Ontario

Ministry of Health

OHIP, Pharmaceuticals and Devices Division

Ontario Guidelines for Notification of Change to Generic Drug Products

Introduction

Paragraph 1 of section 8(1) of Regulation 935 (the "DIDFA Regulation") under the *Drug Interchangeability and Dispensing Fee Act* (DIDFA) requires manufacturers of generic products designated as interchangeable on the ODB Formulary / Comparative Drug Index (the "Formulary") to notify the ministry of changes made to the drug products. This requirement also exists in paragraph 1 of section 12.1(1) of Ontario Regulation 201/96 (the "ODBA Regulation") under the *Ontario Drug Benefit Act* (ODBA), in the case of generic drug products designated as listed drug products on the Formulary. Finally, this requirement applies by policy to generic drug products not designated on the Formulary but otherwise funded under Ontario Public Drug Programs (e.g. generic products funded under the Exceptional Access Program without an interchangeability designation).

The objective of this document is to provide guidance on the submission requirements for a notification of change to a generic drug product described above.

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.

Submission Requirements

All notification of change submissions must include a cover letter with te 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. (Note: Confirmation that the master formulation has not changed, and confirmation that the bioavailability has not been affected is not a requirement for changes to the Product Monograph).

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 also 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 is required.

Filing of Drug Submissions

The OHIP, Pharmaceuticals and Devices Division accepts e-mail submissions.

All submissions and any additional related information must be sent to:
Senior Manager
Drug Benefits Management Unit
Drug Programs Policy and Strategy Branch
OHIP, Pharmaceuticals and Devices Division
Ministry of Health

Please send the submissions to email mailbox DrugSubmissions.MOH@ontario.ca

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