



Prescription Drug Re-Importation Question and Answer Sheet

What is drug re-importation?

Drug re-importation refers to the practice of importing back to the United States prescription drugs that were originally manufactured in the U.S. and exported for sale in another country. Most often, Americans re-import drugs for personal use by filling their prescriptions in Canadian or Mexican pharmacies, either in person, or through mail-order or Internet pharmacies.

Why do consumers and other purchasers of drugs engage in drug re-importation?

Because prescription drugs often are sold at lower prices outside of the United States, some Americans see re-importation as a way to potentially obtain access to other countries' lower drug prices.

What is the law in the U.S. regarding re-importation of prescription drugs?

It is against current U.S. law to re-import prescription drugs (the legal exceptions are that drugs manufactured in the U.S. may be re-imported by the original manufacturer or if the drug is required for "emergency medical care"). It is also illegal to advertise or otherwise promote re-imported drugs.

The Food and Drug Administration (FDA) has a personal use policy that allows individuals who fill a prescription for certain unapproved prescription drugs while abroad to bring that prescription back into this country for personal use. This is not a "legal" exception to the law; rather, it reflects the FDA's discretion to not prosecute these individuals, and can be changed at any time. The policy was originally intended for humanitarian purposes to allow individuals suffering from serious medical conditions to acquire medical treatments legally available in foreign countries but not approved or commercially available in the U.S. However, some Americans view the personal use exception policy as a way to access lower prices for medicines already approved in the U.S.

Although the Food, Drug and Cosmetic Act prohibits re-importation, the federal government has not strictly enforced the law in the past. The FDA has used discretion in dealing with re-importation or importation of prescription drugs for personal use. Many American citizens have been able to cross the Canadian border, purchase a limited supply of prescription drugs, and bring them home. Earlier this year, in recognition of the increase in both Internet-based pharmacies selling drugs from abroad and organized busloads of older persons traveling to Canada to buy medicine, the FDA announced that it plans to enforce the law more rigorously by bringing civil or criminal charges against third party groups that help Americans import drugs from Canada.

What are the FDA's concerns about prescription drug re-importation?

The FDA and the U.S. Customs Agency have voiced concerns about the safety of re-imported prescription drugs. The FDA has stated that, because it does not have oversight over other countries' drug distribution systems, it cannot provide, under a system of legal re-importation, protection against the possibility of counterfeit drugs, untested medications, foreign copies of FDA-approved drugs, expired drugs, contaminated drugs, and drugs stored under inappropriate and unsafe conditions. The U.S. Department of Health and Human Services did not implement an earlier law designed to allow prescription drug re-importation, in part on the grounds that it could not certify the safety of these drugs.

What is AARP's policy on consumer re-importation of prescription drugs?

AARP is concerned about high drug costs and understands the reasons that consumers seek to take advantage of other countries' lower prescription drug prices. While AARP is concerned about the potential health and safety risks associated with purchasing drugs from outside the United States, it also recognizes the risks associated with consumers not taking prescribed medicines simply because they cannot afford to purchase them.

AARP supports policies that will ensure confidence in the safety and integrity of re-imported medications, and believes that safety concerns can be minimized by restricting the legal source of re-importation to Canada - from licensed Canadian pharmacies and wholesalers - for a defined period of time. (Canada is already the source of considerable *de facto* re-importation and safety violations appear to be minimal in extent and insignificant in nature.) In addition, AARP believes that if re-importation is allowed, it is important that the FDA be provided the resources and authority to ensure the safety of re-imported drugs from Canada, and that technological and other safeguards be employed.

AARP does not view re-importation as a panacea for either rapidly rising drug costs or lack of affordable, dependable prescription drug coverage in Medicare. However, AARP believes that re-importation under the preceding terms can help restrain costs, improve access to, and enhance the safety of re-imported pharmaceutical products.

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