BIOSIMILARS SUBMISSION CHECKLIST

When submitting documents and information for biosimilar products, drug manufacturers must submit one copy of the complete submission requirements on a USB flash drive to the Ministry of Health. The USB flash drive should be unlocked and fully executable. Hard/paper copies of drug submissions are no longer accepted.

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, 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 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

• 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 documents

### General

- **Cover letter *Signature Required***

  The cover letter should identify:
  - 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.

- **Letter confirming that written notification of any future changes will be provided *Signature Required***

- **Letter confirming ability to supply for anticipated demand *Signature Required***

- **Letter confirming that Periodic Safety Update Reports submitted to Health Canada will also be submitted to the Ministry of Health *Signature Required***

- **Letter of consent authorizing unrestricted communication and sharing of information *Signature Required***

  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; and
  - 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

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 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 time period during which no promotional materials will be used (from start month and year to end month and year).

Product Monograph

Provide a summary of the post-market authorization risk management plan to monitor and detect both known inherent safety concerns and potentially unknown safety signals

Clinical Studies

Pharmacokinetic studies
- Table of all studies
- Copies of studies

Pharmacodynamic studies
- Table of all studies
- Copies of studies

Clinical efficacy trial(s)
- Table of all studies
- Copies of studies

Safety and immunogenicity studies
- Table of all studies
- Copies of studies
Evidence of switching
- Table of all studies
- Copies of studies

- Table of all known ongoing trials, such as those for indications different than the indication being submitted for review

Access applicable information and templates from:
- [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
- [https://eudract.ema.europa.eu/](https://eudract.ema.europa.eu/)

### 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

### Health Canada Documentation

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

### Submission Template

- Completed biosimilar submission template

### Budget Impact Analysis and Supporting Documentation

- Budget Impact Analysis (BIA) (Reports and Models) *Submit as PDF and Excel*

Include BIAs (reports and models) for the following jurisdictions’ drug plans: British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, and the Non-Insured Health Benefits Program.
<table>
<thead>
<tr>
<th>Reference list of all supporting documentation used and/or cited in the BIAs</th>
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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.