Ontario Public Drug Programs Division

Notice from the Executive Officer: New Regulatory Requirements for Long-Acting Oxycodone Drug Products

January 24, 2013

The purpose of this notice is to provide you with information regarding changes that have been made to Ontario Regulation 201/96 made under the *Ontario Drug Benefit Act* ("ODBA Regulation") and Regulation 935 made under the *Drug Interchangeability and Dispensing Fee Act* ("DIDFA Regulation") that have recently been approved by the Ontario Government. These regulations are now final and made effective retroactively to November 23, 2012.

The Ministry of Health and Long-Term Care ("ministry") posted on November 23, 2012 proposed amendments to subsections 1(1.2), 12(9) and sub-paragraph 3(ii) of section 27 of the ODBA Regulation and subsection 6(8) of the DIDFA Regulation.

I would like to thank all those who submitted comments and participated in the consultation process. As a result of the comments we received, the draft regulations were changed to provide additional information about the types of characteristics that a long-acting oxycodone product must exhibit in order to be considered for public funding under the ODBA and/or be designated as interchangeable under the DIDFA.

In order for a long-acting oxycodone product to be considered for public funding under the ODBA and/or designated as an interchangeable product under the DIDFA, a manufacturer of a long-acting oxycodone oral product must provide evidence satisfactory to the Executive Officer that the drug product exhibits one or more physiochemical properties that, when compared to drug products without any such property or properties, make the drug product either:

- significantly more difficult to alter, break, crush, chew, dissolve or otherwise manipulate in such a way that it could be misused, abused or put to an intended use that is different than the use for which it is prescribed; or

- significantly less effective and less likely to be misused, abused or put to an intended use that is different than the use for which it is prescribed, in the event that it is altered, broken, crushed, chewed, dissolved, or otherwise manipulated.

The evidence referred to above must be 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.

The purpose of the new regulatory requirements is to help address the potential abuse and misuse of controlled-release (long acting) oxycodone tablets, which have become a serious public health and safety issue in Ontario. 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 study suggested that the addition of oxycodone controlled-release (long-acting) tablets to the Ontario Drug Benefit 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.

The ministry believes that these new regulatory requirements may potentially decrease the number of oxycodone overdoses, and help to reduce prescription drug abuse and addictions in Ontario while ensuring that Ontarians continue to receive appropriate access to pain medication in a safe and effective manner. We will continue to work with health care providers and other stakeholders regarding appropriate prescribing and dispensing practices and will closely monitor the dispensing of prescription narcotics and other controlled drugs, including long-acting oxycodone products, through the use of the narcotics monitoring system to ensure the health and safety of all Ontarians.

In addition to the above, a house-keeping reference to the *Narcotics Safety and Awareness Act, 2010* ("NSAA") has been added to sub-paragraph 3(ii) of section 27 of the ODBA Regulation. Because the NSAA only recently came into force in November 2011, the house-keeping addition will provide further clarity that the Executive Officer may suspend the rights of a pharmacy operator and a dispensing physician to receive payment under the ODBA, if they do not comply with the NSAA.

For the authoritative text of the regulations, please visit the e-Laws website at http://www.e-laws.gov.on.ca/html/source/regs/english/2013/elaws_src_regs_r13020_e.htm for the amendments to the ODBA Regulation and http://www.e-laws.gov.on.ca/html/source/regs/english/2013/elaws_src_regs_r13021_e.htm for the amendments made to the DIDFA Regulation.

For general questions relating to long-acting oxycodone drug products, please visit the ministry website at: http://www.health.gov.on.ca/en/public/programs/drugs/ons/oxy_faq.aspx

[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.