CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

pan-Canadian Oncology Drug Review Pre-submission Guidelines

August 2018

RECORD OF UPDATES

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1	March 2016	March 24, 2016
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3	June 2017	June 13, 2017
4	February 2018	February 13, 2018
5	August 2018	August 9, 2018

INQUIRIES

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1. Purpose

The purpose of the pan-Canadian Oncology Drug Review (pCODR) Pre-submission Guidelines is to provide guidance to the Submitter on information and timing of information required by the pCODR program prior to a Submission or Resubmission being filed with pCODR and to provide guidance around Pre-submission Meetings between the pCODR program and the Submitter.

2. Definitions

The capitalized terms in this document are defined in Appendix A.

All references to number of days in this document are in CADTH Business Days, unless otherwise specified.

3. Pre-submission Information Requirements

Note: All Pre-submission Information provided to pCODR will remain confidential. The Pre-submission Information will be tracked internally on the secure and confidential section of the CADTH portal.

Submitters of drugs for pCODR review are requested to provide Pre-submission Information before the anticipated date of filing the complete Submission or Resubmission (e.g., approximately 4 to 6 months advance notice). To facilitate the pCODR review process, Submitters of drugs for pCODR review are requested to provide Pre-submission Information **at least 120 calendar days** before the anticipated date of filing the complete Submission or Resubmission. If the anticipated submission received date falls on a weekend or statutory holiday, the following business day will be applied. The pCODR program will monitor this requirement for all Pre-submission Information submitted to pCODR. Submitters include pharmaceutical manufacturers, provincially recognized clinician-based Tumour Groups and the pCODR Provincial Advisory Group (PAG).

The information required by the pCODR program during the pre-submission phase is detailed in the Pre-submission Information Requirements Form. Requirements for Pre-submission Information are different for Submissions (see Appendix B) and Resubmissions (see Appendix C). These templates may also be downloaded from the pCODR section of the CADTH website, www.cadth.ca/pcodr.

3.1 Pre-submission information for New Submissions to pCODR

Pre-submission information is required by the pCODR program in order to optimize the submission planning and review process. The pCODR program recognizes that Submitters may not be able to complete all sections set out in the Pre-submission Information Requirements Form at the time of providing advanced notification; however, at minimum, the pCODR program will require that a Submitter complete the following:

- Non-proprietary name of drug
- Indication
- Requested reimbursement criteria
- Date of Notice of Compliance (NOC) (issued or anticipated; including day, month, year)
- Anticipated date of filing this submission or resubmission with CADTH (day, month, year)
- Indicate if there is a companion diagnostic test associated with the drug
- Health Canada Review Type

- List of Reimbursement and Regulatory Decision Status in other countries/regions of proposed drug for review, if available.

For the minimum of 120 calendar days to be counted, the above information requirements must be completed and submitted to the pCODR program via the Pre-submission Information Requirements Form. If any of the above information is not provided, the Pre-submission Information Requirements Form may not be accepted.

Other sections within the Pre-submission Information Requirements Form must be completed and updated at the time of filing a submission or resubmission to the pCODR program.

If a Resubmission is because new information becomes available during the review process but before the pERC Final Recommendation is issued, Pre-submission Information does not need to be provided to the pCODR program.

A completed Pre-submission Information Requirements Form is required by pCODR before a pre-submission meeting is agreed upon. While some allowance will be made where information is not available to complete some sections of the form, the pCODR program reserves the right to request further information be provided before permitting the pre-submission meeting.

Tumour Groups will need to work with one of their jurisdictional PAG members to bring forward their intention to make a Submission or Resubmission to the pCODR program through the completion of the Pre-submission Information Requirements Form. The PAG will assist in determining if the Submission or Resubmission would be of local or national scope before the Tumour Group would file a Submission or Resubmission.

If the Submitter is a Tumour Group, the manufacturer of the drug being considered for Submission will be notified by pCODR during the Pre-submission planning phase and following the pre-submission meeting that a Submission is under consideration and given the opportunity to participate in the Submission by providing support to the Tumour Group in collating and preparing clinical and economic information for the Submission.

