Caution:
This consultation draft is intended to facilitate dialogue concerning its contents. Should the decision be made to proceed with the proposal, the comments received during consultation will be considered during the final preparation of the regulation. The content, structure, form and wording of the consultation draft are subject to change as a result of the consultation process and as a result of review, editing and correction by the Office of Legislative Counsel.

CONSULTATION DRAFT

ONTARIO REGULATION

to be 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 subsection:

(2.3) Clause (1) (h) does not apply to a drug product that is not a new drug as defined in the *Food and Drug Regulation*s made under the *Food and Drugs Act* (Canada) 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.

2. The Regulation is amended by adding the following French version:

. . . . .

Commencement

3. [Commencement]