CADTH Biosimilar Summary Dossier

**GENERIC DRUG NAME (BRAND NAME)**

(Manufacturer)

Indication(s): As per CADTH website

**Instructions for Submitters**

Please read the instructions below and consult the recommended documentation before completing the template. If you have any questions regarding the pCODR submission filing process or requirements for a biosimilar, please email pcodrinfo@cadth.ca with the complete details of your question(s).

**Note:** CADTH is committed to providing an open and transparent biosimilar drug review process. To ensure that the CADTH drug review processes are transparent and accountable, CADTH considers it essential that any information provided in the template to support the biosimilar submission be fully disclosable.

**Before Completing the Template**

Please review the following documents to ensure an understanding of the pCODR procedures and submission guidelines:

* Procedures for the CADTH pan-Canadian oncology drug review ([February 2018](https://www.cadth.ca/sites/default/files/pcodr/pCODR%27s%20Drug%20Review%20Process/pcodr-procedures.pdf))
* *CADTH pan-Canadian Oncology Drug Review Submission Guidelines for Biosimilars* ([February 2018](https://www.cadth.ca/sites/default/files/pcodr/pCODR%27s%20Drug%20Review%20Process/pcodr-submission-guidelines-biosimilars.pdf))
* pCODR updates (see [Communications Updates](https://cadth.ca/pcodr/communication-updates)) for any applicable information.

**Completing the Template**

* Complete all sections of the biosimilar template with the exception of sections 5.2, 6.2, 6.3, and 6.4.
* Do not write in sections labelled “To be completed by CADTH reviewers.”
* References must be provided in the following format:
* In-text citations must be numbered in order of appearance.
* A numbered reference list must be provided in the Citing Medicine format at the end of the document in the References section.
* Save the completed template as a Word document using the following file name structure: BrandName\_Template.

**Submitting the Template to CADTH**

* For pCODR: Please incorporate the completed biosimilar submission template saved as a **Word document** into a complete package of category 1 requirements and file the biosimilar submission through the [CADTH Collaborative Workspaces](https://drugreviewsadmin.cadth.ca/IdSrv/account/signin?ReturnUrl=%2fIdSrv%2fissue%2fwsfed%3fwa%3dwsignin1.0%26wtrealm%3durn%253athinktecture%253aidentityserver%253aEnvisionIT%26wctx%3dhttps%253a%252f%252fdrugreviews.cadth.ca%252f_layouts%252f15%252fAuthenticate.aspx%253fSource%253d%25252F&wa=wsignin1.0&wtrealm=urn%3athinktecture%3aidentityserver%3aEnvisionIT&wctx=https%3a%2f%2fdrugreviews.cadth.ca%2f_layouts%2f15%2fAuthenticate.aspx%3fSource%3d%252F).
* Please consult the *CADTH pan-Canadian Oncology Drug Review Submission Guidelines for Biosimilars* for details on how to file the submission package.

Section 1: Biosimilar Product Information (*To be completed by the manufacturer*)

|  |  |
| --- | --- |
| **Biosimilar (Brand Name)** |  |
| **Active Pharmaceutical Ingredient** |  |
| **Manufacturer** |  |
| **Strength(s) / Dosage Form(s) / Route(s) of Administrationa** |  |
| **Health Canada– Approved Indication(s) (or Anticipated Indications)** |  |
| **Health Canada–Approved Reference Product Indications Not Being Sought by the Manufacturer (if Applicable)** |  |
| **NOC Date(s) (or Anticipated NOC Date[s])b** |  |

a Please provide all applicable strength(s)/Dosage Form(s)/Route of Administration, as applicable

b Please provide NOC date(s) according to indication.
NOC = notice of compliance.

Section 2: Reference Product Information (*To be completed by the manufacturer*)

|  |  |
| --- | --- |
| **Reference Product (Brand Name)** |  |
| **Active Pharmaceutical Ingredient** |  |
| **Manufacturer** |  |
| **Strength(s) / Dosage Form(s) / Route(s) of Administration** |  |
| **Health Canada– Approved Indication(s)** |  |

Section 3: Manufacturer’s Reimbursement Request (*To be completed by the manufacturer*)

|  |  |
| --- | --- |
| **Manufacturer’s Reimbursement Request and Rationale** |  |

Section 4: Health Canada’s Assessment of (Biosimilar) for Market Authorization

|  |
| --- |
| 4.1 Authorized Indications (*To be completed by the manufacturer*) |
| **Indications:** Indications have been granted on the basis of similarity between [biosimilar]and the reference biologic drug, [reference product]. Further details can be found in the Health Canada–approved product monographs for [biosimilar] and [reference product]:* [Biosimilar]: *<Insert weblink to product monograph on Health Canada’s website.>*
* [Reference product]: *<Insert weblink to product monograph on Health Canada’s website.>*

