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Drugs

Frequently Asked Questions About Drug Shortages

The following questions are those that are most frequently asked of the CDER Drug Shortage Program along with answers.

Q. How many drug shortages were there in 2010? And do we expect less, as many, or more shortages in 2011?

A: In 2010, there were 178 drug shortages reported to the U.S. Food and Drug Administration, 132 of which involved sterile injectable drugs. In 2011, FDA has continued to see an increasing number of shortages, especially those involving older sterile injectable drugs. These shortages have involved cancer drugs, anesthetics used for patients undergoing surgery, as well as drugs needed for emergency medicine, and electrolytes needed for patients on IV feeding.

Q. What is the major reason for these shortages?

A: A major reason for these shortages has been quality/manufacturing issues. However there have been other reasons such as production delays at the manufacturer and delays companies have experienced receiving raw materials and components from suppliers. Discontinuations are another factor contributing to shortages. FDA can't require a firm to keep making a drug it wants to discontinue. Sometimes these older drugs are discontinued by companies in favor of newer, more profitable drugs.

With fewer firms making older sterile injectable drugs, there are a limited number of production lines that can make these drugs. The raw material suppliers the firms use are also limited in the amount they can make due to capacity issues at their facilities. This small number of manufacturers and limited production capacity for older sterile injectables, combined with the long lead times and complexity of the manufacturing process for injectable drugs, results in these drugs being vulnerable to shortage. When one company has a problem or discontinues, it is difficult for the remaining firms to increase production quickly and a shortage occurs.

Q. What can FDA do to address drug shortages?

A: For manufacturing/quality problems, FDA works with the firm to address the issues. Problems may involve very low risk (e.g. wrong expiration date on package) to high risk (particulate in product or sterility issues). Regulatory discretion may be employed to address shortages to mitigate any significant risk to patients.

FDA also works with other firms making the drugs that are in shortage to help them ramp up production if they are willing to do so. Often they need new production lines approved or need new raw material sources approved to help increase supplies. FDA can and does expedite review of these to help resolve shortages of medically necessary drugs. FDA can't require the other firms to increase production.

When a shortage occurs and a firm has inventory that is close to expiry or already expired, if the company has data to support extension of the expiration dating for that inventory, FDA is able to review this and approve the extended dating to help increase supplies until new production is available.

When the US manufacturers are not able to resolve a shortage immediately and the shortage involves a critical drug needed for US patients, FDA searches for overseas companies that are willing and able to import the drug during the shortage. When a firm is located that is willing and able to import, FDA has utilized regulatory enforcement discretion for temporary importation to meet critical patient needs during the shortage. FDA evaluates the overseas drug to ensure that it is of adequate quality and that the drug does not pose significant risks for US patients. The information about the imported drug, and how patients can access supplies is posted on the FDA Drug Shortage website along with the Dear Healthcare Professional letter from the company that is importing the drug. FDA cannot always find a firm willing and able to import a drug during a shortage, however it is something we explore when there is a critical shortage and US patient needs are not being met.

FDA works to find ways to mitigate drug shortages; however, there are a number of factors that can cause or contribute to drug shortages that are outside of the control of FDA.

Q. How does FDA communicate to the public about drug shortages?

A: FDA works to communicate information about shortages based on information provided by the manufacturers. Companies voluntarily provide the shortage information posted on the FDA website. Manufacturers are not required to report information about shortages to FDA, and are not required to report the reasons for shortages or the expected duration of shortages on the FDA website. FDA appreciates all information that manufacturers provide for posting on the FDA website since we realize how necessary this is for patients and healthcare professionals to be informed when shortages occur and how long they may last. Manufacturers can report any information for posting to drugshortages@fda.hhs.gov.

Q. Are companies required to notify FDA of a potential drug shortage?

A: FDA encourages companies to provide notifications about any issues that could lead to a shortage. Current regulations do not require that companies notify FDA of shortages and the only requirement under current regulations is that companies inform FDA six months in advance for discontinuations of sole source, medically necessary drugs. Early notification may allow prevention of a shortage in some

circumstances. In 2010, for example there were 38 shortages prevented due to companies notifying FDA voluntarily of potential issues that could lead to shortages and FDA was able to work with the company to avoid a shortage.

Q. When FDA takes an action such as sending a warning letter to a company or takes an enforcement action, is the shortage impact considered beforehand?

FDA is responsible for ensuring that safe, effective drugs are available for US patients. When there are severe quality issues identified that could result in harm to patients, there may not be a way to avoid a shortage. However, FDA does everything possible to work with firms to address any potential risks to keep medically necessary products available while also ensuring there is not going to be harm to patients associated with the quality issues.

