DRAFT REGULATION FOR PUBLIC CONSULTATION

ONTARIO REGULATION

made under the

DRUG INTERCHANGEABILITY AND DISPENSING FEE ACT

Amending Reg. 935 of R.R.O. 1990

(GENERAL)

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.

Commencement

3. This Regulation comes into force on the later of October 1, 2016 and the day it is filed.