

# DRUG SUBMISSION REQUIREMENTS CHECKLIST FOR PATENTED DRUG PRODUCTS AND SUBSEQUENT ENTRY BIOLOGICS (SEBs) TO THE BC MINISTRY OF HEALTH

## CATEGORY 1 DOCUMENTS AND INFORMATION REQUIRED FOR PATENTED DRUG PRODUCTS REVIEWED BY THE CANADIAN AGENCY FOR DRUG AND TECHNOLOGIES IN HEALTH (CADTH) COMMON DRUG REVIEW (CDR) AND BY THE BC MINISTRY OF HEALTH

- For **Subsequent Entry Biologics (SEBs)** documents and information please refer to the CDR [Procedure and Submission Guidelines for SEBs](#) (PDF 690KB).
- The BC Ministry of Health has specific SEBs document requirements which are the same as those listed in the document checklist of Ministry-specific Category 1 patented drug products.
  - Note: Not all documents and information listed in the checklists below will be available for SEBs drug submissions. For clarity, drug submission sponsors are asked to prepare a letter printed on company letterhead which is signed by an appropriate senior official, and submitted to the Ministry of Health as a hard and electronic copy, that refers to the specific SEBs documents that may be listed below and that will not be included in the complete drug submission package.
- Send the complete drug submission package of SEBs documents to the Ministry of Health at the same time as the package is submitted to the CDR.

**Category 1** documents and information are required by the CDR review team, the Canadian Drug Expert Committee (CDEC), and the BC Ministry of Health for drug submission review and recommendation processes.

When submitting Category 1 documents and information for (1) **New Drugs**, (2) **Drugs with New Indications**, or (3) **New Combination Products to the CDR for Review**, drug submission sponsors must:

- Follow and meet the required Category 1 documents in the CDR [Drug Submission Guidelines](#) (PDF 1,194MB)
- Submit **one hard copy and one electronic copy** (e.g., CD, DVD, USB flash drive that is unlocked and fully executable) of their complete submission to the Ministry of Health
- Read and follow the checklist of required documents below to ensure the submission package is complete
- Send the complete drug submission package of CDR Category 1 documents to the Ministry of Health at the same time as they submit their drug submission package to the CDR
- Include Ministry-specific Category 1 documents in the submission to the Ministry of Health
- Send the complete drug submission package of CDR and Ministry-specific Category 1 documents to the courier address below:

Couriered Packages to:

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

Regular Correspondence to:

Director, Formulary Management  
Medical Beneficiary and Pharmaceutical Services Division  
BC Ministry of Health

Below are simplified checklists of Category 1 documents required by the CDR and the Ministry of Health.

Note:

- Unless otherwise stated in the checklists (i.e., N/A), all documents must be printed on company letterhead, signed by an appropriate senior official, and submitted to the Ministry of Health as hard and electronic copies
- 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 that include all checklist documents will be reviewed
- 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 go into greater detail
- Drug submission sponsors are not required to send the CDR any Category 1 documents that are specific to the Ministry of Health.

Checklist for required Category 1 documents specific to the CDR	Criteria for submission documents		
	Signature Required	Hard Copy	Electronic Copy
<b>General Documentation</b>			
Completed CDR application overview template	N/A	<input type="checkbox"/>	<input type="checkbox"/>
Cover letter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Executive summary	N/A	<input type="checkbox"/>	<input type="checkbox"/>
Product monograph	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Health Canada Documentation</b>	Signature Required	Hard Copy	Electronic Copy
NOC or Notice of Compliance with conditions (NOC/c)	N/A	<input type="checkbox"/>	<input type="checkbox"/>
Health Canada clinical reviewers' report	N/A	<input type="checkbox"/>	<input type="checkbox"/>
Table of Clarifaxes	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Efficacy, Effectiveness, and Safety Documentation (Including supplementary appendices)</b>	Signature Required	Hard Copy	Electronic Copy
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	N/A	<input type="checkbox"/>	<input type="checkbox"/>
Reference list of clinical studies and errata	N/A	<input type="checkbox"/>	<input type="checkbox"/>
Clinical studies	N/A	N/A	<input type="checkbox"/>
Table of studies	N/A	<input type="checkbox"/>	<input type="checkbox"/>
Reference list of editorial articles (or statement that no editorials)	N/A	<input type="checkbox"/>	<input type="checkbox"/>
Copies of editorial articles	N/A	N/A	<input type="checkbox"/>
Literature search strategies	N/A	N/A	<input type="checkbox"/>
Letter declaring that all known unpublished studies have been disclosed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CONSORT diagrams	N/A	<input type="checkbox"/>	<input type="checkbox"/>
Reference list and copies of new data	N/A	<input type="checkbox"/>	<input type="checkbox"/>
Reference list of articles for validity of outcome measures	N/A	<input type="checkbox"/>	<input type="checkbox"/>
Copies of articles for validity of outcome measures	N/A	N/A	<input type="checkbox"/>
<b>Economic and Epidemiologic Documentation</b>	Signature Required	Hard Copy	Electronic Copy

