

Insert as a new section in Ontario Guidelines for Drug Submission and Evaluation PART III-A.9.

PART III-A.9. TRANSITIONING UNLISTED PRODUCTS FROM EXCEPTION ACCESS PROGRAM (EAP) TO THE FORMULARY

Effective October 1, 2016, Section 12 of the ODBA Regulation is amended to enable the transition of unlisted single source (brand) drugs without a manufacturer's submission that are funded through the Exceptional Access Program (EAP) to the Formulary.

Section 12 of the ODBA Regulation is amended to include the following subsection:

(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.

The new subsection 12 (2.1) of the ODBA Regulation exempts manufacturers of certain single source EAP products from specific submission requirements relating to clinical efficacy and cost effectiveness [i.e. clauses (c), (h) and (i) of subsection 12(1)]. The exemption only applies where the Executive Officer is satisfied that the product is clinically effective and has a low risk of inappropriate utilization based on its past funding under the EAP. The Executive Officer will also take into account the cost appropriateness of the drug product, in accordance with section 19 of the ODBA.

The Ministry may contact a manufacturer about having its single source product transitioned to the Formulary under this exemption. If the exemption is granted, the manufacturer will still be required to make an abbreviated administrative submission to

the Ministry that complies with clauses 12(1) (a), (b), (d), (e), and (f), and section 12.0.2 of the ODBA Regulation (see additional details below). The ministry may require other additional information in order to transition the product.

Submission requirements:

In order for a single source product described in subsection 12(2.1) to be transitioned from the EAP to the Formulary, the manufacturer of the product must make a submission to the Ministry that satisfies the following requirements*:

- Cover letter;
- Evidence that Health Canada has approved the product for sale in Canada, a copy of the product’s drug notification form issued by Health Canada, and a copy of the product monograph approved by Health Canada;
- A letter authorizing the Executive Officer to gain access to all information with respect to the product in the possession of Health Canada, the Patented Medicines Pricing Review Board established under section 91 of the *Patent Act* (Canada), the government of any province or territory in Canada or the Canadian Agency for Drugs and Technologies in Health and authorizing the Executive Officer to disclose any information with respect to the product in the possession of the Ministry to Health Canada, the Patented Medicine Prices Review Board, the government of a province or territory in Canada or the Canadian Agency for Drugs and Technologies in Health;
- Evidence of formulation proportionality (CPID) when multiple strengths are submitted;
- The proposed drug benefit price of the product;
- Evidence that the manufacturer is able to supply the product at the proposed drug benefit price in a quantity sufficient to meet the anticipated demand for the product;
- Certification in writing that no rebates have been provided in respect of the product since the product was approved for sale by Health Canada; and

- Certification confirming Product is not a private label product.

If the above submission requirements are met, then the manufacturer and the Executive Officer will negotiate a drug benefit price for the product, in accordance with section 22 of the ODBA.

As a condition of having its product listed on the Formulary, the manufacturer may be required by the Executive Officer to enter into a product listing agreement with the ministry, in accordance with subsection 12(7) of the ODBA Regulation.

***Note: the above list of submission requirements may not be exhaustive. In some cases, the ministry may require the manufacturer to satisfy additional requirements. These additional requirements will be communicated by the ministry to the manufacturer.**