

## pCODR Procedures

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## INQUIRIES

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## A GENERAL INFORMATION

### A1 Purpose

This document outlines the procedures followed by CADTH's pan-Canadian Oncology Drug Review (pCODR) program in conducting reviews and supporting the pCODR Expert Review Committee (pERC) in making cancer drug funding recommendations.

The pCODR program manages the pCODR process to ensure that every Submission, Resubmission and Request for Advice undergoes a timely review in accordance with the *pCODR Procedures*.

The *pCODR Procedures* describes the tasks and responsibilities of the pCODR program and others involved in the review process as well as the consequences of events and actions taken during the pCODR review process.

### A2 Introduction

CADTH, through the pCODR program, evaluates clinical effectiveness, cost-effectiveness information and patient perspectives on cancer drugs and uses this evaluation to provide cancer drug funding recommendations to Federal drug plans, Provincial/Territorial (P/T) Ministries of Health (excluding Quebec) and Provincial Cancer Agencies. These recommendations are used by jurisdictions to guide their drug funding decisions.

The pCODR process reduces duplication of effort by individual Federal drug plans, P/T Ministries of Health (excluding Quebec) and Provincial Cancer Agencies and ensures that reviews are done in a timely manner. The pCODR program brings consistency and clarity to the cancer drug review process, allowing for greater understanding by all stakeholders while ensuring funding decisions are informed by evidence that has been carefully evaluated by experts.

The work of the pCODR program is guided by eight Guiding Principles as outlined on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)). As part of its eight Guiding Principles, the pCODR program applies an ethical framework to its overall review process. Having transparent review processes and procedures, as outlined in these *pCODR Procedures*, is one component of that ethical framework.

Recommendations are made by a pan-Canadian independent body of pERC members. A pERC member is an appointed position of medical oncologists, hematologists, pharmacists, health economists and patient members. The pERC uses the evidence-based Clinical Guidance Report and Economic Guidance Report as well as input provided by patient groups, registered clinicians and the Provincial Advisory Group (PAG) to evaluate the clinical evidence, cost effectiveness, clinician and patient perspectives of the Drugs under consideration to make funding recommendations. The *pERC Deliberative Framework*, which considers clinical benefit, cost effectiveness, alignment with patient values and implementation feasibility, is used to guide the work of the pERC.

### A3 Definitions

The capitalized terms in this document are defined in Appendix A

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

## A4 Changes to pCODR Procedures

CADTH may amend, from time to time, the *pCODR Procedures* and all matters related to the pCODR program in consultation with the pCODR Advisory Committee (PAC) and/or the Provincial Advisory Group (PAG). CADTH may also seek consultations with other stakeholders, from time to time, such as but not limited to pharmaceutical manufacturers or their representative organizations, tumour groups, and patient groups, for the purposes of revising this document. Amendments to and clarifications of the procedure and all related documents may be affected from time to time by means of communications issued by CADTH and posted on the pCODR section of the CADTH website.

## A5 Disclosure of Information

CADTH is committed to providing an open and transparent drug review process and to being accountable for its recommendations to patients and the public. As such, the pCODR program considers it essential to be able to outline the evidence upon which pERC cancer drug funding recommendations are made. In view of these principles, the pCODR program has developed the *pCODR Disclosure of Information Guidelines* that outline a general approach to managing Disclosable and Non-Disclosable Information, as well as, the definitions of Disclosable Information and Non-Disclosable Information for the purposes of pCODR reviews. These guidelines, which are available on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)), ensure that the disclosure of information obtained through the pCODR review process is handled and managed in a consistent manner and that procedures are in place to protect information that is Non-Disclosable according to definitions provided in the *pCODR Disclosure of Information Guidelines*.

A Sponsor will be deemed to have consented to the *pCODR Disclosure of Information Guidelines* when they file a Submission or supply other information to the pCODR program. By making a Submission or Resubmission to the pCODR program, the Sponsor agrees that the Sponsor will comply with all the requirements set out in the *pCODR Disclosure of Information Guidelines*.

## A6 Code of Conduct, Communications and Conflict of Interest

The pCODR program's conduct, communications and conflicts of interest are governed by the *pCODR Code of Conduct*, the *pCODR Code of Communications* and the *pCODR Conflict of Interest Guidelines*, which are available on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

## A7 Types of pCODR Submissions

The following types of Submissions and Resubmissions can be made to the pCODR program:

- Post-NOC or Post-NOC/c Submission or Resubmission for New Oncology Drugs or for an Oncology Drug with a New Indication(s) for the active treatment of a cancer
- Pre-NOC or Pre-NOC/c Submission or Resubmission for a New Oncology Drug or for an Oncology Drug with a New Indication(s) for the active treatment of a cancer

*Note: if a Submission or Resubmission is made for a Drug with a New Indication used for the active treatment of a cancer and that Drug already has received market authorization in Canada, and sufficient clinical and economic evidence exists to make a Submission, it may not be required that the indication be under review by Health Canada. Please contact the pCODR program for further guidance.*

The following types of Submissions should not be made to the pCODR program:

- Drugs not used for active treatment of cancer, including supportive treatments that may be used in the care of patients with cancer;
- A new indication for which an NOC or NOC/c has not been received and that has been reviewed and rejected by Health Canada.

A Drug can undergo only one type of pCODR review during the same period. For example, if a Drug is at any stage of the review process as a Submission, the pCODR program will not review the Drug concurrently as a Resubmission. An exception to this may be made when the basis for a Submission is a New Indication; the pCODR program will assess this situation on a case-by-case basis considering factors such as where in the pCODR review process the Submission or Resubmission under review is, how distinct the New Indication is from the indication under review, and the resources required for pCODR to review the New Indication.

See the *pCODR Pre-Submission, Submission and Resubmission Guidelines* for more details on types of pCODR Submissions. Sponsors are encouraged to contact the pCODR program for direction whenever there is clarity needed as to whether or not a Submission or Resubmission should be made to the pCODR program.

## A8 Types of Reviews

The Review Team conducts a standard pCODR review for a Submission or Resubmission filed by a Sponsor.

