Understanding Demand-Driven Drug Shortages

The pharmaceutical supply chain is highly nuanced and complex. While the global nature of the supply chain offers a level of resilience, the interdependency of the supply chain also means that multiple markets are impacted when drug shortages occur. The U.S. Food and Drug Administration (FDA) defines a drug as being in shortage when the total commercially available supply of a medical product is not able to meet the current demand. Many countries, including the United States, may experience shortages when a product experiences a disruption or increase in demand.

No matter the driver of a shortage, drug shortages pose challenges to healthcare providers and patients. Since the COVID-19 pandemic, there has been an increase in drug shortages globally. A demand-driven shortage may result from medical surges occurring downstream, such as a sudden increase in patient need for a specific product.

The Healthcare Distribution Alliance (HDA) and its pharmaceutical distributor members — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide — recognize the often-unpredictable nature of demand-driven shortages. The distribution industry works to mitigate these shortages, ensuring patients and providers receive the correct medications.



Meeting a Complex Requirement

<u>Demand-driven shortages</u> are medical surges or other increases in demand that cause an uptick in the need for a product.² Demand-driven shortages differ significantly from supply-driven shortages because demand-driven shortages result from a downstream medical surge. Demand-driven shortages can be challenging to predict based on the public health event or prescribing practices that create the surge. Furthermore, it is difficult for entities to easily predict these types of shortages, as the FDA does not receive notice of sudden increases in demand. However, with notice, including public health forecasting as well as communication with healthcare partners, early detection of demand surges may be possible.





Drivers of Demand-Driven Shortages

HDA and its members consider there to be two categories of demand-driven shortages — disaster-related and non-disaster-related shortages. Disaster-related medical surges include natural disasters and disease outbreaks, such as the COVID-19 pandemic, Mpox and seasonal influenza.³ Non-disaster-related drivers include provider overprescribing, increased patient demand and hoarding practices.⁴ Two recent examples of demand-driven shortages caused by non-disaster-related drivers include the overprescription of Ozempic[®] and Tamiflu[®].

The Ozempic® shortage was believed to be triggered by social media, which resulted in an unpredictable surge and increased patient demand. Social media activity turned the medication's weight-loss side effect into a selling point for off-label prescribing for non-diabetes patients.⁵ Due to an increase in demand, prescriptions for the drug more than doubled to 1.2 million⁶, growing at a rate of 76.9 percent.⁷ The product subsequently went into shortage because the manufacturer could not meet the significant increase in demand due to the significant rise in off-label prescribing for weight loss.

The Tamiflu® shortage resulted from the *polycrisis* phenomenon — a surge in the COVID-19, respiratory syncytial (RSV) and flu viruses occurring simultaneously in the winter of 2022. The supply chain can potentially mitigate disaster-related medical surges by using public health data to forecast demand related to these types of surges, such as RSV and flu season.8 Forecasting allows manufacturers and distributors to use data to anticipate and predict demand to better respond to events, such as the seasonal flu.9 In the winter of 2022, distributors expected a higher level of demand; however, Tamiflu still went into shortage because the surge from COVID-19, RSV and flu was more elevated than even the highest projections for the season.¹¹0 Distributors and healthcare supply chain stakeholders did prepare for a disaster-related surge, but the demand was higher than the highest projection,¹¹¹ resulting in a shortage of specific drugs to treat the three viruses.



Solutions to Mitigate Demand-Driven Shortages

Drug shortages can be mitigated by understanding the drivers behind them. A natural disaster, disease outbreak or other demand surge may have different underlying causes and require a different approach to help mitigate or manage the shortage. Additionally, certain behaviors can also exacerbate these scenarios, such as hoarding or panic buying. To mitigate drug shortages, distributors can use tools such as <u>Vendor Managed Inventory</u> (VMI),¹² ongoing <u>public-private</u> <u>partnerships</u> (PPPs)¹³ and <u>stockpiling</u>.¹⁴

Distributors have limited abilities to mitigate demand-driven shortages, as the drivers are often unpredictable, yet they can still use some tools to provide assistance. For example, to mitigate demand surges, distributors can use PPPs like an early warning system. If a drug is in shortage or near shortage, distributors may use <u>fair-share allocation</u> programs¹⁵ to ensure the supply of the available product meets the customers' needs. Further, distributors work to prevent hoarding by partially filling an order to allocate the product properly.