**Authorization of Indications (if Applicable):** Randomized clinical trials have not been conducted to compare [biosimilar] to [reference product]in patients with[indication(s)]. *<Please provide a short summary of the basis for Health Canada approving indications for which no clinical trial(s) was/were conducted.>* |
| 4.2 Summary of Comparative Clinical Trials (*To be completed by the manufacturer based on the Health Canada–approved (or anticipated) biosimilar product monograph – Section 15*) |
| **4.2.1 Comparative Clinical Trial Design and Patient Demographics**Clinical trials conducted to support similarity between [biosimilar] and the reference biologic drug included:* *<Please provide a short statement describing the trial design and patient population of each study; add a separate bullet point for each study.>*

An overview of the trial design(s) and demographic characteristics of patients enrolled in each clinical study is presented in Table 1.Table 1: Comparative Clinical Trial Design and Patient Demographics

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Study Number  | Trial Design | Patient Population | Dosage, Route of Administration, and Duration | Number of Patients | Mean Age (Range) | Sex |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

abb = abbreviations4.2.2 Comparative Clinical Trial Results<*Please provide a short narrative of the results of each comparative clinical trial (including pharmacokinetics, pharmacodynamics, efficacy, safety, and immunogenicity results), with reference to the results in table form as per Section 15 of the Health Canada–approved (or anticipated) biosimilar product monograph.*>Table <#>: Comparative Clinical Trial Results

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Parameter |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

abb = abbreviations |

**Section 5: Cost Overview**

|  |
| --- |
| 5.1 Cost Comparison (*To be completed by the manufacturer*) |
| Table <#>: Cost Comparison of [Biosimilar] and [Reference Product] for [Indication]a

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Drug / Comparator** | **Strength** | **Dosage Form** | **Price ($)b** | **Recommended****Dosec** | **Average Drug Cost ($)** |
| **Canadian Costs** |
| Biosimilar under reviewd |  |  | $X.XXXX |  |  |
| Reference productd |  |  | $X.XXXX |  |  |
| Other biosimilars |  |  | $X.XXXX |  |  |

<*a Please add separate cost tables for each indication where the dosage of the biosimilar product or the relevant comparators vary by indication.>**<b Provide sources for price information.>**<c Provide sources for the dosage information; please also include a statement if the biosimilar has a fixed dosing schedule or a weight-based dosing schedule for the requested indication(s) and the rationale, where applicable.>**<d Please rename these row headings with brand names of the biosimilar and the reference product.>* |
| 5.2 Summary of Cost Comparison (*To be completed by CADTH reviewers if applicable*) |
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| --- |
| CADTH Comments [if applicable] |

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Section 6: Implementation Considerations

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| 6.1 Patient and Provider Support Programs (*To be completed by the manufacturer*) |
| Will a patient support program be made available by the manufacturer? [ ]  Yes or [ ]  NoWill a health care provider support program be made available by the manufacturer? [ ]  Yes or [ ]  No |
| **6.2 Summary of Patient Input (*To be completed by CADTH reviewers*)** |
| This section is intended to be a summary of the patient input based on the perspectives of patient groups providing input on this biosimilar submission. The original patient input submission(s) are shared with the pan-Canadian Pharmaceutical Alliance (pCPA) and participating drug plans and cancer agencies and are published on CADTH’s website.

|  |
| --- |
| CADTH Comments |

Please see Appendix A for the full input from patient groups. |
| **6.3 Summary of Clinician Input (*To be completed by CADTH reviewers*)** |
| This section is intended to be a summary of the clinician input based on the perspectives of registered clinicians providing input on this biosimilar submission. The original clinician input submission(s) are shared with the pan-Canadian Pharmaceutical Alliance (pCPA) and participating drug plans and cancer agencies and are published on CADTH’s website. |
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| CADTH Comments |

Please see Appendix B for the full input from clinicians. |
| **6.4 Summary of Jurisdictional Input (*To be completed by CADTH reviewers*)** |
| This section is intended to be a summary of the Provincial Advisory Group (PAG) input based on the perspectives of PAG providing input on this biosimilar submission. Input provided by PAG on this submission is used to inform the potential impact and feasibility of adopting into the health system the new biosimilar or a new indication for a biosimilar. |
|

|  |
| --- |
| CADTH Comments |

Please see Appendix C for the full input from jurisdictions. |

Section 7: Public Drug Program Funding Status for Reference Product and Other Funded Biosimilars

For each indication that is approved by Health Canada for the biosimilar (or likely to be approved, in the case of a submission filed on a pre-NOC basis), please provide the publicly available listing status and criteria for the reference product and other funded biosimilars, if applicable. CADTH may update the information provided by the manufacturer with new information provided by the participating jurisdictions, as required.