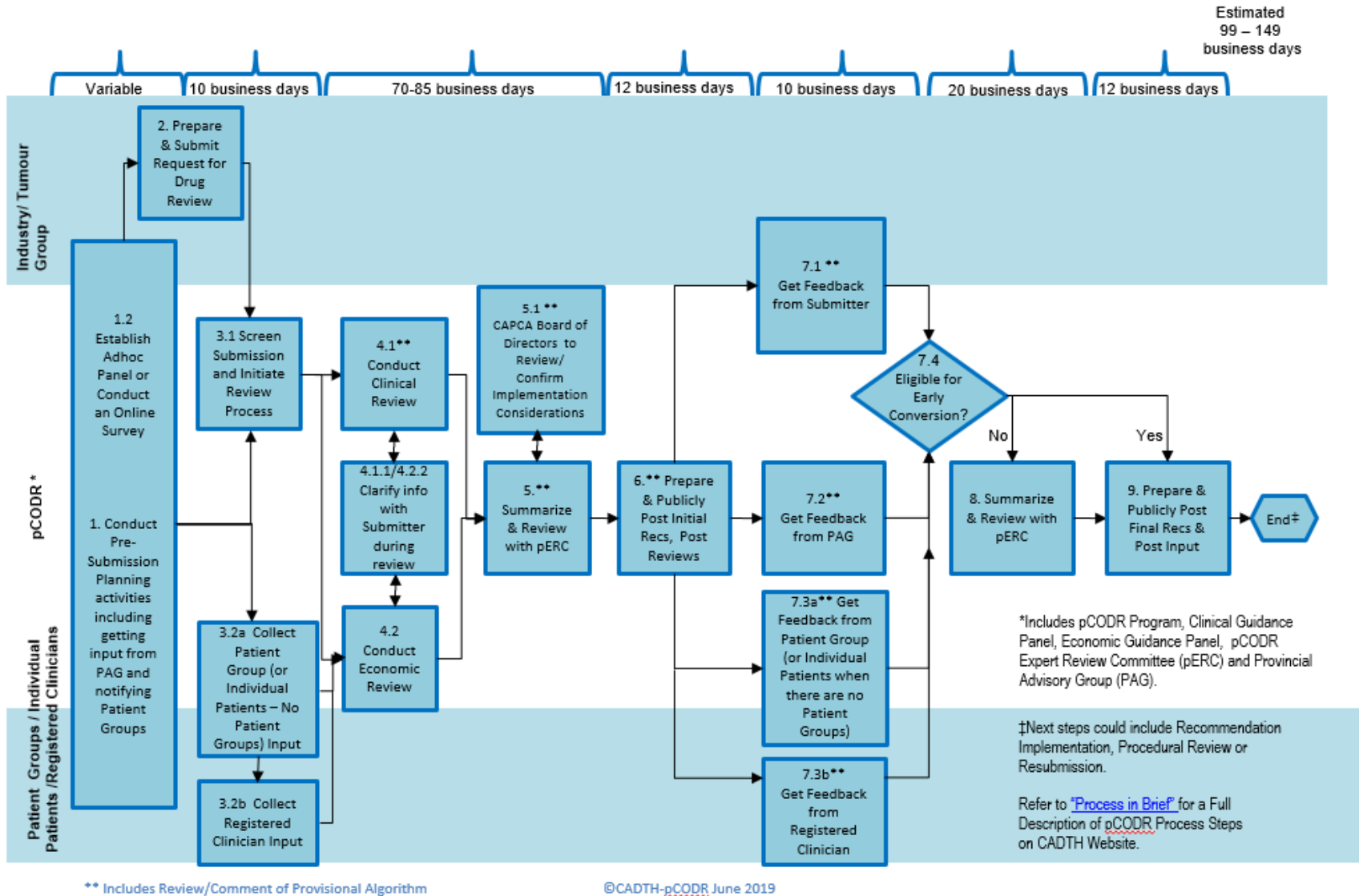
A standard pCODR review consists of the Review Team conducting a systematic review of clinical evidence provided by the Sponsor along with studies identified through independent systematic literature search, and an appraisal of the Sponsor-provided pharmacoeconomic evaluation. This information is presented to pERC for a recommendation.

**Important Note:** Submissions for Biosimilars should be filed directly with the pan-Canadian Pharmaceutical Alliance office and jurisdictions. pCODR reserves the right to request that a Biosimilar Submission undergo a standard review in limited cases. Please contact the pCODR program for further guidance.

## A9 Overview of pCODR Review Process

An overview of the pCODR standard review process and estimated timelines is presented in Figure 1. Details of review process information that will be publicly available on the pCODR section of the CADTH website are presented in Figure 2. Notwithstanding the foregoing, in the event of a Submission being reviewed by the pCODR program that is a Pre-NOC or Pre-NOC/c Submission under review by Health Canada, the pCODR program will not post product strength, product format and NOC date, until such time as regulatory approval has been issued.

Figure 1. pCODR Standard Review Process



For ongoing Submissions, the following review process information will be made publicly available on the pCODR section of the CADTH website as it becomes available:

Figure 2. Review Process Information Posted on the pCODR section of the CADTH Website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr))

Brand Name
Generic Name
Tumour Type
Indication
Funding Request
Review Status
Pre-NOC Submission
NOC Date
Strength
Manufacturer
Sponsor
Submission Date
Submission Deemed Complete Date
Submission Type
*Stakeholder Input Deadline (target date)  *Patient Groups (or registered individual patients and caregivers when there is no patient group) and Clinicians who are registered with pCODR are eligible to provide Input and Feedback. Deadlines for Input and Feedback are by the end of the pCODR business day (5P.M. Eastern Time) of the date noted.
Check-Point Meeting (target date)
pERC Meeting (target date)
Initial Recommendation Issued (target date)
Feedback on Recommendation Deadline (target date)
Final Recommendation Issued (target date)
Notification to Implement Issued

## B POST-NOC or POST-NOC/c SUBMISSION PROCEDURES

Procedures described in section B of this document are those associated with Post-NOC or Post-NOC/c Submissions. Procedures associated with Pre-NOC or Pre-NOC/c Submissions are described in section C of this document, procedures associated with Resubmissions are described in section D of this document, procedures associated with Requests for Advice are described in section E of this document and procedures associated with Manufacturer Non-Submission are described in section F.

### B1 Pre-submission Procedures

Pre-submission procedures include all those procedures related to the period before an anticipated Submission or Resubmission is filed with the pCODR program and are described in section B1 for Post-NOC or Post-NOC/c Submissions. Pre-submission procedures for Pre-NOC or Pre-NOC/c Submissions are described in section C1 and Pre-submission procedures for Resubmissions are described in section D1.

More details related to the Pre-submission process can be found in the *pCODR Pre-submission, Submission and Resubmission Guidelines*, the *pCODR Disclosure of Information Guidelines*, the *pERC Deliberative Framework* and the *pCODR PAG Input on a Review* template, which are available on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

#### B1.1 Notification of an Anticipated Submission by the Sponsor

Sponsors of drugs for pCODR review are requested to provide the Pre-submission Information before the anticipated date of filing the complete Submission or Resubmission. If a Manufacturer, PAG, or a provincially-recognized clinician-based Tumour Group wants to make a Submission to the pCODR program, they must notify the pCODR program at least 120 calendar days in advance of an anticipated Submission of their intent to submit. If a Sponsor fails to meet the 120 calendar days advance notification requirement, a Sponsor will be required to refile the Pre-submission Information with the corrected information and the time will be reset back to day zero for the Sponsor until the requirement is fulfilled (i.e., the new starting date will be from the time of the receipt of the refiled date of the Pre-Submission Requirement Information Form). If the anticipated submission received date falls on a weekend or statutory holiday, the following business day will be applied. The reset of the time will not apply to the updated information in the Pre-Submission Requirement Information Form filed at the time of the Submission or Resubmission. The pCODR program will monitor this requirement for all Pre-submission Information submitted to the pCODR program. If Pre-submission Information is not provided as outlined in the *pCODR Pre-submission, Submission and Resubmission Guidelines*, there may be a delay in the processing and review of the Submission as a result of the incomplete information submitted by the Sponsor.

Sponsors are required to advise the pCODR program of changes in the anticipated date of filing a Submission as soon as possible. Sponsors 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. If the Sponsor does not confirm the targeted Submission filing date and the requested reimbursement criteria in accordance with the above

requirements, there may be a delay in the processing and review of the Submission as a result of the incomplete information submitted by the Sponsor.

## **B1.2 Pre-submission Information**

Pre-submission information is required by the pCODR program in order to optimize the submission planning and review process. A Sponsor will be required to complete the Pre-submission Information Requirements Form using the online form.

