pan-Canadian Oncology Drug Review
Submission Guidelines

June 2017
# RECORD OF UPDATES

<table>
<thead>
<tr>
<th>Update</th>
<th>Version</th>
<th>Reported on pCODR Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original</td>
<td>March 2011</td>
<td>April 1, 2011</td>
</tr>
<tr>
<td>1</td>
<td>May 2011</td>
<td>May 2, 2011</td>
</tr>
<tr>
<td>2</td>
<td>May 2011</td>
<td>May 5, 2011</td>
</tr>
<tr>
<td>3</td>
<td>February 2016</td>
<td>February 1, 2016</td>
</tr>
<tr>
<td>4</td>
<td>February 2016</td>
<td>February 25, 2016</td>
</tr>
<tr>
<td>5</td>
<td>March 2016</td>
<td>March 24, 2016</td>
</tr>
<tr>
<td>6</td>
<td>March 2017</td>
<td>March 16, 2017</td>
</tr>
<tr>
<td>7</td>
<td>June 2017</td>
<td>June 13, 2017</td>
</tr>
</tbody>
</table>
INQUIRIES

Inquiries and correspondence about CADTH’s pan-Canadian Oncology Drug Review (pCODR) program should be directed to:

CADTH pan-Canadian Oncology Drug Review
154 University Avenue, suite 300
Toronto, ON
M5H 3Y9

Telephone: 1-866-988-1444
Fax: 1-866-662-1778
Email: pcodrinfo@cadth.ca
Website: www.cadth.ca/pcodr
TABLE OF CONTENTS

RECORD OF UPDATES .......................................................................................................................... i
INQUIRIES ........................................................................................................................................ ii
TABLE OF CONTENTS ........................................................................................................................ iii

1 Purpose .............................................................................................................................................. 1
2 Introduction ....................................................................................................................................... 1
3 Definitions .......................................................................................................................................... 1

4 The Submission Process .................................................................................................................. 3
   4.1 Pre-submission Requirements ................................................................................................. 3
   4.2 Submissions ............................................................................................................................... 3
       4.2.1 Eligible Submissions ......................................................................................................... 3
       4.2.1.1 Post-NOC or Post-NOC/c Submissions ................................................................. 4
       4.2.1.2 Pre-NOC or Pre-NOC/c Submissions .................................................................. 4
       4.2.2 Commencement of Process ......................................................................................... 5
       4.2.3 Filing of Submissions ................................................................................................. 6
       4.2.4 Screening of Submission for Completeness ............................................................ 6
       4.2.5 Tracking ..................................................................................................................... 7
       4.2.6 Priority and Order of Review ................................................................................... 7
       4.2.7 Inquiries .................................................................................................................... 8
       4.2.8 Disclosure of Information ....................................................................................... 8
   4.3 Post-NOC or Post-NOC/c Submission Requirements .............................................................. 9
       4.3.1 Category 1 Post-NOC or Post-NOC/c Submission Requirements ....................... 10
       4.3.2 Additional Information ............................................................................................. 16
       4.3.3 Post-NOC or Post-NOC/c Submission Requirements for Biosimilars ............. 17
   4.4 Pre-NOC or Pre-NOC/c Submission Requirements ............................................................... 17
       4.4.1 Category 1 Pre-NOC or Pre-NOC/c Submission Requirements ....................... 18
       4.4.2 Category 2 Pre-NOC or Pre-NOC/c Submission Requirements ....................... 19
       4.4.2.1 Category 2 Requirements at time of NOC or NOC/c ..................................... 20
       4.4.3 Additional Information (see section 4.3.2) ............................................................. 20
       4.4.4 Pre-NOC or Pre-NOC/c Submission Requirements for Biosimilars ............... 21

5 The Resubmission Process ............................................................................................................ 21
   5.1 Resubmissions ....................................................................................................................... 21
       5.1.1 Eligible Resubmissions ........................................................................................... 21
       5.1.2 Filing of Resubmissions ......................................................................................... 22
       5.1.3 Priority and Order of Review ............................................................................... 22
       5.1.4 Confidentiality ........................................................................................................ 22
   5.2 Resubmission Requirements ................................................................................................. 22
       5.2.1 For Resubmissions Filed (as described in first three bullets in Table 2) .......... 23
       5.2.2 For All Resubmissions ......................................................................................... 23

APPENDIX A: pCODR Definitions ................................................................................................. 29

APPENDIX B: Participating P/T Ministries of Health and Provincial Cancer Agencies ............ 33

APPENDIX C: Guidance to PAG and Tumour Groups when Making pCODR Submissions ...... 39

APPENDIX D: Delivery of Mail ......................................................................................................... 41

APPENDIX E: Electronic File Format Requirements ........................................................................ 42

APPENDIX F: Submission and Resubmission Checklists ................................................................. 46

APPENDIX F1: Post NOC or NOC/c Submission Requirements Checklist ................................ 47

APPENDIX F2: Pre-NOC or Pre-NOC/c Submission Requirements Checklist ........................ 49
1 Purpose

The purpose of the pan-Canadian Oncology Drug Review Submission Guidelines is to:

- provide guidance to Submitters in the preparation of Submissions.
- ensure Submissions meet the needs of the pan-Canadian Oncology Drug Review (pCODR)

2 Introduction

pCODR evaluates clinical evidence and cost-effectiveness information on new cancer drugs and uses this evaluation to provide cancer drug funding recommendations to Federal drug plans, provincial/territorial Ministries of Health (excluding Quebec) and provincial cancer agencies. These recommendations are used by jurisdictions to guide their drug funding decisions. On April 1, 2014, pCODR was transferred to the Canadian Agency for Drugs and Technologies in Health (CADTH) to consolidate policy direction across Canada’s drug review programs and to strengthen the pCODR governance structure in order to ensure its long-term sustainability.

The review process is initiated when a Drug Submission is made to the pCODR program for a New Oncology Drug or an Oncology Drug with a New Indication or a Biosimilar used for active treatment of cancer. Submissions of Drugs not used for active treatment of cancer, including supportive treatments that may be used in the care of patients with cancer, are to be sent to the Common Drug Review. More information on the Common Drug Review can be found at www.cadth.ca/cdr.

The pCODR process, with its detailed assessment of evidence conducted by an expert review committee, and opportunity for input at various stages of the review process by patients, clinicians, pharmaceutical manufacturers, the Provincial Advisory Group (PAG) and the Submitter, which may be a provincially recognized clinician-based tumour group, reduces duplication of this effort by each individual federal, provincial and territorial drug plan and cancer agency and ensures reviews are done in a timely manner.

The creation of pCODR brings consistency and clarity to the cancer drug review process, allowing for greater understanding by all stakeholders, while ensuring individual federal, provincial and territorial governments can make funding decisions informed by evidence that has been carefully evaluated by experts.

An overview of the pCODR review process is presented in Figure 1. Complete details of the pCODR procedures are outlined in the pCODR Procedures document available on the pCODR section of the CADTH website (www.cadth.ca/pcodr).

3 Definitions

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

All references to number of days in this document are in pCODR Business Days, as defined in Appendix A, unless otherwise specified.
Figure 1. pCODR Review Process

1. Conduct Pre-Submission Planning activities including getting input from PAG and notifying Patient Advocacy Groups

2. Prepare & submit Request for Drug Review

3.1 Screen Submission and Initiate Review Process

3.2 Collect Patient Advocacy Group (or Individual Patients – no patient groups) Input

3.2b Collect Registered Clinician Input

4.1 Conduct Clinical Review

4.1.1/4.2.2 Clarify info with Submitter during review

4.2 Conduct Economic Review

5. Summarize & Review with pERC

6. Prepare & Publicly Post Initial Recomm., Post Reviews

7.1 Get Feedback from Submitter (and impacted manufacturer)

7.4 Eligible for Early Conversion?

No

7.2 Get Feedback from PAG

7.3b Get Feedback from Patient Advocacy Group (or Individual Patients when there are no patient groups)

7.3b Get Feedback from Registered Clinician

Yes

8. Summarize & Review with pERC

9. Prepare & Publicly Post Final Recomm. & Post Input

End

*Includes pCODR Program, Clinical Guidance Panel, Economic Guidance Panel, pCODR Expert Review Committee (pERC) and Provincial Advisory Group (PAG)

†Next steps could include Recommendation implementation, Procedural Review or Resubmission
4 The Submission Process

A Submission to the pCODR program represents a Submission to all Federal drug plans, P/T Ministries of Health and Provincial Cancer Agencies (excluding Quebec). A Submission must adhere to the content, format, and organization guidelines stipulated in this document.

While the pCODR Submission Guidelines describe the information that pCODR requires to conduct the review of the Drug, the Federal drug plans, individual participating P/T Ministries of Health and Provincial Cancer Agencies may require more information to be submitted, for regulatory or decision-making purposes. Refer to the Common Drug Review Submission Guidelines for Manufacturers on the CADTH website (www.cadth.ca/cdr) to prepare the submissions that meet the requirements of, and that are sent to, the participating Federal drug plans and P/T Ministries of Health. Federal drug plans and individual P/T Ministries of Health conduct an assessment of their own submission and will advise the Manufacturer on the completeness of their submission for their individual purposes. Submitters will need to work with each Provincial Cancer Agency to determine if additional requirements must be met for completeness of the submission. Please see Appendix B for a list of contacts from Federal drug plans, each P/T Ministry of Health and Provincial Cancer Agency.

4.1 Pre-submission Requirements

The pCODR process requires that Pre-submission Information be provided at least 120 calendar days before a complete Submission is filed. If the 120th day 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. Detailed Pre-submission Information requirements are outlined in the pCODR Pre-submission Guidelines, which can be found on the pCODR section of the CADTH website (www.cadth.ca/pcodr). At the time of filing a complete Submission, updated Pre-submission Information is required.

Submitters should confirm the targeted date of filing the complete Submission 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. Advance notice of this filing date will allow stakeholders to be notified and is intended to afford them sufficient time to prepare input on a Pending Submission.

Failure to provide the required Pre-submission Information or to confirm the anticipated filing date one month in advance may result in a delay in the processing and review of a Drug Submission by pCODR.

4.2 Submissions

4.2.1 Eligible Submissions

Eligible Submissions include New Oncology Drugs, Oncology Drugs with New Indications and Biosimilars that have or have not received a Notice of Compliance (NOC) or a Notice of Compliance with Conditions (NOC/c) from Health Canada. New Oncology Drugs, Oncology Drugs with New Indications and Biosimilars that have received a NOC or NOC/c are referred to in the pCODR review process as “Post-NOC or Post-NOC/c Submissions”. New Oncology Drugs with a pending NOC or NOC/c, Oncology Drugs with New Indications and Biosimilars that have a pending NOC or NOC/c or for which an application has not been submitted to Health Canada for
review are referred to in the pCODR review process as “Pre-NOC or Pre-NOC/c Submissions”. Following are descriptions for each of these types of eligible submissions:

### 4.2.1 Post-NOC or Post-NOC/c Submissions

A Post-NOC or Post-NOC/c Submission for a New Oncology Drugs are those for New Active Substances that have a NOC or NOC/c and that have not been marketed in Canada, regardless of when the NOC or NOC/c was issued. New Oncology Drugs include new salts of marketed products but do not include the following variations of existing products (line extensions) containing the same Active Substance(s):

- New dosage forms with the same route of administration (e.g., if a drug in tablet form becomes available in capsule form, a Submission for the capsule is not required)
- New strength of the same dosage form (e.g., if a 200 mg tablet becomes available in addition to an already-marketed 100 mg tablet, a Submission for the 200 mg tablet is not required).

A Post-NOC or Post-NOC/c Submission for an Oncology Drug with New Indication(s) are those for a New Indication(s) of a Drug that has either previously been reviewed by the pCODR or marketed prior to the establishment of the pCODR and:

- that has received a NOC or NOC/c for the indication
- the Drug has defined funding criteria by one or more of the Federal drug plans, P/T Ministry of Health / Provincial Cancer Agency and the P/T Ministries of Health, the Provincial Advisory Group (PAG) or Provincial Cancer Agencies have agreed that it should be submitted for review by pCODR; or
- the Drug is not funded by any of the Federal drug plans, P/T Ministries of Health / Provincial Cancer Agencies and the P/T Ministries of Health, PAG, or Provincial Cancer Agencies have agreed that it should be submitted for review by pCODR; or
- the Federal drug plans, P/T Ministries of Health, PAG or Provincial Cancer Agencies have requested the review of the Drug with New Indication(s).

### 4.2.1.2 Pre-NOC or Pre-NOC/c Submissions

A Pre-NOC or Pre-NOC/c Submission is one for a New Drug for which Health Canada is highly likely to issue a NOC or NOC/c within 6 months of the Submitter filing a Submission with the pCODR. In the case of Pre-NOC or Pre-NOC/c Submissions for New Oncology Drugs, the only Submitter that will be allowed to make a submission is the Manufacturer. This is because the Manufacturer is the only Submitter who will likely have the needed information on product price or anticipated product price to conduct an appropriate economic assessment.

A Pre-NOC or Pre-NOC/c Submission for an Oncology Drug with a New Indication(s) is one for which Health Canada is highly likely to issue a NOC or NOC/c within 6 months of the Submitter filing a Submission with the
pCODR or for which the indication is not likely to be submitted to Health Canada for review. Pre-NOC or Pre-NOC/c Submissions for Oncology Drugs with a New Indication may be filed by any Submitter type (see Appendix A for definition of Submitter). For Oncology Drugs with New Indications with no pending NOC (i.e., the indication is not likely to be submitted to Health Canada for review), the indication being submitted would reflect the current established standard of practice.

