Ontario

Ministry of Health

Health Programs and Delivery Division

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

Submission Requirements and Review Process

Table of Contents

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).

For single source drug products to be considered for funding under the Ontario Public Drug Programs, a drug manufacturer must provide a complete submission in accordance with the applicable conditions set out in Ontario Regulation 201/96 (the "ODBA Regulation") made under the *Ontario Drug Benefit Act* (ODBA) and applicable guidelines.

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. Only products considered under the EAP on or before December 31, 2008 are eligible. The exemption only applies where the Executive Officer (EO) is satisfied that the product is clinically effective and has a low risk of inappropriate utilization based on its past funding under the EAP (see subsection 12(2.1) excerpted below for the specific eligibility criteria). The EO 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.

Subsection 12(2.1), O. Reg. 201/96

(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.

Objective

The objective of this document (the “Guidelines”) is to provide guidance on submission requirements and the ministry’s review process for transitioning unlisted single source 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. Checklist for Preparing Submissions

The manufacturer may use the below checklist to help ensure that all submission requirements have been included.

Requirement:	Included
Signed cover letter	☐
Table of contents	☐
Health Canada Documentation: Notice of Compliance; AND Product Monograph	 ☐ ☐
Letter of Consent	☐
Proposed Drug Benefit Price	☐
Ability to Supply Letter	☐
Certification of Providing No Rebates Letter	☐

2. Submission Requirements for Transitioning Unlisted Drug Products from EAP to the Formulary

2.1 Cover Letter and Table of Contents

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 listing requested (e.g. General Benefit or 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 drug product, and, if so, the name of the third party / third parties. See additional information in section 7.1 of these Guidelines.

2.2 Evidence of approval from Health Canada, including:

- A copy of the Notice of Compliance (NOC), if applicable; and
- A copy of the most recent Product Monograph approved by Health Canada.

2.3 Letter of Consent

A letter from the holder of the Health Canada approval authorizing the Executive Officer to gain access to all information with respect to the Drug Product in the possession of Health Canada, the Patented Medicines Pricing Review Board, 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 Drug 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.

See Template Letter of Consent in section 6 below.

2.4 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.

2.5 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 6 below.

2.6 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 *Ontario Drug Benefit Act* (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 6 below.

3. Drug Submission Review Process

3.1 Filing of Drug Submissions

The ministry may contact a manufacturer about having its single source product transitioned to the Formulary under this exemption. A manufacturer that wishes to have a drug product considered for funding under OPDP should contact the ministry to file a submission.

3.2 Written/Verbal Communication

All written and verbal communication between the ministry and a manufacturer takes 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.

3.3 Submission Receipt and Review

The 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.

The targeted time frame for screening is approximately three weeks from the date the submission is received by the ministry.

Only complete submissions (i.e. those that meet all applicable requirements) are eligible for review and consideration for funding under OPDP. Manufacturers must ensure a submission has been deemed complete before finalizing any product listing agreement for the drug product. The complete submission date refers to the date the Notice of Drug Submission Status (NDSS) letter is sent.

3.4 Ministry Communication

Once a submission is screened by the ministry, an 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 may request additional information from manufacturers at any time during the screening and/or review process.

3.5 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 an 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.

4. Format and Organization of Submissions

The Health Programs and Delivery 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 legislativeand 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.

5. 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
Health Programs and Delivery Division
Ministry of Health

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

6. Templates and Checklists

Templates:

- Template Letter of Consent
- 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 a senior company official.

7. Additional Information

7.1 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.

7.2 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

DBP	Drug Benefit Price
DDD	Drugs and Devices Division
DIN	Drug Identification Number
EAP	Exceptional Access Program
EO	Executive Officer
NDSS	Notice of Drug Submission Status
NOC	Notice of Compliance
ODB	Ontario Drug Benefit
ODBA	Ontario Drug Benefit Act
OPDP	Ontario Public Drug Programs

This page intentionally left blank