Q. How does FDA address shortages of medically necessary drugs that have not received FDA approval?

A: FDA is aware that there are drugs being marketed that have not received FDA approval but are medically necessary and have been marketed for many years. When shortages occur for these drugs, FDA addresses these shortages through our normal processes and works with the companies to ensure patient needs are being met while also ensuring there is not any significant risk associated with the drug due to quality, safety, or efficacy that could result in harm to patients. FDA encourages the companies making these drugs to notify us of any changes in supply and also encourages the firms to seek FDA approval to help ensure ongoing quality and safety of these drugs for US patients.

Q. Have FDA standards changed and companies can no longer meet those standards?

A: FDA standards have not changed recently. The companies are responsible for ensuring that the drugs they make are manufactured in quality manufacturing sites so that US patients are not put at risk.

Q. Why are there so many quality problems with drugs occurring recently?

A: Problems can and do occur at any point in the manufacturing process and the manufacturing of sterile injectables is particularly complex and involves many steps where things can go wrong. When problems occur at any step in the process, FDA encourages firms to notify FDA of any potential supply issues so we can help address the problem. Companies are not required to notify FDA of potential supply issues, however we encourage them to report any potential shortages to FDA at drugshortages@fda.hhs.gov so that we can help address the problem.

Q. What is the CDER Drug Shortage Program (DSP)?

A. This program, within the Center for Drug Evaluation and Research (CDER), was established to address potential or actual shortages of drugs that have a significant impact on public health. Through communication, facilitation and negotiation, DSP works with pharmaceutical manufacturers, review divisions, compliance and other components of FDA to manage product shortages.

Who handles non-CDER drug shortages?

- Center for Biologics Evaluation and Research (CBER)
Biological products, including blood and vaccines
Website: [Biological Product Shortages](#)¹
E-mail address for reporting shortages: CBERShortages@fda.hhs.gov. Also, biological product manufacturers and healthcare personnel may report a real or suspected biological product shortage by calling (301) 827-4239.
- Center for Food Safety and Nutrition (CFSAN)
Food, including medical foods and cosmetic products
Center for Food Safety and Nutrition (CFSAN) Website² – 1-888-SAFEFOOD
- Center for Veterinary Medicine (CVM)
Food additives and drugs that will be given to animals
CVMHomeP@CVM.fda.gov
- Center for Devices and Radiological Health (CDRH)
Medical devices and radiation-emitting products
dsmica@cdrh.fda.gov – 1-800-638-2041

Q. Why aren't all drugs in short supply listed on the Drug Shortage web page?

A. The CDER Drug Shortage Program focuses on shortages of medically necessary products since these shortages have the greatest impact on public health. The Drug Shortage page on the FDA website lists shortages primarily of medically necessary products. Shortages that are expected to be resolved quickly or which involve only a particular strength or package size, which has a substitute strength(s) and package size(s), are not usually the focuses of the DSP.

Q. How does the CDER Drug Shortage Program find out about shortages?

A. FDA encourages manufacturers to report shortages to FDA although they are not required to do so. Other components within FDA may provide such notification. The DSP also gets reports from healthcare professionals, patients/individuals, or professional organizations using the electronic mail account (drugshortages@fda.hhs.gov).

How does the CDER Drug Shortage Program verify that a shortage exists?

A. The CDER Drug Shortage team utilizes information from manufacturers, distributors and market share data to determine if a shortage exists.
(DSP defines a drug shortage as follows:

The total supply of all versions of the approved product available at the user level will not meet the current demand. A registered alternative manufacturer will not meet the current and/or projected demands for the potentially medically necessary use(s) at the user level.)

O. Can FDA do anything about pricing of medications?

Pricing issues are not within the purview of FDA.

However, if you have concerns regarding the price of your medications, you may wish to contact the Federal Trade Commission (FTC). The FTC enforces a variety of federal antitrust and consumer protection laws. The FTC seeks to ensure that the nation's markets function competitively, and are vigorous, efficient, and free of undue restrictions. Contact information for the FTC is as follows:

Federal Trade Commission
Bureau of Competition
Office of Policy and Evaluation
Room 394
Washington, D.C. 20580
Phone: (202) 326-3300

Website address: <http://www.ftc.gov>³

When shortages occur, there are often faxed and e-mailed advertisements received by pharmacies from unknown distributors that offer these drugs at higher prices than the pharmacy normally pays. Concerns should be reported to FDA via the Office of Criminal Investigations at the following link: <http://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm>⁴

Q. Where can I obtain additional information on drug shortages?

A. The American Society of Health System Pharmacists⁵ (ASHP) lists drug shortages and additional information.

Links on this page:

1. </BiologicsBloodVaccines/SafetyAvailability/Shortages/default.htm>
2. </Food/default.htm>
3. <http://www.ftc.gov>³
4. <http://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm>⁴
5. <http://www.ashp.org/>