

Ontario Public Drug Programs Drug Submission – Policy Directive

In accordance with Part VII of the Drug Submission Guidelines, the Ministry is publishing this policy directive regarding the drug submission review process.

It is the responsibility of manufacturers to monitor clarifications of, or changes to, the Guidelines through the Ministry's website.

Manufacturers are asked to take note of the following submission requirements and review process for multiple source products:

- *Notice of Change in Product Monograph (PM) matching the innovator submission, effective June 13, 2016.*

When a manufacturer notifies the Ministry that the PM of a generic product has been updated to match the innovator's PM, the Ministry will review changes and determine if the notification is complete or incomplete.

Effective June 13, 2016, the Ministry **will no longer** issue a confirmation letter for a complete submission. The manufacturers **will only** be asked to respond to the Branch if additional information is required to complete the submission. That is, an incomplete letter will be issued to the manufacturers for deficient submissions in this category.

This change in communication process applies **ONLY** to all current and future multiple source submissions for the notice of change in the PM to match the innovator PM.

Please be advised that manufacturers must notify the Ministry of any change to an interchangeable product (including changes to a product monograph), as per paragraph 1 of section 8(1) of Regulation 935 made under the *Drug Interchangeability and Dispensing Fee Act* (DIDFA). Compliance with this requirement is a condition of being designated as an interchangeable product under the DIDFA.