Proposed Regulation Amendments to Set Additional Conditions for Submission Requirements of Long-Acting Oxycodone Drug Products

November 23, 2012

Recent studies suggest that increased rates of opioid prescribing, particularly oxycodone, are contributing significantly to opioid-related harms and deaths. While there are different factors that may contribute to death (in particular, high doses of opioids and the use of opioids 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 (long-acting) 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 across Ontario.

In early 2012, Purdue Pharma Canada, the manufacturer of OxyContin, initiated the removal of its formulation of oxycodone controlled release tablets, OxyContin, and introduced a new formulation, OxyNEO. OxyNEO and OxyContin are two different brand names of the same active ingredient oxycodone, which is indicated for the relief of moderate to severe pain requiring the continuous use of an opioid analgesic preparation for several days or more. Although the active ingredients are the same, the OxyNEO tablet is manufactured differently than the OxyContin tablet, which reportedly makes the tablet more difficult to crush. In addition, it is reported that, if OxyNEO is exposed to water, it results in the formation of a thick gel-like substance.

As a result of the manufacturer discontinuing the production of the OxyContin tablets, the Ministry of Health and Long-Term Care ("ministry") removed OxyContin from the Ontario Drug Benefit (ODB) Formulary on February 29, 2012. Recognizing that some patients will require access to oxycodone, OxyNEO is funded through the Exceptional Access Program in accordance with specific funding criteria. The funding criteria were based on extensive discussions with practising pain specialists, addiction experts and other health care providers, and were designed to balance appropriate use, patient care and the growing problem of opioid addiction in Ontario.

In recent months, in parallel to the shift from OxyContin to OxyNeo, the ministry has taken steps to ensure there is appropriate access to this very potent prescription drug. The ministry is committed to

[1] Dhalla, I et al, *Prescribing of opioid analgesics and related mortality before and after the introduction of long-acting oxycodone,* CMAJ, December 8, 2009; 181 (12), at pp. 891-896.

taking all measures to reduce prescription drug abuse and addictions in Ontario, while ensuring that Ontarians continue to receive appropriate access to prescription opioids in a safe and effective manner.

This notice is to inform you that the Ontario Government is proposing to amend subsections 1(1.2) and 12(9) of Ontario Regulation 201/96 made under the *Ontario Drug Benefit Act* ("ODBA") and subsection 6(8) of Regulation 935 made under the *Drug Interchangeability and Dispensing Fee Act* ("DIDFA"). The proposed amendments would permit a drug product that contains oxycodone as the only active ingredient and that is a long-acting product that has been formulated in a solid dosage form for oral administration to be considered for funding under the ODBA and/or to be designated as an interchangeable product under the DIDFA, if, and only if, specific conditions are met.

The proposed conditions would include:

- providing evidence that would be satisfactory to the Executive Officer that the drug product is tamper-resistant, in that it exhibits physiochemical properties that make it significantly more difficult or ineffective to alter the characteristics of the drug product for purposes of misuse or abuse when compared to drugs without such properties, as demonstrated by,
    - in vitro testing,
    - in vivo testing,
    - another form of testing of equivalent reliability, or
    - a combination of any of the forms of testing mentioned above

In addition to the above, the Ontario Government is also proposing to amend sub-paragraph 3(ii) of section 27 of O. Reg. 201/96 by adding a house-keeping reference to the *Narcotics Safety and Awareness Act, 2010* ("NSAA"). The proposed amendment would provide the Executive Officer with clearer authority to suspend the right of a dispensing physician or operator of a pharmacy to receive payment under the ODBA if the dispensing physician or operator of a pharmacy did not comply with the NSAA.

The proposed regulations would provide that the regulations be made retroactive and would come into force on November 23, 2012.

A copy of the draft regulation is available on the Regulatory Registry website at:

http://www.ontariocanada.com/registry/view.do?postingId=11162&language=en

The content of the final regulations are at the discretion of the Lieutenant Governor in Council ("LGIC") who may make the regulations with any changes that the LGIC considers appropriate.

Interested parties are invited to provide written comments on the proposed change to the draft regulations as part of the review. The ministry will consider comments received on or before **December 24, 2012 at 5:00 p.m. EST** ("comment period."). Please be advised that submissions received after the comment period may not be considered.

Please submit your written comments to:

Executive Officer, Ontario Public Drug Programs
Ministry of Health and Long-Term Care
80 Grosvenor Street, 9th Floor
Hepburn Block, Queen's Park
Toronto ON
M7A 1R3
Fax: 416-325-6647
E-mail: PublicDrugPrgrms.moh@ontario.ca

Statement about Comments

Unless requested and otherwise agreed to by the ministry, all materials or comments received from organizations in response to the notice will be considered public information and may be used and disclosed by the ministry as part of its review. The ministry may disclose materials or comments, or summaries of them, to other interested parties during and after the comment period.

An individual who makes a submission and who indicates an affiliation with an organization in his or her submission will be considered to have made his or her submission on behalf of the affiliated organization.

The ministry will not disclose any personal information contained in a submission of an individual who does not specify an organizational affiliation in his or her submission without the individual's consent unless required by law. However, the ministry may use and disclose the content of the individual's submission to assist the ministry in its review.

If you have any questions about the collection of this information, you can contact the ministry's Freedom of Information and Privacy Coordinator at (416) 327-7040.