Drug Shortages: What Are They and How Do They Differ?

Every day, healthcare distributors connect <u>1,500 manufacturers to 330,000 sites of care</u>¹, while maintaining a <u>0.4 percent net profit margin (after taxes)</u>². The industry can better understand the nature of shortages given the industry's unique vantage point into the healthcare supply chain; in fact, the industry has visibility into both upstream sourcing and manufacturing processes as well as downstream activity (toward sites of care and ultimately, consumers).

Additionally, healthcare distributors have the tools to support government stockpiles, offer product alternatives and fair-share allocation programs, and forecast demand from public health events that may shift demand to manage disruptions, including drug shortages, without significantly impacting patient care. Fair-share allocation programs prevent hoarding and other practices that distort the market by assessing the available supply and customer needs to limit the amount each customer may buy to ensure products are available to as many customers as possible.



The FDA "drug shortage" definition states that a shortage is the total commercially available supply of a medical product not being able to meet the current demand.

Drug Shortage Categories

Drug shortages are a highly complex and nuanced issue because of the global nature of the pharmaceutical industry and supply chain. HDA and its members categorize drug shortages as manufacturer supply-driven shortages and consumer demanddriven shortages.³ The definitions of drug shortages vary, with some labeling products on fair-share allocation (receiving a partial fulfillment of a requested order) or stockouts (temporary inability to receive a product) as products in shortage. HDA and its members align with the <u>FDA's definition</u>⁴ of a drug shortage.



1. Healthcare Distribution Alliance. "Delivering Value Across Healthcare." 2023.

https://hda.org/getmedia/807f7717-3a3a-4e8a-9011-2c8a91502dec/hda-factsheetdeliveringvalueacrosshealthcare-2023.pdf. The second secon

2. HDA Research Foundation. 94th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare. 2023. https://hda.org/publications/94th-edition-hda-factbook-the-facts,-figures-and-trends-in-healthcare/.

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 U.S. Food and Drug Administration. "Drug Shortages: Root Causes and Potential Solutions." Published 2019. Updated February 21, 2020." https://www.fda.gov/media/131130/download.



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How Do Shortages Differ?

No matter the driver and type of shortage, drug shortages occur because of a lack of supply to meet the current demand.



Supply-driven shortages are characterized by the availability of a drug that is affected by upstream disruptions to manufacturing or raw materials supply availability. Drivers of supply-driven shortages are upstream. These are a different category of drug shortages because the causes and potential policy solutions significantly differ from demanddriven shortage scenarios.

Supply-driven short-ages often affect generic drugs because they are rooted in manufacturing quality issues and market access challenges.⁵ As more generic drugs enter the market, the profit margins for low-cost generic drugs decrease further, often resulting in the investment in quality controls to prevent manufacturing quality issues from becom-ing too cost prohibitive.⁶



Demand-driven shortages may occur due to disaster-related or non-disaster-related medical surges that create a sudden uptick in orders. Drivers of demand-driven shortages are downstream. These shortages can be categorized as disaster related and non-disaster related.⁷

- Drivers of disaster demand-driven shortages include medical surges such as the COVID-19 pandemic, natural disasters and flu season.
- Non-disaster-related demand shortage drivers include increased patient demand, hoarding practices or provider overprescribing.

Drug shortages, regardless of the driver, are caused by many factors, such as sourcing difficulties, a disease out-break or hoarding practices. Distributors regularly work to tackle complex drug supply issues and work to ensure the availability of safe and effective medicines.

 Healthcare Distribution Alliance. "HDA RFI Submission Drug Shortages." Published July 2023. https://www.hda.org/getmedia/cc3658b0-cebe-47cd-a944-0af2504ece9a/HDA-RFISubmission-Drug-Shortages.pdf.

6. Ibid.

7. Ibid.

Learn more about the distribution industry's recommendations to mitigate drug shortages from HDA's response to the House Energy and Commerce Committee's <u>drug shortages request for information</u>. Visit <u>https://www.hda.org/drug-shortages/</u> for additional information.

About the Healthcare Distribution Alliance

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between thenation'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.



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