To meet the 120 calendar days advance notification requirements, all Pre-submission Information requirements must be completed using the online Pre-submission Information Requirements Form and submitted to the pCODR program. The Pre-submission Information Requirements Form will not be accepted if the mandatory fields are not completed. A Sponsor will be required to refile the Pre-submission Information with the completed information and the time will be reset back to day zero for the Sponsor until the requirement is fulfilled (i.e., the new starting date will be from the time of the receipt of the refiled date of the Pre-Submission Information Form). While some allowances may be made where information is not available to complete the economic section of the form, the pCODR program reserves the right to request further information be provided before scheduling a pre-submission meeting.

## **B1.3 Pre-submission Meetings**

The purpose of a pre-submission meeting is to provide an opportunity for the Sponsor to introduce a drug to the pCODR program. Information may be sought from the pCODR program on the submission requirements for the drug, including the approach to the clinical and economic evaluation and a dialogue to support the development of a provisional algorithm. Sponsors may also wish to discuss and clarify general submission requirements and procedures for a specific drug or indication.

A pre-submission meeting will be scheduled by teleconference for each Submission and Resubmission, pending the completion of the Pre-submission Information Requirements Form. Sponsors may request an in-person pre-submission meeting with the pCODR program, but this will be limited to one meeting in a six month period in order to ensure fair access to CADTH staff and relevant experts (if appropriate) involved in the pCODR review process. All pre-submission meetings will be scheduled for a maximum of up to one hour and Sponsors are limited to one meeting per drug submission or resubmission.

In addition, Sponsors are encouraged to provide information about drugs/indications in the pipeline (i.e., drugs or indications for which Submissions will be filed more than 12 months from the meeting date) during pre-submission meetings. Sponsors will also be asked to confirm if the anticipated submission date remains on schedule.

More information about the pre-submission meeting and associated requirements can be found in the *pCODR Pre-submission, Submission and Resubmission Guidelines*.

#### **B1.4 Disclosure of Pre-submission Information**

pCODR will treat all Pre-submission Information provided by the Sponsor as Non-Disclosable. Details of the Pre-submission Information will be tracked internally on the secure section of the CADTH portal.

Updated Pre-submission Information must be provided to pCODR as part of the Submission Requirements, as described in the *pCODR Pre-Submission, Submission and Resubmission Guidelines*. Non-Disclosable Information that is provided at the time of the Submission in the updated Pre-submission Information Requirements Form, should be identified as outlined in the *pCODR Disclosure of Information Guidelines*.

#### **B1.5 Public Notification by pCODR of a Pending Submission**

One month prior to the anticipated Submission being filed with pCODR, the pCODR program will post details of the pending Submission on the pCODR section of the CADTH website and an email communication to stakeholders will be issued, which will allow patient groups (or registered individual patient or caregiver in cases where there is no patient group) and registered clinicians time to prepare their input on the Submission.

The pCODR program will post the drug name, the indication for review, and the funding conditions and/or criteria being requested by the Sponsor of the pending Submission, submission type (i.e., new drug or new indication), Notice of Compliance (NOC) status at the time of filing, the target submission date and a target deadline for receiving stakeholder input (i.e., patient group (or registered individual patients and caregivers when there is no patient group) and clinicians who are registered with pCODR on the pCODR section of the CADTH website. The posted information will be based on details provided in the Pre-submission Information Requirements Form - Submissions (see the *pCODR Pre-submission, Submission and Resubmission Guidelines*), unless the pCODR program is otherwise notified by the Sponsor. The deadline date for receiving patient group (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician input and other details are confirmed when the Submission is received.

Once the Submission is filed with pCODR, the pCODR program posts on the pCODR section of the CADTH website the name of a Submission, when it was received and a confirmed deadline date for receiving patient group (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician input and an email communication to stakeholders is issued.

If a submission is not received based on the target submission date, pCODR will modify the input deadline to ensure the review can benefit from the patient group (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician input and to not jeopardize the overall review timeline.

If there is a delay and the Submission is not received on the anticipated target date (e.g., if regulatory approval has been delayed), the website will be updated to clarify that a delay has occurred. A new deadline for receiving patient group input (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician input will be confirmed on the website when the Submission is received. Patient groups (or registered individual patient or caregiver in cases where there is no patient group) and registered clinicians should



not submit their input until after the Submission has been received by the pCODR program and the deadline for input has been confirmed.

### **B1.6 Pre-submission Planning**

Prior to the anticipated Submission being received by pCODR, the pCODR program will begin identifying resources for the pCODR Review Team such as notifying pCODR Clinical Guidance Panels and pCODR Economic Guidance Panel members and/or identifying additional expertise as needed on a review-specific basis, including either the creation of an ad hoc panel or online survey of clinical leads affiliated with provincial cancer agencies with experience in the diagnosis and management of the condition for which the drug under review is indicated to support the development of a provisional algorithm based on their clinical expertise.

### **B1.7 Notifying the PAG and Collecting PAG Input**

PAG input is used by the pCODR program as part of its process in reviewing Submissions and by the pERC when formulating recommendations, as described in the *pERC Deliberative Framework*. PAG may submit information related to a Drug Submission under review by pCODR. A template for submitting PAG input, related to enablers and barriers to implementation of recommendations, the *pCODR PAG Input on a Review* template, is found on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

PAG will be notified by the pCODR program of an anticipated Submission when a Sponsor has indicated their intent to make a Submission and has provided the pCODR program with Pre-submission Information. The pCODR program will share Pre-submission Information with the PAG as they prepare their input on the Submission.

## **B2 Procedures for Preparing and Filing a Submission**

Submission procedures include all those procedures relating to preparing and submitting a Submission to the pCODR program for review and are described in section B2 for Post-NOC or Post-NOC/c Submissions. Procedures for preparing Pre-NOC or Pre-NOC/c Submissions are outlined in section C2 and procedures for preparing Resubmissions are outlined in section D2.

More details on the types of Submissions, Submission Requirements and procedures related to preparing and filing a Submission can be found in the *pCODR Pre-Submission, Submission and Resubmission Guidelines* and the *pCODR Disclosure of Information Guidelines*, which are located on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

### **B2.1 Initiating a pCODR Review**

A Post-NOC or Post-NOC/c Submission is initiated by the Manufacturer, PAG or a provincially-recognized clinician-based Tumour Group filing a Submission with the pCODR program.

## **B2.2 Eligible Sponsors**

### **B2.2.1 Manufacturers**

Post-NOC or Post-NOC/c Submissions from Manufacturers include those for New Oncology Drugs or for an Oncology Drug with a New Indication.

### **B2.2.2 PAG**

Post-NOC or Post-NOC/c Submissions from PAG include those for a New Oncology Drug or an Oncology Drug with a New Indication.

### **B2.2.3 Tumour Groups**

Post-NOC or Post-NOC/c Submissions from provincially-recognized clinician-based Tumour Groups include those for a New Oncology Drug or an Oncology Drug with a New Indication.

## **B2.3 Content of the Submission**

A Submission must adhere to the content, format, and organization guidelines stipulated by the pCODR program in the current *pCODR Pre-Submission, Submission and Resubmission Guidelines*. If the Submission does not adhere to these guidelines, it will be deemed incomplete by the pCODR program and the Submission will not enter in the review queue until the requirements are satisfied.

At the time of filing a Submission, Sponsors should ensure that the Submission conforms to the *pCODR Pre-Submission, Submission and Resubmission Guidelines* and the *pCODR Disclosure of Information Guidelines* in effect at that time.

Submission requirements are generally the same for all Sponsors. Select Submission requirements may be waived at the discretion of the pCODR program, for example, if the Sponsor is not the Manufacturer of the drug being submitted and does not have access to all information required (see *pCODR Pre-Submission, Submission and Resubmission Guidelines*, Appendix F).

