DRUG SUBMISSION REQUIREMENTS CHECKLIST FOR PATENTED DRUG PRODUCTS AND BIOSIMILARS 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 documents and information relating to biosimilars (previously referred to as Subsequent Entry Biologics or SEBs), please refer to the CADTH Common Drug Review Procedure and Submission Guidelines for Subsequent Entry Biologics (PDF 690KB).
- The BC Ministry of Health has specific biosimilars 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 biosimilars 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 biosimilars 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 biosimilars 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
PO BOX 9652 STN PROV GOVT
Victoria BC V8W 9P4

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**		
General Documentation	**Signature Required**	**Hard Copy**	**Electronic Copy**
Completed CDR application overview template	**N/A**	❑	❑
Cover letter	❑	❑	❑
Executive summary	**N/A**	❑	❑
Product monograph	**N/A**	❑	❑
Health Canada Documentation	**Signature Required**	**Hard Copy**	**Electronic Copy**
NOC or Notice of Compliance with conditions (NOC/c)	**N/A**	❑	❑
Health Canada clinical reviewers' report	**N/A**	❑	❑
Table of Clarifaxes	**N/A**	❑	❑
Efficacy, Effectiveness, and Safety Documentation (Including supplementary appendixes)	**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**	❑	❑
Reference list of clinical studies and errata	**N/A**	❑	❑
Clinical studies	**N/A**	**N/A**	❑
Table of studies	**N/A**	❑	❑
Reference list of editorial articles (or statement that no editorials)	**N/A**	❑	❑
Copies of editorial articles	**N/A**	**N/A**	❑
Literature search strategies	**N/A**	**N/A**	❑
Letter declaring that all known unpublished studies have been disclosed	❑	❑	❑
CONSORT diagrams	**N/A**	❑	❑

Reference list and copies of new data	**N/A**	❑	❑
Reference list of articles for validity of outcome measures	**N/A**	❑	❑
Copies of articles for validity of outcome measures	**N/A**	**N/A**	❑
Economic and Epidemiologic Documentation	**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**	❑	❑
Economic model used in the initial submission	**N/A**	❑	❑
Number of patients accessing a new drug to within 20 business days of the submission being filed	**N/A**	❑	❑
Disease prevalence and incidence data, with specified population breakdown (if available)	**N/A**	❑	❑
Pricing and Distribution Documentation	**Signature Required**	**Hard Copy**	**Electronic Copy**
Summary list and/or table on the unit price for all dosage forms, strengths and package sizes, to four decimal places	**N/A**	❑	❑
Method of distribution	**N/A**	❑	❑
Commitment to honour the submitted price	❑	❑	❑
Sharing of Information	**Signature Required**	**Hard Copy**	**Electronic Copy**
Letter authorizing unrestricted sharing of information	❑	❑	❑
Pre-NOC Letters	**Signature Required**	**Hard Copy**	**Electronic Copy**
Letter for sending the NOC or NOC/c to CADTH	❑	❑	❑
Letter for finalized Category 1 requirements if submission filed on a pre-NOC basis	❑	❑	❑

Checklist for required Category 1 documents specific to the Ministry of Health	**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 identify: • a description of the drug submission • 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.	❑	❑	❑
Letter confirming that written notification of any future changes will be provided	❑	❑	❑
Letter confirming the availability of the drug, pre-NOC	❑	❑	❑
Letter confirming ability to supply for anticipated demand	❑	❑	❑
Letter confirming that Periodic Safety Update Reports submitted to Health Canada will also be submitted to the Ministry of Health	❑	❑	❑
Letter declaring that all known unpublished studies have been disclosed	❑	❑	❑
Table of all known ongoing trials for indications different than the indication being submitted for review Access applicable information and templates from:	**N/A**	❑	❑

○ www.clinicaltrials.gov ○ https://eudract.ema.europa.eu/			
Letter of consent authorizing 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.	❑	❑	❑
All Pharmaceutical Advertising Advisory Board (PAAB)-approved promotional materials or draft copies of materials submitted to PAAB	**N/A**	❑	❑

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 documents and information relating to biosimilars (previously referred to as Subsequent Entry Biologics or SEBs), please refer to the CADTH Common Drug Review Procedure and Submission Guidelines for Subsequent Entry Biologics (PDF 690KB).
- The BC Ministry of Health has specific biosimilars 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 biosimilars 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 biosimilars 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 biosimilars 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.

Checklist for required Category 2 documents specific to the CDR **General Documentation**	**Criteria for submission documents** **Signature Required**	**Hard Copy**	**Electronic Copy**
Cover letter confirming that all Category 2 requirements have been provided	❑	❑	❑
Budget Impact Analysis and Supporting Documentation	**Signature Required**	**Hard Copy**	**Electronic Copy**
Budget Impact Analysis (BIA) • Include BIAs for the following jurisdictions' drug plans, in accordance with	**N/A**	**N/A**	❑ **PDF +**

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. ○ 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.			❑ **Excel**
Copies of all supporting documentation used and/or cited in the BIAs	**N/A**	❑	❑
Certified Product Information Document (CPID)	**Signature Required**	**Hard Copy**	**Electronic Copy**
Copy of approved CPID	**N/A**	❑	❑
Additional Information (that may be requested)	**Signature Required**	**Hard Copy**	**Electronic Copy**
Harms and Safety information	**N/A**	❑	❑
Periodic Safety Update Reports as submitted to Health Canada	**N/A**	**N/A**	❑
Clinical Study Reports	**N/A**	**N/A**	❑

Checklist for required Category 2 documents specific to the Ministry of Health **General Documentation**	**Criteria for submission documents** **Signature Required**	**Hard Copy**	**Electronic Copy**
Letter confirming ability to supply for anticipated demand	❑	❑	❑
Budget Impact Analysis (BIA) for BC The BIA for BC must be: • Consistent with the standards published by the Patented Medicines Prices Review Board (PMPRB) (www.pmprb-cepmb.gc.ca/CMFiles/BIA-may0738LVV-5282007-5906.pdf).	**N/A**	❑	❑ **PDF** + ❑ **Excel**
BIA for Other Drug Plans The BIA's for other drug plans in Canada must be: • Consistent with the standards published by the PMPRB (www.pmprb-cepmb.gc.ca/CMFiles/BIA-may0738LVV-5282007-5906.pdf).	**N/A**	**N/A**	❑ **PDF** + ❑ **Excel**
Summary list of the drug submission product's associated patents and the patent expiry dates as documented on the Health Canada Patent Register	**N/A**	❑	❑

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.