



If the Cost of a Medication Is Too Good to Be True, the Drug May Be Counterfeit

In the past few years, a number of developments have occurred, including drug shortages and patients having trouble affording their prescriptions, that might seem to justify importing medications from overseas. The world outside of U.S. borders appears to offer a ready supply of cheaper medications easily obtained through unlicensed distributors, trips across the border, or online pharmacies.

The laws that prohibit importing non-FDA-approved medicines are designed to ensure that patients receive medications that meet the FDA's requirements for safety, purity, and potency. It is illegal to import unapproved, misbranded, adulterated, or foreign versions of U.S.-approved medications into the country. The law also applies to medical devices.

Regardless of the supplier, purchasing or using non-FDA-approved drug products exposes the physician to criminal and civil liability. Medical malpractice insurance may not cover any errors in this area—making physicians personally liable for claims that they provided counterfeit drugs.

The medication doesn't even have to be counterfeit for the physician to suffer legal consequences: Medications that have the correct ingredients but haven't been FDA-approved are still illegal to use.

Physicians and their office staff may inadvertently order counterfeit drugs or devices. Follow these tips to protect yourself and your patients from the risks of illegal medications and devices:

- Require training for everyone involved in purchasing medications.
- Be wary of fax or e-mail blast offers from an unauthorized distributor selling “discounted” foreign medications or devices.
- Have clear policies that dictate how to verify the license of a wholesaler providing medications. For example, require that your staff verify all vendors by checking wholesaler accreditation and licensing at <http://safedr.ug/VAWDaccredited> and <http://safedr.ug/fdalicense>.
- Obtain medications only from secure sources.
- Know the warning signs that a product may be counterfeit:
 - Are prices or deals too good to be true?
 - Was the fax/e-mail offer unsolicited and from an unknown seller?
 - Is the labeling in a foreign language when it's normally in English?
 - Is the package damaged or soiled?
 - Are all tamper seals present and intact?
- If in doubt, call the manufacturer to check if the lot number is still valid and matches the expiration date.
- Educate patients about avoiding counterfeit drugs with free resources like the S.A.F.E.D.R.U.G. checklist at www.safemedicines.org/safedrugs.html.

Contributed by The Doctors Company. For more patient safety articles and practice tips, visit www.thedoctors.com/patientsafety or contact your local representative Sarah Wolfenbarger at (800) 243-3503. For more information on counterfeit medicines, go to www.safemedicines.org.