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Pharma in brief - Canada

Amendments to the *Ontario Drug Benefit Act* and *Drug Interchangeability and Dispensing Fee Act* to facilitate access to unlisted drug products and streamline generic interchangeability

Summary

On October 1, 2016, amendments to regulations made under the *Ontario Drug Benefit Act* ("*ODBA*") and the *Drug Interchangeability and Dispensing Fee Act* ("*DIDFA*") came into force that aim to increase access to existing unlisted drug products and also accelerate the introduction of bioequivalent products into the market by way of a faster review process and less stringent requirements for generic line extension products.

To provide guidance to manufacturers seeking to navigate the drug submission process after this date, the Ontario Public Drug Programs published an addendum to the Ontario Guidelines for Drug Submission and Evaluation on October 6, 2016, which can be found here.

Increased access to unlisted, non-formulary drugs

Section 12 of Ontario Regulation 201/96 made under the ODBA ("ODBA Regulation") was amended to authorize the executive officer to transition unlisted, non-formulary drugs available through Ontario's Exceptional Access Program to the Ontario Drug Benefit Formulary without a full submission by the drug manufacturer, as previously required by the ODBA Regulation.[1]

If the executive officer is satisfied that the drug is clinically effective and has a low risk for inappropriate utilization, then the executive officer may transfer the drug from the Exceptional Access Program to the Ontario Drug Benefit Formulary. The goals of the amendment to the ODBA Regulation are to increase access to drugs that are known to be both safe and effective, increase availability to drugs that require urgent access, and increase availability of drugs that may be less costly than newer listed alternatives.

Faster review for all bioequivalent generic drugs

Amendments to Ontario Regulation 935 made under the *DIDFA* ("DIDFA Regulation") are aimed at permitting an accelerated review process for all generic products that have been issued a Declaration of Equivalence from Health Canada.[2]

Previously, there were two review processes (streamlined and non-streamlined) for listing generic products that had received a Declaration of Equivalence from Health Canada. Approximately 95% of products could be reviewed under the streamlined review process and be listed on the formulary in approximately two months. These products primarily consisted of certain aqueous solutions, solid oral dosage forms for systemic effect, dermatological products that contain one or more glucocorticoids as the only active ingredient(s), and drug products with a transdermal route of administration for systemic effect. However, the remaining 5% of products were subject to a non-streamlined review process, which took approximately four months before listing and required review by the ministry's expert advisory committee, the Committee to Evaluate Drugs.

Increased/alternative access to interchangeability

Additionally, the amendments to the DIDFA Regulation will permit a manufacturer of certain drug products to provide *in vitro* studies to satisfy the executive officer that the drug is interchangeable with a product listed on the formulary.[3] This provision of the DIDFA Regulation will apply to drug products that have a non-systemic effect where Health Canada has not issued a Declaration of Equivalence, and where blood concentrations of the product cannot be measured and clinical studies with a pharmacodynamic endpoint are inappropriate or difficult to conduct.

New types of evidence permissible to allow for generic line extension products

In addition, the amendments to the DIDFA Regulation will allow "generic line extension products" (i.e. new strengths for existing drugs) to be considered for listing where no comparable reference product exists in the same strength.[4]

Prior to the amendments, a generic manufacturer seeking listing on the formulary was required to show bioequivalence to the brand reference product in the same strength already considered to be clinically effective. The amendments now relieve generic manufacturers of this requirement by permitting the executive officer to accept alternative forms of evidence to establish that the generic line extension product is clinically effective, such as bioequivalence data and formulation proportionality data.

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Links:

The Consolidated OBDA Regulation

The Consolidated DIDFA Regulation

Addendum 1 to the Ontario Guidelines for Drug Submission and Evaluation

Communication from the Executive Officer dated September 26, 2016

Footnotes

1 O. Reg 201/96 at ss. 12(2.1).

2 O. Reg 935 at ss. 6(3.1). Subsections 6(5.1), 6(6), 6(7), 6(7.1) and 6(7.2) are revoked.

3 O. Reg 935 at s. 6(6).

4 O. Reg 935 at s. 6(7).

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