

**Ministry of Health
and Long-Term Care**

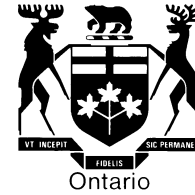
Office of the Minister

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**Ministère de la Santé
et des Soins de longue durée**

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The Honourable Leona Aglukkaq
Health Canada
Brooke Claxton Building, Tunney's Pasture
Postal Locator: 0906C
Ottawa, Ontario K1A 0K9

Dear Minister Aglukkaq:

RE: Request that Generic Oxycodone Controlled-Release Tablets Not Be Approved for Sale in Canada

I am writing to you to seek your help in preventing the reintroduction, as a generic medication, of the more-easily abused form of oxycodone in this country.

As Ministers of Health, we share very serious concerns about the abuse and misuse of prescription narcotics, which, as you well know, has become a serious public health and safety issue in Canada.

Both Ontario and Canada have been hard hit by the growing number of people addicted to prescription narcotics. Many are using them outside their intended medical purposes, trafficking them on the street and, far too often, dying as a result of improper use. While there are different factors that may contribute to death (in particular, high doses of opioids and use with alcohol or other depressant-type drugs), the opioid most commonly found on post-mortem analyses in recent years is oxycodone. One notable study indicated that the addition of oxycodone controlled-release ("CR") tablets to the Ontario drug formulary was associated with a five-fold increase in oxycodone-related mortality and a 41 per cent increase in overall opioid-related mortality.¹ Oxycodone has not only been implicated in increased overdoses and deaths, but has become a public health crisis in many communities, including many First Nations communities.

In recent months, coincident with the introduction OxyNeo, the governments of both Canada and Ontario have taken significant actions to improve the appropriateness of access to this very powerful medication. These actions have not been without consequence for both our governments, but I believe we are beginning to see the benefits

¹ Dhalla, I et al, *Prescribing of opioid analgesics and related mortality before and after the introduction of long acting oxycodone*, CMAJ, December 7, 2009; 121 (8).

among our populations. I strongly believe that we would be doing our constituents a disservice if we allowed these improvements to be eroded by the re-introduction of the non-tamper-resistant formulation to the Canadian market.

I am aware that the patent for OxyContin (the original brand product for oxycodone CR tablets) will expire on November 25, 2012. In anticipation of this date I understand generic manufacturers may have submitted their products for approval to market in Canada. To the best of our knowledge, generic oxycodone CR will not be formulated to be tamper-resistant. Moreover, given the potential for widespread abuse and the susceptibility to diversion and trafficking of this product, we believe that approving the generic oxycodone CR tablets for sale in Canada would further exacerbate the incidences of addiction and death in Canada and contribute to a growing public health crisis.

I understand that the current policy of your department is, if upon review they believe that a generic manufacturer's submission supports the safety, efficacy and quality of the drug, they will issue it a Notice of Compliance (NOC). I urge you to direct your officials to consider the broader public health perspective in their determination of "safety".

Ontario believes that the costs to society of the reintroduction of the more-easily abused version far outweigh the financial benefits that would accrue from the reduced price we would receive and, as you know, Ontario has the most aggressive generic pricing policy in the country. However, only the Federal Government has the authority to approve the sale of generic oxycodone in this country. For this reason I am seeking your help and am strongly urging you not to grant market authorization for generic versions of oxycodone CR tablets in Canada.

Ontario remains committed to the health and public safety of Canadians and hope that the federal government will be a committed partner on this issue.

Sincerely,

Deb Matthews
Minister

- c. Saäd Rafi, Deputy Minister, Ontario
Dr. Arlene King, Chief Medical Officer of Health, Ontario
Diane McArthur, Executive Officer and Assistant Deputy Minister, Ontario
Provincial/Territorial Ministers of Health