

Ministry of Health

Health Programs and Delivery Division

Ontario Guidelines for Valved Holding Chambers

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 it funds eligible benefits (known as listed drug products and listed substances) designated on the ODB Formulary/Comparative Drug Index (the “Formulary”). Additional coverage may be provided for drug products through case by case review under the Exceptional Access Program (the “EAP”).

The *Ontario Drug Benefit Act* (the “ODBA”) defines “listed substance” to mean a substance, other than a drug, designated as a listed substance in the Formulary by the Executive Officer of the Ontario public drug programs (the “Executive Officer”). Valved Holding Chambers (VHCs) are listed substances reimbursed for ODB-eligible persons in certain circumstances.

A submission for a VHC undergoes a similar review process as a drug product, although the manufacturer must satisfy a different set of requirements to be considered for designation as a listed substance on the Formulary.

If a VHC product is listed on the Formulary, the VHC product would be eligible for reimbursement when it is prescribed for ODB-eligible recipients aged 12 years and under. A quantity restriction of one VHC per eligible recipient per year applies to these claims.

Objective

The objective of this document (the “Guidelines”) is to provide guidance on submission requirements and the ministry’s review process. The Guidelines are to be used in the preparation of a VHC submission provided to the Ministry of Health (ministry). The manufacturers, or those filing submissions on their behalf, are responsible for ensuring that all VHCs submissions filed with the ministry contain sufficient information to satisfy the applicable requirements of the legislation and the Guidelines.

1. Checklists 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	<input type="checkbox"/>
Table of contents	<input type="checkbox"/>
Health Canada Documentation:	
Medical Device Licence; AND	<input type="checkbox"/>
Medical Device Establishment Licence	<input type="checkbox"/>
Letter of Consent	<input type="checkbox"/>
Proposed price	<input type="checkbox"/>
Ability to Supply Letter	<input type="checkbox"/>
Certification of Providing No Rebates Letter	<input type="checkbox"/>
Confirmation letter that the submitted product does not pose a choking hazard to children ≤ 12 years of age (i.e. no choking parts with disassembly) and it is suitable for use with all metered dose inhalers (MDIs)	<input type="checkbox"/>
A copy of the device label	<input type="checkbox"/>
Evidence of safety and effectiveness	<input type="checkbox"/>
ODB Financial Impact Information	<input type="checkbox"/>

2. Submission Requirements for Valved Holding Chambers

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 VHC, including the various package sizes.
- Whether the manufacturer has any business agreements with any third party (e.g. consultant, cross-licensed, co-marketing, etc.) with respect to the VHC, 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

- A copy of the Medical Device Licence for the VHC; and
- A copy of the Medical Device Establishment Licence of the manufacturer or distributor of the VHC (as applicable), for the sale or importation of the product in Canada.

2.3 Letter of Consent

A letter authorizing the Executive Officer to gain access to all information with respect to the VHC in the possession of Health 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 VHC in the possession of the ministry to Health Canada, 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 Price

Submit the following two prices:

- Manufacturer list price (price without mark-up): the lowest price per package size and per VHC to four decimal places sold to wholesalers or pharmacies (if direct distribution to pharmacies).

In cases where the cost per VHC is different from the cost per pack divided by the number of VHCs in each package, the lowest price will be used for any designation on the Formulary. If the price is accepted by the ministry and listed on the Formulary, it will apply to all pack sizes of the product.

2.5 Evidence Confirming Ability to Supply

Confirmation that the manufacturer is able to supply the VHC at the proposed list price in a quantity sufficient to meet the anticipated demand for the 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 in subsection 11.5(1) of the *Ontario Drug Benefit Act* (ODBA) with respect to the VHC from the time that Health Canada approved the product for sale in Canada.

See Template Letter Certification of Providing No Rebate in section 6 below.

2.7 Confirmation letter

Confirmation letter that the submitted VHC does not pose a choking hazard to children ≤12 years of age (i.e. no choking parts with disassembly) and it is suitable for use with all metered dose inhalers (MDIs).

2.8 A copy of the device label

2.9 Evidence of safety and effectiveness of the submitted product

- A copy of the completed, dated, and signed New Class II Medical Device Licence Application Form approved by Health Canada.
- A summary of objective evidence to establish that the submitted product is compliant with the safety and effectiveness requirements in accordance with section 10, subsections 11(1) and 12(1) and sections 13 to 20 of the Medical Devices Regulations under the *Food and Drugs Act* (Canada).

2.10 ODB Financial Impact Information

ODB market share penetration or impact analysis on ODB expenditure, including the underlying assumptions for the calculations.

3. Submission Review Process

3.1 Filing of Submissions

A manufacturer that wishes to have a VHC considered for designation as a listed substance on the Formulary must file a submission with the ministry.

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

VHC 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 products that are the subject of complete submissions (i.e. those that meet all applicable requirements) are eligible for review and consideration for designation as listed substances on the Formulary. The date that the ministry deems a submission complete, as well as the type of review (i.e. first review or reconsideration), determines the subsequent priority of the review of the product. The complete submission date refers to the date when 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 VHC within the same submission is assigned a unique VHC 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.

3.5 Manufacturer's Response

A manufacturer must make reference to the VHC (product name) the master file number and the VHC 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.

3.6 Review by the Advisory Committee

Complete submissions undergo review by the ministry's expert advisory committee, the Committee to Evaluate Drugs (CED). The complete submission is sent to a reviewer who reviews the submission and prepares a written report. Submissions are reviewed by the committee members and/or by other reviewers 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 and the ministry may require additional time to review complex submissions. Occasionally, a panel or subcommittee of the committee may be requested to review a specific submission, which will extend the timeline for the review.

The CED discusses each submission, with input from reviewers, other expert external consultants, and the ministry as required. The VHCs are evaluated for the comparative therapeutic efficacy and safety for ODB program recipients, cost-effectiveness in comparison to currently funded alternatives, patient value or input, and impact on other health services. This comprehensive evaluation contributes to the determination of value-for-money for OPDP.

3.7 Communication to Manufacturers

An external advisory committee recommendation letter is issued to a manufacturer after the committee's review. 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.

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 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.

5. Filing of 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 Medical Device Licence holder and the third party confirming the business arrangement between the submitting party and the Medical Device Licence holder, and the submitting party's authority to file and discuss the submission with the ministry, on behalf of the Medical Device Licence holder.

7.2 Notification of Change

The ministry must be notified of changes to the licence, ownership of the product, including any change in the medical conditions, purposes or uses for which the device is manufactured, sold or represented where the changes may affect the quality or performance of the product. The manufacturer must provide evidence to support the change, including where applicable, evidence of Health Canada's approval.

7.3 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
EAP	Exceptional Access Program
MDI	Metered Dose Inhaler
NDSS	Notification of Drug Submission Status
ODB	Ontario Drug Benefit
ODBA	Ontario Drug Benefit Act
OPDP	Ontario Public Drug Programs
VHC	Valved Holding Chamber

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