Although Health Canada cannot provide assurance that an NOC or NOC/c will be issued on a particular date or at all, Submitters may consider filing a Submission with pCODR if there have not been any significant issues raised by Health Canada.

*Note: If the submission is for an Oncology Drug with a New Indication that has not received a NOC or a NOC/c and is not likely to be submitted to Health Canada, please contact the pCODR Program for further guidance.*

All New Oncology Drugs and Oncology Drugs with New Indication(s) that are for active cancer treatment and that may be potentially funded by one or more of the participating Federal drug plans, P/T Ministries of Health/Provincial Cancer Agencies should be submitted to the pCODR for review to be eligible for funding consideration. Submissions may be made either Pre-NOC or Post-NOC.

Submissions for non-Oncology Drugs, including supportive treatments that may be used in the care of patients with cancer, are to be sent to the Common Drug Review. More information on the Common Drug Review can be found at [www.cadth.ca/cdr](http://www.cadth.ca/cdr).

Whenever there is uncertainty about whether a Submission should be made to the pCODR, Submitters are encouraged to contact the pCODR Program for clarity. The pCODR Program may consult with the participating Federal drug plans, P/T Ministries of Health and Provincial Cancer Agencies and the Common Drug Review in those cases where Drugs do not clearly fall into a category described above.

*Note: Submissions should continue to be made directly to Federal drug plans, P/T Ministries of Health/Provincial Cancer Agencies for the following Oncology Drugs until further notice:*

- New single source products that do not contain New Drugs (i.e., combination products),
- Line extensions of existing products, including new dosage forms with the same route of administration and new strengths of the same, dosage form. For other line extensions, contact the pCODR Program for direction,
- Generic products to be used in currently funded regimens.

*Note: Submissions for Biosimilars may be submitted Pre-NOC or Post-NOC.*

### 4.2.2 Commencement of Process

The pCODR process is initiated either:

- by the Manufacturer, a provincially recognized clinician-based Tumour Group, or the PAG filing a Submission with the pCODR Program; or
by the PAG or the pCODR Advisory Committee, filing a Request for Advice with the pCODR Program; or
by the Manufacturer, a provincially recognized clinician-based Tumour Group, or the PAG, filing a Resubmission with the pCODR Program.

Note: If the Submission is being made by a provincially recognized clinician-based Tumour Group or the PAG, please see Appendix C for further guidance and/or contact the pCODR Program for additional clarity. If the Submission pertains to an Oncology Drug with a New Indication that has not received a NOC or a NOC/c and is not likely to be submitted to Health Canada for review, contact the pCODR Program for additional clarity.

Note: Requirements for a Request for Advice will be developed when this mechanism is implemented by pCODR.

4.2.3 Filing of Submissions

Submitters may file a Submission through the secure portal; however, a Submitter must first register on the pCODR section of the CADTH website. Details on registration can be found at: https://www.cadth.ca/p codr/registration. Submissions may also be delivered to the pCODR Program by mail or courier (see Appendix D). Submissions are to be provided on CD or DVD or on a memory stick and not in hard copy. See Appendix E for the format and naming of the files.

At the same time as filing a Submission with pCODR, Submitters should contact individual Federal drug plans, P/T Ministries of Health/Provincial Cancer Agencies, to determine if additional information is required. These individual Federal drug plans, P/T Ministries of Health/Provincial Cancer Agencies will conduct their own assessment of the submission based on their specific requirements and applicable regulations.

- Submitters should not wait until both Category 1 and Category 2 Submission or Resubmission Requirements are satisfied before sending copies to the participating Federal drug plans, P/T Ministries of Health and Provincial Cancer Agencies (see section 4.3 and 4.4 for Category 1 and Category 2 Requirements).

- Instead, Submitters should upload to the portal or send CD/DVD copies or memory stick, as applicable, of Category 1 Submission and Resubmission Requirements to the participating Federal drug plans, P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from the pCODR Program that the Category 1 Requirements have been met.

- Additionally, Submitters should send CD/DVD copies or memory stick, as applicable, of Category 2 Submission and Resubmission Requirements to the participating Federal drug plans, P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from the pCODR Program that the Category 2 Requirements have been met.

4.2.4 Screening of Submission for Completeness

A screening of the Submission is conducted by the pCODR Program within five (5) business days of receipt to ensure that it meets the pCODR requirements outlined in the pCODR Submission Guidelines.
If the Submission is incomplete, the pCODR Program sends a notice to the Submitter advising what information is needed to complete the Submission.

When the Submission is complete, the pCODR Program sends an acknowledgement to the Submitter and publicly posts the date it was deemed complete.

4.2.5 Tracking

The pCODR Program posts the status of the review of all Submissions, Resubmissions, and Requests for Advice on the pCODR section of the CADTH website including target dates in the review process such as the target pERC meeting date.

In general, approximately one month prior to the anticipated submission date, after receiving confirmation from the Submitter to do so, the pCODR Program will post details of a Pending Submission including the Submitter and the target submission date. Stakeholders will also be notified of the funding conditions and/or criteria being requested by the Submitter. This posting is essential to adequately notify stakeholders who may provide input into the pCODR review process.

4.2.6 Priority and Order of Review

All Submissions, Resubmissions, and Requests for Advice made to pCODR are assigned to a tiered queue for review and placement on the pCODR Expert Review Committee (pERC) meeting agenda. The assignment to the review queue and placement on the pERC meeting is made jointly by the pCODR Program and the pERC Chair. Consultation with the Provincial Advisory Group (PAG) is sought as required.

Submissions are accepted on an ongoing basis. The pCODR Program publishes, on the pCODR section of the CADTH website, the targeted pERC meeting upon date on which a Submission may be deliberated. If adequate pre-submission notification is provided to pCODR for resource planning purposes, the targeted pERC meeting date is based on the posted pCODR review times (see Figure 1). In certain circumstances, including but not limited to, unavailability of review resources, pCODR may need to schedule the placement of a Submission or Resubmission on a pERC meeting agenda other than the posted targeted pERC meeting date. This will be communicated to the Submitter and the new targeted pERC meeting date will be publicly posted.

Submissions are logged when they are received, so that there is a record of the date and time of receipt. The date of receipt of a Submission is considered day zero (0) for the purpose of calculating targeted time frames for reviewing the Submission, and the date a Submission is received is posted on the pCODR section of the CADTH website.

Only complete Submissions and Resubmissions, satisfying all of the Submission and Resubmission Requirements, respectively, are entered in the review queue.

Submissions are generally reviewed in the order received (i.e., first come, first served), however, at the time of filing, Submitters may request that a Submission or Resubmission be assessed to determine whether or not it meets priority review criteria. This request will be considered by a three-person panel consisting of the pERC Chair, the pERC Vice Chair and one additional pERC member, according to the following priority review criteria:
• a New Oncology Drug, or Oncology Drug with a New Indication and employed for the active treatment of cancer, where use offers potential substantial improvements on significant outcomes, such as (but not limited to):
  o improved overall survival in the adjuvant setting; or
  o elimination or substantial reduction of treatment side effects associated with standard of care; or
  o measurable and substantial improvements in quality of life over other available therapies in Canada

OR

• a New Oncology Drug, or Oncology Drug with a New Indication and employed for the active treatment of cancer, where no other comparable drug/treatment is currently marketed in Canada

For Submissions meeting priority review criteria, the review timeline is not condensed and prioritization only has an impact if a review queue exists.

The review queue and placement on the pERC meeting agenda is as follows:

• Any Submission meeting priority review criteria
• Any Resubmission meeting priority review criteria
• Submissions for New Oncology Drugs or Oncology Drugs with a New Indication (Pre-NOC, Pre-NOC/c, Post-NOC or Post NOC/c)
• A Request for Advice
• Submissions for a Biosimilar
• Reconsiderations of an Initial Recommendation
• Resubmissions

4.2.7 Inquiries

All inquiries, including clarification of Submission Requirements and the Drug review process, should be directed to the pCODR Program (refer to Inquiries, page ii, for contact information).

The pCODR Program will provide the Submitter with the name of the pCODR Program staff member who will be the contact regarding the Submission.

The pCODR Program reserves the right to waive Submission or Resubmission Requirements as needed in exceptional circumstances.

4.2.8 Disclosure of Information

pCODR is committed to providing an open and transparent drug review process and to the need to be accountable for its recommendations to patients and the public. As such, pCODR considers it essential to be able to outline the evidence upon which the pERC recommendations are made. In view of these principles, pCODR has outlined a general approach to managing the disclosure of information which is detailed in the pCODR Disclosure of Information Guidelines, available on the pCODR section of the CADTH website (www.cadth.ca/pcodr). During the submission screening, a high-level assessment will be conducted to determine if the key information has been made disclosable (e.g. submitted estimates of the incremental cost-utility or cost-effectiveness ratios, that is, the ICURs or ICERs) in order for the review to proceed through the process. A more detailed assessment of Disclosable and Non-Disclosable Information is completed at the pCODR Checkpoint Meeting.
As a principle, it is expected that Non-Disclosable Information within a Submission will be kept to a minimum. The definitions of Disclosable Information and Non-Disclosable Information are outlined in the pCODR Disclosure of Information Guidelines. At the time of filing a Submission it is the responsibility of the Submitter to:

- Clearly highlight specific information in the Submission documents that is Non-Disclosable.
- Complete a summary table, as outlined in the template included in Appendix C of the pCODR Disclosure of Information Guidelines, that identifies: the Non-Disclosable Information, the location in the submission, the exact wording of the Non-Disclosable Information and the general justification for deeming it Non-Disclosable. The justification should identify which type of Non-Disclosable Information is included, as defined in the pCODR Disclosure of Information Guidelines. This table is to be provided as a component of the Submission. If pCODR does not receive a completed table with a Submission or Resubmission or Additional Information submitted, all of the information in the submission will be considered disclosable by pCODR.
- Provide a structured summary of information related to the submitted economic model and budget impact analysis that may be released into the public domain, as outlined in the template included in Appendix A of the pCODR Disclosure of Information Guidelines. Information provided in this summary may be included in reports or recommendations posted on the pCODR section of the CADTH website.

Please refer to the pCODR Disclosure of Information Guidelines for definitions of Disclosable Information and Non-Disclosable Information for pCODR review purposes, requirements for the structured summary of economic information, any structured summaries of clinical information that are submitted and detailed information on how Non-Disclosable Information is managed by pCODR.

A Submitter is deemed to have consented to the pCODR Disclosure of Information Guidelines when it files a Submission or supplies other information related to the Submission to the pCODR Program. The pCODR Disclosure of Information Guidelines constitute an agreement between pCODR and the Submitter.

4.3 Post-NOC or Post-NOC/c Submission Requirements

These requirements outline information that the pCODR Program needs to undertake the Clinical and Economic Reviews of New Oncology Drugs or Oncology Drugs with a New Indication(s) or Biosimilars that have received a NOC or NOC/c. Submission requirements are outlined separately for New Oncology Drugs or Oncology Drugs with New Indication(s) that do not have a NOC or NOC/c (Pre-NOC or Pre-NOC/c Submissions) in section 4.4.

Submissions for Oncology Drugs with New Indication(s) are to contain clinical and economic information relating to the New Indication(s) only.

To expedite the screening of Submissions for completeness and to facilitate the efficient use of documents, Submitters must provide the information in the order prescribed (sections 4.3.1 and 4.3.2) and in accordance with the electronic file requirements (see Appendix E). See Appendix F for Submission Checklists. Submission requirements must be
submitted to the pCODR Program only electronically (e.g., on CD/DVD or memory stick, or on-line submission through the password-protected area of the pCODR section of the CADTH website) and not as hard copies.

Submission Requirements are subdivided into Category 1, Category 2, and Additional Information.

- Category 1 information must all be included when the Submission is filed in order for the review to proceed.
- There are presently no Category 2 requirements for post-NOC or post-NOC/c submissions.
- Additional Information includes information the pCODR Program requires for completion of the review. pCODR may request Additional Information from Health Canada or the Submitter. The Submitter also has the responsibility of advising the pCODR Program regarding any harm or safety issues, including both domestic and global alerts that may arise during the time that the Submission is under review. This may include any communiqués (e.g. “Dear Doctor” letters regarding harm and safety) and any confirmed labeling changes agreed to with international regulatory agencies (e.g. FDA, EMEA) relevant to the Submission while the Submission is under review by pCODR.