Pre-submission Information provided to pCODR should be updated at the time of filing a Submission or Resubmission, as needed.

Submitters are requested to advise the pCODR program of changes in the anticipated date of filing a Submission or Resubmission as soon as possible. Submitters should confirm the anticipated date of filing the complete Submission or Resubmission and the requested reimbursement criteria at least five (5) business days prior to the posting date of a pending submission. Pending submissions are issued one month in advance of the anticipated filing date.

If Pre-submission Information is not provided as outlined in these guidelines or the anticipated Submission or Resubmission filing date is not confirmed in accordance with the above requirements, there may be a delay in the processing and review of the Submission or Resubmission by pCODR.

Submitters should contact the pCODR program if they encounter difficulties obtaining the information necessary to complete the Pre-submission Information Requirements Form.

Pre-submission Information should be provided to pCODR by email at pcodrsubmissions@cadth.ca or through the secure Collaborative Workspaces, which is accessed through the pCODR section of the CADTH website. If Submitters want to provide Pre-submission Information through the secure

Collaborative Workspaces, they must first register on the website. Details on registration can be found on the pCODR section of the CADTH website (www.cadth.ca/pcodr).

3.2 Pre-submission information for Resubmissions to pCODR

In addition to the above requirements outlined in section 3.1 of this guideline, Submitters will be required to complete the *CADTH pan-Canadian Oncology Drug Review Resubmission Eligibility Form* (see Appendix D).

Both the *Pre-submission Information for a Resubmission* and the *CADTH pan-Canadian Oncology Drug Review Resubmission Eligibility Form* **must be submitted together** in Word document format to pCODR by email at pcodrsubmissions@cadth.ca or through the secure Collaborative Workspaces, which is accessed through the pCODR section of the CADTH website.

4. Pre-submission Meetings

Submitters may request pre-submission meetings with pCODR to discuss and clarify general submission requirements and procedures and/or submission guidelines for a specific drug or indication. In addition, Submitters are encouraged to provide information about drugs/indications in the pipeline (i.e., drugs or indications for which Submissions will be filed more than 12 months from the meeting date) during pre-submission meetings.

The information and advice provided by the pCODR program at the pre-submission meeting will be based on the *pCODR Submission Guidelines* in effect at the time of the meeting and the information provided will be non-binding. At the time of filing the complete Submission, Submitters should ensure that the Submission conforms to the requirements in effect at that time. Submitters should note that pCODR may request Additional Information or material after receipt of the Submission in order to complete the review.

If the Submitter is a Tumour Group, the Pre-submission meeting may also be used to determine which Submission Requirements, as outlined in the *pCODR Submission Guidelines*, may be waived. The PAG member representing the Tumour Group's Provincial Cancer Agency or Ministry of Health may also be invited to attend the pre-submission meeting.

Requests for pre-submission meetings should be made at least four months in advance of the anticipated filing date of the Submission and directed to pCODR by email at pcodrinfo@cadth.ca.

4.1 Frequency and Duration of Pre-submission Meetings

In order to ensure fair access to pCODR program staff and relevant experts (if appropriate) involved in the pCODR review process:

- there will be a limit of one meeting per anticipated Submission.
- individual manufacturers are limited to one meeting in a six month period, however if the schedule permits, additional meeting time may be afforded.

All pre-submission meetings will be scheduled for a maximum of up to *one and a half* hours.

Manufacturers are encouraged to discuss more than one Submission per meeting and to provide information on drugs in their pipeline.

4.2 Pre-submission Meeting Requirements

At the time of requesting the meeting, Submitters will be required to provide a completed Pre-submission Information Requirements Form (see Appendix B and C), the purpose of the meeting, a draft meeting agenda and proposed attendees.

Five business days prior to the scheduled meeting, Submitters are required to provide a final agenda, the list of confirmed attendees and presentation slides to allow pCODR program staff sufficient time to prepare for the discussion otherwise the meeting may be cancelled without prejudice to the Submission.

