

Medication Safety Issue Brief

Counterfeit Drug Prevention and Identification

3

of 6 in a series

Series III

The need for hospitals to become aware of the potential for counterfeit drugs is part three in a six-part series that highlights underlying causes of and solutions to medication errors. This series is a joint effort of the American Hospital Association, the American Society of Health-System Pharmacists and *Hospitals & Health Networks*, with generous support from McKesson Corp. You may tear this card out for future reference. Additional copies are available in PDF format, along with those from two previous series, on the ASHP and *H&HN* Web sites (www.ashp.org and www.hhnmag.com).

• SUMMARY

The U.S. drug supply is purportedly one of the safest in the world and yet counterfeit medications do make their way to pharmacy shelves and into the hands of unsuspecting patients. The World Health Organization reports that about \$35 million in counterfeit drugs are sold in the United States each year. Worldwide, between 6 percent and 10 percent of prescription drugs on the market are counterfeit, WHO estimates. The Food and Drug Administration conducted 22 investigations into counterfeit drugs in 2002 and again in 2003; that's up from an average of five investigations per year through the late 1990s. Counterfeit drugs can cause serious harm to patients, including allergic reactions, and deny them access to potentially life-saving treatments.

• ISSUE BRIEF

The proliferation of counterfeit drugs in the U.S. market is attributed in part to heightened awareness of the issue. But, it's also attributed to the use of more sophisticated techniques by counterfeiters. With today's technology, counterfeiters are able to produce drugs and labels that closely resemble the genuine product.

"The regulatory framework is not as sound as one would like," says Doug Scheckelhoff, director of the American Society of Health-System Pharmacists' section of pharmacy practice managers. "Most of the breakdown in the pharmacy supply chain comes at the secondary wholesale level." Adds Tom McGinnis, the FDA's director of pharmacy affairs, "There's not much counterfeiting in the U.S. But, counterfeiters around the globe would love to get their products to the U.S. market."

Medications that are prone to counterfeiting are high-cost, high-volume products, frequently injectables (see Action Resources on the flip side). For example, in 2002 the FDA reported the appearance of counterfeit Epogen, an injectable used to boost the production of red blood cells in cancer and transplant patients, among others. Boxes of vials with 2,000 units per milliliter of Epogen were relabeled and sold as containing 40,000 U/ML. The 2,000 U/ML vials sell for about \$224 a box, while a box of the 40,000 U/ML vials sell for \$1,800, notes Scheckelhoff.

Another problem is the presence of diverted products on the market. Diverted products are either stolen goods that are resold to distributors or medications that are meant for another market entirely. These are often stored in unfavorable conditions that diminish their effec-



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ACTION Resources

The National Association of Boards of Pharmacy compiles a National Specified List of Susceptible Products—items it deems susceptible to adulteration, counterfeiting or diversion. The organization recommends strict licensing requirements for distributors of these medications by the states and advocates that every state adopt this standard list rather than compile individual, varying lists. More information is available at www.nabp.net.

1. Combivir
2. Crixivan
3. Diflucan
4. Epivir
5. Epogen
6. Gamimune
7. Gammagard
8. Immune globulin
9. Lamisil
10. Lipitor
11. Lupron
12. Neupogen
13. Nutropin AQ
14. Panglobulin
15. Procrit
16. Retrovir
17. Risperdal
18. Rocephin
19. Serostim
20. Sustiva
21. Trizivir
22. Venoglobulin
23. Viagra
24. Videx
25. Viracept
26. Viramune
27. Zerit
28. Ziagen
29. Zocor
30. Zofran
31. Zoladex
32. Zyprexa

ADDITIONAL RESOURCES:

- FDA Web site, www.fda.gov/counterfeit.
- *Dangerous Doses*, a novel by investigative reporter Katherine Eban, www.dangerousdoses.com.
- Safemedication.com, a Web site by ASHP.
- The Healthcare Distribution Management Web site, www.healthcaredistribution.org.

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tiveness or they have slightly different compositions than the intended product.

• INITIATIVES

Ensuring the authenticity of prescription medication is the responsibility of the state and federal governments, with support from manufacturers, wholesalers, pharmacists and providers, as well as patients. The following is a look at what is being done, or can be done, to prevent counterfeit drugs from entering the marketplace. These measures will not come without cost to hospitals. "The bulk of the cost of securing medications will fall on manufacturers, who will likely pass it on to hospitals and other purchasers," Scheckelhoff says.

Federal: The Pharmacy Drug Marketing Act, passed in 1988, mandates the use of drug pedigrees to record a drug's history from the point of manufacturer to point of use. The FDA, however, has not enforced the law, citing administrative and practical challenges of the paper-based system. The proliferation of radio frequency identification, however, promises to provide an efficient, secure way to track a drug's origins. The FDA is encouraging manufacturers to adopt RFID technology and believes the technology could be ready for widespread use by 2007.

State: State laws govern and license pharmaceutical wholesalers and distributors. The National Association of Boards of Pharmacy advocates the adoption of strict state laws concerning the licensing of these businesses. The NABP also proposes stricter sentences for those convicted of counterfeiting.

Manufacturers, Wholesalers and Distributors: Manufacturers can decrease the likelihood of counterfeiting by reducing the need for repackaging by providing products in unit-of-use packages. The adoption of RFID by the industry is deemed a highly effective way to prevent counterfeiting, as is the use of tamper-evident packaging.

Providers: Hospitals can reduce their risk of purchasing counterfeit drugs by buying only from recognized group purchasing organizations and distributors. Hospitals should also minimize or eliminate the use of secondary distributors. If a secondary distributor is necessary, the hospital should ask to see the drug pedigree. Hospitals can also reduce the risk of counterfeiting by destroying used boxes and packages of medications so they cannot be stolen and reused. Pharmacists play an important role. "Pharmacists are the last defense against counterfeit drugs," McGinnis says. "If they see anything different and the pharmaceutical company hasn't sent an advanced notice of a product or label change, they should notify the FDA."

Patients: Patients should pay attention to their medications and become familiar with their shape, color, taste and dosage. If any differences are detected or the patient notices different results, a pharmacist should be notified. •

