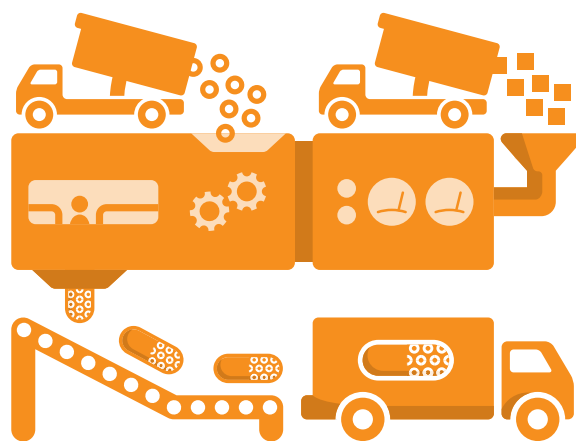


# An Era of Drug Shortages

## Best practices to prepare your pharmacy

Heather Cooley, *Director of Supply Chain Services, McKesson*  
Cathy Leventis, *Director of Clinical Services, McKesson*



Most healthcare organizations including long-term care pharmacies are not immune from drug shortages. According to a national survey of directors of pharmacy, 53% of the respondents reported that one to ten medication errors occurred in their facility as a result of a drug shortage.<sup>1</sup>

To help your pharmacy mitigate these outcomes, it is important to understand not only the underlying causes of drug shortages but also the proactive measures that you can take along with the resources that are available to help you.

### Drug shortages on the rise

The U.S. Government Accountability Office reports that the total number of active shortages, which includes both new and ongoing shortages from the prior year, has increased since 2007.<sup>2</sup> According to a study on drug shortages, more than 80% of drugs in short supply are generics, and of those, 80% are injectables that treat cancer, cardiovascular disease, infection, central nervous system conditions and pain.<sup>3</sup>

### Underlying causes

Determining the causes of drug shortages is difficult. In fact, the reason for nearly half of all shortages reported in 2013 was unknown. When shortages can be explained, they often fall into these categories: manufacturing problems (25%), supply and demand issues (17%), and raw material problems (2%).<sup>4</sup>

- **Manufacturing problems.** More than half of the drugs on the shortage lists are manufactured by just one or two companies. This means there is little cushion when a production or quality problem develops during the complex manufacturing process.<sup>5</sup>

- **Supply and demand issues.** Demand for drugs can be challenging to predict. For example, an unexpected spike in flu cases in January 2014 caused a shortage in IV saline solution.<sup>6</sup> Because manufacturers typically run production lines at maximum capacity, it is difficult to quickly switch production schedules and stem a shortage of just-in-time products.

- **Raw material problems.** Eighty percent of the active ingredients used by drug manufacturers originate outside of the United States, and 40% of the finished drugs that Americans take are manufactured overseas.<sup>7</sup> When there is an issue with quality control or a raw materials shortage, the repercussions are felt far and wide. The pharmaceutical industry truly is a global business, and its players are interconnected and dependent on one another.

### What's being done?

The Food and Drug Administration (FDA) has implemented several initiatives including the FDA Safety and Innovation Act and Strategic Plan for Preventing and Mitigating Drug Shortages to help reduce drug shortages over the long term. According to the FDA, these efforts helped prevent 170 new shortages in 2013.<sup>8</sup> In addition, the pharmaceutical industry has launched its own initiatives to better prevent and forecast shortages.

### Three phases of drug shortage management

<b>Assessment:</b>	<b>Audit the current situation, inventory and potential effects of the shortage. Investigate causes of the shortage and estimate how long it might last.</b>
<b>Preparation:</b>	<b>Take action before product runs out to help maintain patient care and control costs.</b>
<b>Contingency:</b>	<b>Determine what you will do when a product isn't available and you run out.</b>

Source: ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems

### How can your pharmacy better manage shortages?

Receiving and communicating accurate and complete information is critical to managing a drug shortage. According to the Institute for Safe Medication Practices, more than 80% of healthcare practitioners surveyed said there is a lack of advance warning and information about the duration and/or cause of a drug shortage.<sup>9</sup> To help your pharmacy better prepare for a drug shortage, consider the following best practices.

#### Have a plan

The director of pharmacy should consider developing a plan for managing drug shortages. According to the American Society of Health-System Pharmacists (ASHP), the plan should include three phases: assessment, preparation and contingency.<sup>10</sup> And it should outline responsibilities, communications and decision-making during each phase. Additionally, pharmacies should identify a point person who takes the lead in implementation, coordination and monitoring during a shortage.

### Implement structured communications

Next, understand how your distributor communicates drug shortages. For example, that information may be available through reports and messages in your online ordering platform. If you are uncertain, your account representative should be able to help. After arming yourself with the right information, the next step is to provide timely communications to your team about potential shortages so they can act quickly to manage the risk to your organization and patients.

