

**Note: 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.**

## **ONTARIO REGULATION**

made under the

## **ONTARIO DRUG BENEFIT ACT**

Amending O. Reg. 201/96

(GENERAL)

Note: Ontario Regulation 201/96 has previously been amended. For the legislative history of the Regulation, see the Table of Consolidated Regulations – Detailed Legislative History at [www.e-Laws.gov.on.ca](http://www.e-Laws.gov.on.ca).

**1. Section 1 of Ontario Regulation 201/96 is amended by adding the following subsection:**

(1.2) The executive officer shall not, under section 16 of the Act, make the Act apply in respect of a drug that is a drug product described in subsection 12 (9) of this Regulation, unless the condition set out in paragraph 1 of that subsection is met.

**2. Subsection 12 (9) of the Regulation is revoked and the following substituted:**

(9) A strength and dosage form of 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 shall not be designated as a listed drug product unless the following condition is met:

1. There must be evidence 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,
  - i. in vitro testing,
  - ii. in vivo testing,

- iii. another form of testing of equivalent reliability, or
- iv. a combination of any of the forms of testing mentioned in subparagraphs i to iii.

**3. Subparagraph 3 ii of section 27 of the Regulation is amended by striking out “the *Drug and Pharmacies Regulation Act*” and substituting “the *Drug and Pharmacies Regulation Act, the Narcotics Safety and Awareness Act, 2010*”.**

**Commencement**

- 4. This Regulation comes into force on November 23, 2012.**