

# DRUG SUBMISSION REQUIREMENTS CHECKLIST FOR LINE EXTENSION DRUG PRODUCTS TO THE BC MINISTRY OF HEALTH

## LINE EXTENSION (NEW STRENGTHS) DOCUMENTS REQUIRED FOR DRUG PRODUCTS REVIEWED BY THE BC MINISTRY OF HEALTH

Drug submission sponsors may request a Line Extension from the Ministry of Health to have new strengths of an existing drug listed on the PharmaCare program formulary for the same indication where no other formulation changes have been made.

To request a Line Extension (New Strengths), drug submission sponsors must:

- 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 Line Extension documents to the courier address below:

Courier 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 is a detailed checklist of Line Extension documents required by 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 a hard and electronic copies
- 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

Checklist for required Line Extension (New Strengths) documents	Criteria for submission documents		
	Signature Required	Hard Copy	Electronic Copy
<b>General Documentation</b>			
<b>Cover letter</b> The cover letter, printed on company letterhead and signed by an appropriate senior official, should describe the drug submission and identify: <ul style="list-style-type: none"> <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>Executive summary</b> The executive summary should be a high-level summary of the submission.	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Product monograph</b> <ul style="list-style-type: none"> <li>A copy of the most recent product monograph with the company, drug brand, and non-proprietary names that correspond to the Notice of Compliance (NOC).</li> <li>A copy of the clean and dated product monograph approved by Health Canada.</li> </ul>	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Letter confirming that written notification of any future changes will be provided</b> The letter should be printed on company letterhead and signed by an appropriate senior official.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Letter confirming the availability of the drug, pre-NOC</b> The letter should be printed on company letterhead and signed by an appropriate senior official.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Letter confirming ability to supply for anticipated demand</b> The letter should be printed on company letterhead and signed by an appropriate senior official.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Patents Documentation</b>	<b>Signature Required</b>	<b>Hard Copy</b>	<b>Electronic Copy</b>
<b>Summary list of the drug product's associated patents and the patent expiry dates as documented on Health Canada Patent Register</b>	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Health Canada Documentation</b>	<b>Signature Required</b>	<b>Hard Copy</b>	<b>Electronic Copy</b>
<b>NOC or Notice of Compliance with Conditions (NOC/c)</b>	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Drug Identification Number(s) (DIN)</b>	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Efficacy, Effectiveness, and Safety Documentation (including supplementary appendixes)</b>	<b>Signature Required</b>	<b>Hard Copy</b>	<b>Electronic Copy</b>
<b>Supporting clinical evidence</b>	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Pharmacoeconomic evidence</b>	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>All other information the drug submission sponsor would like the Ministry of Health to consider</b>	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Reference list of key clinical studies and errata</b>	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Copies of key clinical studies and errata</b>	N/A	N/A	<input type="checkbox"/>
<b>Reference list of editorial articles (or statement that there are no editorials)</b>	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Copies of editorial articles</b>	N/A	N/A	<input type="checkbox"/>

<b>Literature search strategies</b>	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Reference list of studies included in submission</b>	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Copies of studies included in submission</b>	N/A	N/A	<input type="checkbox"/>
<b>Letter declaring that all known unpublished studies have been disclosed</b> The letter should be printed on company letterhead and signed by an appropriate senior official.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Table of all known ongoing trials for indications <i>different</i> than the indication being submitted for review</b>	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Budget Impact Analysis (BIA)</b>	<b>Signature Required</b>	<b>Hard Copy</b>	<b>Electronic Copy</b>
<b>A Provincial Budget Impact Analysis (BIA) for BC in both PDF and Excel formats, consistent with the standards published by the Patented Medicines Prices Review Board (PMPRB)</b> Access the PMPRB BIA Guidelines at <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> .	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Pricing and Distribution Information</b>	<b>Signature Required</b>	<b>Hard Copy</b>	<b>Electronic Copy</b>
<b>Summary list and/or table on unit pricing information</b> Include all dosage forms, strengths and package sizes, to four decimal places.	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Method of distribution</b> Provide all available information on how the drug shall be distributed.	N/A	<input type="checkbox"/>	<input type="checkbox"/>
<b>Letter of commitment to honour the submitted price</b> The letter should be printed on company letterhead and signed by an appropriate senior official.	<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>
<b>Letter of consent authorizing the unrestricted communication and sharing of information</b> The letter, printed on company letterhead and signed by an appropriate senior 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>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Communications Documentation</b>	<b>Signature Required</b>	<b>Hard Copy</b>	<b>Electronic Copy</b>
<b>All Pharmaceutical Advertising Advisory Board (PAAB)-approved promotional materials or draft copies of materials submitted to PAAB</b> If the materials are not available at the time of submission, the drug submission sponsor should submit a letter indicating the reason for the delay and when the materials are expected to be available. Once available, the drug submission sponsor should provide them to the Ministry of Health to complete the	N/A	<input type="checkbox"/>	<input type="checkbox"/>

<p>submission.</p> <p>If a drug submission sponsor does not intend to produce and use promotional materials for the product, they may submit a letter, printed on company letterhead and signed by an appropriate senior official, that includes:</p> <ul style="list-style-type: none"> <li>• a request to waive the use of promotional materials</li> <li>• the rationale for not using promotional materials</li> <li>• the period of time during which no promotional materials will be used (from start month and year to end month and year).</li> </ul>			
<b>Periodic Safety Update Report</b>	<b>Signature Required</b>	<b>Hard Copy</b>	<b>Electronic Copy</b>
<p><b>Letter of consent to release Periodic Safety Update Reports as submitted to Health Canada</b></p> <p>The letter, printed on company letterhead and signed by an appropriate senior official, should state that all data on harm as submitted to Health Canada, related to the drug submission under review, including harm and safety issues that may arise while the submission is under review, will be submitted to the Ministry of Health.</p>	<input type="checkbox"/>	<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.