## **B2.4 Filing of Submission**

Submissions may be provided to the pCODR program through the secured [Collaborative Workspaces](#), which is accessed through the [pCODR Registration](#) page. If Sponsors want to file a Submission through the secured [Collaborative Workspaces](#), they must first register with the pCODR program. Details on registration can be found on the pCODR section of the CADTH website.

In exceptional cases, a Sponsor may also deliver a Submission by mail or courier. When filing a Submission, the Sponsor must provide one copy of the Submission on a memory stick or set of CDs/DVDs and deliver it to the pCODR program by mail or by courier, as outlined in the *pCODR Pre-Submission, Submission and Resubmission Guidelines*.

Upon receipt of a Submission, the pCODR program will log its receipt with a record of the date and time of receipt.

## **B2.5 Submission Tracking**

The pCODR program posts target dates during the review process and the status of the review of all Submissions on the pCODR section of the CADTH website. See

Figure 2 for the type of information that is publicly tracked on the pCODR section of the CADTH website as it becomes available. At a minimum, updates to submission tracking information will occur weekly, but may be posted more frequently from time to time.

## **B3 Procedures for Screening Submissions, Initiating the Review Process and Collecting Patient Group (or registered individual patient or caregiver in cases where there is no patient group) and Registered Clinician Input**

Procedures relating to screening Post-NOC or Post-NOC/c Submissions, initiating the review process for Post-NOC or Post-NOC/c Submissions and collecting patient group (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician input for Post-NOC or Post-NOC/c Submissions are outlined in section B3. These procedures are outlined in section C3 for Pre-NOC or Pre-NOC/c Submissions and are outlined in section D3 for Resubmissions.

More details related to these procedures can be found in the *pCODR Pre-Submission, Submission and Resubmission Guidelines*, the *pCODR Disclosure of Information Guidelines*, the *pCODR Procedural Review Guidelines*, the *pCODR Conflict of Interest Guidelines*, *Guidelines for Manufacturers on Application Fees for CADTH Pharmaceutical Reviews*, the *pCODR Patient Engagement Guide*, the *Patient Input Template for CDR and pCODR (or registered individual patient or caregiver in cases where there is no patient group)* and designated *Registered Clinician Input on a Drug Review* template, which are located on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

### **B3.1 Screening Submissions and Initiating the Review Process**

#### **B3.1.1 Receipt of a Submission**

- a) Upon receipt of the Submission, the pCODR program will date and time stamp the Submission to identify the order in which it is screened.
- b) If the Submission is received by pCODR more than ten (10) business days after the target Submission date that was confirmed with the pCODR program one month prior to the Submission being filed, there may be a delay in the processing and review of the Submission, as previously secured review resources may need to be released to complete other reviews.

#### **B3.1.2 Screening a Submission**

- a) Submission screening is conducted to determine if a Submission is complete or incomplete. Submissions will be screened in the order in which they were received at pCODR. The pCODR program will determine whether the Submission is complete, in accordance with the *pCODR Pre-Submission, Submission and Resubmission Guidelines*, within ten (10) Business Days of its receipt (Note: the date of receipt for a Submission is considered day zero for the purpose of calculating timelines).
- b) For Post-NOC or Post-NOC/c Submissions, Category 1 requirements must be met for the Submission to be placed in the review queue and for the review to proceed. The Category 1 Submission Requirements

are described in the *pCODR Pre-Submission, Submission and Resubmission Guidelines*, which are available on the pCODR section of the CADTH website, [www.cadth.ca/pcodr](http://www.cadth.ca/pcodr).

### **B3.1.3 Deeming a Submission Incomplete**

- a) If the Submission is incomplete, the pCODR program will send a notice to the Sponsor advising what information is needed to complete the Submission.
- b) If the Submission is incomplete, the Submission does not enter the review queue, regardless of when it was received by pCODR.
- c) If the deficiencies in the Submission are not resolved within ten (10) Business Days from the date the Submission is deemed incomplete, the pCODR program will confirm the Submission to be incomplete. A complete Submission may be re-filed at a later date without prejudice to re-filing.

### **B3.1.4 Deeming a Submission Complete**

- a) If the Submission is deemed complete, the pCODR program will send an acknowledgement via email to the primary contact provided in the Submission, and may include the target pERC meeting date and the target Checkpoint Meeting date. This information will also be posted on the pCODR section of the CADTH website (see Figure 2).
- b) When the Submission is deemed complete, it is entered into the review queue, as described in section B3.1.5, Prioritization and Order of Review.
- c) When a Submission is deemed complete, pCODR will include the total fee payable by the Sponsor. Fees will be charged at two pCODR process milestones for all submissions. Please refer to the *Guidelines for Manufacturers on Application Fees for CADTH Pharmaceutical Reviews* for additional information about the application fee schedules, milestones for payments and payment methods. CADTH's Finance Department will issue an invoice for the proportion of the application fee owing. All CADTH application fees are due within 30 calendar days of receipt of an invoice.
- d) When the Sponsor receives acknowledgement that Category 1 Submission Requirements are satisfied, the Sponsor must ensure that each participating Federal drug plan, P/T Ministry of Health and Provincial Cancer Agency is provided with one or more copies of the Category 1 Submission Requirements, or part thereof, as directed by the Federal drug plans, Ministries of Health and Provincial Cancer Agencies in Appendix B of the *pCODR Pre-Submission, Submission and Resubmission Guidelines*.
- e) When the Sponsor receives acknowledgement that Category 2 Submission Requirements are satisfied, the Sponsor must ensure that each participating Federal drug plan, P/T Ministry of Health and Provincial Cancer Agency is provided with one or more copies of the Category 2 Submission Requirements, or part thereof, as directed by the Ministries of Health and Provincial Cancer Agencies in Appendix B

of the *pCODR Pre-Submission, Submission and Resubmission Guidelines*.

- f) Sponsors should note that the pCODR program may request Additional Information even after a Submission has been deemed complete in order to complete the review.

### **B3.1.5 Prioritization and Order of Review**

#### **B3.1.5.1 Order of Review**

Submissions are accepted on an ongoing basis. The date of Submission receipt is considered day zero (0) for the purpose of calculating targeted time frames for the review of the Submission. Target dates within the review process are then posted on the pCODR section of the CADTH website. Only Submissions that have been deemed complete are entered in the review queue.

The pCODR program screens Submissions in the order they are received, that is, on a “first-come, first-served” basis, and reviews Submissions based on the order in which they are deemed complete. An exception to this order of review is:

- a) If, as a result of a procedural review (see the *pCODR Procedural Review Guidelines*), it is determined that additional work on a Submission is required, work on the Submission will be given priority within the pCODR process and the Submission will be given priority placement on the pERC meeting agenda at which it will be re-deliberated.

**Please Note:** The pCODR priority review process has been put on hold effective August 9, 2018. Pending submissions (issued one month in advance of the anticipated filing date) posted on the CADTH website on or before August 9, 2018, that have requested priority review will have their requests assessed upon submission and, if granted, maintained until they have received a Notification to Implement a pERC Final Recommendation or they have been withdrawn. In the future, CADTH will review the pCODR priority review process, as required, in consultation with the jurisdictions and stakeholders. This change aligns with the CADTH Common Drug Review program.