4.3 Types of Pre-submission Meetings

4.3.1 Anticipated Submissions Meetings

The purpose of these meetings is to provide an opportunity for the Submitter to introduce a drug to pCODR. Information may be sought from pCODR on the submission requirements for the drug, including the approach to the economic evaluation. An anticipated submission meeting is held when a submission to pCODR is *anticipated to occur within four months*, irrespective of Health Canada's targeted date for issuing the NOC or NOC/c. These meetings are generally one hour in length, however if more than one anticipated submission is presented, consideration will be given to schedule up to one and a half hours.

4.3.2 General pCODR Process Meetings

The purpose of these meetings is for the pCODR program to clarify the submission requirements and procedures with Submitters who have not previously submitted a drug for pCODR review. This information can typically be communicated through emails and teleconferences, with in person meetings reserved for exceptional situations. These meetings are generally 45 minutes in length.

APPENDIX A: pCODR Definitions

pCODR Definitions

The following definitions shall apply to this document, unless otherwise stated.

Additional Information — any information that is requested by the pCODR program, Guidance Panel, pERC, and required to complete the review of the Submission or Resubmission, or to explain or clarify information related to the Submission or Resubmission. Providing this information does not affect the review queue; however, if there is a delay in providing it or if the quantity and complexity of the requested information is significant, there may be a consequent delay in completion of the review. In exceptional cases, PAG may request additional information on a Submission which extends beyond the submitted scope of the review. Revision of review scope may be considered by pCODR in very limited instances, based on jurisdictional input, feasibility to conduct the revised review and clinical importance. All three criteria must be met for scope modification.

Business Day — any day (other than a Saturday, Sunday, statutory holiday, or company holiday) on which CADTH is open for business during normal business hours.

Companion Diagnostic Test - A companion diagnostic test is a medical device that provide information that is essential for the safe and effective use of corresponding drugs or biological products. They can identify patients who are likely to benefit or experience harms from particular therapeutic products, or monitor clinical response to optimally guide treatment adjustments. Companion diagnostics detect specific biomarkers that predict more favourable responses to particular therapeutic products.

Drug - an active substance considered to be a Drug under the Canadian *Food and Drugs Act* and *Food and Drug Regulations*, which is sold for human use (e.g., includes biosimilars, radiopharmaceuticals, among others)**.**

Manufacturer — a Drug Manufacturer.

PAG — Provincial Advisory Group provides operational, as well as some strategic advice, to ensure pERC recommendations are useful to drug funding decision makers. The PAG consists of appointed representatives from each of the Federal drug plans, provincial/territorial Ministries of Health and Provincial Cancer Agencies participating in the pCODR. The PAG is accountable to the pCODR Advisory Committee.

Pre-submission Information — the information required by pCODR during the pre-submission phase, as detailed in a Pre-submission Information Requirements Form, in order to optimize the submission planning and review process. Submitters are requested to file this information at least 120 calendar days before the anticipated date of filing the complete submission. If the 120th day falls on a weekend or statutory holiday, the following business day will be applied.

Provincial Cancer Agencies - those provincially funded organizations or programs mandated with implementing a broad range of cancer-related health services, such as cancer control strategies, provision of care delivery, and cancer research and systems innovation.

Resubmission — the request by the Submitter to have an original Submission, that is under review or had received a Final Recommendation, reviewed again through the pCODR process on the basis of New Information that was not previously provided in the original Submission or considered by pERC.

Submission - a submission to the pCODR consisting of:

- an electronic request (e.g., on CD/DVD or on-line submission through the password-protected area of the pCODR section of the CADTH website) provided by the Submitter with

supporting documentation, to have a Drug funded by a Federal drug plan, P/T Ministry of Health or Provincial Cancer Agency participating in the pCODR process; or

- a request, together with supporting documentation, if any, made by the PAG, to consider the funding status of Drugs already funded or previously reviewed for funding by one or more of the participating Federal, Provincial or Territorial Ministries of Health or Provincial Cancer Agencies, as required.

Submitter — the person, corporation, or entity filing a Submission or Resubmission.

