

Ministry of Health

Drugs and Devices Division

## **PART III-B.5.**

# **Ontario Guideline for Notification of Change to Generic Drug Products**

Updated: December 2019

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## **PART III-B.5. NOTIFICATION OF CHANGE TO DRUG PRODUCTS**

Paragraph 1 of Section 8(1) of the DIDFA Regulation requires that manufactures notify the ministry of changes made to the drug products designated as interchangeable.

**8. (1)** The following condition must be met in order for a drug product that has been designated as interchangeable to continue to be designated as interchangeable:

1. The manufacturer of the product shall give the executive officer notice of any change made to the product, including a formulation change, and of any change in the ownership of the manufacturer.

The ministry must be notified of the changes in ownership, Drug Identification Number (DIN), company name, drug product name, formulation or significant changes to the Product Monograph. Significant changes include any changes to indications or substantive changes to contraindications, adverse effects or warning/precautions.

All notification of change submissions must include one electronic copy of a cover letter with the following:

- A description of the change(s) and a brief rationale for the change(s);
- The drug product(s) including the DIN(s) affected by the change(s);
- Confirmation that the master formulation has not changed, and confirmation that the bioavailability has not been affected\*; and
- Confirmation that Health Canada has approved the change(s).

The cover letter must contain the appropriate manufacturer's letterhead, dated and signed by the senior company official.

If the Product Monograph has been updated, the manufacturer is required to provide the updated Product Monograph (annotated/ tracked and non-annotated) with the most recent date of revision and control number.

The ministry will review the changes and determine if the notification is complete or incomplete based on the above requirements. The ministry will not issue a confirmation letter for complete submissions.

Manufacturers should monitor for update notices from the Drugs and Devices Division, as well as updates to the Formulary which can be found on the ministry's website:

<https://www.formulary.health.gov.on.ca/formulary/>.

For incomplete submissions, manufacturers will be asked to respond to the ministry with the information required to complete the submission. In such cases, an incomplete letter will be issued.

The ministry reserves the right to ask manufacturers for additional information regarding any changes made to the drug product.

**\*Note:** In all cases, if bioavailability has been affected, a new comparative bioavailability study (or a justification for not providing a study), or the scientific data provided to Health Canada are required.

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