4.3.1 Category 1 Post-NOC or Post-NOC/c Submission Requirements

a) Signed Cover Letter

A signed cover letter (an electronic signature is acceptable) from the Submitter, confirming that all the required information has been provided. It should also indicate:

- A clear description of the Submission being filed (i.e., Category 1 requirements for Pre-NOC or Pre-NOC/c Submission);
- the updated or new information that was not provided in the Pre-submission Information
- the New Indication when filing a Submission for an Oncology Drug with a New Indication
- notification that a request for an assessment of priority review criteria is being requested and justification for the request
- a statement clarifying whether the submitted price is the current marketed price or the disclosable price that may become effective and disclosed following the release of the pERC Initial Recommendation [section 4.3.1(h)].
- the names of the primary and backup contact(s) that the pCODR Program can contact regarding the Submission. [Note: The Submitter may designate the consultant(s) preparing the Submission as primary and/or backup contact(s).]

b) Updated Pre-submission Information Requirements Form

Pre-submission Information Requirements are outlined in the pCODR Pre-submission Guidelines as provided on the pCODR section of the CADTH website
Updates to Pre-submission Information should include but not be limited to:

- Revising any information that has changed since the Pre-submission Information was provided to pCODR
- If a specific population has been defined in a submitted request for funding criteria, the rationale and supporting references for the specified population should be clearly identified.

c) **Summary Table Listing Submitted Non-Disclosable Information**

Requirements for the Summary Table Listing Submitted Non-Disclosable Information are outlined in the *pCODR Disclosure of Information Guidelines*, which are available on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

d) **Health Canada NOC or NOC/c**

A copy of the NOC or NOC/c, dated and signed by Health Canada. If the Drug in the Submission has received an NOC/c, the Manufacturer must provide a copy of the Letter of Undertaking that outlines the confirmatory studies intended to verify the Drug’s clinical benefit, including an indication of time frames.

e) **Product Monograph**

The Product Monograph should show the date it was approved by Health Canada and the company and product names.

f) **Efficacy, Effectiveness, and Safety Evidence**

The following are required:

- a copy of the Clinical Overview (Module 2.5) and Clinical Summary (Modules 2.7.1, 2.7.3, 2.7.4, and 2.7.6) from Module 2 of the Common Technical Document; OR
- a copy of the Clinical Studies section of the Comprehensive Summaries or equivalent documentation accepted by Health Canada (as described in Health Canada’s New Drug Submission Guideline) if the Submission is not filed with Health Canada in the Common Technical Document format; and
- copies of published and unpublished studies that address key clinical issues. Head-to-head comparison clinical trials between the submitted drug product and principal comparators are of particular interest. While almost any study design may be considered, the pCODR Expert Review Committee (pERC) will, as part of the pERC Deliberative Framework, assess the level of uncertainty in trial results introduced by different study designs. Note: *Phase 1 studies and letters from clinicians should be not be provided.*

It is preferred that unpublished data are submitted in manuscript format; however, if unavailable in manuscript format, the following information should be included in clearly labelled sections:
- Objective and rationale of study
- Interventions
- Study population (including eligibility criteria, baseline characteristics, and sample size)
- Methods (including randomization method, blinding method, handling of withdrawals and drop-outs, allocation concealment, and outcome measurement)
- Information about pre-planned extension of trial (if relevant)
- Results (all beneficial and harmful patient effects, including an itemization of fatal and non-fatal serious adverse events; number of withdrawals and drop-outs with reasons; and measures of dispersion, such as standard deviation or standard error, must be provided for continuous outcomes; numerators and denominators must be provided for dichotomous outcomes)
- Data analysis
- Conclusions

Note: Unpublished information provided to pCODR will be managed according to the pCODR Disclosure of Information Guidelines, which are available on the pCODR section of the CADTH website (www.cadth.ca/pcodr). If unpublished data include Non-Disclosable Information, as defined in the pCODR Disclosure of Information Guidelines, a structured summary of clinical information for disclosure may be included.

- Diagrams following the CONSORT reporting standards or similar diagrams that document the flow of patients through the trials, identified as pivotal trials in Health Canada documentation. (Appendix G contains an example of the format and type of required information.) All information in the sections of the sample diagram is to be provided, including reasons for discontinuation and loss to follow-up at each stage of the study. If applicable, the following are to be incorporated into the CONSORT or similar diagram:
  - Additional phases of the study (e.g., screening, washout, baseline, treatment, follow-up) and reasons for discontinuing between phases;
  - Assessments at different time points and reasons for discontinuing between time points; and
  - Analysis populations for each outcome if they differ (primary outcome, key secondary outcomes, harms) and reasons why patients were excluded from each outcome analysis.
  - Copies of editorial articles and errata relating to published studies included in the Submission (Note: If none are available, a statement confirming this should be provided.)
  - New data, generated since the last date that data were reported in the studies included in the Submission. (Typically, the studies submitted to the pCODR are the same as those submitted to Health Canada, and sometimes these studies are ongoing, with data collected after submission to Health Canada. The data resulting after the study has been submitted to Health Canada is required.) These data will be accepted in a variety of formats, including late draft, Clinical Study Report excerpts, synopsis, abstract, or
conference proceedings. (Note: If none are available, a statement confirming this should be provided.)

- Copies of references supporting the validity of outcome measures (e.g., appropriate references could include disease dependent information that are informed by literature or key opinion leaders research, as well as numerous cancer-related research consortia that can be referred to for guidance) in studies (if available). If no references are provided, a statement is required to confirm that a search has been undertaken but no references have been located.

- A tabulated list of Canadian and international published and unpublished clinical trials. (See Appendix H table template. The template can be downloaded from the password-protected area of the pCODR section of the CADTH website. All parts of the template must be completed as per instructions in footnotes below the table).

- A list of all completed published studies, including editorial articles and errata relating to them, and unpublished studies included in the Submission and where they are located in the Submission, including the section in the Submission and the Submission page number, and, when available, a PDF copy of the abstract or publication should be inserted in the table. (Note: All Phase 3 studies, described in the Common Technical Document, are to be listed.)

- A list of all completed published and unpublished studies not included in the Submission (Note: For Drugs available for 10 years or more in Canada or internationally, the pCODR Program should be contacted for guidance as to what to include in the table.)

- A list of all ongoing studies for all indications.

- A signed declaration that all known, unpublished clinical trials have been disclosed (see Appendix I letter template). The template may be downloaded from the password-protected area of the pCODR section of the CADTH website.

Note: As per the pCODR Disclosure of Information Guidelines, information that the Submitter determines may be Non-Disclosable Information and that is provided in any of these documents must be specifically identified by highlighting and should be listed in the Summary Table Listing Submitted Non-Disclosable Information.

g) Economic and Epidemiologic Information

The following are required:

- An appropriate pharmacoeconomic evaluation is required for all Submissions. For additional information on appropriate methodologies, please also refer to the CADTH document Guidelines for the Economic Evaluation of Health Technologies: Specific Guidance for Oncology Products.

- The economic model must be in unlocked (or executable) format. In the executable form, the economic model itself is considered non-disclosable.

- The economic model should permit probabilistic sensitivity analyses.

- Documentation detailing the methods used in the modeling exercise and basic user information must be included.
• A structured summary of economic information as outlined in the pCODR Disclosure of Information Guidelines with necessary components included as Disclosable Information.

The pCODR program must be able to vary individual parameters, view the calculations, and run the model to generate results. The following table identifies the type of information that the pCODR program requires for its examination of the model and the preferred format for receiving it:

<table>
<thead>
<tr>
<th>Information Elements</th>
<th>Preferred Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basis for the pharmacoeconomic study (model, spreadsheet)</td>
<td>A model (or a spreadsheet) that is unlocked (or executable). The user should be able to specify inputs, view calculations, and run various analyses.</td>
</tr>
<tr>
<td>Media</td>
<td>Uploaded to the secure portal, CD-ROM/DVD or memory stick</td>
</tr>
<tr>
<td>Software requirements</td>
<td>The software and system requirements to run the model must be specified. The submitted model must be in an agreed-upon format. Where specialized programs have been used, pCODR must be provided the necessary requirements to run the model (i.e., licences, laptop with model and software), which will be returned at the end of the review process. Please note that anything other than Excel would be considered as specialized programs, and would require the Submitter to provide the software to support the use of the economic model.</td>
</tr>
<tr>
<td>Basic user guide to the model</td>
<td>Electronic format</td>
</tr>
<tr>
<td>Model documentation (manuscripts or a summary of the model report may be submitted)</td>
<td>Electronic format</td>
</tr>
<tr>
<td>Description of the statistical analyses included in the model (data sources, methods, and results)</td>
<td>Electronic format</td>
</tr>
<tr>
<td>Cost/price information table including data sources and assumptions</td>
<td>Electronic format</td>
</tr>
</tbody>
</table>

Note: The model will not be released to any third parties.

In addition:

• Economic evaluations should generally be conducted from a health systems perspective.
• If statistical analyses of data sets are included in the model, a description of the data sources and analyses conducted and results from the analyses should be provided.
• If there is a companion diagnostic test associated with the drug, the model should include relevant costs and consequences (e.g., rates of true- and false-positives, and true- and false-negatives) of any required
biomarker testing into the pharmacoeconomic evaluations. The source(s) and assumption(s) of the relevant inputs should be provided as well.

The following budget impact analysis (BIA) information is required in the Submission to pCODR:

- one non-specific BIA model and report. The BIA should be non-specific in that the model it is based on should be flexible enough to be applied to the context of any of the participating Federal drug plans, P/T Ministries of Health or Provincial Cancer Agencies, which may differ with respect to funding of comparators or the design of the program responsible for drug funding.
- the following supporting documentation for the non-specific BIA:
  - all market research information used in the BIA
  - documents cited in the BIA
  - Disease prevalence — the prevalence or incidence of the disease(s) or condition(s) for which the Drug is under review should be provided for the Canadian population.
  - For Drugs which require reconstitution or dose preparation, the method of dose preparation, dose stability and specifics around potential drug wastage should be addressed.
  - If there is a companion diagnostic test associated with the drug, please provide the budget impact analyses for drugs and companion diagnostics in combination and separately, as some jurisdictions fund the two health technologies through separate mechanisms.

Note: Province/program specific BIAs do not need to be included in the Submission to pCODR, however, province/program specific BIAs must be provided directly to each of the participating Federal drug plans, P/T Ministries of Health/Provincial Cancer agencies in accordance with their requirements, as well as a copy of the non-specific BIA included in the pCODR Submission.

h) Pricing and Availability Information

Submitted prices, reported as price per smallest unit to four decimal places and per smallest dispensable unit for all dosage forms, strengths, and package sizes.

Note: The submitted price is the price that is effective for all pCODR participants. It can be:

- the current market price in Canada or
- the disclosable price that may become effective and disclosed following the release of the pERC Initial Recommendation.

Note: If applicable, the disclosable price for a companion diagnostic(s) must also be provided.

i) Letter Authorizing Unrestricted Sharing of Information

This letter from the holder of the NOC or NOC/c, on company letterhead and signed by an appropriate senior official (an electronic signature is acceptable),
should permit unrestricted sharing of information regarding the Drug product between and within the pCODR and:

- Participating Provincial Cancer Agencies
- Participating Federal Drug Plans and P/T Ministries of Health
- F/P/T governments, including their agencies and departments
- P/T health authorities, including regional health authorities
- Pan-Canadian Pharmaceutical Alliance Office
- Health Canada
- Patented Medicine Prices Review Board

This letter template is provided in Appendix J. The template may also be downloaded from the password-protected area of the pCODR section of the CADTH website.

Note: When a third party (e.g., NOC holder, Manufacturer, or distributor) is involved in filing a Submission, a letter is required from all of the parties that may have information regarding the product on file with Health Canada.

j) Companion Diagnostics

If applicable, provide a reference list and copies of articles that highlight the clinical utility of the companion diagnostic(s) under review. In this context, clinical utility refers to evidence of improved health outcomes as a result of biomarker testing. If no references are provided, a statement will be required to confirm that a search has been undertaken but no references have been located. Disclosable price for a companion diagnostic(s) must also be provided.

4.3.2 Additional Information

The following additional information may be requested by the pCODR Program, and is assessed on a case-by-case basis. Additional Information is information the pCODR Program requires for completion of the review and generally pertains to design, methodology and clinical data results. The pCODR may request Additional Information from Health Canada or the Submitter. The Submitter also has the responsibility of advising the pCODR Program regarding any harm or safety issues, including both domestic and global alerts that may arise during the time that the Submission is under review. This may include any communiqués (e.g. “Dear Doctor” letters regarding harm and safety) and any confirmed labeling changes agreed to with international regulatory agencies (e.g. FDA, EMEA) relevant to the Submission while the Submission is under review by pCODR.

Examples of Additional Information that may be requested include:

a) Health Canada Reviewers’ Report

The pCODR Program may request the Health Canada Reviewers’ Report for each Submission. To avoid delays in providing the report to the pCODR, Manufacturers are encouraged to request the report from Health Canada as soon as they are assured that a NOC or NOC/c will be issued and to forward it immediately to the pCODR Program upon receipt.
b) Periodic Safety Update Reports (PSURs)

The pCODR Program may contact the Manufacturer for this information.

c) Clinical Study Report

The pCODR Program may request the Clinical Study Report or parts of it in searchable electronic format (Microsoft Word or searchable PDF on CD).

d) Copies of Clarifaxes

pCODR may request copies of Clarifaxes concerning responses relating to the NOC or NOC/c being issued by Health Canada, or that would be relevant to pCODR (Note: Clarifaxes on animal toxicology and chemistry, and/or manufacturing and control may not be relevant; it is up to the Submitter to determine whether or not these clarifaxes have an impact on labelling for use in humans).

All Additional Information provided will be managed in accordance with the pCODR Disclosure of Information Guidelines, which are available on the pCODR section of the CADTH website (www.cadth.ca/pcodr).

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.

Note: For Additional Information received during the review, please contact individual pCODR participating members to see if they require this information as part of their provincial Submission.

4.3.3 Post-NOC or Post-NOC/c Submission Requirements for Biosimilars

The Submitter will be required to submit a completed Biosimilar Submission Template in addition to providing the above submission requirements. Please contact the pCODR program for further guidance about the Category 1 Post-NOC or Post-NOC/c Submission Requirements for Biosimilars.

4.4 Pre-NOC or Pre-NOC/c Submission Requirements

Note: Pre-NOC or Pre-NOC/c Submissions for New Oncology Drugs will only be accepted if made by the Manufacturer. This is because the Manufacturer is the only Submitter who will likely have the needed information on product price or anticipated product price to conduct appropriate an economic assessment. Other Submitter types may not have this information available. Pre-NOC or Pre-NOC/c submissions for drugs with New Indications may be filed by any Submitter type (see definition of Submitter). For New Oncology Drugs filed Pre-NOC or Pre-NOC/c, the Drug must have received the NOC or NOC/c before it will be placed on the pERC agenda.