Pharmacoeconomic evaluation for the full population identified in the approved Health Canada indication(s) to be reviewed by CDR	N/A	<input type="checkbox"/>	<input type="checkbox"/>
Economic model used in the initial submission	N/A	<input type="checkbox"/>	<input type="checkbox"/>
Number of patients accessing a new drug to within 20 business days of the submission being filed	N/A	<input type="checkbox"/>	<input type="checkbox"/>
Disease prevalence and incidence data, with specified population breakdown (if available)	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Pricing and Distribution Documentation</b>	<b>Signature Required</b>	<b>Hard Copy</b>	<b>Electronic Copy</b>
Summary list and/or table on the unit price for all dosage forms, strengths and package sizes, to four decimal places	N/A	<input type="checkbox"/>	<input type="checkbox"/>
Method of distribution	N/A	<input type="checkbox"/>	<input type="checkbox"/>
Commitment to honour the submitted price	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Sharing of Information</b>	<b>Signature Required</b>	<b>Hard Copy</b>	<b>Electronic Copy</b>
Letter authorizing unrestricted sharing of information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Pre-NOC Letters</b>	<b>Signature Required</b>	<b>Hard Copy</b>	<b>Electronic Copy</b>
Letter for sending the NOC or NOC/c to CADTH	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Letter for finalized Category 1 requirements if submission filed on a pre-NOC basis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<b>Checklist for required Category 1 documents specific to the Ministry of Health</b>	<b>Criteria for submission documents</b>		
<b>General Documentation</b>	<b>Signature Required</b>	<b>Hard Copy</b>	<b>Electronic Copy</b>
<b>Cover letter</b> The cover letter, printed on company letterhead and signed by an appropriate senior official, should identify: <ul style="list-style-type: none"> <li>• a description of the drug submission</li> <li>• each indication, strength and the Drug Identification Number (DIN) to be reviewed</li> <li>• the name of each vendor/associate company working on the submission</li> <li>• contact information for the primary and backup person who can be contacted regarding the submission under review.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Letter confirming that written notification of any future changes will be provided</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Letter confirming the availability of the drug, pre-NOC</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Letter confirming ability to supply for anticipated demand</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Letter confirming that Periodic Safety Update Reports submitted to Health Canada will also be submitted to the Ministry of Health</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Letter declaring that all known unpublished studies have been disclosed</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Table of all known ongoing trials for indications different than the indication being submitted for review</b> Access applicable information and templates from: <ul style="list-style-type: none"> <li>○ <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a></li> <li>○ <a href="https://eudract.ema.europa.eu/">https://eudract.ema.europa.eu/</a></li> </ul>	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Letter of consent authorizing unrestricted communication and sharing of information</b> The letter, printed on company letterhead and signed by an appropriate senior	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

official, authorizes the Ministry of Health to share information with respect to the drug product under review, with: <ul style="list-style-type: none"> <li>○ Health Canada</li> <li>○ Other provinces and territories</li> <li>○ CADTH/CDR (Canadian Agency for Drugs and Technologies in Health/Common Drug Review)</li> <li>○ PMPRB</li> <li>○ Health authorities including regional health authorities</li> <li>○ Contracted third party reviewers who are subject to a signed confidentiality agreement.</li> </ul>			
<b>All Pharmaceutical Advertising Advisory Board (PAAB)-approved promotional materials or draft copies of materials submitted to PAAB</b>	<b>N/A</b>	<input type="checkbox"/>	<input type="checkbox"/>

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

**CATEGORY 2 DOCUMENTS AND INFORMATION REQUIRED FOR PATENTED DRUG PRODUCTS REVIEWED BY THE CANADIAN AGENCY FOR DRUG AND TECHNOLOGIES IN HEALTH (CADTH) COMMON DRUG REVIEW (CDR) AND BY THE BC MINISTRY OF HEALTH**

- For **Subsequent Entry Biologics (SEBs)** documents and information please refer to the CDR [Procedure and Submission Guidelines for SEBs](#) (PDF 690KB).
- The BC Ministry of Health has specific SEBs document requirements which are the same as those listed in the document checklist of Ministry-specific Category 2 patented drug products.
  - Note: Not all documents and information listed in the checklists below will be available for SEBs drug submissions. For clarity, drug submission sponsors are asked to prepare a letter printed on company letterhead which is signed by an appropriate senior official, and submitted to the Ministry of Health as a hard and electronic copy, that refers to the specific SEBs documents that may be listed below and that will not be included in the complete drug submission package.
- Send the complete drug submission package of SEBs documents to the Ministry of Health at the same time as the package is submitted to the CDR.