- b) If Submissions to pCODR are queued (see section B3.1.5.2), prioritization is requested and it is determined that priority review criteria are met, the Submission will be given priority placement among queued Submissions and priority placement on the target pERC meeting agenda at which it will be deliberated upon. When the Submission is removed from the queue, the review will generally follow the estimated timelines and work on the Submission will not be given greater priority within pCODR.

#### **B3.1.5.2 Queuing of Submissions**

- a) In periods when the number of new Submissions and/or Resubmissions significantly exceeds the projected volumes and/or when resources are limited, work on a Submission will not start immediately after the Submission is deemed complete and the pCODR program may need to

schedule the Submission on a later pERC meeting agenda than the targeted pERC meeting date (i.e., the Submission will be queued). The Sponsor will be notified that the Submission has been queued and the website will be updated to reflect this.

- b) The pCODR program removes Submissions from the queue as soon as possible. When the Submission is removed from the queue, the Sponsor is notified and the status on the website is updated with a target pERC meeting date.

### B3.1.5.3 Prioritization

*Please Note: The pCODR priority review process has been put on hold effective August 9, 2018. Pending submissions (issued one month in advance of the anticipated filing date) posted on the CADTH website on or before August 9, 2018, that have requested priority review will have their requests assessed upon submission and, if granted, maintained until they have received a Notification to Implement a pERC Final Recommendation or they have been withdrawn. In the future, CADTH will review the pCODR priority review process, as required, in consultation with the jurisdictions and stakeholders. This change aligns with the CADTH Common Drug Review program.*

- a) At the time a Submission is made, Sponsors may request that a Submission 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):
  - improved overall survival in the adjuvant setting; or
  - elimination or substantial reduction of treatment side effects associated with standard of care; or
  - 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

The request will be assessed and the determination of whether priority review criteria have been met will be made within ten (10) Business Days of receipt of the Submission. This determination will be posted on the pCODR section of the CADTH website.

- b) Submissions meeting priority review criteria must undergo all steps in the pCODR review process and as such, will generally follow the estimated pCODR review times. Because the review timeline is not

condensed, prioritization only has an impact on, one, the order of review if Submissions have been queued and, two, placement on the pERC meeting agenda.

All Submissions will be assigned to a tiered queue for placement on the pERC meeting agenda pursuant to the following order:

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

#### **B3.1.5.4 Placement on pERC Meeting Agenda**

- a) The pCODR program publishes on the website the targeted pERC meeting date upon which a Submission may be deliberated. If adequate Pre-submission notification is provided to the pCODR program for resource planning purposes, the targeted pERC meeting date is based on the estimated pCODR review times (see Figure 1).
- b) Subject to section B3.1.5.3, all Submissions will be assigned to a tiered queue for placement on the pERC meeting agenda pursuant to the following order:
  - Any Submission undergoing a procedural review
  - Submissions for New Oncology Drug Submissions or Oncology Drugs with a New Indication (Pre-NOC, Pre-NOC/c, Post NOC or Post-NOC/c)
  - A Request for Advice
  - Reconsiderations of an Initial Recommendation
  - Resubmissions
- c) In certain circumstances including, but not limited to, unavailability of review resources, the pCODR program may need to schedule the placement of a Submission or Resubmission on a pERC meeting agenda other than the posted targeted pERC meeting date.

The pCODR program and pERC can only accommodate a certain number of new submissions or resubmissions per pERC meeting. Even if a submission is targeted for deliberations at a certain pERC meeting, (as reported on the website), deliberations on a Submission may be moved to the next possible pERC meeting. Reasons for this include:

- times of peak activity
- the number of Submissions or Resubmission on the meeting agenda

- the complexity of Submissions or Resubmission on the meeting agenda
  - the number of Reconsiderations of an Initial Recommendation
  - NOC or other Category 2 Submission Requirements have not been received and assessed as complete
  - A delay in the review has occurred (see B4.1.2 and B4.2.2 for reasons why a delay may occur).
- d) The assignment to the review queue and placement on the pERC meeting agenda are made jointly by the pCODR program and pERC Chair. Consultation with the PAG is sought as required.
- e) If a change is made to the target pERC meeting date for a Submission, the Sponsor will be notified and the pCODR section of the CADTH website will be updated to reflect the new target pERC meeting date.

### **B3.1.6 Withdrawal Process**

Anytime after a Submission is deemed complete, and before a pERC Final Recommendation is posted on the pCODR section of the CADTH website, a Submission may be withdrawn from the pCODR review process.

#### **B3.1.6.1 Withdrawal of Market Authorization by Health Canada**

- a) If at any time during the pCODR process, Health Canada withdraws market authorization for a Drug that is the subject of a Submission under review, the provisions of this section (B3.1.6.1) shall apply.
- b) In the case of a Manufacturer Submission, the Manufacturer must advise the pCODR program, in writing, within five (5) Business Days and must provide the following information:
- the date on which the market authorization was withdrawn
  - the reason why the market authorization was withdrawn
- c) The pCODR program will stop the review of a Submission immediately upon being notified of, or learning about, the withdrawal of market authorization for the Drug under review.
- d) The pCODR program will advise the Sponsor, the Manufacturer of the drug under review (if not the Sponsor) and PAG, in writing, that the review has been stopped and this will be posted on the pCODR section of the CADTH website. The pCODR review process for this Drug will not continue, but the pCODR program will retain a record of the review up to the point that it was stopped.
- e) Notwithstanding the foregoing, if at the time of the withdrawal of market authorization, a pERC Initial Recommendation or pERC Final Recommendation has been made by pERC but has not yet been publicly posted, the



pCODR program will proceed with public posting of the Recommendation.

- f) The pCODR program will retain one complete copy of the Submission on file.
- g) If and when Health Canada reinstates the market authorization and the Sponsor wants the Drug to be reviewed by pCODR, the Sponsor will be required to file a Resubmission in accordance with the *pCODR Pre-Submission, Submission and Resubmission Guidelines*. The Resubmission must contain information, including Health Canada information, which addresses the reason(s) for the withdrawal and reinstatement of market authorization. The Resubmission will be placed in the queue for review as described in section B3.1.5.

#### **B3.1.6.2 Voluntary Withdrawal of a Submission**

- a) A Sponsor may request that a Submission be withdrawn from the review process up to the time that a pERC Final Recommendation is posted on the pCODR website. The Sponsor must submit a dated written Request for Withdrawal to the pCODR program that contains the following information:
  - the name and signature of the Sponsor
  - the reason that the Request for Withdrawal is being made
  - whether or not the Sponsor expects to submit the withdrawn Submission again, and if so, the anticipated time frame.
- b) Upon receipt of a Request for Withdrawal from a Sponsor, the pCODR program will withdraw the Submission as follows:
  - the pCODR program will stop its review of the Submission and will inform the Sponsor of this in writing and post this information on the website.
  - If PAG is not the Sponsor, the pCODR program will notify PAG when it receives a Request for Withdrawal of a Submission.
  - If the Manufacturer of the drug under review is not the Sponsor, the pCODR program will notify the Manufacturer that it has received a Request for Withdrawal of a Submission.
  - The pCODR program will post the general reason for the withdrawal on the website.
  - If PAG is not the Sponsor, the PAG may request, within twenty (20) Business Days of notification of the Request for Withdrawal, or at the next scheduled PAG meeting (whichever occurs first) that the pCODR program continues the review of the Drug that is the subject of the withdrawn Submission.

