Fact Sheet: Continued Progress on Reducing Drug Shortages

On October 31, 2011, President Obama issued an Executive Order directing the Food and Drug Administration, in cooperation with the Department of Justice, to take action to help reduce and prevent drug shortages, protect consumers, and prevent stockpiling and exorbitant pricing of drugs in shortage. On the same day that the Executive Order was announced, FDA issued a letter to all pharmaceutical manufacturers reminding them of their responsibility to report the discontinuation of certain drugs to FDA. The letter also encouraged manufacturers to voluntarily disclose to FDA potential prescription drug shortages in cases where disclosure is not currently required by law.

Today, in response to the President' s Executive Order, the FDA is issuing an interim final rule that will require manufacturers that are the only producer of certain drug products to report to the FDA all interruptions in manufacturing of products that are life supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition. Early notification of potential drug shortages is an essential tool in helping FDA work with drug manufacturers, hospitals, doctors, and patients to prevent or mitigate a drug shortage before it becomes a crisis. The rule builds on FDA' s current work to ensure Americans have access to the medicine they need.

Recent Progress on Drug Shortage Efforts

Today' s FDA action to improve notification of potential shortages of important drugs is one of a series of steps the Agency has taken to combat the shortage of prescription drugs and ensure that patients have access to the lifesaving medicines they need.

- Since the President's October 31, 2011 Executive Order, FDA has prevented96 drug shortages (86 from one firm).Prior to October 31, 2011,the number of shortages prevented since January 2010 was 137, bringing the total number of shortages prevented in the past 2 years to 233.
- Increased awareness due to the Executive Order and FDA's letter to manufacturers has resulted in an increase in voluntary notifications by industry of potential shortages. Prior to October 31, 2011, FDA received approximately 10 voluntary notifications per month. In the month following the Executive Order, FDA received 61 notifications, a six-fold increase.

- FDA is on-track to increase its staff in the FDA Drug Shortage Program to coordinate response activities and expedited actions like inspections that can help to alleviate shortages.
- FDA continues development of a tracking database which will monitor numbers of drug shortages, reasons for shortages and what FDA is doing to help address and prevent shortages. The agency has prioritized work on this database to make it as useful as possible and anticipates completion in 2012.

The Executive Order and FDA's letter to manufacturers have also resulted in more collaborative efforts to prevent and mitigate drug shortages.

- FDA is working with DOJ to address stockpiling and exorbitant pricing issues of drugs in shortage. FDA has already started communicating recent reports of alleged stockpiling and price gouging to DOJ, as directed by the Executive Order.
- FDA is working to analyze reports received from various sources about stockpiling of drugs in shortage and exorbitant pricing of these products. This is part of an effort to provide DOJ with information on an ongoing basis, as DOJ determines whether these reported activities are consistent with applicable laws. DOJ has reached out to the National Association of Attorneys General to consider whether these activities violate applicable state and local law.
- FDA is meeting with stakeholders, including the Generic Pharmaceutical Association, Pharmaceutical Research Manufacturers of America, and the Biotechnology Industry Organization, and with the three largest drug wholesalers to discuss the development of strategies to prevent and reduce shortages.

Early Notification Legislation

The Administration also announced on October 31, 2011, its support for bipartisan legislation (S. 296 and H.R. 2245) that would require all prescription drug shortages to be reported to FDA and would give FDA new authority to enforce these requirements. While additional manufacturing capacity is necessary to fully address the drug shortage problem, additional early disclosure can have a significant, positive impact on addressing the incidence and duration of drug shortages.

Key Facts About Drug Shortages

- Between 2005 and 2010, the number of drug shortages per year tripled from 61 to 178. From January through October of this year, FDA has tracked 220 drug shortages.

- FDA closely studied 127 of the more serious drug shortages that occurred between January 1, 2010, and August 26, 2011. Of these, shortages of sterile injectables account for 102 drugs in shortage (80% of the total 127), even though sterile injectable drugs comprise a small percentage of the overall prescription drug market. These include critical products such as oncology drugs, anesthetics, parenteral (intravenous) nutrition drugs, and many drugs used in emergency rooms. Forty-three percent of these shortages were due to product quality issues such as particulates, microbial contamination, impurities and stability changes resulting in crystallization.
- During 2010 and 2011, oncology drugs accounted for 28 percent of shortages, followed by antibiotics at 13 percent. [1]

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[1] "A Review of FDA's Approach to Medical Product Shortages Drug Shortage Report": *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm275051.htm.*