

PATENTED DRUGS SUBMISSION CHECKLIST

When drug manufacturers submit documents and information to the Common Drug Review (CDR) for review, they must:

- include Ministry-specific documents in the submission to the Ministry of Health;
- follow and meet the required documents in the [CDR Drug Submission Guidelines](#);
- send the complete drug submission package of CDR documents to the Ministry of Health at the same time they submit their drug submission package to the CDR; and
- submit **one copy** of the complete submission requirements on a USB flash drive to the Ministry of Health;

Note: The USB flash drive should be unlocked and fully executable. Hard/paper copies of drug submissions are no longer accepted.

Below is a detailed checklist of documents required by the Ministry of Health and the CDR. Read and follow the checklist to ensure the submission package is complete.

Send the USB flash drive with the complete submission package to our courier address:

Director, Formulary Management
Pharmaceutical Services Division
BC Ministry of Health
1515 Blanshard Street
Victoria BC V8W 3C8

Regular correspondence can be sent to:

Director, Formulary Management
Pharmaceutical Services Division
BC Ministry of Health
PO BOX 9652 STN PROV GOVT
Victoria BC V8W 9P4

Note for all checklists:

- All letters submitted specifically to the Ministry of Health, unless otherwise stated in the checklist, must be prepared on company letterhead, signed by an appropriate senior official, and submitted as an electronic copy (documents may be signed using an e-signature. When printing hard copies to sign and scan, use blue ink)
- Some documents must be submitted in multiple electronic formats (e.g., *Submit as PDF and Excel*)
- Documents required by the CDR (e.g., letters) should be addressed to the CDR

- Documents required by the Ministry of Health (e.g., letters) should be addressed to the Director of Formulary Management at the Ministry of Health
- Only complete drug submission packages that follow the checklist criteria and include all checklist documents will be reviewed
- If BC-specific Category 1 documents are not ready at the time CDR Category 1 documents are submitted, then the BC specific Category 1 documents can be sent later when the BC-specific and CDR Category 2 documents are submitted
- The checklist of required Category 1 documents specific to the CDR should not be used to replace the CDR [Drug Submission Guidelines \(PDF 1,194MB\)](#), which is more detailed.
- Drug submission sponsors are not required to send any Category 1 documents that are specific to the Ministry of Health to the CDR.
- If you have any questions about specific drug submissions, or the drug submission process, send an email to the Ministry of Health Formulary Management team at: DrugReviewProcess@gov.bc.ca

Checklist of required Category 1 documents specific to the Ministry of Health

BC Ministry of Health Documentation
<p><input type="checkbox"/> Cover letter *Signature Required*</p> <p>The cover letter should identify</p> <ul style="list-style-type: none"> • the type of drug submission to be reviewed; • each indication, strength and the Drug Identification Number (DIN) to be reviewed; • the name of each vendor/associate company working on the submission; and • contact information for the primary and backup person who can be contacted regarding the submission under review.
<p><input type="checkbox"/> Letter confirming written notification of any future changes will be provided *Signature Required*</p>
<p><input type="checkbox"/> Letter confirming the availability of the drug pre-Notice of Compliance (NOC) *Signature Required*</p>
<p><input type="checkbox"/> Letter confirming ability to supply for anticipated demand *Signature Required*</p>
<p><input type="checkbox"/> Letter confirming that Periodic Safety Update Reports submitted to Health Canada will also be submitted to the Ministry of Health *Signature Required*</p>

<input type="checkbox"/> Letter declaring all known unpublished studies have been disclosed *Signature Required*
<input type="checkbox"/> Table of all known ongoing trials for indications different than the indication being submitted for review Access applicable information and templates from: <ul style="list-style-type: none"> • www.clinicaltrials.gov • https://eudract.ema.europa.eu/
<input type="checkbox"/> All Pharmaceutical Advertising Advisory Board (PAAB)-approved promotional materials or draft copies of materials submitted to PAAB

