

Feds must step up and restrict generic oxycodone, Ontario says

It would be a “complete abdication of responsibility” for the federal government to allow generic oxycodone to come on the market once the patent on the brand-name version expires Nov. 25, Ontario Health Minister Deb Matthews charges.

Matthews and other provincial health ministers have been campaigning for Health Canada to, at the very least, delay its decision on whether or not to allow generic formulations of oxycodone to be distributed across Canada, until more research on the highly addictive opioid is conducted.

“What I’m asking them to do is look at the full health impact. Health Canada has a responsibility to look at safety and I’m asking them to define safety broadly to include social and other health impacts,” Matthews says. Federal Health Minister Leona Aglukkaq “has a responsibility to set policy and I think the policy has to be that you look at safety from a broader perspective. You don’t just look at if this drug is properly taken. Is it safe? Because we know this drug is not properly taken in many, many cases.”

But a legal expert says the federal government’s hands may be tied, while other experts say Ottawa must examine other grounds on which to prevent generic oxycodone from hitting the market, and the streets.

Matthews also wrote a letter to Aglukkaq in June calling for a prohibition on the introduction of generic oxycodone, after the brand Oxycontin was reformulated in February by manufacturer Purdue Pharma L.P., following a similar move in the United States in 2010.

“I’m hoping that she will understand that this is not like any other drug. I’ve never ever asked for this before. This is one drug that has caused way too much damage and I just think that now we have an opportunity to get it off the streets — we must get it off the streets,”



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Drug abusers often crush oxycodone, dissolve it in water and then inject it.

Matthews says. “I’m asking for an outright ban; do not give it a notice of compliance. It is just too dangerous and has devastating consequences.”

Concerns over the drug prompted Purdue Pharma L.P. to replace controlled-release Oxycontin with a newer formula called OxyNEO, which is believed to be more tamper-resistant than the original formulation because it is harder to crush and turns into a gel when dissolved in water.

“It is the introduction of the generic that is the danger,” Matthews says. “The only advantage of the generic is that it’s cheaper. It’s cheaper but it opens the door to far, far, far more expensive interventions in the health care and public sector system. Talk to the police, talk to the pharmacists, talk to addiction workers and front line staff, I don’t think you would find anyone advocating for the reintroduction of the easily tampered-with form of Oxycontin.”

But Nathaniel Lipkus, a lawyer and Canadian patent and trademark agent with Gilbert’s LLP in Toronto, Ontario,

says federal options may be limited. “Health Canada has a broad discretion to look at a drug and decide whether it’s safe and effective based on the data they’ve been presented. But with generic drugs, they’re actually required to approve a product where the product has been shown to be bioequivalent to an already approved drug.”

“So according to the law, as long as a generic can show that they are bioequivalent, I don’t know that there’s a clear mechanism whereby Health Canada can refuse to approve the generic application,” Lipkus adds.

Even examining other options could open the door to legal challenges, Lipkus says. “They would have to sit on the application. They would have to issue a decision saying we will not approve the generic applications that are sitting on our desk and the generic companies would say we want that decision so we that can appeal it.”

“If they issued that decision, generic companies would then bring an application in federal court to say that the

reviewers for the Ministry of Health have exceeded their jurisdiction and they've acted improperly in not granting the application," he adds.

But nothing stops the federal government from introducing a higher standard of approval for drugs in a class and declaring that the old formulation doesn't measure up,

Lipkus says. "But in order to do that they basically have to make a revisionist finding that Oxycontin was not safe and effective."

"Then what would happen to Purdue Pharma?" he asks. "You can imagine class actions being filed because Purdue was selling a product that they knew was not safe and effective and that Health Canada had said very clearly was not safe and effective."

In such a scenario, the federal government basically has to decide whether it wants to take on the brand-name manufacturer or the generics. "They're going to get sued one way or the other," says Lipkus. "It happens all the time in these drug cases because there is a lot at stake. In some cases the minister says either the brand is going to sue me or the generic is going to sue me, which one would I rather sue me?"

Others say that the federal government should explore still other options.

The federal government can consider classifying the drug as addictive, which would allow it to more strictly control its use, much in the manner of morphine, says Richard Gold, professor of law at McGill University in Montréal, Que. "It's a problem of how do we regulate the grant of prescriptions by physicians on the one hand and how do we control access through Health Canada and

provinces' ability to control access? We have plenty of legislation dealing with drugs and there are different categories of drugs all the way from completely illegal to ones that we can only use in certain circumstances and have those been explored. That would seem to be the appropriate place to deal with this problem, not the issue of genericization."

The health impacts of oxycodone should supersede other considerations, argues Dr. Tania Bubela, assistant professor in the Department of Public Health Sciences at the University of Alberta in Edmonton. "I think it's much more sensible to take a stand against the drug in and of itself as opposed to bringing the red herring of whether it's a name brand or a generic version of the drug."

"I think what needs to be put into play is if this specific drug is causing addictions and usage issues particularly in First Nations communities than the real attention needs to be paid to accessibility of the drug per se — you already have problems with the name brand drug," she adds.

Matthews says Canada's health ministers concur, in particular, because of the impact on Aboriginal communities. "What I've said is put aside your briefing book. She is an Aboriginal woman, she knows these communities. Go talk to the chiefs. Go out with street workers. Go out with a community health centre outreach team. Talk to frontline workers and if she does that and still comes back and says: 'no I think we should do it anyway,' I would be very surprised."

"Health Canada has responsibility for First Nations' health. It is in First Nations communities and this is the

biggest problem. The minister is an Aboriginal woman herself — I don't get it. I don't understand why they're not there, why they're not the ones pushing us to do more."

Ontario will not include generic oxycodone within its formulary and recently allocated \$15 million to provide more treatment for prescription drug addicts. Addiction levels will only continue to rise if a generic version of the older form of oxycodone is allowed on market and result in social costs well beyond the price savings to provincial formularies, Matthews argues. That position is supported by a recent Canadian Health Policy Institute study which concluded the additional social costs would outstrip savings from the use of generic oxycodone by \$352 million to \$415 million annually (www.canadianhealthpolicy.com/downloads/research-pdfs/skinner-september-2012-oxycodone-study-final.pdf).

Prescriptions of oxycodone increased by 850% between 1991 and 2007 in Ontario and after the drug was added to the province's formulary in 2000, associated deaths increased five times with overall opioid-related deaths increasing by more than 40%, according to a report commissioned by Matthews (www.health.gov.on.ca/en/public/publications/mental/docs/way_forward_2012.pdf). The report also indicated that treatment for opioid addictions were a spiralling problem, rising to 18.6% of those seeking treatment for addiction in fiscal 2010/11, from 10.6% in fiscal 2005/06.

Aglukkaq was unavailable for comment. — Adam Miller, *CMAJ*

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