Tumour Groups — A clinical and/or research group, officially affiliated with a provincial cancer agency or a provincial/territorial Ministry of Health, where medical/surgical cancer specialists, health care professionals and researchers with common interest/expertise in managing tumours related to a specific area of the body (e.g. breast or lung) work together to share information, make new discoveries and develop consistent protocols/best practices for treating patients.

APPENDIX B: pCODR Pre-submission Information Requirements Form – Submissions

SUBMITTER/MANUFACTURER INFORMATION
***Name of submitter/manufacturer:** ***Primary contact for submission:** *Provide name, title, email, phone number* ***Back-up/secondary contact for submission:** *Provide name, title, email, phone number*
DRUG INFORMATION
***Name of drug (non-proprietary and brand):** **Is the brand name to be kept confidential until Notice of Compliance (NOC) or Notice of Compliance with conditions (NOC/c) is issued?** Yes ☐ No ☐ Not applicable ☐ ***Indication to be reviewed:** *State if the indication is approved or under review by Health Canada* **Dosing (schedule and duration) and route of administration**: **Available strengths:** ***Requested reimbursement criteria**: **A copy of the product monograph[1] is included with this advance notification:** Yes ☐ No ☐ **Type of submission (check as appropriate):** ☐ New drug ☐ New indication
COMPANION DIAGNOSTIC
***Please indicate if there is a companion diagnostic test associated with the identification of the eligible patient population for the proposed drug submission:** Yes ☐ No ☐

* Required Field that must be completed

[1] Manufacturers are asked to provide a PDF copy of the current approved product monograph (not required for submissions filed on a pre-NOC basis, or if not yet available from Health Canada for submissions to be filed on a post-NOC basis).

HEALTH CANADA REVIEW TYPE

***The drug is undergoing review by Health Canada through an expedited pathway:**
☐ N/A (standard review pathway)
☐ Priority review
☐ Notice of Compliance with conditions (NOC/c) filed at the outset
☐ Other expedited pathway (please specify)

HEALTH CANADA CONSENT LETTER

As described in *Notice to Industry: Aligned Reviews Between Health Canada and Health Technology Assessment Organizations*, manufacturers can consent to Health Canada sharing information and documents with CADTH. Please indicate below if you are willing to participate in the information sharing process between Health Canada and CADTH. **Note:** Submitters are required to provide Health Canada with a completed consent form to participate in this process.

☐ **Yes, Health Canada will be or has been provided with a completed consent form.**
☐ **No, Health Canada will not be provided with a completed consent form.**

KEY DATE INFORMATION (DAY-MONTH-YEAR)

Date drug accepted for review by Health Canada: DD-MM-YYYY
***Date of NOC (issued or anticipated): DD-MM-YYYY**
***Anticipated date of filing this submission with CADTH: DD-MM-YYYY**

PRESUBMISSION MEETING

Please indicate if you would like to request a Pre-submission meeting[2]: Yes ☐ No ☐

Please confirm the date of your last presubmission meeting with pCODR: DD-MM-YYYY

CANADIAN TRIALS & PATIENT ACCESS PROGRAMS

- *Provide the total number of Canadian patients and the number of patients per province who participated in the trials submitted for review.*
- *Provide total number of Canadian patients and the number of patients per province acquiring the drug through Health Canada's Special Access Program (SAP) and/or compassionate programs.*

CLINICAL OVERVIEW

This section should not exceed ONE page and should include:

[2] Pre-submission meetings are not applicable for biosimilars; please see pCODR Submission Guidelines for Biosimilars

- *place in therapy (e.g., first-line, niche), current standard of care (including best supportive care), and treatment algorithm used in Canada*
- *provide a diagram for an algorithm of the current drugs funded in Canada and how the proposed drug under review would be positioned in this setting*
- *a brief overview of key trials including outcomes, relevant data, trial design, limitations, mean number of treatment cycles per patient or duration of treatment, doses used*
- *citations and hyperlinked URLs to main articles or pivotal trial, if clinical data are published, or to an abstract or poster.*
- *NCI clinical trial number and URL*

ECONOMIC OVERVIEW

This section should not exceed ONE page and should include:

- *a brief overview, description of model parameters (outcomes, comparators and rationale for choice, doses [% intensity], dosing schedule, number of cycles, etc., as applicable)*
    - *If possible, indicate if the anticipated pharmacoeconomic evaluation will be a cost-utility analysis, cost-minimization analysis, or other (please specify).*
- *a cost table for comparators*
- *high-level information on budget impact analyses highlighting differences for CADTH's jurisdictional customers[3] based on comparators or based on design of the program responsible for drug funding.*

INTERNATIONAL COMPARISONS

- *Please provide a direct URL link to the respective regulatory and reimbursement decisions. The following template example below may be used:*

**Regulatory status of [Drug Name and Indication] in the following countries:*

Country/Regulatory Body	*Regulatory Status & Date*	*Direct URL to drug approval decision*
U.S.		
UK		
EMA		
Australia		

**Health Technology Assessment decision in the following countries/organizations:*

Country/HTA organization	*Recommendation & Date or Review Status*	*Direct URL to HTA recommendation*
Quebec INESSS		
UK NICE		
Scotland SMC		

* Required Field that must be completed

[3] The term "CADTH's jurisdictional customers" refers to the federal drug plans, provincial and territorial Ministries of Health and provincial cancer agencies that participate in the pCODR process.

Germany IQWiG		
France HAS		
Australia PBAC		

- *For submissions to pCODR, provide hyperlinked URLs to the following international guidelines for the drug and indication(s) under review, if available:*
    - *NCCN*
    - *ASCO*
    - *ESMO*

APPENDIX C: pCODR Pre-submission Information Requirements Form – Resubmissions

SUBBMITTER/MANUFACTURER INFORMATION
***Name of submitter/manufacturer:** ***Primary contact for resubmission:** *Provide name, title, email, phone number* ***Back-up/secondary contact for resubmission:** *Provide name, title, email, phone number*
DRUG INFORMATION
***Name of drug (non-proprietary and brand):** ***Indication to be reviewed:** *State if the indication is approved or under review by Health Canada* **Dosing (schedule and duration) and route of administration**: **Available strengths:** ***Requested reimbursement criteria**: ***Date of Notice of Compliance (NOC) or Notice of Compliance with conditions (NOC/c) (issued or anticipated):** ***Anticipated resubmission filing date**: DD-MM-YYYY **A copy of the most recently approved product monograph[4] is included**: Yes ☐ No ☐
COMPANION DIAGNOSTIC
***Please indicate if there is a companion diagnostic test associated with the identification of the eligible patient population for the proposed drug submission:** Yes ☐ No ☐
HEALTH CANADA REVIEW TYPE
***The drug is undergoing review by Health Canada through an expedited pathway:** ☐ N/A (standard review pathway) ☐ Priority review ☐ Notice of Compliance with conditions (NOC/c) filed at the outset ☐ Other expedited pathway (please specify)

* Required Field that must be completed

[4] A copy of the product monograph is not required if the resubmission is based on new cost information only.

PRESUBMISSION MEETING

Please indicate if you would like to request a Pre-submission meeting[5]: Yes ☐ No ☐

Please confirm the date of your last Pre-submission meeting with pCODR: DD-MM-YYYY

HEALTH CANADA CONSENT LETTER

As described in *Notice to Industry: Aligned Reviews Between Health Canada and Health Technology Assessment Organizations*, manufacturers can consent to Health Canada sharing information and documents with CADTH. Please indicate below if you are willing to participate in the information sharing process between Health Canada and CADTH. **Note:** Submitters are required to provide Health Canada with a completed consent form to participate in this process.