Checklist of required Category 1 documents specific to the CDR

CDR Documentation
<input type="checkbox"/> Completed New CDR application overview template The CDR consolidated template replaces the need for the following: <ul style="list-style-type: none"> • Letter confirming disclosure of all known unpublished studies The letter authorizes the Ministry of Health to share information about the drug product under review with <ul style="list-style-type: none"> • Health Canada; • other provinces and territories; • Canadian Agency for Drugs and Technologies in Health/Common Drug Review (CADTH/CDR); • Patented Medicine Prices Review Board (PMPRB); • health authorities including regional health authorities; and • contracted third party reviewers who are subject to a signed confidentiality agreement.
<input type="checkbox"/> Cover letter *Signature Required*
<input type="checkbox"/> Executive summary
<input type="checkbox"/> Product monograph

Health Canada Documentation

NOC or Notice of Compliance with conditions (NOC/c)

Table of Clarifaxes

Efficacy, Effectiveness, and Safety Documentation (Including Supplementary Appendixes)

Common Technical Document sections 2.5, 2.7.1, 2.7.3, 2.7.4, 5.2, or statement indicating any section(s) not required for the Health Canada submission

Reference list of clinical studies and errata

Clinical studies

Table of studies

Reference list of editorial articles (or statement that no editorials)

Copies of editorial articles

Reference list and copies of new data

Reference list of articles for validity of outcome measures

Copies of articles for validity of outcome measures

Economic and Epidemiologic Documentation

Pharmacoeconomic evaluation for the full population identified in the approved Health Canada indication(s) to be reviewed by CDR

Economic model used in the initial submission

- Number of patients accessing a new drug to within 20 business days of the submission being filed**

- Disease prevalence and incidence data, with specified population breakdown (if available)**

Pricing and Distribution Documentation

- Summary list and/or table on the unit price for all dosage forms, strengths and package sizes, to four decimal places**

- Method of distribution**

Sharing of Information

- Letter authorizing unrestricted sharing of information *Signature Required***

Pre-NOC Letters

- Letter for sending the NOC or NOC/c to CADTH *Signature Required***

- Letter for finalized Category 1 requirements if submission filed on a pre-NOC basis *Signature Required***

Checklist of required Category 2 documents specific to the Ministry of Health

BC Ministry of Health Documentation
<p><input type="checkbox"/> Drug Product Request Form for Patented Drug Products *Applies to Common Drug Review (CDR) Submissions Only*</p> <p>Access and complete the Ministry of Health Drug Product Request Form for CDR Submissions (DOCX) as a Word document. In the template, include the following:</p> <ul style="list-style-type: none">• Each indication, strength and the Drug Identification Number (DIN) to be reviewed.• The name of the drug manufacturer and each vendor/associate company working on the submission.• Contact information for the primary and backup person who can be contacted regarding the submission.• A high-level executive summary describing the submission.
<p><input type="checkbox"/> Budget Impact Analysis (BIA) for B.C. *Submit as PDF and Excel*</p> <p>The BIA for BC must be consistent with the standards published by the PMPRB (PDF).</p>
<p><input type="checkbox"/> BIAs for Other Drug Plans *Submit as PDF and Excel*</p> <p>The BIA's for other drug plans in Canada must be consistent with the standards published by the PMPRB (PDF).</p>
<p><input type="checkbox"/> Summary list of the drug submission product's associated patents and the patent expiry dates as documented on the Health Canada Patent Register</p>

Checklist for required Category 2 documents specific to the CDR

Budget Impact Analysis and Supporting Documentation
<p><input type="checkbox"/> Budget Impact Analysis (BIA) *Submit as PDF and Excel*</p> <ul style="list-style-type: none">• Include BIAs in accordance with the individual requirements of British Columbia (BC), Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, and the Non-Insured Health Benefits Program.<ul style="list-style-type: none">○ When data specific to Prince Edward Island are unavailable, the BIA for Prince Edward Island is to be based on Nova Scotia data.• The base unit price used in the BIAs must be the same as the price submitted in the Category 1 requirements and must be clearly identified in each BIA. Jurisdiction-specific markups or discounts can then be applied, if applicable.

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| <input type="checkbox"/> Copies of all supporting documentation used and/or cited in the BIAs |
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Additional Information (must be requested)
<input type="checkbox"/> Harms and Safety information
<input type="checkbox"/> Periodic Safety Update Reports as submitted to Health Canada
<input type="checkbox"/> Clinical Study Reports

Important: The Ministry of Health reserves the right to ask for additional information as required. The drug submission sponsor must submit any required electronic documentation in accordance with copyright permissions.