Distributors use several tools to mitigate drug shortages:

- VMI is used to manage the commercial product inventory in the <u>Strategic National Stockpile</u> (SNS)¹⁶ by rotating and cycling the stockpile inventory through commercial channels to reduce the risk of products expiring in the SNS. VMI substantially reduces the impacts of an event because it ensures that commercial products will be available through the SNS for an event.
- PPPs provide an opportunity for the public and private sectors to mitigate drug shortages, such as an early warning system to detect pharmaceutical demand surges. To provide visibility into the supply chain during the COVID-19 pandemic, baby formula shortage and the 2022 surge of COVID-19/RSV/flu, distributors voluntarily participated in the Supply Chain Control Tower (SCCT).¹⁷ The SCCT is a PPP between industry stakeholders, including distributors and the public sector, to provide visibility into the supply chain to inform decision-making during public health emergencies.
- The industry supports stockpiling efforts, including those of hospitals and governments, that may be used to mitigate shortages. As stockpiles outside the SNS are established, distributors maintain that they should be cooperative and transparent with the SNS.

Conclusion

HDA and its members recognize the complexities of demand-driven drug shortages, which can be triggered by a diverse range of drivers. The best tools distributors and the entire healthcare supply chain have to mitigate these unique shortages are to maintain <u>operational</u> and enhance <u>supply chain resilience</u>. Ultimately, while a distributor may work to mitigate different drug shortages, it is vital to understand the cause so the supply chain can adequately respond.

About the Healthcare Distribution Alliance

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA's nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.

- U.S. Food and Drug Administration. "Drug Shortages: Root Causes and Potential Solutions 2019." Last updated February 21, 2020. https://www.fda.gov/media/131130/download.
- Healthcare Distribution Alliance. "HDA RFI Submission on Drug Shortages."
 Published July 2023. https://www.hda.org/getmedia/cc3658b0-cebe-47cd-a944-0af2504ece9a/HDA-RFI-Submission-Drug-Shortages.pdf.
- 3. Healthcare Distribution Alliance. "HDA RFI Submission on Drug Shortages."
- 4. Healthcare Distribution Alliance. "HDA RFI Submission on Drug Shortages."
- Johnson, Arianna. "What to Know About Ozempic: The Diabetes Drug Becomes a Viral Weight Loss Hit (Elon Musk Boasts Using It) Creating A Shortage." Forbes, December 26, 2022. https://www.forbes.com/sites/ariannajohnson/2022/12/26/what-to-know-aboutozempic/?sh=1519ccf65adb.
- Murphy, Tom. "What's behind shortages of Adderall, Ozempic and other meds?" Associated Press, April 30, 2023. https://apnews.com/article/drug-shortages-adderall-ozempic855632a04a17c2bf75b6a89e4c08ef79.
- IQVIA. Long, Doug. U.S. Pharmaceutical Trends, Issues & Outlook for HDA. Presented March 13, 2023
- 8. Healthcare Distribution Alliance. "HDA RFI Submission on Drug Shortages."
- 9. Healthcare Distribution Alliance. "HDA RFI Submission on Drug Shortages."
- 10 IQVIA. Long, Doug. U.S. Pharmaceutical Trends, Issues & Outlook for HDA

- 11. Ibio
- Healthcare Distribution Alliance. "Pandemic and All-Hazards Preparedness Act Reauthorization: Background and Opportunities to Enhance Resilience." 2023. https://www.hda.org/getmedia/c77c0197-674d-46cf-a870-8017ac070ae0/PAHPA-Background-andOpportunities-to-Enhance-Resilience.pdf.
- Healthcare Distribution Alliance. "The Importance of Public-Private Partnerships." 2023. https://www.hda.org/getmedia/ecf2c869-91e8-4190-a419-36fa3542df45/The-Importance-of-Public-Private-Partnerships.pdf.
- Healthcare Distribution Alliance. "Drug and Medical Product Availability: Distributors Promote a Resilient Supply Chain." https://www.hda.org/getmedia/45f48c39-69e6-4ff8-8919-af1c4cfb7432/Drugand-Medical-Supply-Shortages.pdf.
- Healthcare Distribution Alliance. "Drug and Medical Product Availability: Distributors Promote a Resilient Supply Chain."
- Department of Health and Human Services Administration for Strategic Preparedness and Response. "Strategic National Stockpile." https://aspr.hhs.gov/SNS/Paces/default.aspx.
- Healthcare Distribution Alliance. "U.S. Healthcare Supply Chain Monitoring Structure: Issues and Recommendations." 2023. https://www.hda.org/getmedia/3f1f79ea-5d32-4897-b81b899d290732ec/HDA-FactSheet-US-HC-Supply-Chain-Monitoring-Structure-FINAL.pdf.

