it comes to industrywide drug shortages, all wholesalers face similar challenges.

Prescription drug shortages are an ongoing and industrywide problem, and no distributor is immune to the inventory challenges they pose. While drug shortages affect only 1% of all prescriptions,¹ that slim percentage can add up to frustration for millions of U.S. patients and their healthcare providers, as upwards of 5.9 billion prescriptions are dispensed each year.² Although these shortages cannot be predicted or prevented by entities near the end of the supply chain, pharmacies can strengthen their ability to adapt and endure by understanding the causes, tapping into up-to-date resources, and consulting their distributors for guidance.



The FDA reports that today's shortages are more severe and longer lasting than historical norms.



Disruptions in the drug supply chain

The U.S. drug supply chain is globally fragmented, vastly complex and famously guarded with manufacturing information since disclosure is not required.³ As a result, any number of factors along the supply chain can spark a shortage — from ongoing product rationalization and global recalls to natural disasters. When these or other events cause certain drugs to be in short supply, distributors and their customers may feel the effects immediately, or not for some time, depending on how each supplier distributes products across its supplier base. In some cases, products are distributed evenly when a batch comes through. In other cases, the distributor that happens to be first in line will get the majority of the product and appear to have a superior buying strategy — until the next delivery, when it's another distributor's turn.

Although drug shortages had been on the decline from 2013 through 2017, the FDA reports that today's shortages are more severe and longer lasting than historical norms. In fact, the top five longest-running drug shortages have kept those drugs in short supply for an average of nearly eight years — and counting.⁴

Despite the inherent uncertainty and frustration associated with drug shortages, understanding common causes and staying up-to-date with changes in the marketplace is a valuable way to enhance visibility and prepare your organization to respond accordingly.

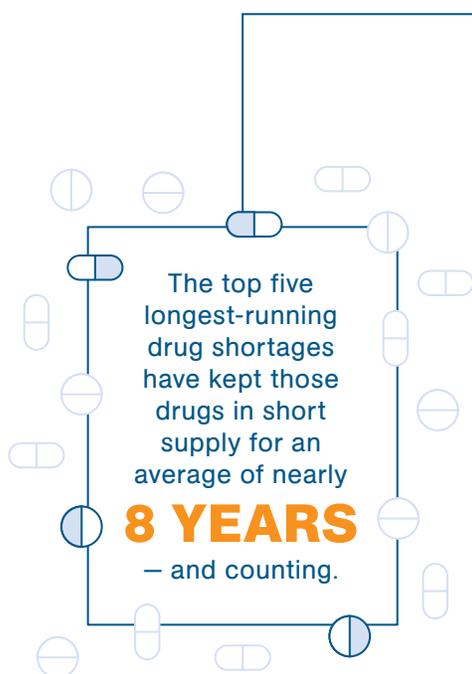
MOST COMMON CAUSES OF SHORTAGES

Diminishing complexity: Sorting out the causes

The supply of both generic drugs and branded products may be interrupted by events in any of three key categories: marketwide supply constraints, product-specific issues and ongoing supplier rationalization. Within those categories, some of the most common causes of shortages include:

Sourcing limitations

A common misconception is that drugs generally have five or six suppliers. In reality, more than 60% of molecules have only one or two suppliers.⁵ This leaves little room for error, since disruptions to single- or dual-source supply chains tend to have a more pronounced effect on the market than those with more suppliers.



Global recalls

Global recalls can have a significant impact on service levels. And when those recalls affect multiple products, such as recalls on the raw materials or methodologies used in the manufacturing process for a family of drugs, the remedy can be so costly and extensive that it forces some suppliers out of the market — further constricting an already tight supply.

Manufacturing issues

In addition to quality issues that may be addressed by global recalls, manufacturing challenges are among the most common drivers of shortages in the drug industry, according to the Food and Drug Administration.⁶ These issues can include limited production capacity due to single or dual sourcing, along with complex manufacturing processes and long lead times that can make certain drugs more vulnerable to shortages.⁷ Products with a narrow therapeutic index, and those that are difficult and costly to make, may also face supply constraints.

Generic deflation

As margins shrink on generic drugs, manufacturers may eliminate these products, shifting the production burden to other makers that may not be prepared to immediately absorb the added volume.

Discontinuing products

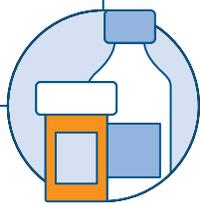
Much like generic deflation, ongoing product rationalization is a fact of life in the U.S. drug market. Suppliers may eliminate name-brand or generic products from their portfolios altogether, or discontinue certain pack sizes — resulting in shortages of those products.

