

**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

### **DRUG INTERCHANGEABILITY AND DISPENSING FEE ACT**

Amending Reg. 935 of R.R.O. 1990

(GENERAL)

Note: Regulation 935 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. Subsection 6 (8) of Regulation 935 of the Revised Regulations of Ontario, 1990 is revoked and the following substituted:**

(8) 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 interchangeable 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.

#### **Commencement**

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