Biosimilars Clinician Input Template for CADTH pCODR Program

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| Name of the Biosimilar and Indication |  |
| Name of the Registered Clinician |  |
| Title |  |
| Specialty (if applicable) |  |
| Membership: (e.g., Provincial Cancer Agency, National Cancer Organization or Other) |  |
| Email |  |
| Telephone Number |  |
| If this is a joint clinician submission, please list the names of the other clinicians, their title and specialty (if applicable). Please note all clinicians listed must also register with CADTH.  *Please Note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declaration Template even if the submission is made jointly.* |  |
| Do you have experience with prescribing the biosimilar under review? |  |

**Introduction**

Biologic drugs come from living organisms or from their cells and are often made using biotechnology.

They are used to treat diseases and medical conditions including anemia, diabetes, inflammatory bowel disease, psoriasis, rheumatoid arthritis, hormone deficiency, and some forms of cancer.

A biosimilar is a drug demonstrated to be highly similar to a biologic drug (known as the reference biologic drug) that was already authorized for sale by the regulatory body, Health Canada. Biosimilars are approved based on having no clinically meaningful differences compared with the reference biologic drug product in terms of safety, purity, and efficacy. Biosimilars may enter the market after the expiry of reference biologic drug patents and data protection.

To help inform the advice that you provide to CADTH and that will be shared with the pan-Canadian Pharmaceutical Alliance and participating jurisdictions making a funding decision, please consider the following:

1. **Awareness About Biosimilars**
   1. How familiar are you with biosimilars and how they are approved in Canada? (Please specify: very familiar, somewhat familiar, not at all familiar.) If you are familiar with biosimilars, how was this information obtained (e.g., government or not-for-profit organization, industry, general website, other [please specify])?

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* 1. Are you aware whether there are other brands of biosimilars that may be available to treat the requested indication(s)? If yes, please specify.

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1. **Initiating a Patient on a Biosimilar**
   1. In which circumstances would you initiate a patient on a biosimilar? Please describe if there are considerations with initiating a biosimilar in the adjuvant or metastatic setting.

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1. **Switching a Patient to a Biosimilar**
   1. In which circumstances would you switch a patient to a biosimilar from the reference biologic drug? Please describe if there are considerations with switching a patient to a biosimilar in the adjuvant or metastatic setting.

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1. **About the Biosimilar Under Review**
   1. As a biosimilar is considered to be effective and safe by the regulatory body and using a biosimilar could help to increase access by other patients to new therapies, would this information be a factor in your prescribing decision?

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* 1. What information might be helpful to inform your decision to initiate or switch to a biosimilar? Please describe if there were any benefits or side effects experienced with the biosimilar.

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1. **Accessibility Considerations**
2. Are you aware whether there is a patient support program for the biosimilar under review; if so, please describe the program for the biosimilar (e.g., administration, testing, monitoring)?

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1. Please describe whether there are any potential barriers to prescribing a biosimilar.

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1. **Implementation Questions**

The Ministries of Health and provincial cancer programs across Canada are concerned about the sustainability of high-quality cancer control services. The rising cost of cancer drugs is becoming a major challenge to the sustainability of cancer care funding. While tremendous progress has been made in recent years in the cancer drug system, more is needed to be done to ensure innovative treatments are available to patients, while ensuring value for money for the public.

If applicable, we will be seeking your clinical opinion on the following implementation issues, if and when the new treatment is reimbursed. Your responses would be taken into consideration, amongst other factors, when Ministries of Health and provincial cancer programs make their final funding decisions.

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**Appendix: Clinician Group Conflict of Interest Declaration**

**Please Note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.**

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| **Name of registered clinician:** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Name of drug and indication under review:** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**Conflict of Interest Declarations**

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. Conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

* financial support from the pharmaceutical industry or other entities e.g., educational or research grants, honoraria, gifts, and salary;
* affiliations or personal or commercial relationships with drug manufacturers or other interest groups.

***Section A: Payment Received***

1. Have you received any payments over the previous two years from any company or organization that may have direct or indirect interest in the drug under review?

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| □ | Yes |
| □ | No |

If no, please go to Section B

1. What form of payment did you receive? (Check all that apply.)

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| □ | Advisory role (e.g., advisory boards, HTA submission advice) | □ | Program or Operating Funding (e.g., website) |  |
| □ | Conference attendance | □ | Research/educational grants |  |
| □ | Royalties | □ | Travel grants |  |
| □ | Gifts | □ | Sponsorship of Events |  |
| □ | Honoraria | □ | Other, please specify: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. Please provide the names of companies and organizations and the amounts of the payments in the box below.

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***Section B: Holdings or Other Interests***

Have you received or is it in possession of stocks or options of more than $10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list in the table below.

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***Section C: Affiliations, personal or commercial relationships***

Do you have personal or commercial relationships either with a drug or health technology manufacturer (including such manufacturer’s parent corporation, subsidiaries, affiliates and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations and outline the nature of these relationships in the table below.

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I hereby certify that I have disclosed all relevant information with respect to any matter involving a Party that may place me in a real, potential or perceived conflict of interest situation.

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| Date: \_\_\_\_\_\_\_\_\_\_\_\_ | Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |