

# Understanding **Supply-Driven** Drug Shortages

The global nature of the pharmaceutical supply chain has evolved over the past 30 years to create geographical redundancies and economic efficiencies. While strides have been made, shortages of medications and products can still happen due to many drivers. Drug shortages can occur when the supply is unable to meet demand.



## Drivers of Supply-Driven Shortages

Supply-driven drug shortages often result from upstream drivers, such as manufacturing and quality issues.<sup>1</sup> As of 2022,<sup>2</sup> generic medications, which represent 90.2 percent of prescription drugs dispensed in the United States, are most often impacted by supply-driven shortages. Moreover, these types of shortages are primarily affected by upstream manufacturing or raw material supply availability disruptions.

Manufacturing quality issues occur when a specific product is impacted by contamination, a bottleneck in the supply of raw material or active pharmaceutical ingredients (API), a non-sterile environment and many other factors. Products like generic sterile injectables are vulnerable to manufacturing quality issues due to the contamination risks associated with the continuous manufacturing process. Further, investments in robust manufacturing processes to mitigate contamination or quality issues are often cost-prohibitive for manufacturers.

Many countries rely on concentrated sources of API manufacturing<sup>3</sup> and generic manufacturing. So, the supply of API is heavily concentrated, and when strain occurs, the global pharmaceutical supply chain is affected. HDA and its members have advocated for the diversification of the geographic location of manufacturing plants to maintain operational resilience.<sup>4</sup>

Recently, manufacturing quality issues have led to shortages of the critical oncology drug cisplatin, a platinum-based, highly regulated pharmaceutical used for various cancer types. In December 2022, Accord, the manufacturer of cisplatin, received an import ban following an FDA inspection, which found breaches to cGMP and data integrity issues. Accord had a large market share for cisplatin, and the restriction resulted in a market shortage. This drug shortage further demonstrates the importance of diverse geographical manufacturing locations.



## Solutions to Mitigate Supply-Driven Shortages

Supply-driven shortages are often a result of economic considerations. HDA and its members offer several policy recommendations address some of the root causes of supply-driven shortages:

- To mitigate the market access issue, when a PBM only places a higher-cost product on a Tier 1 formulary, the Centers for Medicare & Medicaid Services should give preferred formulary positions to new generics and biosimilars.
- To mitigate manufacturing quality issues, such as a class of drugs experiencing chronic drug shortages due to contamination, the FDA should work with the private sector to conduct a focused review of challenges to specific product classes.
- To mitigate the market access issue of Abbreviated New Drug Applications (ANDA) approved for generic medicines not being launched, the FDA should review the relationship between the number of ANDAs and the number of manufacturers currently in the market, specifically for drugs at high risk of shortage.

## Conclusion

HDA and its members recognize the intricate nature of supply-driven shortages within the pharmaceutical industry and the importance of addressing this issue. The association remains committed to collaborating with various stakeholders as policy proposals are introduced to mitigate and manage drug shortages. By actively engaging with these stakeholders, HDA contributes to developing practical solutions that can alleviate the impact of drug shortages on patients and providers.

### 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.

1. Chapman, Suzannah. Dedet, Guillemine. Lopert, Ruth. Organization for Economic Co-operation and Development, Directorate for Employment, Labor and Social Affairs Health Committee. "Shortages of medicines in OECD countries." March 24, 2022. <https://doi.org/10.1787/b5d9e15d-en>.
2. IQVIA. Long, Doug. U.S. Pharmaceutical Trends, Issues & Outlook for HDA. Presented March 13, 2023.
3. Chapman, Suzannah. Dedet, Guillemine. Lopert, Ruth.
4. Healthcare Distribution Alliance. "Bolstering Disaster Preparedness and Operational Resilience in the Healthcare Supply Chain." 2023. <https://www.hda.org/getmedia/f13bb354-88eb-494e-81ca-2456ea4d795c/Bolstering-Disaster-Preparedness-and-Operational-Resilience-in-the-Healthcare-Supply-Chain.pdf>.