



Rx Focus

Drug Reimportation

Drug reimportation has been a topic of interest for some time, and it is again reaching news headlines. Here in the United States, the Department of Health and Human Services (HHS) Task Force released a report on drug reimportation Dec. 22, 2004. In Canada, government officials are proposing stricter policies on internet pharmacies that send medications to the United States. As long as U.S. drug prices are high, people will look for alternatives such as reimportation through internet pharmacies. Internet pharmacies are cheaper, but the question remains, are they safe?

Drugs are cheaper in other countries such as Canada because the Canadian government's price controls. Price controls allow governments to place a cap, or maximum, on the price of medications in their country. Therefore manufacturers sell the same medications to different countries for different prices.

When a U.S. resident orders a prescription from an internet pharmacy located in Canada, the price of the prescription is cheaper because the medication is subject to Canadian price controls. As drug companies became aware of this, they tightened the supply of drugs to Canada, and in some cases terminated drug supply to internet pharmacies. This caused internet pharmacies to look for sources other than drug manufacturers and wholesalers to meet the ever growing demand of cheaper medication for U.S. residents. In some cases Canadian internet

pharmacies will look to purchase drugs from other Canadian pharmacies, but this supply is limited since drug wholesalers are reducing drug quantities allowed for purchasing, and Canada needs to supply medications to their own citizens. This causes Canadian internet pharmacies to import drugs from other countries also subject to low price. This is why a prescription purchased from a Canadian internet pharmacy may not necessarily come from a drug manufacturer who sold the drug to Canada. The medication could have come from the Caribbean, Australia, or any combination of countries.

This is where issues of medication safety may arise. Some countries have stricter laws and regulations regarding prescription quality than others. By ordering medication from an internet pharmacy there is no guarantee which country the medication originally came from. Some countries, such as Canada, have quality controls on medications that are distributed to their own citizens, but these controls do not apply to drugs that are exported. Storage conditions of medications are very important and can affect the potency and safety of medications. Regulations of different countries and multiple shipping allow more room for error in storage conditions. Having a medication travel through various "middlemen" also leaves room for opportunities where the prescription could be tampered with or counterfeit drugs could be introduced. Consumers also need to be aware that some internet pharmacies could be completely illegitimate.

Canadian Health Minister, Ujjal Dosanjh, stated that Canada is considering allowing Canadian doctors to only write prescriptions for Canadian residents and visitors, which would make it illegal for them to countersign prescriptions from other countries. He also warned if potential drug shortages arise, certain drugs may be prohibited from being exported.

Here in the U.S. the HHS Task Force was formed to examine if large scale reimportation would be a quick fix for high U.S. drug prices. The conclusion of the report is as follows: "Any safe system of importation will likely only produce modest savings on the national level. The small quantity of available drugs to import results in little aggregate cost savings, and intermediaries reap much of the benefit." The average saving to consumers of a hypothetical government run reimportation program is only 1-2%. Essentially, the cost involved to ensure the safety of imported drugs eliminates most potential savings. This is why the Bush administration deemed the program unworkable.

Some are now looking to generics as a safe option to lower drug costs. According to the Task Force report, the prices of generic drugs in other countries are 50% higher than generic prices in the United States. The Task Force report also stated Americans could have saved \$17 billion in 2003 if they had chosen the generic version of their prescriptions.

References:

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February Health Observances

American Heart Month

Sponsored by American Heart Association
www.americanheart.org

Children's Dental Health Month

Sponsored by American Dental Association
www.ada.org

AMD/Low Vision Awareness Month

Sponsored by Prevent Blindness America
www.preventblindness.org

Wise Health Consumer Month

Sponsored by American Institute for Preventive Medicine
www.healthylife.com

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3. Finkelstein, J (2005). Drug Reimportation Dilemma: Drug Safety vs. Access. *AMNews*. Retrieved January 6, 2005, from <http://www.ama-assn.org/amendnews/2004/07/05/gvsa0705.htm>
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Industry Report

New Drug: Lyrica™ (Pregabalin)

Pfizer was recently granted FDA approval of Lyrica™, a gabapentinoid, for neuropathic pain management associated with diabetic peripheral neuropathy (DPN) and postherpetic neuralgia (PHN). It is the first drug to be FDA approved for both of these neuropathic pain states. The FDA rejected approval for generalized anxiety disorder and is currently reviewing approval for adjunctive treatment of partial seizures in adults. The European Commission approved Lyrica for seizure use in July 2004. Lyrica will be classified in the U.S. as a controlled substance. Although it will be classified with a lower potential of misuse/abuse, this classification is expected to lower drug usage. Especially since Neurontin (gabapentin) is commonly used for DPN, and is available as generic. Lyrica potentially has some leverage since it is FDA approved for DPN, while Neurontin is not. The results of six, double-blind, placebo-controlled trials demonstrated both rapid (as early as one week), and sustained (up to 12 weeks) pain relief with Lyrica. Common adverse effects reported are dizziness, peripheral edema, blurred vision, weight gain, and difficulty with concentration or attention.



New Drug Approvals

Clolar™

Approved: 12/28/04

Chemical Name: Clofarabine

Manufacturer: Genzyme Corp.

Therapeutic Class: Anti-Cancer Agent

Approved Indication: IV infusion treatment of pediatric patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens.

Average Wholesale Price: unavailable at this time

Notes: This medication will not be covered for members of CBCA RX plans.

Prialt®

Approved: 12/28/04

Chemical Name: Ziconotide intrathecal infusion

Manufacturer: Elan Pharmaceuticals

Therapeutic Class: N-type calcium channel blocker (NCCB)

Approved Indication: Management of severe chronic pain in patients for whom intrathecal therapy (IT) is warranted and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or IT morphine.

Average Wholesale Price: Unavailable at this time

Notes: This medication will not be covered for members of CBCA RX plans.

Macugen®

Approved: 12/20/04

Chemical Name: Pegaptanib sodium injection

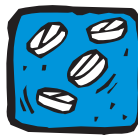
Manufacturer: Eyetech Pharmaceuticals, Inc.

Therapeutic Class: Anti-vascular endothelial growth factor therapy (VEGF)

Approved Indication: New therapy to slow vision loss in people with the eye disease neovascular (wet) age-related macular degeneration

Average Wholesale Price: \$1,381.94

Notes: This medication will not be covered for members of CBCA RX plans.



New Generic Approvals

Ciclopirox Olamine Cream

Approved: 1/3/05

Manufacturers: Fougera & Glades Pharmaceuticals

Brand Name Equivalent: Loprox® Cream

Approved Indication: Antifungal cream



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