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Ontario pharmacists concerned about the risks arising from approval of generic OxyContin

BY KATHIE LYNAS



"Prescription drugs can't be viewed as commodities; just because a patent expires doesn't mean we should give the go-ahead to generics"

— Allan Malek, Senior Vice President, Ontario Pharmacists' Association The federal government's approval of generic versions of OxyContin is a matter of great concern to the Ontario Pharmacists' Association (OPA), which fears it will worsen the public health crisis related to narcotic abuse and misuse, and lead to a resurgence in pharmacy armed robberies and break-ins.

Health Canada approved 6 generic versions of the drug on November 27, 2012 — just one day after the expiration of Purdue Pharma's patent for oxycodone, the active ingredient in OxyContin. All the provincial and territorial premiers, along with many health professionals, the Ontario Association of Chiefs of Police and the OPA, had urged the federal government to delay such authorization until a complete review of the risks could be undertaken.

However, the federal minister of health, Leona Aglukkaq, said she is required by law not to withhold approval for a drug otherwise considered safe and effective for its intended use. To do so, she said, would undermine the integrity of Health Canada's scientific review process.

That view is narrow and short-sighted, says Allan Malek, Senior Vice President, Professional Affairs, Drug Information & Continuing Education with the OPA. "Prescription drugs can't be viewed as commodities; just because a patent expires doesn't mean we should give the go-ahead to generics.

"The OPA believes the review process should be overhauled to take a more holistic view," he adds. "There are social impacts from these kinds of drugs and that should be part of the consideration."

Concerns about safety of pharmacists

Earlier this year, Purdue Pharma began phasing out OxyContin in Canada and replaced it with OxyNEO, a formulation considered more difficult to abuse. Since the change, there has been a decline in robberies and break-ins at pharmacies in many Ontario communities.

"We would anticipate that with a re-introduction of oxycodone to the market, we are going to see a resurgence in robberies," says Mr. Malek. "The OPA advocates for the best quality care for patients but we also have to look at representing the interests of our members, and that includes their safety and security in the workplace."

Ontario's planned regulations not a solution

Ontario Health Minister Deb Matthews quickly responded to the federal announcement of approval — by revealing plans to regulate limited access to generic OxyContin. The Ontario Drug Benefit (ODB) plan would only fund the generics if they were in a tamperresistant form, the minister said.

The Ontario government is attempting to do what it can with the tools it has available, says Mr. Malek, but the OPA is not confident that Matthews' plan will do much to mitigate the risks.

"Tamper-resistant does not mean tamperproof; we saw that with OxyNEO," he says. "Almost before the new drug hit the market, we saw websites popping up that gave tips on how to break down the OxyNEO formulation.

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"I don't believe making it tamper-resistant is going to solve anything," he adds. "And these new generics will be coming into the market at 25% of the brand price — which makes them more accessible and cheaper on the street."

Health care professionals, addiction specialists and all levels of government need to come together to develop broad solutions to deal with widespread abuse and misuse of narcotics, according to Mr. Malek.

"This goes well beyond oxycodone. We need to address all the issues — drug abuse, drug diversion, prescribing habits and better approaches to managing patients' chronic pain."

(See guest editorial on this topic on page 6.)

BC government reveals plans to lower generic drug prices to 20% of brand-name price by April 2014

Beginning in April 2013, the British Columbia government will pay 25% of the brand-name price for generic drugs and one year later, the price will be lowered to 20% — lower than what currently exists in any other province.

Health minister Margaret MacDiarmid revealed the regulatory timetable on November 23, 2012, and predicted the reductions would save the province \$110 million in public drugplan spending over 2 years.

The government's move from 35% to 25% wasn't a surprise; it had been announced earlier in 2012, when the province cancelled its services agreement with pharmacists and introduced new legislation. The precise timing of the changes and the 20% target, however, hadn't previously been known.

The British Columbia Pharmacy Association (BCPhA) is pleased that the province heard pharmacists' request for a reasonable notice period so they can begin to adjust, says the association's executive director, Geraldine Vance. The BCPhA also welcomes the government's decision not to follow Ontario's example by banning professional allowances.

"The price reduction is going to have a major impact on pharmacy across BC, so leaving rebates and professional allowances in place will certainly help to buffer the negative impact," Ms. Vance told *CPJ*.

The BC government first announced its plans to reduce generic prices in 2010. Although its goal had been to move to 25% of the brand-name equivalent price right away, the province negotiated an agreement with pharmacy associations that included a reduction to 35%.

In March 2012, the provincial health ministry said the agreement was not producing adequate savings, and revealed plans to terminate the deal and bring in legislation to set generic prices through regulation.

Next priority for BCPhA: A process for expanded clinical services

The now-terminated Pharmacy Services Agreement included a formal process for developing more funded clinical services. The BCPhA is now focused on working with the province to create a comparable process to guide future negotiations.

"The loss of that formal structure was one of the biggest losses stemming from the agreement's termination," says Ms. Vance. "A key priority now is to develop some kind of structured process for exploring other clinical-services opportunities for our profession."

The current government supports the concept of further expanding pharmacist services, says Ms. Vance. However, BC will soon be gearing up for a provincial election, expected to be held in May 2013, and the BCPhA is developing plans to raise the profile of the issue during the campaign.

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Geraldine Vance,
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British Columbia
Pharmacy Association