Biosimilars Submission Checklist

Only drug submission packages that follow the checklist criteria and that include all checklist documents will be reviewed. If you have 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

All letters, unless otherwise stated, must be prepared on company letterhead and signed by an appropriate senior official. Documents may be signed with an e-signature.

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 • contact information for the primary and backup person who can be contacted about 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 authorizes the Ministry of Health to share information with respect to the drug product under review with • Health Canada • other provinces and territories • CDA/CDR (Canada's Drug Agency/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 If the materials are not available, submit a letter indicating the reason for the delay and when the materials are expected to be available. Once they are available, provide them to the Ministry of Health to complete the submission. If promotional materials for the product will not be produced, 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 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
- 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

❑ Method of distribution

Please provide wholesaler name and contact information

Health Canada Documentation

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

❑ Letter of Undertaking

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.
❑ Reference list of all supporting documentation used and/or cited in the BIAs
❑ Copies of all supporting documentation used and/or cited in the BIAs

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.

How to submit your documents

The Ministry of Health accepts submissions in two formats:

Dropbox

Dropbox is a secure online file storage service. Request access to Dropbox by emailing DrugReviewProcess@gov.bc.ca

Email

1. **Compress:** Remove non-essential graphics. Compress the submission, preferably with Microsoft Windows
2. **Rename:** Rename the compressed file to remove ".zip" Government email programs reject emails with a .zip attachment
3. **Encrypt:** Encrypt the submission package using AES-128 encryption standards or better, preferably using Microsoft Windows
4. **Submit:** Send the compressed, encrypted file to DrugReviewProcess@gov.bc.ca. Send the decryption password to the same address in a separate email. Drug Review staff will confirm they have received the submission