Although most of the Pre-NOC or Pre-NOC/c Submission Requirements are the same as those for other Submissions (section 4.2), the additional/different requirements for Pre-NOC or Pre-NOC/c Submissions are listed below.
• Category 1 information must be included when the Submission is filed in order for the review to proceed.
• Category 2 information must be provided to the pCODR Program as soon as the NOC or NOC/c has been issued, and must be provided at least six Business Days prior to the targeted pERC meeting date. Please note any substantive changes (e.g., beyond minor edits and/or corrections) to the final Product Monograph compared to the draft Product Monograph will be deemed to be significant by pCODR and may result in the rescheduling of the posted targeted pERC meeting date. Depending on the nature, extent and complexity of the information, pCODR may need to adjust the timelines for the review. Category 2 requirements must be satisfied before the Drug review is placed on the pERC agenda.

Note: If the Submission pertains to an Oncology Drug with a New Indication that has not received a NOC or a NOC/c and is not likely to be submitted to Health Canada for review, contact the pCODR Program for additional clarity.

4.4.1 Category 1 Pre-NOC or Pre-NOC/c Submission Requirements

a) Signed Cover Letter

A signed cover letter (an electronic signature is acceptable) from the Submitter, confirming that all the required information has been provided. It should also indicate:

• the updated or new information that was not provided in the Pre-submission Information
• the New Indication when filing a Submission for an Oncology Drug with a New Indication and if it has been submitted to Health Canada for review
• notification that a request for an assessment of priority review criteria is being requested and justification for the request
• A clear description of the Submission being filed (i.e., Category 1 requirements for Pre-NOC or Pre-NOC/c Submission);
• Intention to provide Category 2 requirements at the time of NOC or NOC/c as soon as the NOC or NOC/c has been issued, and must be provided at least six Business Days prior to the targeted pERC meeting date. Please note that any substantive changes (e.g., beyond minor edits and/or corrections) to the final Product Monograph compared to the draft Product Monograph will be deemed to be significant by pCODR and may result in the rescheduling of the posted targeted pERC meeting date. Depending on the nature, extent and complexity of the information, pCODR may need to adjust the timelines for the review. Category 2 requirements must be satisfied before the Drug review is placed on the pERC agenda;
• A statement clarifying whether the submitted price is the current marketed price or the disclosable price that may become effective and disclosed following the release of the pERC Initial Recommendation [section 4.3.1(h)];
• The names of the primary and backup contact(s) that the pCODR Program can contact regarding the Submission. [Note: The Submitter may designate the consultant(s) preparing the Submission as primary and/or backup contact(s)].
b) Health Canada Screening Acceptance Letter
   A copy of the Screening Acceptance Letter indicating that an application has been accepted by Health Canada to review the Drug for sale in Canada.

c) Updated Pre-submission Information Requirements Form (see section 4.3.1)

d) Draft Health Canada Product Monograph
   A draft Product Monograph only is required at the time of filing a Submission. The draft Product Monograph should show the company and product names that correspond to the NOC.

e) Efficacy, Effectiveness, and Safety Evidence (see section 4.3.1)

f) Economic and Epidemiologic Information (see section 4.3.1)

g) Pricing and Availability Information (see section 4.3.1)

h) Letter Authorizing Unrestricted Sharing of Information (see section 4.3.1)

i) Letter of Authorization
   A Letter of Authorization from the Manufacturer, applying for an NOC or NOC/c, printed on company letterhead and signed by an appropriate senior official (an electronic signature is acceptable), allowing Health Canada to share information with the pCODR.

   This letter template is provided in Appendix K. The template may also be downloaded from the password-protected area of the pCODR section of the CADTH website.

j) Table Listing Clarifaxes
   A table listing the Clarifaxes and the responses during the Health Canada review of the Drug that have been received at the time the Submission is filed with pCODR. The topic for clarification, date, response, and date of responses are to be provided.

k) Copies of Clarifaxes
   Copies of all Clarifaxes and responses to the point of the NOC or NOC/c being issued by Health Canada.

   As with all other documents provided to pCODR as part of the Submission, specific information in the clarifaxes that may be potentially Non-Disclosable Information, as per the pCODR Disclosure of Information Guidelines, should be clearly highlighted.

l) Companion Diagnostics (see section 4.3.1)

4.4.2 Category 2 Pre-NOC or Pre-NOC/c Submission Requirements

Category 2 information must be provided to the pCODR Program as soon as the NOC or NOC/c has been issued to allow the review to be completed without delay, and must be provided at least six Business Days prior to the targeted pERC meeting date. Any substantive changes (e.g., beyond minor edits and/or corrections) to the final Product Monograph compared to the draft Product Monograph will be deemed to be significant by pCODR and may result in the rescheduling of the posted targeted pERC meeting date. Depending on the nature, extent and complexity of
the information, pCODR may need to adjust the timelines for the review. Category 2 requirements must be satisfied before the Drug review is placed on the pERC agenda.

4.4.2.1 Category 2 Requirements at time of NOC or NOC/c

a) Signed Cover Letter

A signed cover letter (an electronic signature is acceptable) from the Submitter, confirming that all the required information has been provided. It should also indicate:

- A clear description of the Submission being filed (i.e., Category 2 requirements for a Pre-NOC or Pre-NOC/c Submission at time of NOC or NOC/c);
- the date the NOC or NOC/c was received;
- Intention to provide the remaining Category 2 requirements, for Pre-NOC/c submissions, as soon as the NOC or NOC/c has been issued to allow the review to be completed without delay, and must be provided at least six Business Days prior to the targeted pERC meeting date. Any substantive changes (e.g., beyond minor edits and/or corrections) to the final Product Monograph compared to the draft Product Monograph will be deemed to be significant by pCODR and may result in the rescheduling of the posted targeted pERC meeting date. Depending on the nature, extent and complexity of the information, pCODR may need to adjust the timelines for the review. Category 2 requirements must be satisfied before the Drug review is placed on the pERC agenda.

b) Health Canada NOC or NOC/c

A copy of the NOC or NOC/c, dated and signed by Health Canada, as soon as it has been issued.

c) Product Monograph

The Health Canada-approved Final Product Monograph (showing the date it was approved by Health Canada) and the company and product names that correspond to the NOC or NOC/c should be provided at the time of NOC or NOC/c, to allow the review to proceed as quickly as possible. The Final Product Monograph should be accompanied by a version showing the revisions (with track changes visible) that occurred following the Product Monograph meeting. This is required so that review team members are able to focus on any changes that may have occurred from the initially provided version and the final labelling.

4.4.3 Additional Information (see section 4.3.2)
4.4.4 Pre-NOC or Pre-NOC/c Submission Requirements for Biosimilars

The Submitter will be required to submit a completed *Biosimilar Submission Template* in addition to providing the above submission requirements. Please contact the pCODR program for further guidance about the Category 1 Pre-NOC or Pre-NOC/c Submission Requirements for Biosimilars.

5 The Resubmission Process

5.1 Resubmissions

Manufacturers, provincially recognized clinician-based Tumour Groups and the PAG may file Resubmissions when New Information becomes available that was not provided in the original Submission.

New Information is new clinical information (not previously submitted or published) in support of improved efficacy or safety or new cost information that significantly impacts the cost-effectiveness of the Drug.

If the New Information is in support of improved efficacy, it must be from a randomized controlled trial. If the New Information is in support of improved safety, case-control or cohort studies will be accepted if randomized controlled trials are not available.

*Note: Information requested by the pCODR Program to clarify a Submission, such as Additional Information outlined in section 4.3.2, is not considered New Information and does not affect the place of a Submission in the review queue.*

5.1.1 Eligible Resubmissions

Resubmissions from Manufacturers, provincially recognized clinician-based Tumour Groups, and the PAG are limited to New Oncology Drugs or Oncology Drugs with New Indications or Biosimilars that have a NOC or NOC/c and Pre-NOC or Pre-NOC/c Submissions that are undergoing review through the pCODR process or for which Final Recommendation has been issued by the pCODR Program.

The pCODR Program may accept Resubmissions under the following circumstance(s):

- New Information becomes available after a pERC Final Recommendation has been issued; or
- New Information becomes available during the review process before the pERC Final Recommendation has been issued; or
- New Information becomes available that affects funding conditions and/or criteria recommended by pERC and accepted by participating Federal drug plans, P/T Ministries of Health and Provincial Cancer Agencies in their decisions to fund.

The Submitter of the New Information does not need to be the same as the Submitter of the original Submission or Resubmission.
5.1.2 Filing of Resubmissions

Resubmissions may be filed through the secure portal; however, a Submitter must first register on the pCODR section of the CADTH website. Resubmissions may also be delivered to the pCODR Program by mail or courier (Appendix D). Submitters should wait until the Resubmission has been deemed complete by pCODR before sending information to individual Federal drug plans, P/T Ministries of Health and Provincial Cancer Agencies.

Screening of Resubmission for Completeness

An initial screening of the Resubmission is conducted by the pCODR Program within ten (10) days of receipt to ensure that it is complete. The pCODR Program verifies whether the Resubmission is complete in accordance with this document.

If the Resubmission is incomplete, the pCODR Program sends a notice to the Submitter advising what information is needed to complete the Resubmission.

When the Resubmission is complete, the pCODR Program sends an acknowledgement to the Submitter and publicly posts the date the Resubmission was deemed complete.

5.1.3 Priority and Order of Review

Contained in section 4.2.6 of this document. The information for Submissions applies to Resubmissions as well.

Inquiries

Contained in section 4.2.7 of this document. The information for Submissions applies to Resubmissions as well.

5.1.4 Confidentiality

Contained in section 4.2.8 of this document. The information for Submissions applies to Resubmissions as well.

5.2 Resubmission Requirements

The following table identifies the type of information that the Submitter must provide in filing a Resubmission, depending on when the Resubmission is being filed relative to the status of the Drug in the pCODR process and the reason the Submitter is resubmitting.

Table 2. Guidance for Filing a Resubmission

<table>
<thead>
<tr>
<th>When During the Review Process is the Resubmission Being Filed</th>
<th>Reason For Filing a Resubmission</th>
<th>What the Submitter Must Submit to pCODR</th>
</tr>
</thead>
</table>

pCODR Submission Guidelines
© June 2017 CADTH-pCODR | PAN-CANADIAN ONCOLOGY DRUG REVIEW
### 5.2.1 For Resubmissions Filed (as described in first three bullets in Table 2)

New Information, data, and reference material that were not included in the original Submission are required in addition to the information described in the following section “For All Resubmissions.”

### 5.2.2 For All Resubmissions

The following information must be supplied when making any Resubmission and organized in the Resubmission CD/DVD with documents clearly labelled identifying the sections (See Appendix E).

#### a) Signed Cover Letter

A signed cover letter (an electronic signature is acceptable) from the Submitter, confirming that the information is new and stating the anticipated change or outcome.

The letter should also provide:

<table>
<thead>
<tr>
<th>Resubmission is filed before Final Recommendation is issued</th>
<th>New clinical information supporting improved efficacy</th>
<th>New randomized controlled clinical trial(s) and new pharmacoeconomic evaluation and BIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resubmission is filed after Final Recommendation is issued</td>
<td>New clinical information supporting improved safety</td>
<td>New case-control or cohort study (studies) and new pharmacoeconomic evaluation and BIA</td>
</tr>
<tr>
<td>Resubmission is based on New Information that affects coverage criteria and is filed after Final Recommendation is issued</td>
<td>New cost information</td>
<td>New pharmacoeconomic evaluation and BIA</td>
</tr>
<tr>
<td>Resubmission is filed after withdrawn market authorization has been re-instated</td>
<td>If Submission is withdrawn — all Submission requirements; If Resubmission is withdrawn — all Resubmission requirements. For both, Health Canada information addressing reason for withdrawal and reinstatement of market authorization.</td>
<td></td>
</tr>
<tr>
<td>Resubmission is filed after voluntary withdrawal</td>
<td>Depending if Submission, Resubmission, or Request for Advice is withdrawn — all Submission, Resubmission, or Request for Advice requirements; updated documents (e.g., revised Product Monograph), any New Information (if applicable) and a list of changes since withdrawal.</td>
<td></td>
</tr>
</tbody>
</table>
• justification for the Resubmission — the rationale for the Resubmission
• statement clarifying whether the submitted price is the current marketed price or the disclosable price that may become effective and disclosed following release of the pERC Initial Recommendation [Section 5.2.2 (g)]
• the names of the primary and backup contact(s) the pCODR Program can contact regarding the Resubmission. [Note: The Manufacturer may designate the consultant(s) preparing the Submission as primary and/or backup contacts.]

b) Updated Pre-submission Information Requirements Form

Pre-submission Information Requirements are outlined in the pCODR Pre-submission Guidelines as provided on the pCODR section of the CADTH website (www.cadth.ca/pcodr). Updates to Pre-submission Information for Resubmissions should include but not be limited to:

• Correcting any information that has changed since the Pre-submission Information was submitted to pCODR
• If a specific population has been defined in a submitted request for funding criteria, the rationale and supporting references for the specified population should be clearly identified.

c) Product Monograph

A copy of the most recent product monograph, showing the date it was approved by Health Canada and the company and product names that correspond to the NOC or NOC/c.

d) New Information

• A list of all New Information not included in the original Submission, or previous Resubmissions, which is being included in the current Resubmission
• Copies of all New Information and supporting documentation.

