Ontario

Ministry of Health

OHIP, Pharmaceuticals and Devices Division

Ontario Guidelines for Transitioning Generic Drug Products from the Exceptional Access Program (EAP) to the Ontario Drug Benefit Formulary/ Comparative Drug Index

Submission Requirements and Review Process

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Introduction

The Ontario Public Drug Programs (OPDP) provides funding for a number of publicly funded drug programs. The largest program is the Ontario Drug Benefit (ODB) program and eligible benefits are listed on the ODB Formulary/Comparative Drug Index (the "Formulary"). Additional coverage may be provided through case by case review under the Exceptional Access Program (EAP).

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).

Objective

The objective of this document (the "Guidelines") is to provide guidance on submission requirements and the ministry's review process for transitioning generic drug products from EAP to the Formulary. The Guidelines are to be used in the preparation of a drug product submission provided to the Ministry of Health (ministry). Some sections of the Guidelines are general in nature and must be read in conjunction with applicable legislation. The manufacturers, or those filing submissions on their behalf, are responsible for ensuring that all drug product submissions filed with the ministry contain sufficient information to satisfy the applicable requirements of the legislation and the Guidelines.

1. Submission Requirements for Transitioning Generics Drug Products from EAP to the Formulary

The information below refers to the types of classifications of generic products under the EAP and the requirements for transitioning these products to the Formulary.

1.1 Type 1 Product

A Type 1 product is a generic drug 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 Ontario Regulation 201/96 (the "ODBA Regulation") under the *Ontario Drug Benefit Act* (ODBA).

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. These 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.

Manufacturers are required to comply with the following requirements:

1.1.1 A cover letter and table of contents must accompany the submission. The cover letter must clearly state:

- The name of the drug product, the DIN of the product, its active pharmaceutical ingredient(s), strength(s), and dosage form(s) (including the various package sizes).
- The type of Formulary listing proposed for the drug product (e.g. General Benefit, Limited Use).
- Whether the manufacturer has any business agreements with any third party (e.g. consultant, cross-licensed, co-marketing, etc.) with respect to the product, and, if so, the name of the third party / third parties. See additional information in section 6.1 of these Guidelines.

1.1.2 Proposed Drug Benefit Price

Submit a proposed drug benefit price (DBP) for the multiple source drug product. The proposed DBP (to four decimal places) should include, where applicable:

- The price per smallest unit (e.g. tablet, capsule, gram, millilitre, etc.); and
- The price per smallest dispensable unit for each package size (e.g., bottle, kit, ampoule, pre-filled syringe, vial combination package, etc.).

If the price of the smallest unit is accepted by the ministry and listed on the Formulary, it will apply to all package sizes of the product.

1.1.3 Evidence Confirming Ability to Supply

Confirmation that the manufacturer is able to supply the drug product at the proposed drug benefit price in a quantity sufficient to meet the anticipated demand for the drug product.

See Template Letter of Ability to Supply in section 5 below.

1.1.4 Certification Confirming That No Rebates Were Provided

The manufacturer must certify in writing that no rebates were provided to persons listed under subsection 11.5(1) of the ODBA with respect to the drug product from the time that Health Canada approved the drug product for sale in Canada.

See Template Letter Certification of Providing No Rebate in section 5 below.

1.2 Type 2 Product

A Type 2 product is a generic product funded under EAP that has not 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 provide a complete submission in accordance with the applicable conditions set out in the regulations under the ODBA and the 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. See the Ontario Guidelines for Generic Drug Products posted on the ministry's website regarding the submission requirements and the ministry's review process.

1.3 Type 3 Product

A Type 3 product is 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 (EO) is satisfied that it is in the public interest to do so. In making this public interest determination, the EO 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 EO 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 EO and generic manufacturer would become the effective reimbursement price for the interchangeable category.

Manufacturers are required to comply with the following requirements:

1.3.1 A cover letter and table of contents must accompany the submission. The cover letter must clearly state:

- The name of the drug product, the DIN of the product, its active pharmaceutical ingredient(s), strength(s), and dosage form(s) (including the various package sizes).
- The type of Formulary listing proposed for the drug product (e.g. General Benefit, Limited Use)

- Whether the manufacturer has any business agreements with any third party (e.g. consultant, cross-licensed, co-marketing, etc.) with respect to the product, and, if so, the name of the third party / third parties. See additional information in section 6.1 of these Guidelines.

