

Ontario Public Drug Programs Drug Submission – Addendum #1 to Ontario Guidelines for Drug Submission and Evaluation

The Ontario Public Drug Programs (OPDP) is publishing an addendum (Addendum #1) to the Ontario Guidelines for Drug Submission and Evaluation (Guidelines) to assist the manufacturers in making drug submissions to the OPDP. Addendum #1 contains information about the regulatory amendments below that were recently approved by the Ontario government and come into force on October 1, 2016.

Regulation 935 made under the *Drug Interchangeability and Dispensing Fee Act (DIDFA)*:

1. Subsection 1 (1) of Regulation 935 of the Revised Regulations of Ontario, 1990 is amended by adding the following definition:

“generic line extension drug product” means a drug product that the executive officer has agreed to designate as a listed drug product under the *Ontario Drug Benefit Act* as a result of a submission that meets the requirements and includes the information required by subsection 12 (5.1) of Ontario Regulation 201/96 (General) made under that Act;

2. (1) Section 6 of the Regulation is amended by adding the following subsection:

(3.1) Clauses (1) (c) and (h) do not apply to a product that has been designated by Health Canada as equivalent to the original product or to another listed interchangeable product with which it would be designated as interchangeable.

(2) Subsections 6 (5.1), (6), (7), (7.1) and (7.2) of the Regulation are revoked and the following substituted:

(6) Clause (1) (h) does not apply to a drug product that has a non-systemic effect where blood concentrations of the product cannot be measured and clinical studies with a pharmacodynamics endpoint are inappropriate or difficult to conduct if all of the following conditions are met:

1. The manufacturer provides in vitro studies that satisfy the executive officer that the product is interchangeable with the original product.
2. The manufacturer satisfies the executive officer that the in vitro studies described in paragraph 1 are scientifically justified, appropriate for the drug class and can demonstrate equal drug product performance.

(7) Subsection (1) does not apply to a generic line extension drug product that the executive officer has agreed to designate as interchangeable with another product.

Ontario Regulation 201/96 made under the *Ontario Drug Benefit Act (ODBA)*:

1. Section 12 of Ontario Regulation 201/96 is amended by adding the following subsections:

(2.1) Clauses (1) (c), (h) and (i) do not apply to the manufacturer of a drug product if the executive officer is satisfied that the product is clinically effective and has a low risk for inappropriate utilization if designated as a listed drug product for the indication or indications in the submission and,

- a) the executive officer has, since December 31, 2008 or earlier, made the Act apply in respect of the supplying of the drug in accordance with section 16 of the Act for the indication or indications in the submission; or
- b) (b) the executive officer has, since December 31, 2008 or earlier, made the Act apply in respect of the supplying of the drug in accordance with section 16 of the Act for a different indication or indications, and the Canadian Agency for Drugs and Technologies in Health has issued a positive funding recommendation in respect of the drug product for the indication or indications in the submission.

(5.1) In the case of a drug product that Health Canada has approved for sale in Canada based on a new drug submission filed in accordance with the *Food and Drug Regulations* made under the *Food and Drugs Act (Canada)*, a manufacturer may satisfy the condition set out in clause (1) (h) by submitting all of the following to the executive officer:

1. Evidence that satisfies the executive officer that the formulation of the submitted product is proportional to the formulation of another drug product sold by the manufacturer that contains the same active ingredient or ingredients in the same dosage form as the submitted product, but in a different strength.
2. Evidence that satisfies the executive officer that the other drug product described in paragraph 1 is bioequivalent to an original product with the same active ingredient or ingredients in the same strength and dosage form.

3. Clinical evidence referred to in clause (1) (h) with respect to the original product described in paragraph 2.

Addendum #1 will be posted on the ministry's website by October 6, 2016, and will be effective and strictly enforced as of **October 6, 2016**. Any submission made to OPDP on or after October 6, 2016 must comply with the applicable provisions in Addendum #1.

Addendum #1 will be available through the following link by October 6:

http://www.health.gov.on.ca/en/pro/programs/drugs/drug_submissions/drug_submissions.aspx