



American Society of
Health-System Pharmacists®

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ASHP Strategies to Protect Against Drug Counterfeiting

This list was developed to serve as a resource for health-system pharmacists in their ongoing efforts to ensure the integrity of drug products used in U.S. health systems. These actions should help prevent the acquisition of counterfeit drug products. Note: this list will continue to be revised as new information becomes available, so please check for updated information. Suggested additions to the list should be sent to: sections@ashp.org

Product Source:

1. Contact your primary wholesaler and inquire about their anti-counterfeiting measures and sources of product. Make sure your suppliers are taking steps to limit its sources of products to authorized manufacturers and authorized distributors.
2. Check the FDA website at least weekly for new reports of counterfeit products detected in the pharmaceutical supply chain. The FDA MedWatch website is at: <http://www.fda.gov/medwatch/SAFETY/2003/safety03.htm>. For questions about a specific product you can reach the FDA at 888-463-6332.
3. Check your group purchasing organization (GPO) website for reports of counterfeit products. Websites for the national GPOs are:

http://amerinet-gpo.com	http://medassets.com
http://broadlane.com	http://mhainc.com
http://www.consorta.com	http://www.novationco.com
http://healthtrustpg.com	http://www.premierinc.com
http://medmanagement.com/services/purchasing.asp	
4. Contact your Board of Pharmacy, Department of Health, or other appropriate state agency periodically to determine whether there are problematic wholesalers in your state. Board of Pharmacy contact information can be found at: <http://www.nabp.org>

Distributors:

5. Limit or eliminate the use of secondary distributors unless you can verify that they are an authorized distributor purchasing from authorized manufacturers and are in good standing with your State Board of Pharmacy or other licensing agency. Verify that they are in compliance with the HDMA Voluntary Guidelines for Pharmaceutical System Integrity available at <http://www.healthcaredistribution.org>

Security Measures:

6. Re-evaluate pharmacy department security measures to minimize risk of diversion or entry of counterfeit products. Consider the following:
 - monitoring access by cameras and ID readers
 - using automated supply stations where additional controls are needed
 - assuring delivery of drugs to the pharmacy directly, not to a loading dock
 - altering drug packages for products in inventory to make them less resalable (eg. mark box with hospital name, tear off box tops)
 - completely destroying empty drug packages and vials so that they may not be removed from the trash and refilled with counterfeit product
 - removing drugs from floor stock if considered at risk for diversion
 - reconciling purchasing records with billing or administration records
 - assuring that staff placing drug orders are not “receiving” inventory
 - using sequential purchase order numbers to increase accountability
 - using invoice approval as an additional verification of appropriate purchasing

High Risk Products:

7. Pay particular attention to products considered to be at ‘high risk’ for counterfeiting. Be mindful that expensive drug products and drugs in short supply are more likely to be counterfeited than other medications. The following list of high-risk medications was developed by the State of Florida as part of its anti-counterfeiting legislation:

Anti-retrovirals:

Combivir (lamivudine/zidovudine)	Crixivan (indinavir sulfate)
Epivir (lamivudine)	Retrovir (zidovudine)
Videx (didanosine)	Viracept (nelfinavir mesylate)
Viramune (nevirapine)	Zerit (stavudine)
Ziagen (abacavir sulfate)	Sustiva (efavirenz)
Trizivir (abacavir sulfate/lamivudine/zidovudine)	

Anti-infectives:

Diflucan (fluconazole)

Rocephin (ceftriaxone sodium)

Other high cost products:

Epogen (epoetin alfa)

Immune globulin (various brands)

Lamisil (terbinafine)

Lupron (leuprolide acetate)

Neupogen (filgrastim)

Nutropin AQ (somatropin, e-coli)

Procrit (epoetin alfa)

Risperdal (risperidone)

Serostim (somatropin, mannanian)

Zocor (simvastatin)

Zofran (ondansetron)

Zoladex (goserelin acetate)

Zyprexa (olanzapine)

Education:

8. Educate all pharmacy staff on the problem of counterfeiting, what they should look for, and how to report a suspicious product. Provide additional training and instruction to those pharmacy staff who order and/or receive products from distributors. Alert clinical and staff pharmacists to consider counterfeit product as a possible reason for an unusual adverse drug reaction or unusual response to a medication.
9. Consider how nursing, medical staff, and patients should be alerted to the potential for counterfeit products. Review policies for medication acquisition with your Pharmacy and Therapeutics Committee to assure that necessary controls are in place.

Patient Feedback or Complaints:

10. Take comments and complaints about products seriously and investigate them promptly. Many counterfeit products were discovered only after patients complained of a change in effectiveness or a change in taste of their oral medications.

Unauthenticated Product:

11. If you encounter a questionable product, contact the manufacturer and wholesaler to determine follow-up steps to verify authenticity. If the product is confirmed not to be authentic, then the FDA should be contacted through the MedWatch program (<http://www.fda.gov/medwatch/>) or at 800-332-1088.