### Ask the right questions

If a manufacturer has a limited supply of a drug, it may not be able to support a high-volume order from a distributor. As a result, you may not receive the product. To learn about the status of a particular drug, consider contacting the manufacturer directly and ask them the following questions:

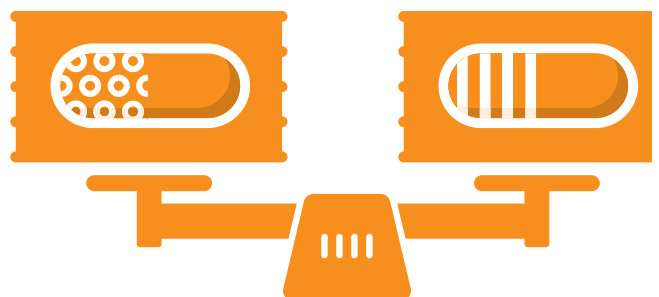
- Are you shipping your purchase orders to my distributor in full?
- Are any shipments delayed?
- Are you reducing shipment quantities to my distributor?
- If you have a limited supply, can you ship drugs directly to my facility?

### Don't feed the gray market

Purchasing products from unofficial supply channels not only puts your patients at risk, as products may be contaminated and stored improperly, but it perpetuates the problem by keeping gray market wholesalers in business.

### Keep it balanced

Having the right amount of inventory is a true balancing act. Keeping inventory too lean can cause issues, but stockpiling a formerly scarce product once it becomes available is not a good practice either. Talk to your distributor about inventory optimization technologies and programs that can help you find the right solution for your needs.



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### Additional resources

ASHP has a host of information to help your pharmacy effectively respond to and manage drug shortages. Other resources that you may find helpful include:

- [Industry Rx Backorder News](#)
- [FDA List of Drug Shortages](#)
- [FDA Safety and Innovation Act](#)
- [FDA's Strategic Plan for Preventing and Mitigating Drug Shortages](#)
- [Verify Wholesale Drug Distributor Licenses](#)

In conclusion, drug shortages are a complex, global issue. To better equip your pharmacy, consider the resources that you currently have at your disposal including your pharmacy and supply chain leadership, your distribution partner, and industry associations. They can help you find accurate and timely information on drug shortages to ensure that your actions are as effective as possible.

### Sources:

- <sup>1</sup> [Planning for Drug Shortages in LTC](#), McKnight's, January 27, 2014
- <sup>2</sup> [Drug Shortages: Public Health Threat Continues. Despite Efforts to Help Ensure Product Availability](#), U.S. Government Accountability Office, February 10, 2014
- <sup>3</sup> [IMS Study Reveals Drug Shortages in U.S. Disruptive Yet Narrowly Concentrated](#), IMS Institute for Healthcare Informatics, November 14, 2011
- <sup>4</sup> [National Drug Shortages Annual New Shortages by Year January 2001 to December 31, 2014](#), University of Utah Drug Information Service, accessed February 1, 2015
- <sup>5</sup> [IMS Study Reveals Drug Shortages in U.S. Disruptive Yet Narrowly Concentrated](#), IMS Institute for Healthcare Informatics, November 14, 2011
- <sup>6</sup> [Growing IV Saline Shortage Has Providers Scrambling During Bad Flu Season](#), Modern Healthcare, January 23, 2014
- <sup>7</sup> [Global Initiative](#), U.S. Food and Drug Administration, accessed February 1, 2015
- <sup>8</sup> [Examining Drug Shortages and Recent Efforts to Address Them](#), U.S. Food and Drug Administration, February 10, 2014
- <sup>9</sup> [Drug Shortages: National Survey Reveals High Level of Frustration, Low Level of Safety](#), Institute for Safe Medication Practices, September 23, 2010
- <sup>10</sup> [ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems](#), American Society of Health-System Pharmacists, August 1, 2009

### McKesson Alternate Site Pharmacy<sup>SM</sup>

#### McKesson Corporation

One Post Street  
San Francisco, CA 94104

[McKessonAlternateSiteRx.com](http://McKessonAlternateSiteRx.com)  
[alternatesite@mckesson.com](mailto:alternatesite@mckesson.com)  
**800.571.2889**

### About the authors:

**Heather Cooley** is the director of supply chain services at McKesson. In her 20-year career at McKesson, Heather also has worked in operations and purchasing as well as technology.

**Cathy Leventis, M.S., R.Ph.** is the director of clinical services at McKesson and leads customer clinical programs for drug utilization management, drug expense analysis/cost reduction, and manufacturer contract compliance. Cathy's more than 22 years of clinical and pharmacy practice experience includes a role as a NICU clinical pharmacist at Northwestern Memorial Hospital. She is also an active member in ASHP.

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