

## ICHHP Position Statement - Manufacturer Drug Shortages

Pharmaceutical manufacturers, distributors, group purchasing organizations, and regulatory bodies have a responsibility when making decisions regarding manufacturing and distribution that may create drug product shortages. It is important they keep in mind those decisions may compromise the quality and safety of patient care.

The Illinois Council of Health-System Pharmacists (ICHHP) supports the following principles with regard to pharmaceutical manufacturer shortages:

- Healthcare systems, hospitals, pharmacies:
  - Implement infrastructure in advance to ensure effective management when a drug shortage occurs, for example, a drug shortage team, resource allocation team, and established processes for therapeutic substitutions to ensure patient safety.
  - Establish policies and procedures to secure products in times of acute shortages and prioritize/redistribute health system supply
- Establish policies and procedures and follow regulatory compliance, to ensure the quality of products is obtained from alternative distribution sources.
  - Engage information technology in the dissemination and coordination of handling a drug shortage situation.
- The FDA:
  - Establishes a rapid and reasonable mechanism to respond to changes in demand of products that require allocation from the FDA.
  - Strongly considers in its definition of “medically necessary” drug products the patient safety risks created by use of alternate drug products.
  - Investigates the causes of the shortages for potential questionable motives.
- Manufacturers, wholesalers and other distributors:
  - Give priority distribution to providers caring for patients at the highest risk of an adverse outcome without the product that is in short supply.
  - Provide timely communication regarding shortages and potential shortages, including projected time frames for resolution.

- Laws and regulations should be enacted that require pharmaceutical manufacturers to notify the appropriate government body at least 12 months in advance of voluntarily discontinuing a drug product and at least 6 months before the interruption of supply of life-sustaining medication.
- Pharmacy workforce
  - Assist in the identification and implementation of clinical and operational plans when products are not available so as to minimize the risk of adverse events.
  - Utilize national guidelines and technical assistance bulletins, and other resources including the ASHP drug shortages website and the FDA drug shortages website.
  - Communicate with national professional organizations and governmental agencies to assist in identification of shortages and potential consequences
  - Avoid stockpiling inventory beyond reasonable patient care needs.
- ICHP does not support the use of the gray market as a source for products in short supply (refer to Pharmaceutical Gray Market Position Statement.)
- ICHP does not support the use of non-FDA approved medications unless authorized by the FDA

## References

1. American Society of Health-System Pharmacists. ASHP Guidelines on Managing Drug Product Shortages. Am J Health-Syst Pharm 2018; 75:1742-50.

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