1.3.2 Proposed Drug Benefit Price

Submit a proposed drug benefit price (DBP) for the drug product. The proposed DBP (to four decimal places) should include, where applicable:

- The price per smallest unit (e.g. tablet, capsule, gram, millilitre, etc.); and
- The price per smallest dispensable unit for each package size (e.g. bottle, kit, ampoule, pre-filled syringe, vial combination package, etc.).

If the price of the smallest unit is accepted by the ministry and listed on the Formulary, it will apply to all package sizes of the product.

1.3.3 Evidence Confirming Ability to Supply

Confirmation that that the manufacturer is able to supply the drug product at the proposed drug benefit price in a quantity sufficient to meet the anticipated demand for the drug product.

See Template Letter of Ability to Supply in section 5 below.

1.3.4 Certification Confirming That No Rebates Were Provided

The manufacturer must certify in writing that no rebates were provided to persons listed under subsection 11.5(1) of the ODBA with respect to the drug product from the time that Health Canada approved the drug product for sale in Canada.

See Template Letter Certification of Providing No Rebate in section 5 below.

1.4 Type 4 Product

A Type 4 product is 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 EO is satisfied that the benefit designation is in the public interest.

In making this public interest determination, the EO 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 EO 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 EO and generic manufacturer would become the effective reimbursement price for the interchangeable category.

Manufacturers of Type 4 products will be invited to provide a complete submission in accordance with the applicable conditions set out in the regulations under the ODBA and the DIDFA.

See the Ontario Guidelines for Generic Drug Products posted on the ministry's website regarding the submission requirements and the ministry's review process.

*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), the manufacturer may apply under the ODBA to have its generic product listed on the Formulary as the original reference product.

2. Drug Submission Review Process

2.1 Filing of Drug Submissions

Manufacturers of Type 1, 2, 3 or 4 Products will be invited to file a submission with the ministry for funding consideration under the OPDP.

2.2 Written/Verbal Communication

All written and verbal communication between the ministry and a manufacturer must take place through a single primary contact from the manufacturer. The ministry requires written notification in order to change a manufacturer's primary contact, or any other information related to contact information (e.g. address, telephone number, e-mail address etc.). It is the manufacturer's responsibility to keep this information current and accurate.

2.3 Submission Receipt and Review for Formulary Products

Generic drug product submissions are screened for compliance with applicable requirements in the legislation and these Guidelines by ministry staff in sequence, according to the date and time of receipt.

In order for a generic drug product to be considered for inclusion in a future monthly Formulary update by the EO, the submission must be received by the new submission deadline (date and time). The new submission deadline dates for generic drug products are available on the ministry's website. There are no exceptions for late submissions.

Only complete submissions (i.e. those that meet all applicable requirements are eligible for review and consideration for funding under OPDP.

If a submission is incomplete, the manufacturer's provision of additional information to complete the submission is subject to the subsequent monthly submission deadlines for the corresponding monthly Formulary updates. The complete submission date refers to the date when the Notice of Drug Submission Status (NDSS) letter is sent out.

The ministry endeavours to process streamlined generic drug submissions (for designation as listed drug products under the ODBA) one week after the monthly new submission deadline cut-off date.

2.4 Ministry Communication

Once a submission is screened by the ministry, a NDSS is issued to the manufacturer. Each submission is assigned a unique master file number, and each individual drug product within the same submission is assigned a unique drug product file number. The NDSS will indicate the status of the submission (i.e. complete or incomplete) as well as the assigned file numbers. The NDSS for an incomplete submission will state the reasons why the submission was deemed incomplete.

The ministry reserves the right to request additional information needed to address any uncertainties associated with a submission or to resolve questions that may arise during the review. The ministry and the Committee to Evaluate Drugs (CED) may request additional information from manufacturers at any time during the screening and/or review process.

