Understanding Prescription Drug Shortages

PhRMA member companies are committed to researching and developing safe and effective medicines for patients. Our members, who manufacture branded innovative medicines, are also dedicated to maintaining quality manufacturing and working closely with the U.S Food and Drug Administration (FDA), supply chain partners and health care providers to prevent and mitigate drug shortages.

These commitments include making significant and sustained investments in the design and maintenance of all aspects of their supply chains, including quality systems for manufacturing facilities and the careful selection and oversight of suppliers such as contract manufacturing organizations.

As a matter of course, innovative biopharmaceutical manufacturers prepare for unforeseen events through robust, adaptable business continuity plans to help ensure they can meet the needs of patients, prescribers, health care facilities and public health authorities who depend on their medicines.

Why do prescription drug shortages occur?

Drug shortages can occur for many reasons, with manufacturing quality issues being a primary driver. Other sources of drug shortages may include production delays and delays in receiving raw materials and other components from suppliers, natural disasters and/or other public health emergencies as well as significant changes in demand to due to shifts in clinical practice.

What is driving the current shortage of certain cancer medicines?

The FDA has reported shortages of certain cancer drugs, including methotrexate, cisplatin and carboplatin. Public reports indicate the shortages are due to quality control issues, selected plant closures and other manufacturer issues. FDA is working with multiple manufacturers to seek to increase supply and considering other measures to address the shortages.

Is it true that generic drugs are more likely to experience shortages than innovative branded drugs?

Yes. According to FDA data, generic drugs comprise about 70% of drug shortages in the United States.[i] Older, sterile generic injectable drugs are particularly vulnerable to shortage, as there are a small number of manufacturers and limited production capacity for these products. They also require long lead times and have a complex manufacturing process. If one company has a problem or discontinues a product, it is difficult for the remaining firms to increase production quickly and a shortage occurs.[ii]

What steps do manufacturers take to avoid or mitigate drug shortages?

Innovative biopharmaceutical companies have extensive measures in place to help prevent and mitigate potential drug shortages including:

- Globally resilient supply chains to help ensure continuous supply of innovative medicines to meet patient needs.
- Robust inventory management systems that address:
    - Data on anticipated demand reflecting historical demand and supply data.
    - Mitigation plans for products and raw materials and the processes used for manufacture or distribution.
    - Logistics planning to ensure continuity in shipping of supplies.
    - Risk management strategies, including alternative manufacturing locations or distribution routes and channels, emergency planning for things like emergency power generation and inventory reserves and ongoing maintenance and modernization of manufacturing facilities and quality systems.

How do manufacturers engage with the FDA on drug shortages?

Manufacturers work closely with the FDA to address the underlying causes of shortages and to mitigate and avoid potential additional shortages. Companies also work with the FDA to respond to surges in demand, including seeking expedited approval of manufacturing changes in times of public health emergencies such as the COVID-19 pandemic.

The FDA itself has taken a range of measures to help address drug shortages, including expedited reviews of new drug and biologics applications, expedited requests to facilitate expanded manufacturing capacity and exercising regulatory flexibility and discretion to increase supplies of critically needed medications.[iii]

For example, when a shortage occurs and a biopharmaceutical manufacturer has inventory that is close to expiry or already expired, the FDA may work with the manufacturer to expedite review and approval of an extended expiration date if there are data to support potential extension of the expiration date.

What policy solutions does PhRMA support to address prescription drug shortages?

The industry supports efforts to address the root cause of long-standing prescription drug shortages.

Given the majority of drug shortages are for generic medicines, particularly generic injectable medicines, we support:

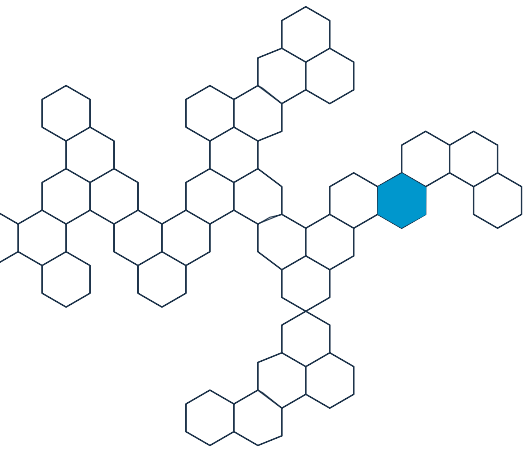
- Public policies to spur increased infrastructure investments by generic manufacturers, which may include but are not limited to consideration of government-guaranteed purchasing commitments.
- Public policies focused on increasing supply chain resiliency, including working with trading partners to expand regional manufacturing capacity, as well as increased federal investments and public-private partnerships to support innovation in biopharmaceutical manufacturing processes.
- Tax and other investment incentives for new manufacturing facilities and the expansion and enhancement of existing facilities.

Could the drug price setting provisions in the Inflation Reduction Act (IRA) make drug shortages worse?

Yes. The generic drug market is highly concentrated and becoming more so. Low profit margins have driven consolidation among manufacturers to just a few players. One study found that 40% of generic drugs were supplied by only one manufacturer, and the median number of manufacturers per drug was just two.[iv] These findings appear consistent with analysis by the FDA and others, which suggests that some drugs have gone into shortage because manufacturers do not have strong financial incentives to begin or continue to market them.

The government price setting provisions in the IRA will only exacerbate this risk because there will be even tighter margins for generics looking to enter the market when the brand or innovator medicine is priced so low.

Former FDA Commissioner Scott Gottlieb, MD, has stated that the government price setting provisions in the IRA, including the inflation rebate provisions, are already contributing to underinvestment in safe and sustainable generic supplies.[v] Without sufficient volume or revenue to justify entering the market, generic manufacturers may not do so and the industry's broader financial viability will be at risk.[vi]



i https://www.fda.gov/media/131130/download

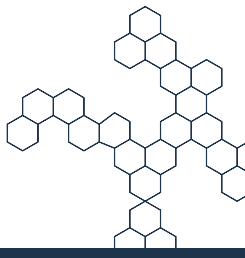
ii https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages

iii https://www.fda.gov/media/169302/download?utm_medium=email&utm_source=govdelivery

iv https://www.nber.org/papers/w23640

v https://www.axios.com/2023/05/22/americas-drug-shortages-reach-new-heights

vi https://healthpolicy.usc.edu/research/mitigating-the-inflation-reduction-acts-potential-adverse-impacts-on-the-prescription-drug-market



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