Diagrams following the CONSORT reporting standards or similar diagrams that document the flow of patients through the trials, identified as pivotal trials in Health Canada documentation(Appendix G contains an example of the format and type of required information.) All information in the sections of the sample diagram is to be provided, including reasons for discontinuation and loss to follow-up at each stage of the study. If applicable, the following are to be incorporated into the CONSORT or similar diagram:

• Additional phases of the study (e.g., screening, washout, baseline, treatment, follow-up) and reasons for discontinuing between phases; and
• Assessments at different time points and reasons for discontinuing between time points; and
• Analysis populations for each outcome if they differ (primary outcome, key secondary outcomes, harms) and reasons why patients were excluded from each outcome analysis.

An updated tabulated list of Canadian and international published and unpublished clinical trials that were not identified in the original Submission to pCODR (see Appendix H table template). The template can also be downloaded from the password-protected area of the pCODR section of the CADTH website. The list
should include a list of all completed published studies, including editorial articles and errata relating to them, unpublished studies, and a list of all ongoing studies for all indications.

Search strategies used to locate published studies in medical literature databases. All search terms that were used (i.e., MESH headings and keywords) and the names of databases (e.g., MEDLINE, EMBASE, Cochrane, etc.) that were searched are required. Search results are not required.

A signed declaration that all known, unpublished clinical trials have been disclosed (Appendix H letter template). The template may be downloaded from the password-protected area of the pCODR section of the CADTH website.

Note: As per the pCODR Disclosure of Information Guidelines, information that the Submitter determines may be Non-Disclosable Information and that is provided in any of these documents must be specifically identified by highlighting and should be listed in the Summary Table Listing Submitted Non-Disclosable Information.

e) Information if Drug has a Notice of Compliance with Conditions (NOC/c)

- Status of the confirmatory studies listed in the Letter of Undertaking if the Resubmission is for a Drug with an NOC/c
- Most recent interim analysis results for confirmatory studies listed in the Letter of Undertaking.

f) Economic and Epidemiologic Information

The following are required:

- An appropriate pharmacoeconomic evaluation - required for all Resubmissions. For additional information on appropriate methodologies, please also refer to the CADTH document Guidelines for the Economic Evaluation of Health Technologies: Specific Guidance for Oncology Products.
- The economic model must be in unlocked (or executable) format.
- Documentation detailing the methods used in the modeling exercise and basic user information must be included.
- The economic model should permit probabilistic sensitivity analyses
- A structured summary of economic information as outlined in the pCODR Disclosure of Information Guidelines

The pCODR program must be able to vary individual parameters, view the calculations, and run the model to generate results. The following table identifies the type of information that pCODR requires for its examination of the model and the preferred format for receiving it:

Table 3. pCODR Pharmacoeconomic Information Requirements

<table>
<thead>
<tr>
<th>Information Elements</th>
<th>Preferred Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basis for the pharmacoeconomic study</td>
<td>A model (or a spreadsheet) that is unlocked (or executable). The user should be able to specify inputs, view calculations, and run various analyses.</td>
</tr>
</tbody>
</table>
### Media
- Uploaded to the secure portal, CD-ROM/DVD or memory stick

### Software requirements
- The software and system requirements to run the model must be specified. The submitted model must be in an agreed-upon format.
- Where specialized programs have been used, pCODR must be provided the necessary requirements to run the model (i.e., licences, laptop with model and software), which will be returned at the end of the review process. Please note that anything other than Excel would be considered as specialized programs, and would require the Submitter to provide the software to support the use of the economic model.

### Basic user guide to the model
- Electronic format

### Model documentation (manuscripts or a summary of the model report may be submitted)
- Electronic format

### Description of the statistical analyses included in the model (data sources, methods, and results)
- Electronic format

### Cost/price information table including data sources and assumptions
- Electronic format

---

**Note:** The model will not be released to any third parties.

### In addition:
- Economic evaluations should generally be conducted from a health systems perspective.
- If statistical analyses of data sets are included in the model, a description of the data sources and analyses conducted and results from the analyses should be provided.
- If there is a companion diagnostic test associated with the drug, the model should include relevant costs and consequences (e.g., rates of true- and false-positives, and true- and false-negatives) of any required biomarker testing into the pharmacoeconomic evaluations. The source(s) and assumption(s) of the relevant inputs should be provided as well.

### The following budget impact analysis (BIA) information is required in the Submission to pCODR:
- one non-specific BIA model and report. The BIA should be non-specific in that the model it is based on should be flexible enough to be applied to the context of any of the participating Federal drug plans, P/T Ministries of Health or Provincial Cancer Agencies, which may differ with respect to funding of comparators or the design of the program responsible for drug funding.
- the following supporting documentation for the non-specific BIA:
o all market research information used in the BIA
o documents cited in the BIA
o Disease prevalence — the prevalence or incidence of the disease(s) or condition(s) for which the Drug is under review should be provided for the Canadian population.

o For Drugs which require reconstitution or dose preparation, the method of dose preparation, dose stability and specifics around potential drug wastage should be addressed.

o If there is a companion diagnostic test associated with the drug, please provide the budget impact analyses for drugs and companion diagnostics in combination and separately, as some jurisdictions fund the two health technologies through separate mechanisms.

Note: Province/program specific BIAs do not need to be included in the Submission to pCODR, however, province/program specific BIAs must be provided directly to each of the participating Federal drug plans, P/T Ministries of Health /Provincial Cancer agencies in accordance with their requirements, as well as a copy of the non-specific BIA included in the pCODR Submission.

g) Pricing Information

- Submitted prices, reported as price per smallest unit to four decimal places and per smallest dispensable unit for all dosage forms, strengths, and package sizes.

Note: The submitted price is the price that is effective for all pCODR participants. It can be:

- the current market price in Canada or
- the disclosable price that may become effective and disclosed following the release of the pERC Initial Recommendation.

Note: If applicable, the disclosable price for a companion diagnostic(s) must also be provided.

h) Letter Authorizing Unrestricted Sharing of Information

This letter from the holder of the NOC or NOC/c, on company letterhead and signed by an appropriate senior official, should permit unrestricted sharing of information regarding the Drug product between and within the pCODR and:

- Participating Provincial Cancer Agencies
- Participating Federal Drug Plans and P/T Ministries of Health
- P/T governments, including their agencies and departments
- P/T health authorities, including regional health authorities
- Pan-Canadian Pharmaceutical Alliance Office
- Health Canada
- Patented Medicine Prices Review Board.

This letter template is provided in Appendix J. The template may also be downloaded from the password-protected area of the pCODR section of the CADTH website.
Note: When a third party (e.g., NOC holder, Manufacturer, or distributor) is involved in filing a Submission, a letter is required from all of the parties that may have information regarding the product on file with Health Canada.

i) List of Funding Decisions by pCODR Participants

A summary of the funding status of the Drug by all participating Federal drug plans, P/T Ministries of Health and Provincial Cancer Agencies at the time of the Resubmission, including all funding conditions and/or criteria if applicable.

Note: For a Resubmission for a Biosimilar, the Submitter will be required to submit a revised Biosimilar Submission Template in addition to providing the above submission requirements. Please contact the pCODR program for further guidance about the Resubmission Requirements for Biosimilars.
APPENDIX A: pCODR Definitions

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

Additional Information - any information that is requested by pCODR, 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.

Biosimilar - a biologic drug (i.e., a drug derived from living sources versus a chemically synthesized drug) demonstrating a high degree of similarity to an already authorized biologic drug (i.e., a “reference product” that has been authorized in Canada, or in some circumstances can be an authorized non-Canadian biologic from a jurisdiction that has an established relationship with Health Canada). Similarity between a biosimilar and the reference product is established in accordance with Health Canada’s Guidance Document: Information and Submission Requirements for Biosimilar Biologic Drugs, for the authorized indications.

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

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.

CDR - Common Drug Review

Clarifax - a Health Canada request for clarification that is faxed to the manufacturer. The purpose of a Clarifax is to expand on, add precision to or re-analyze existing information or data in the submission. Clarifaxes do not contain requests for new data, such as new Clinical and/or Pre-Clinical information, including bioavailability data that were not previously submitted.

Disclosable Information - has the meaning given to it in the pCODR Disclosure of Information Guidelines.

Disclosure of Information Guidelines - the guidelines adopted by the pCODR to ensure the appropriate protection and disclosure of information obtained through the pCODR review process. The Disclosure of Information Guidelines outline the steps and procedures that pCODR put into place to ensure disclosure of information is handled in a consistent manner.

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, also known as a Pharmaceutical Manufacturer.

New Active Substance - a therapeutic substance that has never before been approved for marketing in Canada in any form. It may be:

- a chemical or biological substance not previously approved for sale in Canada as a Drug
• an isomer, derivative, or salt of a chemical substance previously approved for sale as a Drug in Canada but differing in properties regarding safety and efficacy
• a biological substance previously approved for sale in Canada as a Drug, but differing in molecular structure, nature of the source material, or manufacturing process.

New Oncology Drug - a therapeutic substance for the active treatment of cancer that has never before been approved for marketing in Canada in any form. It may be:
• a chemical or biological substance not previously approved for sale in Canada as a Drug
• an isomer, derivative, or salt of a chemical substance previously approved for sale as a Drug in Canada but differing in properties regarding safety and efficacy
• a biological substance previously approved for sale in Canada as a Drug, but differing in molecular structure, nature of the source material, or manufacturing process.

Non-Disclosable Information - has the meaning given to it in the pCODR Disclosure of Information Guidelines.

Notice of Compliance (NOC) - authorization issued by Health Canada to market a Drug in Canada when regulatory requirements for the safety, efficacy, and quality are met.

Notice of Compliance with Conditions (NOC/c) - authorization issued by Health Canada to market a Drug under the Notice of Compliance with Conditions policy. This indicates that the sponsor has agreed to undertake additional studies to confirm the clinical benefit of the product.

Oncology Drug with a New Indication - a Drug for the active treatment of cancer that was either previously reviewed by the pCODR or marketed prior to the establishment of the pCODR and that has or has not received a NOC or NOC/c for a New Indication(s) and:
• the Drug has defined funding criteria by one or more Drug Plans / Provincial Cancer Agencies and the Federal drug plans, P/T Ministries of Health, PAG or Provincial Cancer Agencies have agreed that it should be submitted; or
• the Drug is not funded by any of the Federal drug plans, P/T Ministries of Health / Provincial Cancer Agencies and the P/T Ministries of Health, PAG, or Provincial Cancer Agencies have agreed that it should be submitted; or
• the Federal drug plans, P/T Ministries of Health, PAG or Provincial Cancer Agencies have requested the review of the Drug with New Indication(s).

P/T - provincial and territorial.

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 the Federal drug plans, each of the provincial Ministries of Health and provincial cancer care agencies participating in the pCODR. The PAG is accountable to the pCODR Advisory Committee.

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.

pCODR Director - the pCODR program staff person hired by CADTH to provide leadership, development, and delivery of pCODR.

pCODR Program - The Director and staff make up the pCODR Program. The Director is responsible for the leadership, development, and delivery of pCODR. The pCODR program staff is responsible for the administrative duties associated with the pCODR process.
pCODR Advisory Committee - Provides strategic advice for pCODR's ongoing development and management, and provides advice on cancer-specific issues to ensure the pCODR program meets the needs of the federal, provincial/territorial (P/T) governments and cancer agencies.

pERC - the pCODR Expert Review Committee assesses the clinical evidence and cost effectiveness of new cancer drugs, and uses this information to make recommendations to the federal, provincial and territorial governments to guide their drug funding decisions. The pERC is an advisory body composed of up to 16 individuals with expertise in drug therapy / drug evaluation and patient members.

PMPRB - Patented Medicine Prices Review Board. PMPRB is an independent quasi-judicial body established by Parliament in 1987 under the Patent Act. The PMPRB has a dual role: (1) Regulatory - To ensure that prices charged by patentees for patented medicines sold in Canada are not excessive; and (2) Reporting - To report on the pharmaceutical trends of all medicines and on the research and development spending by pharmaceutical patentees.

Pre-NOC or Pre-NOC/c Submission - those submissions made to pCODR prior to and in the absence of authorization issued by Health Canada. The submission may be for a New Drug or New Indication for which Health Canada is highly likely to issue a NOC or NOC/c within 6 months of the Submitter filing a Submission with the pCODR. In the case of Pre-NOC or Pre-NOC/c Submissions for New Drugs, the only Submitter that will be allowed to make a submission is the Manufacturer. In the case of Pre-NOC or Pre-NOC/c Submissions for Oncology Drugs with New Indications, any Submitter type may file the Submission.

Pre-submission Guidelines - the guidelines that have been adopted by pCODR provide guidance to Submitters on the information required by pCODR prior to a Submission being filed and to provide guidance around pre-submission meetings between pCODR and the Submitter.

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.

Request for Advice - a written request made by the PAG or the pCODR Advisory Committee, through PAG, to the pERC for advice on specific therapeutic, clinical or pharmacoeconomic issues, or regarding a pERC Recommendation, which may result in a new Recommendation.

Submission - a submission to the pCODR program consisting of:

- an electronic request (e.g., on CD/DVD or memory stick) 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 drug plans, P/T Ministries of Health or Provincial Cancer Agencies, as required.

Submission Guidelines - the guidelines adopted by the pCODR program that outline how Submissions and Resubmissions must be prepared and submitted.

Submission Requirements - information that is required by the pCODR Program to undertake the Clinical and Economic Reviews of Drugs and other information that is required by the Federal drug plans, P/T Ministries of Health or Provincial Cancer Agencies in making funding decisions. The Requirements apply to Submissions and Resubmissions.