API issues

Changes to the requirements for active pharmaceutical ingredients (APIs) can contribute to drug shortages. Market intelligence regarding APIs is very difficult for non-vertically integrated wholesalers to obtain since supplier sources for these ingredients are considered proprietary. Even with this lack of visibility, it's well known that many suppliers have API sources in China, India, Eastern Europe and other overseas locations — making geopolitical and regional issues two potential disruptors worth following.

Disasters

When hurricanes, fires or other disasters sweep through an area where drugs or APIs are produced, the effects to the drug supply chain can be



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Resources to study and share

Drug shortages happen. But by taking advantage of online resources provided by the federal government, industry associations, and distributors, pharmacies can gain improved visibility into issues and events affecting the availability of prescription medications. Here are just a few ways to stay in step with these issues:

- Search the online database of the **FDA** or connect on Facebook, Twitter, or LinkedIn to stay current.
- Check drug shortages and discontinued drugs, or report a shortage at **ashp.org**, the American Society of Health-System Pharmacists.
- Take advantage of communications and tools (email newsletters, downloadable white papers, etc.) focused on the state of the industry and specific shortages.
- Set **Google alerts** to receive breaking news about specific drugs or manufacturers.



devastating, too. For example, when Hurricane Maria struck Puerto Rico, the powerful storm affected roughly 50 pharmaceutical manufacturing sites, including makers of top-selling biologics and components.⁸

Pricing strategies

When a manufacturer drops its market price on a high-demand product to expand market share, a drug shortage may occur. Since these measures to undercut the market may be enacted overseas, rather than in the U.S. market,⁹ the resulting shortages may come as more of a surprise to distributors and pharmacists here at home.

Enhancing infrastructure: Investing in agility

Just as healthcare systems continue to invest in internal systems and processes to better anticipate and respond to dynamic conditions, distributors are making considerable investments to help tame the supply chain infrastructure. By enhancing system efficiencies, improving business processes, and hiring and developing talented team members, forward-thinking distributors are equipped to act with agility.

Invariably, and unfortunately, drug shortages are sure to arise even under the most watchful eyes. And when they do, some distributors already have a dedicated team and system to work in conjunction with their inventory management protocols to source backup inventory for short-term supply issues. Savvy distributors also maintain strong supplier relationships to position themselves to make quick, well-informed decisions on product-specific intelligence. These are just a few of the strategies that support a stable supply, whenever possible, at a competitive cost.

From a supply chain perspective, it's important to understand that by the time drug shortages become public, those products are already being closely monitored by suppliers — so it's not an option for distributors to simply order more of the product in the early days of a shortage. It's also difficult to compare service levels of various distributors since everyone measures these levels differently. With no common definition of service levels across the industry, comparing percentages is an apples-to-oranges comparison at best. And when distributors do receive shipments of hard-to-obtain products, their methods of doling these items out to their customers are as varied as the methods of the suppliers themselves. So, if a distributor sends the drug to one hospital but not another, they could be basing delivery on any number of factors, including the day and time each order was received as well as the criticality of the patient.



Even though drug shortages are beyond the control of distributors and healthcare systems, both must be prepared with a plan for dealing with them.

Fueling performance: Maintaining care while controlling costs

Even though generic medications and brand-name drugs can both be susceptible to shortages, generic products may be more vulnerable to production issues. Generic drugs typically share a production line with many other products, and redundancy is generally not built into their processes.¹⁰ When a common generic drug is suddenly unavailable, healthcare systems must entertain the possibility that the most effective alternative may be a higher-cost name brand. They may also incur increased personnel costs to manage the pharmacy automation systems and electronic medical record (EMR) changes that can be required when alternative medications must be prescribed.¹¹

Even though drug shortages are beyond the control of distributors and healthcare systems, both must be prepared with a plan for dealing with them. Just as organizations prepare for emergencies such as natural disasters, strategic planning is essential for managing product shortages.¹² Deciding beforehand how drugs in short supply will be allocated, which alternatives each formulary will allow, and how information about shortages will be communicated to staff and patients can save valuable time and reduce the chances of unnecessary debate when shortages may already have tensions running high.

SUMMARY

Drug shortages are not new to the healthcare industry, and present distributors with a vexing problem that's likely to persist. Shortages can occur for a variety of reasons at almost any point throughout the drug supply chain, and issues such as lack of visibility into factors like API production can make it difficult to anticipate shortages before pharmacies begin to feel the effects. To help mitigate disruption from these inevitable shortages, distributors and pharmacies must seek out and share industry insights, prepare protocols for dealing with drugs in scarce supply, and communicate clearly and transparently with colleagues, customers and patients.



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