

Generic Drug Shortages:

FDA has taken the first important steps to prevent drug shortages.

What else can be done to support these efforts?

The US Food & Drug Administration (FDA) recently issued an important **report** on the causes of the critical shortages of generic drugs used daily in hospitals. These drugs are vital to patient care. Hospitals devote countless hours of staff time at the cost of millions of dollars a year to find alternatives when needed medications are unavailable.

Civica Rx is a non-profit, non-stock corporation founded by hospital systems and philanthropists to stabilize the supply of essential generic medications. Civica Rx applauds the work of the FDA in seeking to alleviate drug shortages. Civica also welcomes the opportunity to collaborate to rapidly and effectively resolve the crisis.

WHAT DOES THE FDA REPORT SAY?

The report identifies three root causes for drug shortages:

- Lack of incentives for manufacturers to produce less profitable drugs.
- The market does not recognize and reward manufacturers for "mature quality systems" that focus on continuous improvement and early detection of supply chain issues.
- Logistical and regulatory challenges make it difficult for the market to recover from disruption.

Many drugs in shortage are lifesaving products commonly used in surgeries and emergency departments.

THE FDA PROPOSES THREE SOLUTIONS

The report also recommends enduring solutions to address drug shortages. These solutions include:

- Creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages.
- Developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities.
- Promoting sustainable private sector contracts (e.g., payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.



Civica's goal is that small rural hospitals have the same access to vital drugs at the same prices as large urban hospital systems.

In addition, the report describes legislative proposals in the President's FY2020 Budget and planned FDA initiatives to prevent and mitigate shortages that look at improved data sharing, risk management, lengthened expiration dates for drugs, and internationally harmonized guidelines for a pharmaceutical quality system.

ADDITIONAL SOLUTIONS PROPOSED BY CIVICA RX

Civica Rx fully supports the FDA findings and recommendations and suggests additional actions for consideration to help mitigate and prevent drug shortages:

- Develop a list of essential medicines that would serve as a trigger for other initiatives within government and the private sector to develop and implement.
- Assess drug shortages as a national security threat.
- Offer government incentives to encourage manufacturers to establish and maintain high-quality domestic manufacturing facilities and practices, develop redundancy in operations, expand capacity, and create conditions to prevent or mitigate shortages.
- Create a strategic stockpile program for drugs on the essential medicines list, similar to the programs run by the Biomedical Advanced Research and Development Authority (BARDA).
- Enhance supply chain transparency by requiring manufacturers to list the location of production at every step, put the manufacturing city, state, and country on the product label, and specify the site of Active Pharmaceutical Ingredient production on the company's website.

For more information please visit www.civicarx.org