**Category 2** documents and information are required by Canadian drug plans only, including the Ministry of Health, for drug submission review and recommendation processes. CADTH provides secretariat support to the drug plans by gathering Category 2 requirements and ensuring that the documents are complete. The CDR does not use Category 2 documents and information as part of their review and recommendation processes.

When submitting Category 2 documents and information for (1) **New Drugs**, (2) **Drugs with New Indications**, or (3) **New Combination Products to the CDR for Review**, drug submission sponsors must:

- Follow and meet the Category 2 requirements in the [CDR Drug Submission Guidelines](#) (PDF 1,194MB)
- Submit **one hard copy and one electronic copy** (e.g., CD, DVD, USB flash drive that is unlocked and fully executable) of their complete submission to the Ministry of Health
- Read and follow the checklist of required documents below to ensure the submission package is complete
- Send the complete drug submission package of CDR Category 2 documents to the Ministry of Health at the same time as they submit their drug submission package to the CDR

- Include Ministry-specific Category 2 documents in the submission to the Ministry of Health
- Send the complete drug submission package of CDR and Ministry-specific Category 2 documents to the courier address below:

Couriered Packages to:

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

Regular Correspondence to:

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

Below are simplified checklists of Category 2 documents required by the CDR and the Ministry of Health.

Note:

- Unless otherwise stated in the checklists (i.e., N/A), all documents must be printed on company letterhead, signed by an appropriate senior official, and submitted to the Ministry of Health as hard and electronic copies
- 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 that include all checklist documents will be reviewed
- The checklist of required Category 2 documents specific to the CDR should not be used to replace the CDR [Drug Submission Guidelines](#) (PDF 1,194MB) which go into greater detail
- Drug submission sponsors are not required to send the CDR any Category 2 documents that are specific to the Ministry of Health.

<b>Checklist for required Category 2 documents specific to the CDR</b>	<b>Criteria for submission documents</b>		
<b>General Documentation</b>	<b>Signature Required</b>	<b>Hard Copy</b>	<b>Electronic Copy</b>
<b>Cover letter confirming that all Category 2 requirements have been provided</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Budget Impact Analysis and Supporting Documentation</b>	<b>Signature Required</b>	<b>Hard Copy</b>	<b>Electronic Copy</b>
<b>Budget Impact Analysis (BIA)</b> <ul style="list-style-type: none"> <li>• Include BIAs for the following jurisdictions’ drug plans, in accordance with their individual requirements: 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"> <li>○ When data specific to Prince Edward Island are unavailable, the</li> </ul> </li> </ul>	<b>N/A</b>	<b>N/A</b>	<input type="checkbox"/> <b>PDF</b> + <input type="checkbox"/> <b>Excel</b>

BIA for Prince Edward Island is to be based on Nova Scotia data.			
<ul style="list-style-type: none"> <li>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.</li> </ul>			
<b>Copies of all supporting documentation used and/or cited in the BIAs</b>	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Certified Product Information Document (CPID)</b>	Signature Required	Hard Copy	Electronic Copy
<b>Copy of approved CPID</b>	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Additional Information (that may be requested)</b>	Signature Required	Hard Copy	Electronic Copy
<b>Harms and Safety information</b>	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Periodic Safety Update Reports as submitted to Health Canada</b>	N/A	N/A	<input type="checkbox"/>
<b>Clinical Study Reports</b>	N/A	N/A	<input type="checkbox"/>

<b>Checklist for required Category 2 documents specific to the Ministry of Health</b>	<b>Criteria for submission documents</b>		
<b>General Documentation</b>	Signature Required	Hard Copy	Electronic Copy
<b>Letter confirming ability to supply for anticipated demand</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Budget Impact Analysis (BIA) for BC</b> The BIA for BC must be: <ul style="list-style-type: none"> <li>Consistent with the standards published by the Patented Medicines Prices Review Board (PMPRB) (<a href="http://www.pmprb-cepmb.gc.ca/CMFiles/BIA-may0738LVV-5282007-5906.pdf">www.pmprb-cepmb.gc.ca/CMFiles/BIA-may0738LVV-5282007-5906.pdf</a>).</li> </ul>	N/A	<input type="checkbox"/>	<input type="checkbox"/> PDF + <input type="checkbox"/> Excel
<b>BIA for Other Drug Plans</b> The BIA's for other drug plans in Canada must be: <ul style="list-style-type: none"> <li>Consistent with the standards published by the PMPRB (<a href="http://www.pmprb-cepmb.gc.ca/CMFiles/BIA-may0738LVV-5282007-5906.pdf">www.pmprb-cepmb.gc.ca/CMFiles/BIA-may0738LVV-5282007-5906.pdf</a>).</li> </ul>	N/A	N/A	<input type="checkbox"/> PDF + <input type="checkbox"/> Excel
<b>Summary list of the drug submission product's associated patents and the patent expiry dates as documented on the Health Canada Patent Register</b>	N/A	<input type="checkbox"/>	<input type="checkbox"/>

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