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Pharma in brief - Canada

Updated guidelines for Ontario formulary drug submission released

Summary

The Ontario Ministry of Health and Long-Term Care recently updated the Ontario Guidelines for Drug Submission and Evaluation (**"Guidelines"**). These Guidelines govern drug submissions for inclusion on the Ontario Drug Benefit Formulary or for listing as an interchangeable drug.

Despite various amendments to the regulations under the *Ontario Drug Benefit Act* and the *Drug Interchangeability and Dispensing Fee Act* (**"Regulations"**), this is the first time the Guidelines have been updated since 2000.

Background

The Guidelines provide practical information and guidance to manufacturers making drug submissions to the province of Ontario in order to have drug products listed on the Ontario Drug Benefit Formulary or as interchangeable products under the *Drug Interchangeability and Dispensing Fee Act*.

The changes

This update to the Guidelines consolidates changes made to the Regulations as well as related changes to submission policy. The Guidelines do not address recent proposed changes to the Regulations intended to streamline generic interchangeability (found here).

The Guidelines can be found at the link below and include an executive summary of these changes.

Highlights of changes to the Regulations since 2000 include:

- exemption from the requirement to provide *in-vivo* bioequivalence studies for dermatological glucocorticoids and certain aqueous solutions;
- limiting the price for most interchangeable drug products to 25% of the price of the original product;
- a rapid review process for single-source products that can take place prior to receiving a Notice of Compliance from Health Canada if certain criteria are met;
- a requirement that manufacturers confirm that no rebates were provided to listed persons and that the product is not a private label product; and
- allowing the Executive Officer to consider making an interchangeability designation for products containing the same amounts of the same or similar active ingredients in the same or similar dosage form.

Highlights of changes to submission policy since 2000 include:

- streamlined processes in listing single-source products that have been reviewed by the Common Drug Review or the pan-Canadian Oncology Drug Review, and multiple-source products that have received a Declaration of Equivalence from Health Canada;
- limitations that have been imposed on the consideration of non-prescription medications and natural health products;
- a requirement that manufacturers advise that there are no outstanding patent issues; and
- a challenge mechanism for non-streamlined multi-source product submissions.

Link:

The Guidelines can be found here: Ontario Guidelines for Drug Submission and Evaluation

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