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 P/T 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: Participating P/T Ministries of Health and Provincial Cancer Agencies

Note: The Submitter may not need to wait until both Category 1 and 2 Submission Requirements, if applicable, are satisfied before sending copies to the participating Federal drug plans, P/T Ministries of Health and Provincial Cancer Agencies, unless otherwise stated. Please refer to the table below for contact information on what to send and the timing of their applications.

Submitters are strongly encouraged to contact the relevant Federal drug plans, Ministry of Health or Provincial Cancer Agencies to determine if additional requirements are needed for their local reviews.

For Resubmissions, Submitters should wait until the Resubmission has been deemed complete by pCODR before sending information to individual Federal drug plans, P/T Ministries of Health and Provincial Cancer Agencies.

In addition to Category 1 and Category 2 Submission Requirements or Resubmission Requirements, as applicable, Submitters must also prepare and provide a program/plan specific BIA for each of the Federal drug plans, P/T Ministries of Health and Provincial Cancer Agencies.

<table>
<thead>
<tr>
<th>Province</th>
<th>Contact/Send Submission to:</th>
<th>What to Send</th>
</tr>
</thead>
</table>
| British        | Director of Formulary Management Pharmaceutical Services Division British Columbia Health Services 3-2 1515 Blanshard Street Victoria, BC V8W 3C8 | • Submitters should send CD/DVD copies of Category 1 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 1 Requirements have been met.  
• Submitters should send CD/DVD copies of Category 2 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 2 Requirements have been met.   |
| Columbia       |                                                                                                                                                                 |
| British        | Provincial Pharmacy Professional Practice Leader British Columbia Cancer Agency 2410 Lee Avenue Victoria, BC V8R 6V5 | • Submitters should send CD/DVD copies of Category 1 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 1 Requirements have been met.  
• Submitters should send CD/DVD copies of Category 2 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 2 Requirements have been met.   |
| Columbia       |                                                                                                                                                                 |
### Alberta

**Executive Director**  
Pharmaceutical Funding and Guidance Branch  
Alberta Health and Wellness  
10025 Jasper Avenue, 11th Floor  
P.O. Box 1360, STN Main  
Edmonton, AB T5J 2N3

- Submitters should send CD/DVD copies of Category 1 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 1 Requirements have been met.
- Submitters should send CD/DVD copies of Category 2 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 2 Requirements have been met.

**Alberta**

**Director, Cancer Services**  
Tom Baker Cancer Clinic Pharmacy  
Alberta Health Services  
1331-29th Street NW  
Calgary, AB T2N 4N2

- Submitters should send CD/DVD copies of Category 1 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 1 Requirements have been met.
- Submitters should send CD/DVD copies of Category 2 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 2 Requirements have been met.

### Saskatchewan

**Executive Director**  
Drug Plan & Extended Benefits Branch  
Saskatchewan Ministry of Health  
3475 Albert Street, 2nd Floor  
Regina, SK S4S 6X6

- Submitters should send CD/DVD copies of Category 1 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 1 Requirements have been met.
- Submitters should send CD/DVD copies of Category 2 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 2 Requirements have been met.

### Saskatchewan

**Provincial Leader**  
Oncology Pharmacy Services  
Saskatchewan Cancer Agency  
c/o Saskatoon Cancer Centre  
20 Campus Drive  
Saskatoon, SK S7N 4H4

- Submitters should send CD/DVD copies of Category 1 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 1 Requirements have been met.
<table>
<thead>
<tr>
<th>Province</th>
<th>Contact Person</th>
<th>Submission Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manitoba</td>
<td>Pharmaceutical Consultant Provincial Drug Programs Manitoba Health</td>
<td>• Submitters should send CD/DVD copies of Category 2 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 2 Requirements have been met.</td>
</tr>
<tr>
<td></td>
<td>1014 - 300 Carlton Street Winnipeg, MB R3B 3M9</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Submitters should send CD/DVD copies of Category 1 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 1 Requirements have been met.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Submitters should send CD/DVD copies of Category 2 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 2 Requirements have been met.</td>
</tr>
<tr>
<td></td>
<td>Director of Provincial Oncology Drug Program CancerCare Manitoba</td>
<td></td>
</tr>
<tr>
<td></td>
<td>675 McDermot Avenue Winnipeg, Manitoba R3E 0V9</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Submitters should send CD/DVD copies of Category 1 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 1 Requirements have been met.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Submitters should send CD/DVD copies of Category 2 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 2 Requirements have been met.</td>
</tr>
<tr>
<td>Ontario</td>
<td>Director, Ontario Public Drug Programs Ontario Ministry of Health and Long-term Care 5700 Yonge Street 3rd Floor Toronto, ON M2M 4K5</td>
<td>• Submitters should send copies of submissions after receiving confirmation from pCODR that the requirements for Category 1 and Category 2 have been met.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Submitters must provide three complete submissions in hard-copy format plus PE and BIA unlocked models on CD or DVD.</td>
</tr>
<tr>
<td>Ontario</td>
<td>Director Provincial Drug Reimbursement Programs Cancer Care Ontario</td>
<td>• Submission content information should be consistent with what is being sent to OPDP.</td>
</tr>
<tr>
<td>Province</td>
<td>Contact Details</td>
<td></td>
</tr>
<tr>
<td>------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>New Brunswick</td>
<td>Executive Director Pharmaceutical Services, New Brunswick Department of Health</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PO Box 5100, 520 King Street, 6th Floor HSBC Place, Fredericton, NB, E3B 5G8</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Hard copy of cover letter</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• One CD/DVD copy of Category 1 and Category 2 requirements (at the same time.)</td>
<td></td>
</tr>
<tr>
<td>New Brunswick</td>
<td>Provincial Director of Pharmacy, New Brunswick Cancer Network Department of Health</td>
<td></td>
</tr>
<tr>
<td></td>
<td>520 King Street, Fredericton, NB, E3B 6G3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Hard copy of cover letter</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• One CD/DVD copy of Category 1 and Category 2 requirements (at the same time.)</td>
<td></td>
</tr>
<tr>
<td>Nova Scotia</td>
<td>Director, Pharmaceutical Services, Nova Scotia Department of Health and Wellness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PO BOX 488 - 1690 Hollis Street, Halifax, NS, B3J 2R8</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Submitters should send CD/DVD copies of Category 1 Submissions Requirements to</td>
<td></td>
</tr>
<tr>
<td></td>
<td>participating P/T Ministries of Health and Provincial Cancer Agencies after</td>
<td></td>
</tr>
<tr>
<td></td>
<td>receiving confirmation from pCODR that the Category 1 Requirements have been</td>
<td></td>
</tr>
<tr>
<td></td>
<td>met.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Submitters should send CD/DVD copies of Category 2 Submissions Requirements to</td>
<td></td>
</tr>
<tr>
<td></td>
<td>participating P/T Ministries of Health and Provincial Cancer Agencies after</td>
<td></td>
</tr>
<tr>
<td></td>
<td>receiving confirmation from pCODR that the Category 2 Requirements have been</td>
<td></td>
</tr>
<tr>
<td></td>
<td>met.</td>
<td></td>
</tr>
<tr>
<td>Nova Scotia</td>
<td>Medical Lead, Provincial Medical Oncology Program, Cancer Care Nova Scotia</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4th Floor, Bethune Bldg., 1275 South Park Street, Halifax, NS, B3H 2Y9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Submitters should send CD/DVD copies of Category 1 Submissions Requirements to</td>
<td></td>
</tr>
<tr>
<td></td>
<td>participating P/T Ministries of Health and Provincial Cancer Agencies after</td>
<td></td>
</tr>
<tr>
<td></td>
<td>receiving confirmation from pCODR that the Category 1 Requirements have been</td>
<td></td>
</tr>
<tr>
<td></td>
<td>met.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Submitters should send CD/DVD copies of Category 2 Submissions Requirements to</td>
<td></td>
</tr>
<tr>
<td></td>
<td>participating P/T Ministries of Health and Provincial Cancer Agencies after</td>
<td></td>
</tr>
<tr>
<td></td>
<td>receiving confirmation from pCODR that the Category 2 Requirements have been</td>
<td></td>
</tr>
<tr>
<td></td>
<td>met.</td>
<td></td>
</tr>
<tr>
<td>Prince Edward Island</td>
<td>Pharmacy Consultant</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Submitters should send CD/DVD copies of Category 1 Submissions Requirements to</td>
<td></td>
</tr>
<tr>
<td>Province</td>
<td>Contact Information</td>
<td>Requirements</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-------------------------------------------------------------------------------------</td>
<td>--------------</td>
</tr>
</tbody>
</table>
| Health System Planning & Development Department of Health and Wellness 20 Fitzroy Street, Charlottetown Prince Edward Island, C1A 7N8 | participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 1 Requirements have been met.  
• Submitters should send CD/DVD copies of Category 2 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 2 Requirements have been met. |                          |
| Prince Edward Island    | Medical Director  
PEI Cancer Treatment Centre  
60 Riverside Dr  
Charlottetown, PE C1A 8T5 | • Submitters should send CD/DVD copies of Category 1 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 1 Requirements have been met.  
• Submitters should send CD/DVD copies of Category 2 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 2 Requirements have been met. |                          |
| Newfoundland and Labrador | Clinical Pharmacist  
Department of Health and Community Services, Pharmaceutical Services Division, Newfoundland and Labrador  
57 Margaret's Place  
St. John's, NL A1C 3Z3 | Manufacturers should submit requests for drug coverage through NLPDP according to national minimum submission requirements for brand name and single source drugs as follows:  
• Evidence of approval from Health Canada - NOC, DIN, Product Monograph.  
• Proposed Drug Benefit Price and evidence of the manufacturer’s ability to supply.  
• Clinical data on therapeutic use, safety and adverse drug reactions.  
• Pharmacoeconomic evaluation including a NLPDP-specific budget impact analysis.  
• Letter authorizing communication with Health Canada, other provinces, territories, federal drug programs, Patent Medicine Prices Review Board (PMPRB), expert committees and pCODR.  
Only one copy of a submission of a drug product is required. Submissions in CD/DVD format are encouraged. |              |
Submissions must meet the submission requirements of pCODR.

<table>
<thead>
<tr>
<th>Newfoundland and Labrador</th>
<th>Clinical Chief Cancer Care Program, Eastern Health Dr. H. Bliss Murphy Cancer Centre 300 Prince Philip Drive St. John’s, NL A1B 3V6</th>
</tr>
</thead>
</table>
|                           | • Submitters should send CD/DVD copies of Category 1 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 1 Requirements have been met.  
  • Submitters should send CD/DVD copies of Category 2 Submissions Requirements to participating P/T Ministries of Health and Provincial Cancer Agencies after receiving confirmation from pCODR that the Category 2 Requirements have been met. |

* Refer to the website for Federal drug plans and P/T Ministry of Health requirements.
APPENDIX C: Guidance to PAG and Tumour Groups when Making pCODR Submissions

It is expected that when making a Submission to pCODR, Tumour Groups and PAG may not have the same access to information as a Manufacturer. Therefore, guidance is provided below outlining how information may be obtained or when Submission requirements may be waived.

Other details relevant to Tumour Groups and PAG Submitters can be found in the pCODR Procedures document on the pCODR section of the CADTH website (www.pcodr.ca).

a) Signed Cover Letter
   Provide as per section 4.3.1(a). In addition, outline any Submission Requirements that may have been waived in consultation with the pCODR Program.

b) Updated Pre-submission Information
   All Submitters should complete the Pre-submission Information Requirement Form as outlined in the pCODR Pre-submission Guidelines on the pCODR section of the CADTH website.
   In addition, PAG and Tumour Group Submitters may wish to include the following information:
   • Rationale for the Submission
   • Role of the Manufacturer in the Submission process
   • Status of reviews by other Provincial Cancer Agencies
   • Role and collaboration with other Provincial Cancer Agencies in a pCODR Submission
   • Plan for obtaining pharmacoeconomic evidence
   • Plan for obtaining clinical evidence
   • Completed COI forms

c) Summary Table Listing Submitted Non-Disclosable Information
   If Non-Disclosable Information is provided in a Submission that a Tumour Group or PAG does not want put into the public domain (e.g. reviews conducted within provincial cancer agencies, specific jurisdictional data, academic manuscripts under embargo), a Summary Table Identifying Submitted Non-Disclosable Information should be provided as described in the pCODR Disclosure of Information Guidelines.

d) Health Canada NOC or NOC/c
   Requirement waived if manufacturer not involved in the Submission or if Submission is for an Oncology Drug with a New Indication that has not been submitted to Health Canada.

e) Product Monograph
   Provide as per section 4.3.1(e).
   Health Canada approved product monographs are publicly available and can be found in the Health Canada Drug Product Database: http://webprod.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp

f) Efficacy, Effectiveness and Safety Evidence
   Clinical information usually available only to the Manufacturer, may be waived if it cannot be obtained such as:
   • Excerpts from the Common Technical Document
   • Clinical Study Reports
   • Periodic Safety Update Report
• Health Canada Reviewer Reports

The Submitter should ensure that they have attempted to systematically identify all available clinical information within the scope of the Submission they are submitting to pCODR. Systematic reviews conducted within Provincial Cancer Agencies may be provided as a component of the clinical information supporting efficacy, effectiveness and safety evidence. As part of a systematic search, lead authors or principal investigators should be contacted when clinical information includes unpublished studies or non-industry sponsored trials.

A tabulated list of all published and unpublished studies must be provided. If these studies are not identified with the support of the Manufacturer, unpublished studies should be identified through clinical trial registries.

