Insert as a new section in Ontario Guidelines for Drug Submission and Evaluation PART III-B.6

PART III-B.6 TRANSITION OF GENERICS PRDUCTS FROM EXCEPTIONAL ACCESS PROGRAM (EAP) TO THE FORMULARY

As part of the Ministry's efforts to improve Ontarians' access to safe and effective drugs, the Ministry may approach manufacturers of generic products funded under EAP to have their products transitioned to the Formulary as General or Limited Use Benefits under the ODB Program.

The process for transitioning these generic EAP products to the Formulary will depend on the existence and Formulary transition of the brand reference product and whether the generic product is already listed as Off-Formulary Interchangeable (OFI). The table below describes the types of classifications of generic products under the EAP and the expectations for transitioning these products to the Formulary.

***Note:** The submission requirements described in the table below may not be exhaustive. The ministry may require other additional information in order to transition the product to the Formulary, and will communicate those requirements to the manufacturer.

Table 1: Transitioning process for Generic EAP Products

Classification of EAP Generic Product	**Transitioning Process**
Type 1 product A generic product funded under EAP that has been designated as OFI with a brand reference product. The brand reference product is available in Ontario and will be transitioned to the Formulary under section 12(2.1) of the ODBA Regulation.	Manufacturers of Type 1 products will be invited to have their products transitioned to the Formulary at the same time the brand reference product is transitioned to the Formulary. Type 1 products will need to comply with the generic pricing rules set out in section 11 of the ODBA Regulation in order to be listed on the Formulary. Please refer to PART III-B.1. h of the Guidelines for additional information on the pricing rules for generic drugs. In order to transition Type 1 products to the Formulary, an abbreviated administrative submission is required that contains the following: • Cover letter; • 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 confirming Product is not a private label product; • Certification that no rebates were provided to a person listed under subsection12.1(1) of the DIDFA since Health Canada approved the product for sale in Canada; and • Evidence of formulation proportionality (CPID) when multiple strengths are submitted.

Classification of EAP Generic Product	Transitioning Process
Type 2 product A generic product funded under EAP that has <u>not</u> been designated as OFI with a brand reference product. The brand reference product is available in Ontario and will be transitioned to the Formulary under section 12(2.1) of the ODBA Regulation.	Manufacturers of Type 2 products will be invited to make a submission under DIDFA to be listed on the Formulary at the same time the brand reference product is transitioned to the Formulary. Type 2 products will need to comply with the generic pricing rules set out in section 11 of the ODBA Regulation in order to be listed on the Formulary. Please refer to PART III-B.1. h of the Guidelines for additional information on DIDFA submission requirements and pricing rules for generic drugs. In order to transition Type 2 products to the Formulary, a full submission under DIDFA is required. Refer to Part III-B.1 & 2 of the Guidelines for submission requirements.

Classification of EAP Generic Product	Transitioning Process
Type 3 product Refers to a generic product funded under EAP that has been designated as OFI with a brand reference product. The brand reference product is not available in Ontario and/or will not be transitioned to the Formulary under section 12(2.1) of the ODBA Regulation.	Manufacturers of Type 3 products will only be invited to have their products transitioned to the Formulary if the Executive Officer is satisfied that it is in the public interest to do so. In making this public interest determination, the Executive Officer will consider whether the product is clinically effective and has a low-risk for inappropriate utilization based on its prior funding under the EAP. These products that are transitioned to the Formulary will not be subject to the generic pricing rules set out in section 11 of the ODBA Regulation, provided that the reference brand product has never been listed as a benefit on the Formulary. The drug benefit price of a Type 3 product would be negotiated by the Executive Officer and the manufacturer, pursuant to section 22 of the ODBA. If several Type 3 products are designated as interchangeable with one another on the Formulary, then the lowest drug benefit price negotiated between the Executive Officer and generic manufacturer would become the effective reimbursement price for the interchangeable category. In order to transition Type 3 products to the Formulary, an abbreviated administrative submission is required that contains the following: • Cover letter; • 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 confirming Product is not a private label product; • Certification that no rebates were provided to a person listed under subsection12.1 (1) of the DIDFA since Health Canada approved the product for sale in Canada; and • Evidence of formulation proportionality (CPID) when multiple strengths are submitted.

Classification of EAP Generic Product	Transitioning Process
Type 4 product A generic product funded under EAP that has not been designated as OFI with a brand reference product. The brand reference product is not available in Ontario and/or will not be transitioned to the Formulary under section 12(2.1) of the ODBA Regulation.	Manufacturers of Type 4 products will only be invited to make a submission under DIDFA for the purposes of being listed as a benefit on the Formulary if the Executive Officer is satisfied that the benefit designation is in the public interest. In making this public interest determination, the Executive Officer will consider whether the product is clinically effective and has a low-risk for inappropriate utilization based on its prior funding under the EAP. Since the brand reference product for Type 4 products is not available in Ontario and/or will not be transitioning to the Formulary, the brand reference product would be listed as "Not-a-Benefit" or "NAB" to facilitate any interchangeability designation with the these products. Type 4 products that are transitioned to the Formulary will not be subject to the generic pricing rules set out in section 11 of the ODBA Regulation, provided that the reference brand product has never been listed as a benefit on the Formulary. The drug benefit price would be negotiated by the Executive Officer and the manufacturer, pursuant to section 22 of the ODBA. If several Type 4 products are designated as interchangeable with one another on the Formulary, then the lowest drug benefit price negotiated between the Executive Officer and generic manufacturer would become the effective reimbursement price for the interchangeable category. In order to transition Type 4 products to the Formulary, a full submission under DIDFA is required. Refer to Part III-B.1 & 2 of the Guidelines for submission requirements.* *Note: where DIDFA submission requirements cannot be met (e.g. brand reference is no longer available and there is no generic product designated as equivalent by Health Canada), then the manufacturer may apply under the ODBA to have its generic product listed on the Formulary as the original reference product. Please refer to Part III-A.1 of the Guidelines for ODBA submission requirements. In this scenario, manufacturers are encouraged to contact the ministry on clarification of the submission requirements prior to making the submissions.