Ontario Public Drug Programs Division, Ministry of Health and Long-Term Care

Regulation amendments to optimize appropriate access to unlisted, non-Formulary drug products and further streamline submission requirements for generic drug products

September 26, 2016

The purpose of this notice is to provide you with information regarding recent amendments to Ontario Regulation 201/96 made under the *Ontario Drug Benefit Act* ("ODBA Regulation") and Regulation 935 made under the *Drug Interchangeability and Dispensing Fee Act* ("DIDFA Regulation"). The amendments have been approved by the Ontario Government and come into force on **October 1, 2016**.

A notice was posted on the ministry's website on June 1, 2016, that provided stakeholders with information on the proposed amendments to the ODBA Regulation and DIDFA Regulation. Stakeholders were given a 45-day period to comment on the proposed regulatory amendments. I would like to thank all those who submitted comments and participated in the consultation process.

The amendments to the ODBA Regulation and DIDFA Regulation establish the following:

- Enable more appropriate access to certain drugs through Formulary listing, which are currently only available under the Exceptional Access Program;
- Allow for the remaining generic products with a Declaration of Equivalence designation from Health Canada to be reviewed under the faster, streamlined drug submission process; and
- Allow for new strengths of a generic product that do not have a comparable reference product to be considered for listing based on evidence other than product-specific clinical studies.

For the authoritative text of the consolidated DIDFA Regulation, please visit the e-Laws website at: https://www.ontario.ca/laws/regulation/900935

For the authoritative text of the consolidated ODBA Regulation, please visit the e-Laws website at: https://www.ontario.ca/laws/regulation/960201

Ontario

The Ontario Public Drug Programs (OPDP) is publishing an addendum to the Ontario Guidelines for Drug Submission and Evaluation (Guidelines) to assist the manufacturers in making drug submissions to the OPDP resulting from the recent regulatory amendments as described above. The addendum will be posted by October 6, 2016.

For this information, please visit the ministry's website at: Drug Submissions

Any questions regarding the changes to the ODBA Regulation and DIDFA Regulation can be directed to:

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