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Ontario pharmacists concerned about federal oversight of imported medications in light of birth-control pill recalls

Ontario pharmacists are among the Canadian health professionals publicly calling for more rigorous oversight of imported drugs, in light of 3 recalls of oral contraceptives across Canada since April 2013.

More than 620,000 packages of 3 types of generic birth-control pills were recalled in Canada between April and September. These include Alysena from Apotex, and Freya-28 and Esme-28, both of which are manufactured in India for Mylan Pharmaceuticals in the United States. All the recalls were connected to problems with too many placebos in place of active-ingredient doses.

The recalls have raised questions about the product integrity of some medications sold in Canada, said the Ontario Pharmacists Association (OPA) in a September 11 news release. The OPA urges Health Canada to increase scrutiny of brand and generic manufacturers for all aspects of drug production, including the packaging of finished products both in and outside of Canada.

The Society of Obstetricians and Gynaecologists of Canada and the College of Family Physicians of Canada have also raised red flags about federal oversight of quality and safety in the manufacture and distribution of oral contraceptives and other medications.

Pharmacists have a number of concerns with respect to the recalls, including some related to the recall process itself, said the OPA CEO, Dennis Darby, in an interview with *CPJ*.

“There was no real notice,” he says. “Pharmacists found out at the same time as the media and public, so they didn’t have a chance to prepare. As the media reports were coming out, the OPA was getting calls from pharmacists asking what they should do.”

Many pharmacists have been able to deal with the birth-control pills in question by taking an extra step for patients, Mr. Darby says. “Because one can see if the packages were prepared incorrectly, many pharmacists are opening up the packages in front of the patient to make sure all is fine. In this case, it was relatively easy for pharmacists to find out if there was a mistake—but that’s not always going to be the case for a recall.”

It is critical for Health Canada to ensure the highest standards of oversight over pharmaceutical products imported into the country, he adds.

“As medications become more globally sourced, we ask the question—how do we make sure that we have a quality assurance system in place that can reassure Canadians and health care professionals that the products we are providing to patients meet the quality standards we expect?”

Because these oversight issues are the responsibility of federal regulators, the OPA would like to work with the Canadian Pharmacists Association and other provincial pharmacist associations to address some of these areas of concern, says Mr. Darby.

BY KATHIE
LYNAS

“How do we make sure that we have a quality assurance system in place that can reassure Canadians?”

—Dennis Darby, Chief Executive Officer, Ontario Pharmacists Association

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