

Guide to drug shortages and policy solutions

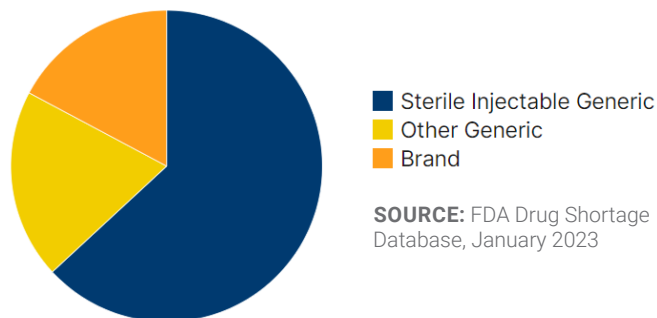
Drug shortages occur when drug supply chains cannot respond quickly enough to changes in demand or supply.

Historically shortages have primarily affected **generic sterile injectable drugs** because of a combination of economic and technological factors – these drugs are hard to make reliably, but price competition makes it difficult for manufacturers to keep up manufacturing standards. These drugs are primarily made in facilities in the United States and Europe.

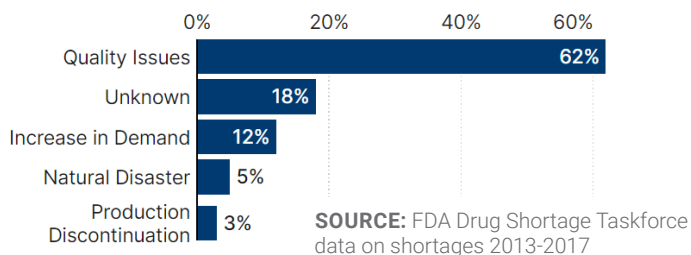
Manufacturing quality issues have persistently been the top reason for shortages, with the prevalence of other causes varying from year to year.

In the last 20 years, no shortages appear to have been caused by export restrictions related to geopolitics. However, shortages due to **geopolitical conflicts** are a **potential future shock**.

Drug shortages by type



Drug shortages by cause



Different strategies are needed to address existing and potential shortages. Addressing shortages requires a close look at prevention mechanisms that lower the chance of and the likely size of a specific shock type. Buffering strategies are the fallback strategy for when the shock could not be sufficiently minimized.

Decrease chance of shock by

- Preventing manufacturing quality disruptions
- Considering vulnerability to shocks when selecting suppliers, manufacturing locations and inventory locations

Decrease size of shock by

- Diversifying supply chains
- Hardening infrastructure
- Using early detection and containment mechanisms
- Limiting opportunities for panic buying

Buffer impact of shock by

- Developing and maintaining ability to scale up production quickly
- Setting up stockpiles or first-in-first-out inventories
- Developing systems for efficient response

An effective strategy is multipronged, addressing all three elements to varying degree. What strategy is most effective and most cost-effective **depends on the nature of the shock**.

The next page lays out how strategies should differ across different shock types.

FOR MORE INFORMATION

➔ www.brookings.edu/articles/drug-shortages-a-guide-to-policy-solutions/

Mapping shortage preparation strategy to nature of the shock

Trigger type	Shock characterization	Appropriate strategy
Pandemics and CBRN* threats	<ul style="list-style-type: none"> Primarily a demand shock For some triggers, drugs at risk of shortage are known For some triggers, drugs, tests, or vaccines may not exist 	<ul style="list-style-type: none"> Early detection and containment mechanisms are important For buffering against medical countermeasures, key decision is how much to stockpile versus use other buffering strategies like holding excess capacity For buffering against new pathogens, need infrastructure to develop vaccines, drugs, and tests, scale up production quickly, and get it to patients quickly
Natural disasters	<ul style="list-style-type: none"> Supply disruption of varying strength Can affect any part of the supply chain Vulnerability can be assessed 	<ul style="list-style-type: none"> In the short term, buffering is the primary option (stockpiling, diversification, excess capacity) In the short term, vulnerability to natural disasters can be assessed In the long term, can prepare by strategically selecting where facilities are located, how they are constructed, where inventory is stored
Manufacturing quality	<ul style="list-style-type: none"> Most common in final stage of generic sterile injectable production Most production is in the U.S. and Europe These shortages have economic underpinnings 	<ul style="list-style-type: none"> Buffering strategies can help but key to address the root cause of quality lapses because otherwise product not made to specification may reach patients, causing harm Markets currently do not allow generic manufacturers to differentiate themselves on reliability of supply Policy solutions must shift hospital buying behavior away from heavy emphasis on price towards reliability For outpatient multiple source generic injectables, need to eliminate Medicaid inflation rebates, which currently do not allow manufacturers to pass on legitimate cost increases
Geopolitical risk	<ul style="list-style-type: none"> Not a current trigger but a possible one Greater exposure for upstream supply chains Would be a supply disruption, potentially long-term and widespread 	<ul style="list-style-type: none"> A strategic approach is necessary because of the sheer size of potential disruption: <ul style="list-style-type: none"> Need to revise the essential medicines list Need better analytics to identify vulnerabilities Must consider full supply chains Need to consider common links between drugs For priority supply chains, lower risk though diversification, selective onshoring, otherwise friend-shoring For priority supply chains with much geopolitical risk exposure, apply buffering strategies When onshoring, address the possibility of other shock types

*CBRN stands for chemical, biological, radiological, and nuclear