Insert as a new sub-section in Ontario Guidelines for Drug Submission and Evaluation PART III-B.2.o replaces PART III-B.2.f,g,h,l,m

PART III-B.2. REQUIREMENTS FOR SPECIFIC CASES (REGULATORY EXEMPTIONS)

o. Streamline Submissions for all Generic Products with a Declaration of Equivalence (DOE) from Health Canada

6. (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.

Subsection 6(3.1) "streamlines" submission requirements for certain drug products. Streamlined submissions are exempt from the Certified Product Information Document (CPID)/master formulation requirement in clause 6(1)(c) and in vivo bioequivalence study requirement in clause 6(1) (h). Streamlined submissions are also not reviewed by the ministry's Committee to Evaluate Drugs.

Subsection 6(3.1) of the DIDFA Regulation applies to a generic product with a Declaration of Equivalence (DOE) with the brand reference product or another listed interchangeable product with which the generic product would be designated as interchangeable.

<u>Submission Requirements</u>

To be eligible for the exemption set out subsection 6(3.1) of the DIDFA Regulation, the manufacturer is required to clearly identify in the submission that,

- The submitted drug product has a DOE on the Notice of Compliance with the reference product; and
- The reference product is:
    - identical to the listed original/innovator product, or,
    - a non-Canadian reference product, approved under Health Canada's Non-Canadian Reference Product policy (refer to Part III-B.2.i), or,

- another listed interchangeable with which the submitted product would be designated as interchangeable, if the original/innovator product is no longer marketed (Refer to Part II-B.2.k for more information).

If this exemption does not apply, the manufacturer must satisfy all the requirements specified in clauses 6(1) (c) and 6(1) (h) of the DIDFA Regulation. Alternatively, if the generic product is an aqueous solution described in subsection 6(5) of the DIDFA Regulation then the studies described in that provision can be submitted, instead of the in vivo studies described in clause 6(1) (h).