- The pCODR program will advise the Sponsor of PAG’s request regarding whether or not the review of the Drug will continue.
  - When PAG requests that the pCODR program continue the review of a Drug, the review will be based on information available in the public domain and will proceed as a Submission by PAG.
  - The pCODR program will retain one complete copy of the Submission on file.
- c) Notwithstanding the foregoing, if at the time of the voluntary withdrawal, a pERC Initial Recommendation or pERC Final Recommendation has been made by pERC but has not yet been publicly posted, the pCODR program will proceed with public posting of the Recommendation.
- d) If a Sponsor wishes to re-initiate a review of a voluntarily withdrawn Submission, the Sponsor is required to file a Resubmission in accordance with the *pCODR Pre-Submission, Submission and Resubmission Guidelines* in order for the review to proceed. The Resubmission is to include a list of changes since the Submission was withdrawn. All updated documents (not limited to New Information, e.g., updated Product Monograph) must be provided. The Resubmission will be placed in the queue for review, as described in section B3.1.5.

### **B3.1.7 Temporary Suspension of Review**

Any time after a Submission is deemed complete, and before a pERC Final Recommendation is posted on the pCODR section of the CADTH website, a review may be temporarily suspended.

In the event that questions or issues outside of the regular review process arise (e.g., legal or regulatory issues) regarding the Submission under review, the pCODR program, following discussions with the Sponsor, may temporarily suspend the review of the Submission in the following manner:

- The pCODR program will advise the Sponsor and the Manufacturer of the drug under review (if not the Sponsor) in writing that the review of the Submission is temporarily suspended and will post the date of its suspension and the general reason for suspension on the pCODR section of the CADTH website.
- Once the issue is resolved, the pCODR program also has the discretion to extend the temporary suspension as deemed necessary or to resume the review at the stage where it was suspended.
- The Sponsor and the Manufacturer of the drug under review (if not the Sponsor) will be advised in writing, and it will be posted on the website when the review process resumes along with the anticipated target dates for the steps of the review process.

### **B3.1.8 Initiation of Review Process**

If a Submission is deemed complete, the review is initiated by pCODR. Target dates during the review process will be posted on the pCODR

section of the CADTH website as outlined in Figure 2. Upon initiation of the review, the pCODR program:

- a) Provides the Sponsor with a contact name within the pCODR program to whom all inquiries about that Submission are to be directed.
- b) Identifies issues, if any, related to the Submission and communicates these to the Sponsor.
- c) Determines the appropriate approach for undertaking the review, based on the Submission, and develops a work plan for review of the Submission.
- d) Establishes a Review Team by identifying Clinical Guidance Panel members, Economic Guidance Panel members, methodological expertise and any additional expertise that may be required to conduct a pCODR review, based on the nature of the Submission, and in consideration of the team members' qualifications, expertise, and compliance with the *pCODR Conflict of Interest Guidelines*. For selected oncology drug products, the pCODR program may also establish an ad hoc clinical panel and/or distribute an online survey to the clinical leads affiliated with provincial cancer agencies with experience in the diagnosis and management of the condition for which the drug under review is indicated to support the development of a provisional algorithm based on their clinical expertise. Some key factors for establishing an ad hoc clinical panel may include the potential for challenging implementation issues or delivery of care considerations.
- e) Collates and forwards the PAG input on the Submission to the Review Team, including recruited Panel members.

### **B3.1.9 Composition of the Review Team**

- a) The unique composition of each Review Team is established based on the nature of the review and in consideration of the proposed team members' qualifications, expertise and compliance with the *pCODR Conflict of Interest Guidelines*.
- b) The Review Team is composed of individuals with methodological expertise (i.e., the Methods Team), members of the pCODR Clinical Guidance Panels and members of the pCODR Economic Guidance Panels.
- c) Additional expertise, including an ad hoc clinical panel with experience in the diagnosis and management of the condition for which the drug under review is indicated, may be required as determined by the pCODR program and/or the pERC Chair or PAG Chair.

### **B3.1.10 Disclosure of the Review Team**

- a) Names of the individuals appointed to the Clinical Guidance Panels, Economic Guidance Panels and additional expertise are posted on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).
- b) The names of members of a Review Team, including members of the ad hoc clinical panel or clinical leads who respond to the survey, will

not be disclosed to the Sponsor when communication with the Sponsor is required during a Submission, including at the Checkpoint Meeting.

- c) Names of individual Panel Members or individuals providing methodological expertise are not ascribed to individual Clinical Guidance Reports or Economic Guidance Reports.

### **B3.2 Collect Patient Group (or registered individual patient or caregiver in cases where there is no patient group) Input and Registered Clinician Input**

- a) Patient group (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician input is used by pCODR as part of its process in reviewing drugs and by pERC in formulating funding recommendations. Registered patient groups (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician(s) are invited to submit information related to a drug Submission under review by pCODR. The *pCODR Patient Engagement Guide* and a template for submitting patient group input and the *Patient Input Template for CDR and pCODR* can be found on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)). For registered clinician(s), there will be a drug and indication specific template for clinician(s) to provide their input for each review. Patient groups (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician(s) are required to use the template on the pCODR section of the CADTH website to submit their input.
- b) Registered patient groups (or registered individual patient or caregiver in cases where there is no patient group) may submit patient-related information to pCODR. Please note that individual patient or caregiver input will not be accepted in cases where patient group(s) representing the particular tumour exist. In these cases, individual patients or caregivers who wish to provide input are encouraged to work with a patient group to have that group include the information in its submission. Individual patients or caregivers who wish to provide input on a drug or indication are encouraged to first contact pCODR for direction by emailing [pcodrinfo@cadth.ca](mailto:pcodrinfo@cadth.ca)
- c) Similarly, registered clinicians may submit information as set out in each designated *Registered Clinician Input on a Drug Review* template. Registered clinician(s) includes physicians who treat cancer patients (e.g., oncologist, urologist), oncology nurses and oncology pharmacists. Of note, the input from an oncology pharmacist and oncology nurse must be part of a joint submission with a registered physician treating the cancer indication. Registered clinician(s) who submit information on a specific drug and indication under review will not be eligible to participate as a Clinical Guidance Panel member for that same review. For each drug and indication under review, a clinician may only submit once (e.g., if a clinician submits an individual input, that clinician should not be included in a joint submission for that same drug and indication). Please note that comments may be attributed to a specific individual clinician and that registered clinicians who submit input will be identified as a contributor to the specific input. CADTH's pCODR program maintains the discretion to remove any information that may be out of scope of the review or not within the intent of the clinician input template.

- d) Patient groups (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician(s) must register with pCODR prior to submitting input on a drug review. Information on registration can be found on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).
- e) Patient groups (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician(s) must submit input by the posted deadline date (within 10 business days of the pCODR program receiving a Submission) in order that the information can be used by the pCODR Review Team to develop the review plan (i.e. protocol) - a critical step that takes place early in the review.

## B4 Clinical and Economic Review Procedures

Clinical and economic review procedures include all those procedures related to preparing the Clinical Guidance Report and Economic Guidance Report and are described in section B4 for Post-NOC or Post-NOC/c Submissions. Clinical and economic review procedures for Pre-NOC or Pre-NOC/c Submissions are described in section C4 and clinical and economic review procedures for Resubmissions are described in section D4.

More details related to procedures for clinical and economic reviews can be found in the *pCODR Clinical Guidance Report* template, the *pCODR Economic Guidance Report* template, the *pCODR Disclosure of Information Guidelines*, the *pCODR Clinical Guidance Panel Terms of Reference* and the *pCODR Economic Guidance Panel Terms of Reference*.