☐ **Yes, Health Canada will be or has been provided with a completed consent form.**
☐ **No, Health Canada will not be provided with a completed consent form.**

CANADIAN TRIALS & PATIENT ACCESS PROGRAMS

- *Provide the total number of Canadian patients and the number of patients per province who participated in the trials submitted for review.*
- *Provide total number of Canadian patients and the number of patients per province acquiring the drug through Health Canada's Special Access Program (SAP) and/or compassionate programs.*

RESUBMISSION INFORMATION

Previous submitter/manufacturer:

- *Indicate if it is the same or a different submitter/manufacturer who filed the original submission.*

Rationale for the resubmission:

- *Indicate if the reason for the resubmission is due to new clinical or new economic evidence.*
- *Identify reasons or points in the pCODR Expert Review Committee (pERC) recommendation, as applicable, that the new information addresses.*

CADTH PAN-CANADIAN ONCOLOGY DRUG REVIEW RESUBMISSION ELIGIBILITY FORM

Please ensure that you also complete the CADTH pan-Canadian Oncology Drug Review Resubmission Eligibility Form: Yes ☐

[5] Pre-submission meetings are not applicable for biosimilars; please see pCODR Submission Guidelines for Biosimilars

NEW[6] CLINICAL INFORMATION

This section should not exceed ONE page and should include:

- *a description of any new clinical information that was not available at the time of the last review by the CADTH pan-Canadian Oncology Drug Review (pCODR)*
- *details that address the following points, as relevant to the new clinical information available for the resubmission:*
- *place in therapy (e.g., first-line, niche), current standard of care (including best supportive care), and treatment algorithm used in Canada*
- *provide a diagram for an algorithm of the current drugs funded in Canada and how the proposed drug under review would be positioned in this setting*
- *a brief overview of key trials including outcomes, relevant data, trial design, limitations, mean number of treatment cycles per patient or duration of treatment, doses used*
- *citations and hyperlinked URLs to main articles or pivotal trial, if clinical data are published, or to an abstract or poster.*
- *NCI clinical trial number and URL*

NEW[2] ECONOMIC INFORMATION

This section should not exceed ONE page and should include:

- *a description of any new economic information that was not available at the time of the last review by pCODR*
- *details that address the following points, as relevant to the new economic information available for the resubmission:*
  - *a <u>brief overview</u>, description of model parameters (outcomes, comparators and rationale for choice, doses [% intensity], dosing schedule, number of cycles, etc., as applicable)*
    - *If possible, indicate if the anticipated pharmacoeconomic evaluation will be a cost-utility analysis, cost-minimization analysis, or other (please specify).*
  - *a cost table for comparators*
  - *<u>high-level information</u> on budget impact analyses highlighting differences for CADTH's jurisdictional customers[7] based on comparators or based on design of the program responsible for drug funding.*

INTERNATIONAL COMPARISONS

- *Please provide a direct URL link to the respective regulatory and reimbursement decisions. The following template example below may be used:*

  **Regulatory status of [Drug Name and Indication] in the following countries:*

Country/Regulatory Body	*Regulatory Status & Date*	*Direct URL to drug approval decision*
U.S.		

[6] "New" clinical or economic information in accordance with the pCODR Procedures and Submission Guidelines; please review the appropriate document for how new clinical and economic information is defined.

[7] The term "CADTH's jurisdictional customers" refers to the federal drug plans, provincial and territorial Ministries of Health and provincial cancer agencies that participate in the pCODR process.

UK		
EMA		
Australia		

**Health Technology Assessment decision in the following countries/organizations:*

Country/HTA organization	*Recommendation & Date or Review Status*	*Direct URL to HTA recommendation*
Quebec INESSS		
UK NICE		
Scotland SMC		
Germany IQWiG		
France HAS		
Australia PBAC		

- *For submissions to pCODR, provide hyperlinked URLs to the following international guidelines for the drug and indication(s) under review, if available:*
  - *NCCN*
  - *ASCO*
  - *ESMO*

* Required Field that must be completed, if available.