**Step 1:** Use the following abbreviations to complete the table. Use a separate row for each indication and add more rows if necessary.

|  |  |
| --- | --- |
| **Abbreviation** | **Description** |
| **EX** | Exception item for which coverage is determined on a case-by-case basis |
| **FB** | Full benefit |
| **NB** | Not a benefit |
| **RES** | Restricted benefit with specified criteria (e.g., special authorization, exception drug status, limited use benefit) |
| **UR** | Under review |
| **‒** | Information not available |

**Funding Status for [Name of reference product] (*To be completed by the manufacturer*)**

|  |  |  |
| --- | --- | --- |
| Indication(s) | pCODR Participating Jurisdictions |  |
| **BC** | **AB** | **SK** | **MB** | **ON** | **NB** | **NS** | **PE** | **NL** | **NIHB** | **DND** | **VAC** |
| **Indication 1** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Indication 2** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Indication 3** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Indication 4** |  |  |  |  |  |  |  |  |  |  |  |  |

AB = Alberta; BC = British Columbia; DND = Department of National Defence; MN = Manitoba; NB = New Brunswick; NIHB = Non-Insured Health Benefits Program; NL = Newfoundland and Labrador; NS = Nova Scotia; ON = Ontario; PE = Prince Edward Island; SK = Saskatchewan; VAC =Veterans Affairs Canada.

**Funding Status for [Name of other biosimilars] (*To be completed by the manufacturer*)**

|  |  |  |
| --- | --- | --- |
| Indication(s) | pCODR Participating Jurisdictions  |  |
| **BC** | **AB** | **SK** | **MB** | **ON** | **NB** | **NS** | **PE** | **NL** | **NIHB** | **DND** | **VAC** |
| **Indication 1** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Indication 2** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Indication 3** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Indication 4** |  |  |  |  |  |  |  |  |  |  |  |  |

AB = Alberta; BC = British Columbia; DND = Department of National Defence; MN = Manitoba; NB = New Brunswick; NIHB = Non-Insured Health Benefits Program; NL = Newfoundland and Labrador; NS = Nova Scotia; ON = Ontario; PE = Prince Edward Island; SK = Saskatchewan; VAC =Veterans Affairs Canada.

**Step 2:** For all restricted benefit entries (RES), please state the criteria used by each public drug program/cancer agency. Use a separate table for each indication and add or delete rows as necessary.

**Restricted Benefit Criteria for (Name of reference product) for the treatment of (state the indication) (*To be completed by the manufacturer*)**

|  |  |
| --- | --- |
| Drug Program/Cancer Agency | Criteria for Restricted Benefit |
| **Add name**  |  State the exact criteria  |
| **Add name**  |  State the exact criteria  |
| **Add name**  |  State the exact criteria  |

**Restricted Benefit Criteria for (Name of other biosimilar) for the treatment of (state the indication) (*To be completed by the manufacturer*)**

|  |  |
| --- | --- |
| Drug Program/Cancer Agency | Criteria for Restricted Benefit |
| **Add name**  |  State the exact criteria  |
| **Add name**  |  State the exact criteria  |
| **Add name**  |  State the exact criteria  |

**Appendix A: CADTH Biosimilars Patient Group(s) Input**

**Important Note for Patient Group(s):**

Please use the [**Biosimilars Patient Input Template for CADTH CDR and pCODR Programs**](https://www.cadth.ca/sites/default/files/pcodr/pCODR%27s%20Drug%20Review%20Process/CADTH-pt-input-biosimilars-review.docx) and the [**Patient Group Conflict of Interest Declaration**](https://www.cadth.ca/sites/default/files/pcodr/pCODR%27s%20Drug%20Review%20Process/pcodr-patientad-coi-declaratio.doc) to submit your input.

**Appendix B: CADTH Biosimilars Clinician(s) Input**

Important Note for Registered Clinician(s):

Please use the [Biosimilars Clinician Input Template for CADTH pCODR Program](https://www.cadth.ca/sites/default/files/pcodr/pCODR%27s%20Drug%20Review%20Process/CADTH_clinician-input-biosimilars-pcodr.docx) and the [pCODR Registered Clinician Conflict of Interest Declaration](https://www.cadth.ca/sites/default/files/pcodr/pCODR%27s%20Drug%20Review%20Process/pcodr-clinician_coi-declaration.docx) to submit your input.

**Appendix C: CADTH Biosimilars Provincial Advisory Group Input**

Important Note for Provincial Advisory Group:

Please use the [Biosimilars Provincial Advisory Group Input Template for CADTH pCODR Program](https://www.cadth.ca/sites/default/files/pcodr/pCODR%27s%20Drug%20Review%20Process/CADTH_PAG-input-biosimilars-pcodr.docx)  to submit your input.

**Appendix D: References**