### B4.1 Conduct Clinical Review

A Review Team prepares an evidence-based Clinical Guidance Report based on material provided by the Sponsor, studies identified through independent systematic literature searches and input on the Submission provided by the PAG, by registered patient groups (or registered individual patient or caregiver in cases where there is no patient group), registered clinician(s) and input from additional expertise, including the ad hoc clinical panel or clinical leads affiliated with provincial cancer agencies.

- a) The Methods Team and the Clinical Guidance Panel develop a review plan, also known as the protocol, for the review of the Submission. Input on the protocol may be provided by PAG, pERC members, the Economic Guidance Panel and other experts, as required. The Review Team considers the patient-important outcomes and issues identified through patient group (or registered individual patient or caregiver in cases where there is no patient group) input when developing the protocol. Similarly, input from registered clinician(s) is also considered when developing the protocol.
- b) The Methods Team conducts an independent systematic literature search in line with the protocol to supplement the data provided in the Submission. Guidance and clarifications are sought from the Clinical Guidance Panel on an on-going basis and as required.
- c) Relevant information provided through patient group (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician input is summarized and included in the Clinical Guidance Report. Input on key implementation issues, including information about the provisional algorithm from the ad hoc clinical panel and/or clinical leads

affiliated with provincial cancer agencies with experience in the diagnosis and management of the condition for which the drug under review is indicated will also be summarized.

- Submitted patient group (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician input is summarized by the pCODR program and forwarded to the Review Team to use in the development of the review protocol.
  - The patient group (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician input are each incorporated into their own sections in the Clinical Guidance Report.
  - Any identifying personal information will be removed prior to sharing the patient group input (or registered individual patient or caregiver in cases where there is no patient group).
- d) Relevant information provided through PAG input is summarized and included in the Clinical Guidance Report.
- Submitted PAG input is summarized by the pCODR program and then finalized by the PAG. This summary is forwarded to the Review Team to use in the development of the review protocol.
  - The PAG input is incorporated into its own section in the Clinical Guidance Report.
- e) The Methods Team summarizes and critically appraises the relevant information provided in the Submission and identified through the independent literature search.
- f) The Clinical Guidance Panel members review the information summarized by the Methods Team and provide in the Clinical Guidance Report an interpretation of the systematic review results and clinical guidance for consideration by the pERC.
- g) Regular and frequent interactions occur amongst the members of the Review Team throughout the process regarding the review of the Submission.

#### **B4.1.1 Clarify Clinical Information with Sponsor at Checkpoint Meeting**

- a) A Checkpoint Meeting with the Sponsor will be held during the review. The purpose of the pCODR Checkpoint Meeting with the Sponsor is: (1) to directly clarify information in the Submission and any Additional Information being provided with members of the pCODR Review Team and (2) to discuss the management of Non-Disclosable Information included in the Submission. The Checkpoint Meeting is not for the purposes of confirming information that the pCODR Review Team will include in the report or to solicit the pCODR Review Team's interpretation of the Submission. If procedures relating to the Checkpoint Meeting are not followed as outlined here in the *pCODR Procedures*, the review of the Submission may be delayed or suspended.
- b) When the Submission is deemed complete, the Sponsor will be notified of the target Checkpoint Meeting date. When notified of this date, the Sponsor must contact the pCODR program to schedule the Checkpoint Meeting.

- c) If a Checkpoint Meeting is not held by the target date, the pCODR program cannot guarantee the review will be completed within the posted timelines and/or the review may be temporarily suspended.
- d) If the Sponsor is not the Manufacturer of the drug under review and the Manufacturer has contributed substantive clinical or economic information to the review, the Manufacturer may be invited to attend the Checkpoint Meeting with the Sponsor.
- e) The Checkpoint Meeting will occur in two parts and the objective of each part of the meeting differs. Part one of the Checkpoint Meeting will be to clarify information in the Submission and any Additional Information being provided. Part two of the Checkpoint Meeting will be to discuss the management of Non-Disclosable Information included in the Submission. Generally, part one and part two of the Checkpoint Meeting will be scheduled consecutively (with a short break in between), to minimize Sponsor travel obligations.
- f) The Checkpoint Meeting will occur as a teleconference or in a webinar format with the Review Team to maintain their anonymity. (Note: pCODR will disclose a general list of individuals involved in pCODR reviews but will make best efforts to not divulge Submission specific Review Teams as outlined in section B3.1.10). The anonymity of the Review Team is preserved by pCODR in order to protect pCODR participants from undue influence, to maintain the integrity of assessments without fear of reprisal and to limit the potential for harassment and intimidation of Review Team members in their professional capacity. The Sponsor must not attempt to identify members of the Review Team during or any time after the interactive meeting. Both part one and part two of the meeting will be recorded by the pCODR program and a record of the meeting will be retained on file at CADTH.
- g) Following the meeting, the pCODR program will provide the meeting attendees with a Record of Decisions from the meeting via email. Decisions will include both those related to Additional Information and clarification of the Submission as well as the review of Non-Disclosable Information in the Submission. The Record of Decisions may be shared with Authorized Recipients, as defined in the *pCODR Disclosure of Information Guidelines*.

#### **B4.1.1.1 Additional Information and Clarification of the Submission**

- a) While conducting the Clinical Review, the Review Team considers whether it needs Additional Information from the Sponsor or requires further clarification of information provided in the Submission. If so, the pCODR program will compile a list of questions and provide them to the Sponsor ten (10) Business Days in advance of the scheduled Checkpoint meeting. If, when the need for Additional Information is identified by the Review Team and is determined to be time-sensitive information, the pCODR program will not wait until the Checkpoint Meeting but will contact the Sponsor as soon as possible.

- b) At the Checkpoint Meeting, the Sponsor will have an opportunity to provide responses to the clarifying questions and the request for Additional Information, which were provided ten (10) Business Days in advance by the pCODR program.
- c) An electronic version of the Sponsor responses to the clarifying questions and requests for Additional Information must be provided to the pCODR program at least one (1) business day in advance of the scheduled Checkpoint Meeting so that these can be provided to the pCODR Review Team prior to the interactive meeting to allow the pCODR Review Team sufficient time to review the responses.
- d) Any Additional Information provided to the pCODR program at this Checkpoint Meeting is subject to the *pCODR Disclosure of Information Guidelines* (see the pCODR section of the CADTH website). Thus, the Sponsor must also provide a supplement to the Summary of Non-Disclosable Information table that identifies any Non-Disclosable Information included in the Additional Information. This supplementary table will be discussed during the review of Non-Disclosable Information component of the Checkpoint Meeting (see section B4.1.1.2)
- e) Attendees from CADTH can include pCODR program staff, Clinical Guidance Panel members, Economic Guidance Panel members and individuals with methodological expertise who are assigned to the Review Team.
- f) Sponsor and Manufacturer attendees are required to attend the Checkpoint Meeting with the pCODR program in-person and cannot attend via teleconference. There is a maximum of four Sponsor attendees, which should include individuals with clinical and economic content expertise who will be able to provide adequate clarification to the Review Team. Sponsor attendees may differ for part one and part two of the meeting. No legal representation is permitted at the Checkpoint Meeting. The Sponsor should select relevant attendees based on the nature and type of questions posed by the pCODR program; relevant attendees may be external to the Sponsor's organization if necessary. A list of attendees must be provided to the pCODR program at least five (5) business days in advance of the meeting, otherwise the meeting may be rescheduled to a later date and the overall review timelines will be adjusted.
- g) Members of the Review Team will be present at Checkpoint Meeting and anonymous communication between the Review Team and the Sponsor will be facilitated by the pCODR program.
- h) The duration of part one of the Checkpoint Meeting will be a maximum of one hour. Sponsors will be provided with approximately 30 minutes to present responses to the



submitted questions. The remainder of the meeting will allow for further clarifications based on the submitted questions and presented responses.

