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 coverage of a Line Extension from the Ministry of Health to have new strengths of an existing drug, including biosimilars, listed on the PharmaCare program formulary for the same indication where no other formulation changes have been made.

Documents required for Line Extensions (New Strengths) for patented products and biosimilars are the same.

- Note: Not all documents and information listed in the checklist below will be available for line Extension of biosimilar products. 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 biosimilars documents that may be listed below and that will not be included in the complete drug submission package.

To request coverage for a Line Extension, 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:	Regular Correspondence to:
Director, Formulary Management Medical Beneficiary and Pharmaceutical Services Division BC Ministry of Health 1515 Blanshard Street Victoria BC V8W 3C8	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 specific to the Ministry of Health, including Line Extensions of biosimilar products	Criteria for submission documents		
General Documentation	**Signature Required**	**Hard Copy**	**Electronic Copy**
Cover letter The cover letter, printed on company letterhead and signed by an appropriate senior official, should describe the drug submission and identify: • each indication, strength and the Drug Identification Number (DIN) to be reviewed • the name of each vendor/associate company working on the submission • contact information for the primary and backup person who can be contacted regarding the submission under review.	❑	❑	❑
Executive summary The executive summary should be a high-level summary of the submission.	**N/A**	❑	❑
Product monograph • 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). • A copy of the clean and dated product monograph approved by Health Canada.	**N/A**	❑	❑
Letter confirming that written notification of any future changes will be provided The letter should be printed on company letterhead and signed by an appropriate senior official.	❑	❑	❑
Letter confirming the availability of the drug, pre-NOC The letter should be printed on company letterhead and signed by an appropriate senior official.	❑	❑	❑
Letter confirming ability to supply for anticipated demand The letter should be printed on company letterhead and signed by an appropriate senior official.	❑	❑	❑
Patents Documentation	**Signature Required**	**Hard Copy**	**Electronic Copy**
Summary list of the drug product's associated patents and the patent expiry dates as documented on Health Canada Patent Register	**N/A**	❑	❑
Health Canada Documentation	**Signature Required**	**Hard Copy**	**Electronic Copy**
NOC or Notice of Compliance with Conditions (NOC/c)	**N/A**	❑	❑
Drug Identification Number(s) (DIN)	**N/A**	❑	❑
Efficacy, Effectiveness, and Safety Documentation (including supplementary appendixes)	**Signature Required**	**Hard Copy**	**Electronic Copy**
Supporting clinical evidence	**N/A**	❑	❑
Pharmacoeconomic evidence	**N/A**	❑	❑
All other information the drug submission sponsor would like the Ministry of Health to consider	**N/A**	❑	❑
Reference list of key clinical studies and errata	**N/A**	❑	❑
Copies of key clinical studies and errata	**N/A**	**N/A**	❑
Reference list of editorial articles (or statement that there are no editorials)	**N/A**	❑	❑

Copies of editorial articles	**N/A**	**N/A**	❑
Literature search strategies	**N/A**	❑	❑
Reference list of studies included in submission	**N/A**	❑	❑
Copies of studies included in submission	**N/A**	**N/A**	❑
Letter declaring that all known unpublished studies have been disclosed The letter should be printed on company letterhead and signed by an appropriate senior official.	❑	❑	❑
Table of all known ongoing trials for indications *different* than the indication being submitted for review	**N/A**	❑	❑
Budget Impact Analysis (BIA)	**Signature Required**	**Hard Copy**	**Electronic Copy**
A Provincial Budget Impact Analysis (BIA) for BC that is consistent with the standards published by the Patented Medicines Prices Review Board (PMPRB) Access the PMPRB BIA Guidelines at www.pmprb-cepmb.gc.ca/CMFiles/BIA-may0738LVV-5282007-5906.pdf.	**N/A**	❑	❑ **PDF** + ❑ **Excel**
Pricing and Distribution Information	**Signature Required**	**Hard Copy**	**Electronic Copy**
Summary list and/or table on unit pricing information Include all dosage forms, strengths and package sizes, to four decimal places.	**N/A**	❑	❑
Method of distribution Provide all available information on how the drug shall be distributed.	**N/A**	❑	❑
Letter of commitment to honour the submitted price The letter should be printed on company letterhead and signed by an appropriate senior official.	❑	❑	❑
Sharing of Information	**Signature Required**	**Hard Copy**	**Electronic Copy**
Letter of consent authorizing the unrestricted communication and sharing of information 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: • Health Canada • Other provinces and territories • CADTH/CDR (Canadian Agency for Drugs and Technologies in Health/Common Drug Review) • PMPRB • Health authorities including regional health authorities • Contracted third party reviewers who are subject to a signed confidentiality agreement.	❑	❑	❑
Communications Documentation	**Signature Required**	**Hard Copy**	**Electronic Copy**
All Pharmaceutical Advertising Advisory Board (PAAB)-approved promotional materials or draft copies of materials submitted to PAAB 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**	❑	❑

submission. 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: • a request to waive the use of promotional materials • the rationale for not using promotional materials • the period of time during which no promotional materials will be used (from start month and year to end month and year).			
Periodic Safety Update Report	**Signature Required**	**Hard Copy**	**Electronic Copy**
Letter of consent to release Periodic Safety Update Reports as submitted to Health Canada 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.	❑	❑	❑

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.