U.S. Bill to Import Canadian Drugs Gets Chilly Reception North of the Border

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(BNA) -- U.S. lawmakers looking to imports from Canada as a cure for soaring pharmaceutical prices are on the wrong track, Canadian sources told Bloomberg BNA.

Legal experts warn that Canada's regulatory system puts major hurdles in the way of mass drug exports, and the Canadian pharmaceutical industry warns that it would oppose mass exports because that would potentially put Canadian patients at risk.

The concept of reducing U.S. drug costs by importing lower-cost products from Canada is "not terribly practical" for a range of reasons, Tim Squire, a partner in the Toronto office of Fasken Martineau DuMoulin LLP, said March 13.

Even if the U.S. made mass imports possible, Canada might not be able to provide them due to legal and regulatory constraints, Squire, co-chair of the law firm's international life sciences industry group, told Bloomberg BNA. "It's just not that straightforward," he said.

Greater interest in Canadian imports was prompted by a recent U.S. legislative proposal from a group of congressional Democrats. The lawmakers, including Sen. Bernie Sanders (I-Vt.) and Rep. Elijah E. Cummings (D-Md.), offered a bill in late February that would instruct the Department of Health and Human Services to issue rules allowing wholesalers, pharmacies and individuals to import qualifying prescription drugs from licensed Canadian sellers.

Differing Approvals, Views on Risks

The two countries have relatively similar drug approval processes, but there are cases on both sides of the border where drugs are approved for different indications or dosages, Squire said. The differences reflect differing views on the risks of specific products to consumers, which is more of an issue for products that pose more of a risk than consumer products or electronics, he said.

Practically speaking, Health Canada and the U.S. Food and Drug Administration apply the same standards, but while they sometimes accept each other's data, the processes aren't identical, he said. "That's a possibility in the future, just not yet," he said.

Canada would also have to change its specific policy on imports and exports of health products, which currently limits the ability of companies to import drugs for re-export, Squire said. The policy requires a product to meet all Canadian requirements, including labeling rules requiring both English and French, at the moment that it's imported, creating extra costs if the product is exported, he said.

"It's impractical, not impossible," he said.

Canadian Drugs Not So Cheap

American politicians are also working under the mistaken premise that Canadian drugs are so much cheaper than those in the U.S. that mass imports would make sense, Squire said. Canada regulates prescription drug prices through the Patented Medicine Prices Review Board, but the controls don't apply to products such as generics, he said.

The federal agency isn't the biggest driver of lower prices; that's the Pan-Canadian Pricing Alliance, through which provincial health plans bargain directly with pharmaceutical companies for lower prices on high-volume products, he said. Some provinces also regulate generics, with Ontario limiting their prices, depending on dosage form, to 25-30 percent of patented products' prices.

In addition, Canada's pricing controls don't apply to exports, so there is no guarantee Canadian products would be sold for the same prices in the U.S., he said. "If you can escape a price control, why wouldn't you?" he said. "I don't think there are such huge savings to be had."

The current weakness of the Canadian dollar against its U.S. counterpart also makes Canadian drugs look cheaper on paper, but that would expose U.S. consumers to significant price swings, he said. Loosening U.S. rules on personal imports of prescription drugs might be a more sensible way to help U.S. consumers in the longer term, Squire said. U.S. residents can currently import up to a three-month supply from Canada, but only if the therapy is not already available in the U.S., which excludes most Canadian products, he said. “Maybe a quicker fix would be to loosen those restrictions,” he said.

That would also require some changes in Canada, as most provinces restrict pharmacies from filling prescriptions written by a physician who isn’t located in the province, he said.

Canada’s patent-holding pharmaceutical companies are “concerned” by the recent legislative initiatives in Congress because of their potential impact on the supply of prescription drugs for Canadians, Pamela Fralick, president of industry group Innovative Medicines Canada, said March 13.

“Canada cannot supply medicines and vaccines to a market 10 times larger than its own population without endangering Canadian supplies and causing shortages,” Fralick told Bloomberg BNA in an email. The Canadian Generic Pharmaceutical Association said it is unable to respond to questions about the U.S. bill because the association’s focus is on the domestic legal, regulatory and policy climate.

Canada Focused on Domestic Prices

The Canadian government isn’t paying close attention to the U.S. bill, as Health Minister Jane Philpott’s mandate is focused on lowering drug prices in Canada, not the U.S., Andrew MacKendrick, the minister’s spokesman, said March 14.

As far as he’s aware, no one has approached Health Canada about changing its current approach to drug exports, MacKendrick told Bloomberg BNA. “If that’s something they wish to bring up, they’re welcome to do so,” he said.

Health Canada is aware of the U.S. bill and will continue to monitor its progress as it moves through the legislative process, the department said March 14. Export and import of health products is governed by a Health Canada policy and a guidance document outlining packaging and labeling requirements for foreign products, the department told Bloomberg BNA in an email.

In general, health products exported from Canada must meet the relevant requirements of Canada’s Food and Drugs Act and its regulations, including ensuring that exported products are not adulterated, manufactured in unsanitary conditions or manufactured, sold or advertised in a false or misleading way, it said.

The policy allows for exceptions where some requirements are dropped if the exporter is the holder of a drug establishment license and provides contract packaging or labeling services to a foreign company for products that are ultimately exported from Canada for sale and consumption in a foreign jurisdiction.

For More Information

Health Canada’s policy on drug exports is available at http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/pol-0060_biu-uif-eng.php.
The department’s policy on packaging and labeling of foreign products is available at http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui_67_tc-tm-eng.php.