DRAFT REGULATION FOR PUBLIC CONSULTATION

ONTARIO REGULATION

made under the

ONTARIO DRUG BENEFIT ACT

Amending O. Reg. 201/96

(GENERAL)

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) 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.

Commencement

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