

Ministry of Health

Drugs and Devices Division

# **Drug Submission – Policy Directive**

## **Addendum # 5 to the Ontario Guidelines for Drug Submission and Evaluation**

The Ontario government is committed to providing timely access to new clinical and cost-effective proven medicines and reduce the administrative burden for businesses and red tape for the industry wherever possible. The Drugs and Devices Division (DDD) is publishing an addendum to the Ontario Guidelines for Drug Submission and Evaluation (Guidelines) to assist manufacturers in making submissions to the DDD.

Addendum # 5 contains information about the regulatory amendments to Ontario Regulation 201/96 under the *Ontario Drug Benefit Act* (ODBA) and Regulation 935 under the *Drug Interchangeability and Dispensing Fee Act* (DIDFA) that were recently approved by the Ontario government, and come into force on January 1, 2020.

Manufacturers must continue to make submissions to the Drugs and Devices Division to have their products considered by the Executive Officer for listing and funding, in accordance with Ontario Regulation 201/96 under the ODBA and Regulation 935 under the DIDFA, as applicable.

Manufacturers are asked to take note of the following changes, effective January 1, 2020:

### **1. Removal of the Drug Notification Form (DNF) for all submissions under the ODBA and DIDFA.**

*Amendments to Ontario Regulation 201/96 made under the ODBA:*

Subclause 12 (1) (a) (i) of the Regulation is amended by striking out “a copy of the product’s drug notification form issued by Health Canada”.

*Amendments to Regulation 935 made under the DIDFA:*

Clause 6 (1) (a) of the Regulation is amended by striking out “a copy of the product’s drug notification form issued by Health Canada”.

The Drug Notification Form (DNF) is not required for all submissions. Manufacturers must continue to provide confirmation that the manufacturer is able to supply the Drug Product at the proposed drug benefit price in a quantity sufficient to meet the anticipated demand for the Drug Product. The ministry’s [template letter](#) is available on the ministry’s website.

**2. Simplified requirements for biosimilar drug product submissions.**

*Amendments to Ontario Regulation 201/96 made under the ODBA:*

(1) Subsection 1 (1) of Ontario Regulation 201/96 is amended by adding the following definitions:

“biologic drug product” means a drug derived from living organisms or their cells;

“biosimilar product” means a biologic drug product that has been approved for sale in Canada by Health Canada based on information comparing the biosimilar product to an original biologic product;

“original biologic product” means the original source of a biologic drug product in a particular strength and dosage form.

(2) Section 12 of the Regulation is amended by adding the following subsection:

(2.2) Clauses (1) (h) and (i) do not apply to the manufacturer of a biosimilar product if the executive officer is satisfied that the product is safe, therapeutically effective or efficacious, and appropriate for public funding, having regard to,

- a) its approval for sale in Canada by Health Canada;
- b) the availability or funding of other drug products that treat the same or similar indications, including the original biologic product; and
- c) any other information available to the executive officer.

Please refer to the Guideline for Biosimilar Products posted on the ministry’s website at [Drug Submissions](#) for more information on the comprehensive submission requirements.

### 3. Simplified requirements for generic line extension submissions.

*Amendments to Ontario Regulation 201/96 made under the ODBA:*

(1) Subsection 1 (1) of Ontario Regulation 201/96 is amended by adding the following definitions:

“generic line extension drug product” means a drug product with the same active ingredient or ingredients in the same or similar dosage form as an original product, but in a strength for which no original product exists;

(2) Subsection 12 (5.1) of the Regulation is revoked and the following substituted:

(5.1) Clauses (1) (h) and (i) do not apply to a generic line extension drug product if the executive officer is satisfied that the product is safe, therapeutically effective or efficacious, and appropriate for public funding, having regard to,

- a) its approval for sale in Canada by Health Canada, and
- b) any other information available to the executive officer.

*Amendments to Regulation 935 made under the DIDFA:*

The definition of “generic line extension drug product” in subsection 1 (1) of Regulation 935 is revoked and the following substituted:

“generic line extension drug product” has the same meaning as in Ontario Regulation 201/96 (General) made under the *Ontario Drug Benefit Act*;

Please refer to the Guideline for Generic Line Extension Product posted on the ministry’s website at [Drug Submissions](#) for more information on the comprehensive submission requirements.