

Why does the U.S. restrict medication imports from other countries?

Many people simply cannot afford the cost of brand-name medications in the U.S. Some families must make difficult choices between medications, buying food, or paying rent. This is nothing new. Congress first recognized the problem almost 50 years ago in 1959 and held extensive hearings, but the problem was never addressed. This forces those who pay for medications out of pocket without prescription drug insurance to search for lower prices, even outside the U.S.

Canada is a prime source of low-cost, brand-name drugs. But why are drug prices lower in Canada? The Canadian government determines the reimbursement for new prescription medications in negotiations with manufacturers on behalf of the public. As a result, brand-name medications are about 40 percent to 60 percent less expensive in Canada than they are in the U.S.

Why are there restrictions against importation?

The safety of the drug supply is Congress' primary concern in restricting importation. The Prescription Drug Marketing Act (PDMA) passed in 1987 prohibits anyone other than the pharmaceutical manufacturer from importing that product into the U.S. This includes drugs manufactured in the U.S. that are then exported to another country. The PDMA was passed by Congress because of concerns that counterfeit medications may have been getting into the U.S. supply system. The law also tries to prevent pharmacies and others from re-importing brand-name medications produced in this country – but less expensive in foreign countries – back into the U.S. Because the U.S. is the only country that allows pharmaceutical manufacturers to set the prices of their medications, the PDMA may unintentionally protect the manufacturer-set prices in this country.

Some members of Congress have proposed legislation that would allow the re-importation of large quantities of brand-name prescription medications from Canada and other countries. These proposals would require any medications re-imported into the U.S. to be certified as safe and effective by the FDA. However, these legislative proposals did not include provisions that



would give the FDA sufficient resources for inspections and testing to ensure that re-imported drugs meet the agency's standards for safety and effectiveness. It should be noted, however, that patients are allowed to import medications for personal use.

Are imported medications from Canada safe?

The standards for safety, effectiveness and product quality testing in Canada are similar to those in this country. Also, the standards for pharmacist education and the registration of pharmacists and pharmacies are similar in the U.S. and Canada. A U.S. consumer purchasing a prescription medication in person from a licensed Canadian pharmacy should have no safety concerns.

There are serious safety concerns when medications – supposedly from Canada – are purchased on the Internet. For example, in August 2005 the FDA conducted an operation at the New York, Miami, and Los Angeles airports and found that nearly half of the imported drugs intercepted by the FDA from four selected countries were shipped to fill orders that consumers believed were placed with “Canadian pharmacies.” Of the drugs being promoted as “Canadian,” based on accompanying documentation, 85 percent actually came from 27 other countries. A number of these products were found to be counterfeit. These results demonstrate that some Internet sites claiming to be “Canadian” were in fact selling drugs of dubious origin, safety and efficacy.

The cost savings in Canada only apply to brand-name medications. The Canadian government does not negotiate the cost of generic medications and, in general, the cost of generic medications is higher in Canada than in the U.S.

What is the European experience with importation?

Parallel distribution of medications between European Union countries was introduced over two decades ago, based on the knowledge that medication prices vary, sometimes substantially among countries. The low-cost countries are the source of medications for this program. Within each country, the distribution model leads to healthy competition between direct imports from a manufacturer and parallel imports through a distribution center in a low-cost country. Parallel-imported products often come from the same plant that produces the domestic versions. The experience has been very good while keeping the cost of Europe's medications in check. These savings have substantially benefitted federal and other health plans and consumers. The parallel distribution is highly regulated, and it is anticipated that this practice will lead to a virtual equalization of medication prices in Europe, and thus become obsolete.



Key messages

- ✓ Brand-name medication prices are high in the U.S. because the government does not negotiate prices with manufacturers.
- ✓ Consumers seek brand-name medications from foreign countries because of their lower cost.
- ✓ Patients are allowed to import medications for personal use; others are not.
- ✓ The European experience with importation is positive.