APPENDIX D: CADTH pan-Canadian Oncology Drug Review Resubmission Eligibility Form

1. APPLICANT INFORMATION (TO BE COMPLETED BY SUBMITTER)
Name of submitter/manufacturer: **Primary contact for resubmission:** *Provide name, title, email, phone number* **Back-up/secondary contact for resubmission:** *Provide name, title, email, phone number*
2. DRUG INFORMATION (TO BE COMPLETED BY SUBMITTER)
Name of drug (non-proprietary and brand): **Indication:** **Requested reimbursement criteria**: **Date of Notice of Compliance (NOC) or Notice of Compliance with conditions (NOC/c) (issued or anticipated):** DD-MM-YYYY **Anticipated resubmission filing date**: DD-MM-YYYY
3. RATIONALE FOR THE RESUBMISSION INFORMATION (TO BE COMPLETED BY SUBMITTER)
Indicate if the reason for the proposed resubmission is for new clinical and/or new economic evidence. Check all that apply: **New clinical information** ☐ ***Improved efficacy*** ☐ ***Improved safety*** ☐ ***Randomized Controlled Trial(s)*** Yes ☐ No ☐ **New economic information** ☐
4. ISSUES ADDRESSED BY THE NEW INFORMATION (TO BE COMPLETED BY SUBMITTER)
• Using the table below, identify the issues raised in the CADTH pCODR Expert Review Committee (pERC) recommendation that the new information addresses. Add or remove rows as required.

Issue raised in the pERC recommendation document (applies to the initial recommendation if a final recommendation has not been issued)	**Identify new evidence that addresses the issue**
Clearly state the issue identified in the pERC recommendation	Add brief summary of new evidence
Clearly state the issue identified in the pERC recommendation	Add brief summary of new evidence
Clearly state the issue identified in the pERC recommendation	Add brief summary of new evidence

5. SUMMARY OF NEW CLINICAL INFORMATION (TO BE COMPLETED BY SUBMITTER)

This section should not exceed three (3) pages in length, using a minimum 11 point font on 8 ½" by 11" paper, and should include:

- *a description of any new clinical information that was not available at the time of the last pCODR review*
- *a brief overview of new clinical studies including a description of the study design, population, intervention, comparators and outcomes*
- *a brief summary of the key results from the new studies*
  - *citations and hyperlinked URLs to main articles or pivotal trial, if clinical data are published, or to an abstract or poster, if clinical data are published*
  - *NCI clinical trial number and URL*

6. SUMMARY OF NEW ECONOMIC INFORMATION (TO BE COMPLETED BY SUBMITTER)

This section should not exceed three (3) pages in length, using a minimum 11 point font on 8 ½" by 11" paper, and should include:

- *a description of any new economic information that was not available at the time of the last pCODR review.*

7. ELIGIBLITY ASSESSMENT (FOR CADTH USE ONLY)

Issue raised in pERC recommendation document	**CADTH assessment**
To be completed by CADTH	*To be completed by CADTH*

8. CONCLUSION (FOR CADTH USE ONLY)
Based on the information provided by the Submitter, it is concluded that the resubmission: • **Meets the eligibility criteria for the pCODR process** ☐ • **Does not meet the eligibility criteria for the pCODR process** ☐ **Date of Decision:**
9. REASON(S) FOR CONCLUSION (FOR CADTH USE ONLY)
To be completed by CADTH
10. REQUEST FOR RE-EVALUATION (IF APPLICABLE, TO BE COMPLETED BY SUBMITTER)
This section should not exceed one page in length, using a minimum 11 point font on 8 ½" by 11" paper, and should include: • *a description of any discrepancies or errors*
11. CADTH RESPONSE & DECISION (FOR CADTH USE ONLY)
To be completed by CADTH **Date of Decision:**

Note: Please submit this form together with the Pre-Submission Information – Resubmission form as a Word document to the pCODR program by email at pcodrsubmissions@cadth.ca or through the secure Collaborative Workspaces, which is accessed through the pCODR section of the CADTH website.

