FACT SHEET

UNDERSTANDING PRESCRIPTION DRUG SHORTAGES

Drug shortages demand attention and collaboration from all stakeholders involved in providing life-saving medicines to patients. While the number of drug shortages has declined substantially in recent years, any drug shortage places substantial burdens on health care providers who may have to ration medicines or identify alternative treatments. This includes the biopharmaceutical companies producing innovative drugs and biologics, as well as generic drug and biosimilar manufacturers, wholesalers, distributors, pharmacies and health care providers.

WORKING COLLABORATIVELY TO REDUCE THE IMPACT OF SHORTAGES

Innovative biopharmaceutical companies have extensive measures in place to help prevent and mitigate potential drug shortages, including risk management systems. Manufacturers are the U.S. Food and Drug Administration's (FDA) source for most drug shortage information. The agency works closely with biopharmaceutical companies to prevent or reduce the impact of shortages.

The FDA provides health care providers and patients up-to-date information on discontinued medicines and medicines in short supply. Patients should discuss with their health care provider potential alternative treatments if any of their medications are impacted by a shortage.

WHY DRUG SHORTAGES OCCUR

The factors that contribute to drug shortages are complex and multidimensional and can occur for various reasons and at different points throughout the drug supply chain. These factors may include:

- Shifts in clinical practices
- Wholesaler and pharmacy inventory practices
- Changes in hospital and pharmacy contractual relationships with suppliers and wholesalers
- Raw material shortages
- Natural disasters
- Public health emergencies
- Manufacturing issues

For example, a manufacturer may experience an unforeseen breakdown in manufacturing equipment that disrupts production.

According to the FDA, quality and manufacturing issues are the primary reason for shortages.[i] For example, there have been numerous shortages for generic sterile injectable medicines over the years. These are often older medicines that rely on older manufacturing sites and processes, which limits production capacity and makes these drugs more vulnerable to shortage.

PREVENTING & MITIGATING SHORTAGES

OUR COMMITMENT

PhRMA member companies are deeply concerned about patients' health and well-being. Our industry is committed to maintaining good manufacturing practices, as well as working closely with the FDA, supply chain partners, health care providers and patients to prevent and mitigate drug shortages of brand-name prescription medicines.

PhRMA members develop risk mitigation plans and invest in risk management systems that focus on the continuity of global supply chains, including supply of brand medicines, to meet patient needs. Manufacturers also work closely with the FDA to address the underlying causes of shortages to avoid potential shortages.

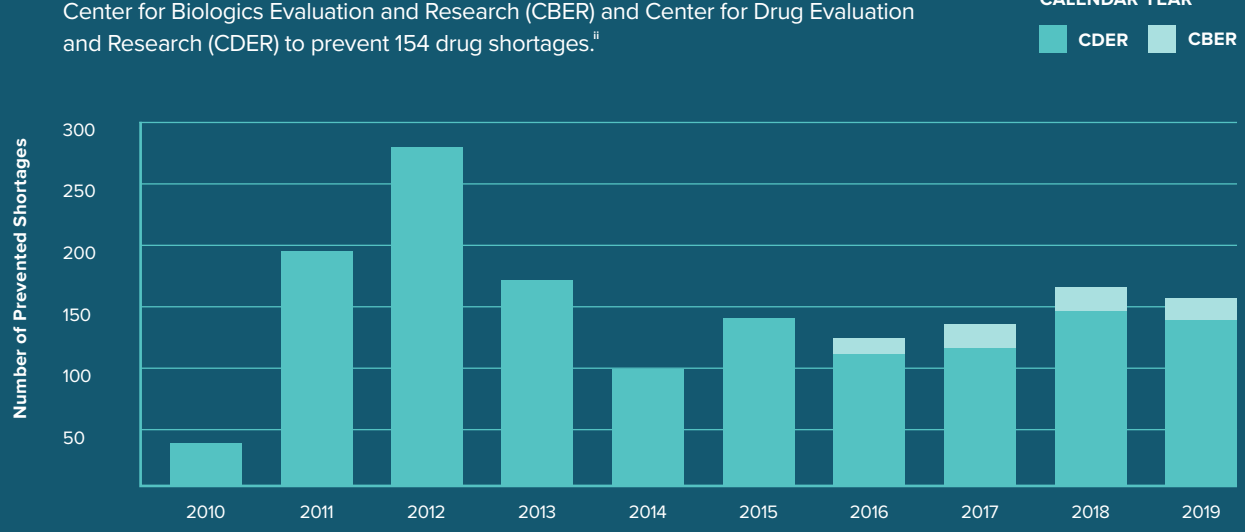
Biopharmaceutical manufacturers have spent decades building global supply chains to ensure patients in the United States and around the world have access to the medicines they need. The industry has made significant investments in the design, maintenance and modernization of their manufacturing facilities and quality control and testing systems.

