FDA Notifies Health Care Providers about the Risks of Purchasing Unapproved Injectable Cancer Medications from Unlicensed Sources

Current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in serious harm to patients. Health care providers are reminded to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States (U.S.).

In certain circumstances, the FDA may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the U.S. through a controlled network, and would not be sold in direct-to-clinic solicitations. If the FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available on the FDA drug shortages website, often in the form of a "Dear Healthcare Professional" letter.[1]

Summary of Issue

Unlicensed, Unknown, Sources Selling Unapproved Versions of Injectable Cancer Medications Which are Not in Short Supply

- FDA is aware of promotions and sales of unapproved injectable cancer medications direct-to-clinics in the U.S, which most likely were administered to patients. Products purchased include a high percentage of sterile injectable medications and medications whose quality could be adversely affected if they are not stored or transported under specific temperatures. Examples of products include unapproved versions of FDA-approved medications such as Faslodex (fulvestrant), Neupogen (filgrastim), Rituxan (rituximab) and Herceptin (trastuzumab).

- In these cases, patients were unknowingly placed at risk when they received medications of uncertain purity, storage, handling, identity, and sourcing.

- Any medication that has not been manufactured in accordance with FDA standards and pursuant to FDA approval—including foreign versions of FDA-approved medications—is considered unapproved. In an effort to protect the health of patients, health care providers should use only FDA-approved versions of these cancer medications.

- Health care providers should be aware that purchasing medications from direct-to-clinic promotions that are from non-verified sources might increase the risk of receiving a potentially unsafe and ineffective product, since the products offered for sale may be unapproved, not manufactured with the quality attributes of FDA-approved products, or counterfeit.

- Medical practices in the U.S. should be aware that importing these medications from foreign sources is in violation of the Federal Food, Drug, and Cosmetic Act (FDCA). For most of these medications, there are FDA-approved versions readily available in the U.S.

Drug Shortages – Injectable Cancer Medications

- FDA is concerned and actively engaged in addressing the current shortages of injectable cancer medications. However, FDA-approved versions of a number of the unapproved medications that have been purchased through direct-to-clinic solicitations are not currently in short supply. The FDA-approved versions of these medications are readily available in the U.S. from wholesale distributors licensed in the U.S.
- A list of current drug shortages is accessible on FDA's website at http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.
- When the manufacturer of an FDA-approved medication cannot immediately resolve the shortage of a medically necessary medication, FDA has allowed temporary importation of the foreign version of that medication through a controlled distribution network until the U.S. shortage of the medication is resolved. FDA identifies foreign versions of the product with the same active ingredient manufactured by reputable firms with good quality profiles. FDA posts the information about the imported medication along with a Dear Healthcare Professional letter on the FDA drug shortages website.[11]

How Healthcare Professionals Can Help Ensure Safety of their Patients

1. Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the U.S. Click on the following link to determine if the wholesale distributor is licensed in the state(s) where it is conducting business. http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm

2. Determine if the medication you have received is FDA-approved by checking the Orange Book (http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm) or Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/).

3. Question whether a price sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, or unapproved.

4. Carefully inspect the product and packaging. Providers should be alert for these signs that the product is not FDA-approved:

    - Packaging looks different
    - Labeling is not in English
    - Dosing recommendations are unfamiliar
    - Dosage form or route of administration is different (e.g., ampule instead of pre-filled syringe)

5. If you receive multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

[1] FDA drug shortages website: http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm

6. Report product quality issues and adverse events to FDA using the MedWatch system http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085568.htm

7. Report suspicious activity regarding marketing and distribution of unapproved injectable cancer medications to FDA's Office of Criminal Investigations at www.fda.gov/oci under "Report Suspected Criminal Activity."

FDA is committed to promoting and protecting the public health by ensuring that safe, effective, and high quality products are available to the American public.