APPENDIX E: pCODR Pre-submission Information Requirements Form – Biosimilars

SUBMITTER/MANUFACTURER INFORMATION
***Name of submitter/manufacturer:** ***Primary contact for submission:** *Provide name, title, email, phone number* ***Back-up/secondary contact for submission:** *Provide name, title, email, phone number*
DRUG INFORMATION
***Name of drug (non-proprietary and brand):** **Is the brand name to be kept confidential until Notice of Compliance (NOC) or Notice of Compliance with conditions (NOC/c) is issued?** Yes ☐ No ☐ Not applicable ☐ ***Indication to be reviewed:** *State if the indication is approved or under review by Health Canada* **Dosing (schedule and duration) and route of administration**: **Available strengths:** ***Requested reimbursement criteria**: **A copy of the product monograph[8] is included with this advance notification:** Yes ☐ No ☐ **Type of submission (check as appropriate):** ☐ Biosimilar
COMPANION DIAGNOSTIC
***Please indicate if there is a companion diagnostic test associated with the identification of the eligible patient population for the proposed drug submission:** Yes ☐ No ☐
HEALTH CANADA REVIEW TYPE
***The drug is undergoing review by Health Canada through an expedited pathway:** ☐ N/A (standard review pathway) ☐ Priority review

* Required Field that must be completed

[8] Manufacturers are asked to provide a PDF copy of the current approved product monograph (not required for submissions filed on a pre-NOC basis, or if not yet available from Health Canada for submissions to be filed on a post-NOC basis).

☐ Notice of Compliance with conditions (NOC/c) filed at the outset
☐ Other expedited pathway (please specify)

HEALTH CANADA CONSENT LETTER

As described in *Notice to Industry: Aligned Reviews Between Health Canada and Health Technology Assessment Organizations*, manufacturers can consent to Health Canada sharing information and documents with CADTH. Please indicate below if you are willing to participate in the information sharing process between Health Canada and CADTH. **Note:** Submitters are required to provide Health Canada with a completed consent form to participate in this process.

☐ **Yes, Health Canada will be or has been provided with a completed consent form.**
☐ **No, Health Canada will not be provided with a completed consent form.**

KEY DATE INFORMATION (DAY-MONTH-YEAR)

Date drug accepted for review by Health Canada: DD-MM-YYYY

***Date of NOC (issued or anticipated): DD-MM-YYYY**

***Anticipated date of filing this submission with CADTH: DD-MM-YYYY**

CANADIAN TRIALS & PATIENT ACCESS PROGRAMS

- *Provide the total number of Canadian patients and the number of patients per province who participated in the trials submitted for review.*
- *Provide total number of Canadian patients and the number of patients per province acquiring the drug through Health Canada's Special Access Program (SAP) and/or compassionate programs.*

CLINICAL OVERVIEW

This section should not exceed ONE page and should include:

- *place in therapy (e.g., first-line, niche), current standard of care (including best supportive care), and treatment algorithm used in Canada*
- *provide a diagram for an algorithm of the current drugs funded in Canada and how the proposed drug under review would be positioned in this setting*
- *a brief overview of key trials including outcomes, relevant data, trial design, limitations, mean number of treatment cycles per patient or duration of treatment, doses used*
- *citations and hyperlinked URLs to main articles or pivotal trial, if clinical data are published, or to an abstract or poster.*
- *NCI clinical trial number and URL*

ECONOMIC OVERVIEW

This section should not exceed ONE page and should include:

- *a brief overview, description of model parameters (outcomes, comparators and rationale for choice, doses [% intensity], dosing schedule, number of cycles, etc., as applicable)*
- *a cost comparison table for the biosimilar under review, the reference product and other biosimilars for the same indication(s) requested (if applicable)*

INTERNATIONAL COMPARISONS

- *Please provide a direct URL link to the respective regulatory and reimbursement decisions. The following template example below may be used:*

  **Regulatory status of [Drug Name and Indication] in the following countries:*

Country/Regulatory Body	*Regulatory Status & Date*	*Direct URL to drug approval decision*
U.S.		
UK		
EMA		
Australia		

  **Health Technology Assessment decision in the following countries/organizations:*

Country/HTA organization	*Recommendation & Date or Review Status*	*Direct URL to HTA recommendation*
Quebec INESSS		
UK NICE		
Scotland SMC		
Germany IQWiG		
France HAS		
Australia PBAC		

- *For submissions to pCODR, provide hyperlinked URLs to the following international guidelines for the drug and indication(s) under review, if available:*
  - *NCCN*
  - *ASCO*
  - *ESMO*