The requirement for a signed declaration that all known studies and information known to the Submitter have been disclosed may be waived if the Manufacturer is not involved in the Submission.

All other clinical information should be provided as per section 4.3.1(f).

g) Economic and Epidemiologic Information

Provide as per section 4.3.1(g). Provincial Cancer Agencies may wish to work with the Manufacturer and/or agencies and organizations that can provide pharmacoeconomic expertise when preparing their Submission. If needed, the Submitter should contact pCODR who may be able to provide direction on where and how support for economic Submission requirements can be found.

h) Pricing and Availability Information

Provide as per section 4.3.1(h).

i) Letter Authorizing Unrestricted Sharing of Information

Provide as per section 4.3.1(i).
APPENDIX D: Delivery of Mail

To the pCODR Program:

pan-Canadian Oncology Drug Review Program, Director
154 University Avenue, suite 300
Toronto, ON
M5H 3Y9

a) Delivery Times

Any Communications will be considered to have been delivered:

- on the day of actual delivery, if by personal delivery
- on the fifth (5th) day following deposit in the mail, if by registered or regular mail
- on the day of transmittal if sent during the normal business hours of the recipient or
on the Business Day during which such normal business hours next occur, if by
electronic means.

If the party sending Communications knows, or ought reasonably to know, of any disruption
or difficulty with the postal system that might affect the delivery of mail, any such
Communications shall not be mailed but shall be given by personal delivery or by
electronic communication.

b) Determining Time Frames

The date on which the Submission or Resubmission is received is considered day zero (0)
for the purpose of calculating time frames.
APPENDIX E: Electronic File Format Requirements

Specifications:

- Media device should be a CD or DVD
- Documents must be provided in MS WORD or PDF format that is unlocked, searchable and printable. Users must have the ability to extract information or combine documents.
- Documents must be easily identified, and thus, labelled as follows:
  - Brand name_Indication_document type (e.g., product monograph, Module 2.5, etc).pdf or doc
- Documents should be organized in CDs or DVDs as follows (Note: the order of the documents follows the Submission Requirements in the pCODR Submission Guidelines)
- Three CDs or DVDs may be allowed if needed to file all Category 1, Category 2 and Economic Submission requirements

Format for Electronic Files for Submissions:

The proposed folders and files reflect the requirements and the order of the requirements for Post-NOC or Post-NOC/c submissions. Other submissions types (e.g., Pre-NOC or Pre-NOC/c submissions) and Resubmissions would be required to meet the same format and naming conventions for the electronic files but would follow the order for including the information as specifically outlined for these submission types.

Note: As outlined in the pCODR Disclosure of Information Guidelines, all confidential information should be summarized in a table in the first folder of the first CD or DVD (01.03_Brand Name_Non-Disclosable Information Table). In addition, a structured summary of economic information that may be disclosed should be provided in the fourth folder of the first CD or DVD (04.02_Brand Name Economic Information for Disclosure). If structured summaries of clinical information for disclosure are included, they should be provided in second folder of the first CD or DVD. Please see the pCODR Disclosure of Information Guidelines on the pCODR section of the CADTH website (www.cadth.ca/pcodr) for more details.

Legend

- Represents the CD or DVD
- Represents one folder and
- Represents a PDF or Word file (document), unlocked and searchable and printable.

CD or DVD #1: Brand Name.Condition.Date

- 01.Brand Name.Condition.General Information
- 01.01.Brand Name.Signed Cover Letter
01.02_Brand Name_Updated Presubmission Information
01.03_Brand Name_ Non-Disclosable Information Table
01.04_Brand Name_Health Canada NOC or NOC/c
01.05_Brand Name_Product Monograph

02_Brand Name_Condition_Clinical Information

02.01_Brand Name_Health_Canada_Module_2
  02.01.01_Brand Name_Module 2.5
  02.01.02_Brand Name_Module 2.7.1
  02.01.03_Brand Name_Module 2.7.3
  02.01.04_Brand Name_Module 2.7.4
  02.01.05_Brand Name_Module 2.7.6

Note 1: Critical studies and all trials discussed in the clinical evidence portion of the submission should be included in this folder (Brand Name_Condition_Clinical Information). Each trial should be a separate document. When feasible the trial should be numbered with the same number as listed in the reference list and the name should be short and concise. For example:

  01. Smith et al. CMAJ.2007.pdf
  03. manufacturer.unpublished.2010.pdf

Note 2: If structured summaries of clinical information for disclosure are part of the submission, they should be included in this folder (Brand Name_Condition_Clinical Information)

02.02_Brand Name_Condition_CONSORT

(Note: may be CONSORT-like diagram)

  02.02.01_Brand Name_CONSORT diagram (Study x)
  02.02.02_Brand Name_CONSORT diagram (Study y)

02.03_Brand Name_Condition_New data generated after NDS

(See Note 1 above for recommendation on labelling references.)

  01. Smith et al. CMAJ 2007.pdf
02.04_Brand Name_Condition_Editorial articles and errata
(See Note 1 above for recommendation on labelling references.)

02.05_Brand Name_Condition_References supporting outcome measures
(See Note 1 above for recommendation on labelling references.)

02.06_Brand Name_Condition_Table-Published_Unpublished studies
- Brand Name_Table of studies

02.07_Brand Name_Condition_Disclosure_unpublished studies
- Brand Name_Signed Disclosure of Unpublished Studies

02.08_Brand Name_Condition_Search strategies
- Brand Name_Search strategy

03_Brand Name_Condition_Epidemiologic Information
- 03.01_Brand Name_Disease Prevalence and Incidence

04_Brand Name_Condition_Pharmacoeconomic Evaluation
- 04.01_Brand Name_Pharmacoeconomic Evaluation
- 04.02_Brand Name_Economic Information for Disclosure

05_Brand Name_Condition_BIA
- 05.01_Brand Name_Condition_BIA_Non-Specific
- 05.02_Brand Name_Supporting Documentation for BIAs
- 05.03_Brand Name_Condition_Pricing, Ability to Supply, Sharing of Information
  - 05.03.01_Brand Name_Pricing and Availability Information
  - 05.03.02_Brand Name_Letter Confirming Ability to Supply
  - 05.03.03_Brand Name_Letter-Unrestricted Sharing of Information
CD or DVD #2: Brand Name_Generic Name_Condition_Economic Model

- 01_Brand Name_Condition_Economic Model and Documentation
  - 01.01_Brand Name_Economic Model
  - 01.02_Brand Name_Economic Documentation

CD or DVD #3: Brand Name_Generic Name_Condition_Category 2

- 01_Brand Name_Condition_Additional Regulatory and Other Information
APPENDIX F: Submission and Resubmission Checklists

Drug Name: ________________________________________________________________

Submitter (Name and Type): ________________________________________________

Category and Designation:
• Post-NOC or Post-NOC/c Review □
  • New Oncology Drug □
  • Oncology Drug with New Indication □
• Pre-NOC or Pre-NOC/c Review □
  • New Oncology Drug □
  • Oncology Drug with New Indication □
• Request for Advice □
• Biosimilar □

Submission Type:
Priority Review Request
• Requested □
• Not Requested □

Submission Type:
• First review □
• Resubmission □

Administrative Issues:
Complete set of Category 1 Submission Requirements provided ____________________
(See list of Submission Requirements)

Category Two Requirements (for Pre-NOC or Pre-NOC/c) provided at Time of Submission ____________________

Number of Zipped File Folders Making a complete Submission ____________________

If not online, number of CD/DVDs or USB Making a Complete Submission ____________________
### APPENDIX F1: Post NOC or NOC/c Submission Requirements Checklist

#### Category 1

<table>
<thead>
<tr>
<th>Signed Cover Letter</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Request for assessment of priority review criteria and justification (if applicable)</td>
<td></td>
</tr>
<tr>
<td>▪ The New Indication when submitting a Drug with New Indications</td>
<td></td>
</tr>
<tr>
<td>▪ Clarification if submitted price is current market price or disclosable price that may become effective and disclosed following release of the pERC Initial Recommendation</td>
<td></td>
</tr>
<tr>
<td>▪ Names of primary and backup contacts to be contacted regarding Submission</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Updated Pre-submission Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Supporting references for specified listing when requested by Submitter</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Summary Table Identifying Submitted Non-Disclosable Information</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Health Canada NOC or NOC/c (dated and signed)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Letter of Undertaking (if NOC/c)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Monograph</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Product Monograph</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Efficacy, Effectiveness, and Safety Evidence</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Clinical Overview and Clinical Summary, including Synopses of Individual Studies (Common Technical Document, Modules 2.5, 2.7.1, 2.7.3, 2.7.4, and 2.7.6) OR Clinical Studies section of Comprehensive Summary in hard copy and Word or searchable PDF format on CD/DVD</td>
<td></td>
</tr>
<tr>
<td>▪ Critical studies that address key clinical issues (published and unpublished)</td>
<td></td>
</tr>
<tr>
<td>▪ Diagrams following CONSORT reporting standards or similar diagrams, documenting flow of patients through studies</td>
<td></td>
</tr>
<tr>
<td>▪ New data generated since the last date that data were reported in studies included in Submission</td>
<td></td>
</tr>
<tr>
<td>▪ Copies of editorial articles and errata relating to published studies</td>
<td></td>
</tr>
<tr>
<td>▪ Copies of references supporting validity of outcome measures OR statement confirming that a search did not identify any</td>
<td></td>
</tr>
<tr>
<td>▪ Tabulated list of published and unpublished studies (Appendix H)</td>
<td></td>
</tr>
<tr>
<td>▪ Signed declaration that all unpublished studies have been disclosed.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Economic and Epidemiologic Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Pharmacoeconomic Evaluation</td>
<td></td>
</tr>
<tr>
<td>▪ Economic Model and Documentation</td>
<td></td>
</tr>
<tr>
<td>▪ Structured Summary of Economic Information for Disclosure</td>
<td></td>
</tr>
<tr>
<td>▪ One non-specific BIA</td>
<td></td>
</tr>
<tr>
<td>▪ Supporting Documentation for the BIAs</td>
<td></td>
</tr>
<tr>
<td>▪ Documentation of all market research information used in BIAs</td>
<td></td>
</tr>
<tr>
<td>▪ Copies of documents cited in the BIAs.</td>
<td></td>
</tr>
<tr>
<td>▪ Disease Prevalence and Incidence Data With Required Breakdown Where Available</td>
<td></td>
</tr>
<tr>
<td>▪ Details of dose preparation, dose stability and wastage, if appropriate</td>
<td></td>
</tr>
</tbody>
</table>
### Pricing and Availability Information

<table>
<thead>
<tr>
<th>Item</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitted pricing reported as price per smallest unit to four decimal places</td>
<td>□</td>
</tr>
<tr>
<td>Method of distribution</td>
<td>□</td>
</tr>
<tr>
<td>Letter Authorizing Unrestricted Sharing of Information</td>
<td>□</td>
</tr>
<tr>
<td>For a Biosimilar, a completed Biosimilar Submission Template</td>
<td>□</td>
</tr>
</tbody>
</table>
## APPENDIX F2: Pre-NOC or Pre-NOC/c Submission Requirements Checklist

### Category 1

*Note: It is the responsibility of the Manufacturer to advise Health Canada of the intent to file a Pre-NOC or Pre-NOC/c Review Submission with the pCODR Program.*

<table>
<thead>
<tr>
<th>Signed Cover Letter</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Description of Submission being filed</td>
</tr>
<tr>
<td>• Request for assessment of priority review criteria and justification (if applicable)</td>
</tr>
<tr>
<td>• Confirmation of intention to provide Category 2 requirements at time of NOC.</td>
</tr>
</tbody>
</table>

Category 2 information must be provided to the pCODR Program as soon as the NOC or NOC/c has been issued, and must be provided at least six Business Days prior to the targeted pERC meeting date. Please note that any substantive changes (e.g., beyond minor edits and/or corrections) to the final Product Monograph compared to the draft Product Monograph will be deemed to be significant by pCODR and may result in the rescheduling of the posted targeted pERC meeting date. Depending on the nature, extent and complexity of the information, pCODR may need to adjust the timelines for the review. Category 2 requirements must be satisfied before the Drug review is placed on the pERC agenda.

| □ □ □ □ □ □ |
| Health Canada Screening Acceptance Letter |
| □ |

| Summary Table Identifying Submitted Non-Disclosable Information |
| □ |

| Updated Pre-submission information |
| □ |

| • Supporting references for specified listing when requested by Submitter |

| □ |

### Product Monograph

| • Draft Health Canada Product Monograph (Microsoft Word copy) |
| □ |

### Efficacy, Effectiveness and Safety Evidence

| • Clinical Overview and Clinical Summary, including Synopses of Individual Studies (Common Technical Document, Modules 2.5, 2.7.1, 2.7.3, 2.7.4 and 2.7.6) OR Clinical Studies section of Comprehensive Summary in hard copy and Microsoft Word or searchable PDF format on CD/DVD. |
| □ |

| • Copies of critical studies that address key clinical issues (published and unpublished) |
| □ |

| • Diagrams following CONSORT reporting standards or similar diagrams documenting flow of patients through studies |
| □ |

| • Copies of editorial articles and errata relating to published studies |
| □ |

| • New data generated since the last date that data were reported in studies included in Submission |
| □ |

| • Copies of references supporting validity of outcome measure OR statement confirming that a search did not identify any |
| □ |

| • Tabulated list of published and unpublished studies (Appendix H) |
| □ |

| • Signed declaration that all unpublished studies have been disclosed |
| □ |

### Economic and Epidemiologic Information

| • Pharmacoeconomic Evaluation |
| □ |

| • Structured Summary of Economic Information for Disclosure |
| □ |

| • Unlocked Economic Model and Documentation |
| □ |

| • One non-specific BIA |
| □ |
- Supporting Documentation for the BIA
- Documentation of all market research information used in BIA
- Copies of documents cited in the BIA
- Disease Prevalence/Incidence Data With Required Breakdown Where Available
- Details on dose preparation, dose stability and wastage, if appropriate

