PART III-A.8. GENERIC LINE EXTENSION PRODUCT

12 (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 strength and dosage form.

3. Clinical evidence referred to in clause (1) (h) with respect to the original product described in paragraph 2.

Subsection 12(5.1) of the ODBA Regulation allows a generic drug product that is a line extension of the generic manufacturer’s own product line to be designated as single source (i.e. original product) and listed on the Formulary. The provision only applies to generic line extensions without a reference product in the same strength.

The manufacturer is required to:
- provide alternative evidence of product safety and efficacy (see details below); and
- provide scientific justification for the therapeutic need for the new strength in accordance with clause 12(1)(i) of the ODBA Regulation.

Line extension products submitted under subsection 12(5.1) require the review and recommendation of the ministry’s Committee to Evaluation Drugs (CED).
To satisfy the exemption in subsection 12(5.1) of the ODBA Regulation, the formulation of submitted product (i.e. the line extension) must be proportional to another product manufactured by the manufacturer (Generic A) and Generic A must be bioequivalent to Brand A. The following requirements must be satisfied:

1) Evidence of formulation proportionality of the submitted strength (i.e., the line extension) to the existing strengths. The approved Certified Product Information Document (CPID) of all strengths is required.

   **Note:** Where a CPID is not available, the ministry will accept the originally approved master formulation, dated and signed by a Senior Quality Assurance personnel.

The master formulation must provide:

   a. The list of ingredients used to formulate the drug;
   b. Information about the bulk formulation (granulation or liquid), if applicable;
   c. Information about coating ingredients, if applicable; and
   d. Information about the finished product expressed in the smallest quantity per unit (e.g., mg/tablet, mg/mL, etc.).

When the master manufacturing batch record is provided as evidence of product formulation, the manufacturer must convert the list of ingredients in the batch record into the smallest quantity per unit required in manufacturing a drug product.

A summary list of ingredients will not be accepted as a master formulation.

2) The manufacturer must submit evidence that Generic A is bioequivalent to a reference brand product of the same strength and dosage form (Brand A) – i.e., comparative bioequivalence study or Declaration of Equivalence from Health Canada.

3) The manufacturer must submit the clinical evidence referred to in clause 12 (1) (h) with respect to Brand A [i.e., clinical evidence of the original product’s safety, effectiveness, etc.].
If the manufacturer cannot satisfy all of the above submission requirements, a full clinical study described under clause 12(1) (h) of the ODBA Regulation is required for the line extension product.

The submission must comply with the all other necessary submission requirements set out in the ODBA Regulation.

**Interchangeability Designation**

If more than one generic line extension product in the same strength and dosage form satisfies the exemption in subsection 12(5.1) and has been approved for designation as a listed drug product under the ODBA, then the Executive Officer may designate the drug products as interchangeable with one another in accordance with section 6(7) of the DIDFA Regulation.

Subsection 6(7) states that a generic line extension product (with a NDS and single-source ODB submission) that is approved for listing on the Formulary does not need to comply with DIDFA interchangeability requirements under subsection (1) of section 6. Instead, subsection 6(7) allows the EO to designate two or more generic line extension products as interchangeable with one another.

6. (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.

Note: the DIDFA Regulation defines a “generic line extension drug product” as 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;

**Pricing for Generic Line Extension Product**

Because a generic line extension product makes a single source submission under the ODBA and not a submission under the DIDFA, the generic pricing rules set out in section 11 of the ODBA Regulation do not apply to NDS generic line extension products that are designated as interchangeable with one another in accordance with subsection 6 (7) of the DIDFA Regulation. Instead, the Executive Officer and the manufacturer will negotiate a Drug Benefit Price (DBP) for the product in accordance with section 22 of the ODBA.

**Generic Line Extensions Approved Based on ANDS**

Subsequent versions of the generic line extension product approved by Health Canada based on an Abbreviated New Drug Status (ANDS) must apply under DIDFA to be listed on the Formulary. These products must have a declaration of equivalence (DoE)
with one of the original NDS generic line extension products described above, or submit comparative studies in accordance with sections 6(1)(h) or 6(5) of the DIDFA Regulation demonstrating interchangeability with one of the original NDS generic products. These subsequent generic entrants are subject to the generic pricing rules and would be priced as a percentage of the DBP of the relevant original product in accordance with section 11 of the ODBA Regulation.