2.5 Manufacturer's Response

A manufacturer should make reference to the drug product (product name/generic name/strength/dosage form/package format and size), the master file number and the drug product file number(s) in all subsequent correspondence to the ministry. If a manufacturer receives a NDSS, which indicates that the submission was deemed incomplete, the manufacturer will be provided with 60 calendar days in which to provide the information required to complete the submission.

Manufacturers are encouraged to respond to requests for additional information in a timely manner to avoid delays in the submission review process.

2.6 Review by Advisory Committee

Certain submissions undergo review by the ministry's expert advisory committee, the CED (e.g. Type 2 or 4 Products without a declaration of equivalence with a brand reference product). The complete submission is sent to a committee member who reviews the submission and prepares a written report. Submissions are reviewed by committee members and/or by other reviewers retained by the ministry who are drawn from an extensive roster of external clinical and pharmacoeconomic consultants. The targeted time frame for the completion of reviews is four to six weeks. The CED or the ministry may require additional time to review complex submissions. Occasionally, a panel or subcommittee of the larger committee may be requested to review a specific submission, which will extend the timeline for the review.

The committee discusses each submission, with input from reviewers, other expert external consultants, and the ministry as required.

2.7 Communication to Manufacturers

An external expert advisory committee recommendation letter is issued to a manufacturer after the committee's review of certain submissions (e.g. Type 2 or 4 Products without declaration of equivalence with a brand reference product) The recommendation letter is sent to the manufacturer generally within four to five weeks after the ratification of the committee's minutes. The recommendation letter will summarize the committee's recommendation and reason(s) for its recommendation.

3. Format and Organization of Submissions

The OHIP, Pharmaceuticals and Devices Division accepts e-mail submissions. The submissions must be well organized and indexed/tabbed with description. Manufacturers must not provide submission information in one continuous document. If the submission is too large to be sent by a single e-mail, the ministry will accept the whole submission via multiple e-mails. If the manufacturer is sending multiple e-mails for one submission, clearly identify that the e-mails belong to the same submission and how many total e-mails pertain to that particular submission.

The ministry expects manufacturers to follow the Guidelines when preparing submissions. The onus is on a manufacturer to provide the ministry with a submission that is complete, accurate and complies with applicable legislative, and policy requirements.

The ministry will not assume responsibility for advising manufacturers of the completeness of their submissions prior to the ministry screening and review. Also, the ministry reserves the right to request additional information at any time during the review process.

4. Filing of Drug Submissions

All submissions and any additional related information must be sent to:
Senior Manager
Drug Benefits Management Unit
Drug Programs Policy and Strategy Branch
OHIP, Pharmaceuticals and Devices Division
Ministry of Health

Please send the submissions to email mailbox DrugSubmissions.MOH@ontario.ca

5. Templates and Checklists

Templates:

- Template Letter Confirming Ability to Supply
- Template Letter Certification of Providing No Rebate

The ministry's template letters and checklists are available on the ministry's website. All template letters must be prepared using the appropriate manufacturer's letterhead, dated and signed by the senior company official.

6. Additional Information

6.1 Third Party Involvement

Where a third party is involved with a submission, a letter must be submitted from each of the NOC/DIN holder and the third party confirming the business arrangement between the submitting party and the NOC/DIN holder, and the submitting party's authority to file and discuss the submission with the ministry, on behalf of the NOC/DIN holder.

6.2 Withdrawal Process

The submitting manufacturer may voluntarily withdraw a submission any time throughout the review process. A written request must be provided by the manufacturer to the ministry with an explanation to withdraw a submission.

List of Abbreviations

CED	Committee to Evaluate Drugs
DBP	Drug Benefit Price
DIN	Drug Identification Number
DIDFA	Drug Interchangeability and Dispensing Fee Act
EAP	Exceptional Access Program
EO	Executive Officer
NAB	Not-A-Benefit
NDSS	Notice of Drug Submission Status
NOC	Notice of Compliance
ODB	Ontario Drug Benefit
ODBA	Ontario Drug Benefit Act
OFI	Off-Formulary Interchangeable
OPDP	Ontario Public Drug Programs

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