<table>
<thead>
<tr>
<th>Pricing and Availability Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Submitted pricing reported as price per smallest unit to four decimal places</td>
</tr>
<tr>
<td>• Method of distribution</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Letter Authorizing Unrestricted Sharing of Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letter of Authorization allowing Health Canada to share information with pCODR</td>
</tr>
<tr>
<td>Table of Clarifaxes that have been provided</td>
</tr>
<tr>
<td>Copies of Clarifaxes</td>
</tr>
<tr>
<td>For a Biosimilar, a completed Biosimilar Submission Template</td>
</tr>
</tbody>
</table>

### Category 2

*To be provided as a single package as soon as NOC or NOC/c is issued*:

<table>
<thead>
<tr>
<th>Signed Cover Letter</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health Canada NOC or NOC/c (dated and signed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>• Letter of Undertaking (if NOC/c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Final Health Canada Product Monograph</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
</tr>
</tbody>
</table>

*Submitters must provide this information as soon as NOC or NOC/c is issued, and at least six Business Days prior to the targeted pERC meeting date. Please note that any substantive changes (e.g., beyond minor edits and/or corrections) to the final Product Monograph compared to the draft Product Monograph will be deemed to be significant by pCODR and may result in the rescheduling of the posted targeted pERC meeting date. Depending on the nature, extent and complexity of the information, pCODR may need to adjust the timelines for the review. Category 2 requirements must be satisfied before the Drug review is placed on the pERC agenda.*
### APPENDIX F3: Resubmission Requirements Checklist

<table>
<thead>
<tr>
<th>Section</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signed Cover Letter</td>
<td>□ Justification for Resubmission</td>
</tr>
<tr>
<td></td>
<td>□ Request for assessment of priority review criteria and justification (if applicable)</td>
</tr>
<tr>
<td></td>
<td>□ Clarification if submitted price is the current market price or intended disclosable price that may become effective and disclosed following release of the pERC Initial Recommendation</td>
</tr>
<tr>
<td></td>
<td>□ Names of primary and backup contacts to be contacted regarding Submission.</td>
</tr>
<tr>
<td>Updated Pre-submission Information</td>
<td>□ Supporting references for specified listing when requested by Submitter</td>
</tr>
<tr>
<td>Summary Table Identifying Submitted Non-Disclosable Information</td>
<td>□</td>
</tr>
<tr>
<td>New Information</td>
<td>□</td>
</tr>
<tr>
<td></td>
<td>□ List of all New Information not previously submitted</td>
</tr>
<tr>
<td></td>
<td>□ Copies of New Information</td>
</tr>
<tr>
<td></td>
<td>□ Diagrams following CONSORT reporting standards, documenting flow of patients through studies</td>
</tr>
<tr>
<td></td>
<td>□ Updated tabulated list of published and unpublished studies (Appendix H)</td>
</tr>
<tr>
<td></td>
<td>□ Search strategies</td>
</tr>
<tr>
<td></td>
<td>□ Signed declaration that all unpublished studies have been disclosed</td>
</tr>
<tr>
<td>If New Information is new clinical information supporting efficacy:</td>
<td>□</td>
</tr>
<tr>
<td></td>
<td>□ new randomized controlled trial(s)</td>
</tr>
<tr>
<td></td>
<td>□ new pharmacoeconomic evaluation</td>
</tr>
<tr>
<td></td>
<td>□ structured summary of economic information for public disclosure</td>
</tr>
<tr>
<td></td>
<td>□ One non-specific BIA</td>
</tr>
<tr>
<td>If New Information is supporting improved safety:</td>
<td>□</td>
</tr>
<tr>
<td></td>
<td>□ new case control or cohort study(ies)</td>
</tr>
<tr>
<td></td>
<td>□ new pharmacoeconomic evaluation</td>
</tr>
<tr>
<td></td>
<td>□ structured summary of economic information for public disclosure</td>
</tr>
<tr>
<td></td>
<td>□ One non-specific BIA</td>
</tr>
<tr>
<td>If New Information is new cost information:</td>
<td>□</td>
</tr>
<tr>
<td></td>
<td>□ new pharmacoeconomic evaluation</td>
</tr>
<tr>
<td></td>
<td>□ structured summary of economic information for public disclosure</td>
</tr>
<tr>
<td></td>
<td>□ One non-specific BIA</td>
</tr>
<tr>
<td>Status of confirmatory studies for Resubmissions of Drug with NOC/c</td>
<td>□</td>
</tr>
<tr>
<td></td>
<td>□ Most recent interim analysis of confirmatory studies for Drug with NOC/c</td>
</tr>
<tr>
<td>Drug Notification Form (Copy of Most Recent Form)</td>
<td>□</td>
</tr>
<tr>
<td>Letter Authorizing Unrestricted Sharing of Information</td>
<td>□</td>
</tr>
<tr>
<td>Pricing and Availability Information</td>
<td>□</td>
</tr>
<tr>
<td></td>
<td>□ Submitted pricing reported as price per smallest unit to four decimal places</td>
</tr>
<tr>
<td></td>
<td>□ Method of distribution.</td>
</tr>
<tr>
<td>List of Federal Drug Plans, P/T Ministry of Health and/or Provincial Cancer Agency funding decisions</td>
<td>□</td>
</tr>
</tbody>
</table>

(pCODR Submission Guidelines © June 2017 CADTH-pCODR | PAN-CANADIAN ONCOLOGY DRUG REVIEW 51)
## APPENDIX F4: General Requirements Checklist

<table>
<thead>
<tr>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depending on the Submission type, the content is organized in the order outlined in sections 4.2, 4.3, or 4.4 of this document or the content of the Resubmission is organized in the order outlined in section 5 of this document.</td>
</tr>
<tr>
<td>Each file submitted electronically is labelled with the brand name of the drug in the Submission or Resubmission and the type of file (e.g., Brand Name X-product monograph)</td>
</tr>
<tr>
<td>Submission (including submitted studies) is provided in English</td>
</tr>
<tr>
<td>Only Non-Disclosable Information, as defined in the pCODR Disclosure of Information Guidelines, and is highlighted</td>
</tr>
<tr>
<td>A table with a summary of all Non-Disclosable Information is provided, as per pCODR Disclosure of Information Guidelines</td>
</tr>
<tr>
<td>A structured summary of economic information that may be publicly disclosed is provided, as per pCODR Disclosure of Information Guidelines</td>
</tr>
<tr>
<td>All required information is included with unpublished studies, under the following headings:</td>
</tr>
<tr>
<td>• Objective and rationale of study</td>
</tr>
<tr>
<td>• Intervention</td>
</tr>
<tr>
<td>• Study population (eligibility criteria, baseline characteristics, and sample size)</td>
</tr>
<tr>
<td>• Methods (including randomization, blinding, handling of withdrawals/drop-outs, allocation concealment, and outcome measurement)</td>
</tr>
<tr>
<td>• Results (all beneficial and harmful patient effects, including an itemization of fatal and non-fatal serious adverse events; number of withdrawals and drop-outs with reasons; measure of dispersion such as standard deviation or standard error must be provided for continuous outcomes; numerators and denominators must be provided for dichotomous outcomes)</td>
</tr>
<tr>
<td>• Data analysis</td>
</tr>
<tr>
<td>• Conclusions</td>
</tr>
<tr>
<td>• Clinical Information for Disclosure (a structured summary as outlined in the pCODR Disclosure of Information Guidelines, when applicable)</td>
</tr>
</tbody>
</table>
APPENDIX G: CONSORT Reporting Standard for Documenting Patient Flow

Note: This is an example of the type of information that is required. It can be provided in a different format as long as all of the information shown in the flowchart below is provided. Any questions regarding this requirement can be sent to the pCODR.

CONSORT Flowchart

Flow Diagram of the progress through the phases of a randomized trial (i.e., enrolment, intervention allocation, follow-up, and data analysis)

Assessed for eligibility (n = …)

Excluded (n = …)
- Not meeting inclusion criteria (n = …)
- Declined to participate (n = …)
- Other reasons (n = …)

Randomized (n = …)

Allocated to intervention (n = …)
- Received allocated intervention (n = …)
- Did not receive allocated intervention (give reasons) (n = …)

Allocated to intervention (n = …)
- Received allocated intervention (n = …)
- Did not receive allocated intervention (give reasons) (n = …)

Lost to follow up (n = …) (give reasons)
Discontinued intervention (n = …) (give reasons)

Lost to follow up (n = …) (give reasons)
Discontinued intervention (n = …) (give reasons)

Analyzed (n = …)
- Excluded from analysis (give reasons) (n = …)

Analyzed (n = …)
- Excluded from analysis (give reasons) (n = …)

APPENDIX H: Template for Listing Canadian and International Published and Unpublished Studies

Note: An example is included to illustrate the level of detail required. This table may be expanded. All parts of the template must be completed as per instructions in footnotes.

List of Canadian and International Published and Unpublished Studies for [Name of Drug in Submission]

<table>
<thead>
<tr>
<th>Study ID*</th>
<th>Alternate Study IDs</th>
<th>Sponsor†</th>
<th>Description‡</th>
<th>Phase**</th>
<th>Start Date</th>
<th>End Date††</th>
<th>Abstracts and Publications‡‡</th>
<th>Location in Submission*** and PDF§</th>
</tr>
</thead>
</table>

*Study ID: Provide the combination of numbers and/or letters assigned by the sponsoring organization to identify the study.
†Sponsor = Sponsor of the study.
‡Briefly describe the study design [e.g., randomized, blinded (double or single), controlled, open label, extension, long-term safety, etc.], number of patients, objective(s), description of each treatment arm (drugs and doses); outcomes specified in protocol; duration of treatment; condition or disease; the summary/description should be concise and brief. Include study title. All information, requested in this bullet, must be included.
**Indicate if Phase 2, 3, or 4 (do not include Phase 1 studies).
††Indicate when the study is scheduled to end or the date completed or stopped.
‡‡Provide complete citations of all abstracts or publications (e.g., published report on interim findings) related to the included unpublished studies. Include editorials and errata related to included published studies.
***Indicate the name of the section under which the included study is located.
§When available, insert a PDF copy of the abstract or publication.
†††Include Phase 3 studies described in the Common Technical Document.
###Contact the pCODR Program for guidance if Drug has been available for more than 10 years in Canada or internationally.
APPENDIX I: Template for Confirming Disclosure of All Known Unpublished Studies

[Manufacturer’s letterhead]

[Date]

Director
pan-Canadian Oncology Drug Review
154 University Avenue, suite 300
Toronto, ON
M5H 3Y9

Dear Director:

Reference: [Brand name, generic name]

This letter confirms that [name of Manufacturer] has disclosed all unpublished studies, known to this manufacturer, including those undertaken by other companies that distribute, market, and license this drug in Canada or in other countries and those undertaken by other groups or individuals as of [date of submission].

[Signature]

[Name and Title of Senior Company Official of Manufacturer of Product]
APPENDIX J: Letter Template for Authorizing Unrestricted Sharing of Information

Note: Only letters free of any restrictions are accepted by the pCODR Program. The letter should authorize the pCODR Program to access from, and to disclose to, the bodies named in the letter any information pertaining to the Drug product at any time. A letter with any restrictions will render the Submission incomplete.

[Manufacturer’s letterhead]

[Date]

Director
pan-Canadian Oncology Drug Review
154 University Avenue, suite 300
Toronto, ON
M5H 3Y9

Dear Director:

Reference: [Brand name, generic name]

This letter authorizes the unrestricted communication with respect to the product within the pCODR Program and with:

- Participating Federal drug plans, P/T Ministries of Health and Provincial Cancer Agencies
- F/P/T governments, including their agencies and departments
- P/T health authorities, including regional health authorities
- Pan-Canadian Pharmaceutical Alliance Office
- Health Canada
- Patented Medicine Prices Review Board

[Signature]

[Name and Title of Senior Company Official of Manufacturer of Product]
APPENDIX K: Letter of Authorization Template for Pre-NOC or Pre-NOC/c Submissions Only

[Drug Submission Sponsor]

[Date]

Director
pan-Canadian Oncology Drug Review
154 University Avenue, suite 300
Toronto, ON
M5H 3Y9

Bureau Director
[Bureau]
Therapeutic Products Directorate
Health Products and Food Branch
Health Canada

Dear Bureau Director [TPD and pCODR]

Re: [Product Name], [Health Canada Submission No.]

This letter serves to authorize the pan-Canadian Oncology Drug Review (pCODR) Program to request that Health Canada provide the pCODR with information submitted by [submission sponsor] to Health Canada regarding the above-noted drug submission. This authorization shall only apply to information submitted up to and including the date of the decision by Health Canada regarding market authorization.

This letter also serves to authorize Health Canada to release the requested information set out above, with the restrictions noted, to the pCODR. Health Canada may also respond to inquiries from the pCODR regarding the information provided pursuant to this letter of authorization. Please note that any reports resulting from the information submitted by your organization prepared by, or on behalf of, Health Canada in consideration of your submission, may also be shared with pCODR subject to any applicable restrictions.

Any information or document released to the pCODR pursuant to this letter of authorization shall be managed in accordance with the pCODR Disclosure of Information Guidelines.

[Signature]

[Name and title of authorizing officer]

[Submission manufacturer corporate name]