For example, a new biopharmaceutical manufacturing facility can take between 5 and 10 years to build, costing $1 to $2 billion.

These complex and carefully managed global supply chains are designed with resiliency in mind to ensure continuity of patient access to medicines, including in the event of a public health issue or other emergency.

NUMBER OF PREVENTED DRUG SHORTAGES PER YEAR, 2010-2019

From January 1 - December 31, 2019, manufacturers worked closely with the FDA's Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) to prevent 154 drug shortages.[ii]



Learn more at PhRMA.org/DrugShortages

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REPORTING DRUG SHORTAGES

Manufacturers of life-saving medicines or those intended to prevent or treat a debilitating disease, are required to notify the FDA six months in advance, or as soon as practicable, of a permanent discontinuance or interruption in manufacturing of the drug that is likely to lead to a meaningful disruption in U.S. supply.[iii] For other medications, manufacturers are encouraged to notify the FDA of any anticipated disruption in supply. The FDA provides annual reports to Congress on actions taken to prevent and mitigate drug shortages.[iv]

The biopharmaceutical industry is committed to providing early notification of potential shortages and working with the FDA and other stakeholders to maintain treatment options and prevent a shortage.

When there is a shortage, the FDA may also engage with other biopharmaceutical companies to determine whether they may have the capacity to help address a shortage. If other manufacturers can ramp up production and are willing to do so, the FDA expedites review of production lines and facilities to help resolve shortages of medically necessary drugs.

In addition, when a shortage occurs and a biopharmaceutical manufacturer has inventory that is close to expiry or already expired, the FDA works with the manufacturer to review and approve an extended expiration date - if the manufacturer has data to support the potential extension for that inventory.

NAVIGATING SHORTAGES DURING THE COVID-19 PANDEMIC

As the biopharmaceutical industry continues to research and develop innovative solutions to help combat the COVID-19 pandemic, the FDA and biopharmaceutical companies are working together to ensure continuity in the medicine supply chain. The FDA is proactively working with manufacturers to prevent and mitigate any potential disruptions due to COVID-19, including expediting the review of a new supplier or manufacturing site as needed to avert shortages.

RECENT POLICIES

The Coronavirus Aid, Relief, and Economic Security (CARES) Act, which was signed into law in March 2020, granted the FDA additional authority to address drug shortages. Among other provisions, manufacturers of life-saving medicines, their active pharmaceutical ingredients, and any associated medical device included with a medicine for its preparation or administration are now required to develop a redundancy risk management plan that identifies and evaluates risks to the drug supply for each establishment in which the drug or active pharmaceutical ingredient is manufactured.

CDER has also required biopharmaceutical manufacturers to complete ongoing evaluations of their entire supply chains, including active pharmaceutical ingredients and finished dosage forms.

[i] U.S. Food and Drug Administration (FDA). Report on Drug Shortages for Calendar Year 2019. https://www.fda.gov/media/139613/download

[ii] U.S. Food and Drug Administration (FDA). Report on Drug Shortages for Calendar Year 2019. https://www.fda.gov/media/139613/download

[iii] Legal Information Institute. U.S. Code 356c - Discontinuance or interruption in the production of life-saving drugs. https://www.law.cornell.edu/uscode/text/21/356c

[iv] Legal Information Institute. U.S. Code 356c - Discontinuance or interruption in the production of life-saving drugs. https://www.law.cornell.edu/uscode/text/21/356c