- i) Sponsors should limit questions for the Review Team to topics raised in the list of submitted questions. Questions outside the scope of the Checkpoint Meeting will not be addressed at the meeting.
- j) Any delays in providing Additional Information requested by the Review Team may result in a corresponding delay in the completion of the review.

#### **B4.1.1.2 Review of Non-Disclosable Information in the Submission**

- a) At part two of the Checkpoint Meeting, pCODR program staff and the Sponsor will discuss the management of Non-Disclosable Information included in the Submission. pCODR program staff and the Sponsor will go through the submitted Summary of Non-Disclosable Information tables and any submitted structured summaries of economic and clinical information, focusing on relevant information that may be included in the pCODR Clinical Guidance Report and the pCODR Economic Guidance Report.
- b) If new Non-Disclosable Information is provided in part one of the meeting, an Addendum to the Summary Table of Non-Disclosable Information an electronic version must be provided by the Sponsor at least one (1) business day in advance of the scheduled Checkpoint Meeting. No additional meeting materials are required.
- c) For this portion of the Checkpoint Meeting, attendees from pCODR will include only pCODR program staff. Sponsor attendees should include at least one senior representative with the authority to make decisions regarding disclosure of information.
- d) The duration of part two of the Checkpoint Meeting will be a maximum of one hour.
- e) The Summary of Non-Disclosable Information Tables and the Structured Summaries of Economic and Clinical Information provided in the Submission will be discussed with the Sponsor to ensure that there is/are:
  - Agreement between the pCODR program and the Sponsor on the information in the Submission that is Non-Disclosable Information for pCODR review purposes, as defined in the *pCODR Disclosure of Information Guidelines*.
  - Discussion of Non-Disclosable Information that is within the scope of the review and could likely to be included in the Clinical Guidance Report and/or Economic Guidance Report that is provided to pERC.

- Decisions on how Non-Disclosable Information relevant to pERC deliberations will be used by pCODR during the review. These decisions will be guided by the *pCODR Disclosure of Information Guidelines*. Decisions may include but are not limited to:
  - If Non-Disclosable Information will be excluded from the Clinical Guidance Report and/or Economic Guidance Report that is provided to pERC
  - If Non-Disclosable Information is excluded, whether a description of the information that was excluded from the Clinical Guidance Report and/or Economic Guidance Report will be provided in the report.
  - If Non-Disclosable Information will be included in the Clinical Guidance Report and/or Economic Guidance Report that is provided to pERC but will be redacted from the publicly posted Clinical Guidance Report and/or Economic Guidance Report and associated pERC Recommendations.
  - If Non-Disclosable Information is included but redacted, if the redaction is indefinite or for a time-limited period and the agreed upon expiry date of the time-limited redaction.
  - If Non-Disclosable Information is included but redacted, what the publicly posted reason for the redaction will be and the public description of the redacted information.
- f) A Checkpoint Meeting *Record of Decisions* will be provided to the Sponsor two (2) Business Days from the date of the meeting.
- g) If agreement on how to manage the disclosure of information in the Submission cannot be reached at the meeting, the Sponsor will have five (5) Business Days following receipt of the Checkpoint Meeting *Record of Decisions* to propose a resolution such as, but not limited to, acceptable wording for public disclosure or use of alternative information that is publicly available and conveys the same intent.

#### **B4.1.2 Delay in the Clinical Review**

- a) During the review, the Review Team considers whether Additional Information is required from the Sponsor. If Additional Information is required, the pCODR program will contact the Sponsor. Any delays in the Sponsor providing such information may result in a corresponding delay in the completion of the review.
- b) In exceptional circumstances, all information for a review may not be finalized at the time of filing and may be provided during the course of the review. Depending on the nature, extent and complexity of the information, the pCODR program may need to adjust the

timelines for the review. All information in a submission is considered final six (6) business days prior to the targeted pERC meeting.

- c) The Review Team may request an extension of deadlines from the pCODR program, depending on the volume or complexity of material to be reviewed. The pCODR program shall have the discretion to grant an appropriate extension. The Sponsor will be notified of any extensions and reasons for the extensions granted by the pCODR program. Resulting changes in the target review dates on the pCODR section of the CADTH website and a general explanation of the changes will be publicly posted on the website.

#### **B4.1.3 Completing the Clinical Guidance Report**

Once the Review Team has completed the Clinical Guidance Report, the report is checked for completeness and compliance with the *Clinical Guidance Report template* and the Sponsor/pCODR agreed handling of Non-Disclosable Information. The Clinical Guidance Report is then finalized for inclusion in the pERC Brief.

### **B4.2 Conduct Economic Review**

The Economic Guidance Panel reviews and appraises the pharmacoeconomic information provided in the Submission, with input from the Clinical Guidance Panel and other members of the Review Team. The results, interpretation and guidance provided in the Clinical Guidance Report, as well as PAG input, patient group (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician input, where applicable and available, are used in the assessment of the pharmacoeconomic information provided in the Submission. The Economic Guidance Report is completed in accordance with the Economic Guidance Report template.

- a) The Economic Guidance Panel determines whether the submitted pharmacoeconomic evaluation is supported by the clinical evidence. Results provided by the Sponsor are confirmed, using the supplied economic model. When relevant, the model is rerun and revised cost-effectiveness estimates are determined.
- b) The Economic Guidance Panel identifies the assumptions and limitations in the submitted budget impact analysis.
- c) The pCODR program prepares cost comparison tables with support from the Economic Guidance Panel.
- d) The Economic Guidance Panel considers the relevant information provided through patient group (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician input, where applicable.
  - Submitted patient group (or registered individual patient or caregiver in cases where there is no patient group) input is summarized and forwarded along to the pCODR Economic Guidance Panel to guide the evaluation of the submitted economic model and the assessment of the assumptions made in the submitted budget impact analysis.
  - The patient group (or registered individual patient or caregiver in cases where there is no patient group) input relevant to the economic evaluation is incorporated as appropriate, and into the Economic Guidance Report.

- The registered clinician input relevant to the economic evaluation is incorporated as appropriate, and into the Economic Guidance Report.
- e) Relevant information provided through PAG input is summarized and included in the Economic Guidance Report.
- Submitted PAG input is summarized by the pCODR program and then finalized by the PAG. This summary is forwarded to the Economic Guidance Panel to guide the evaluation of the submitted economic model and the assessment of the assumptions made in the submitted budget impact analysis.
  - The PAG input relevant to the economic evaluation is incorporated as appropriate, and into the Economic Guidance Report.
- f) The Economic Guidance Panel prepares the Economic Guidance Report, reflecting its findings.

#### **B4.2.1 Clarify Economic Information with Sponsor at Checkpoint Meeting**

See section B4.1.1. Procedures applied to clarifying clinical information with the Sponsor at the Checkpoint Meeting also apply to clarifying economic information with the Sponsor at the Checkpoint Meeting.

#### **B4.2.2 Delay in the Economic Review**

See section B4.1.2. Procedures applied to delays in the clinical review also apply to delays in the economic review.

#### **B4.2.3 Completing the Economic Guidance Report**

See section B4.1.3. Procedures applied to completing the Clinical Guidance Report also apply to completing the Economic Guidance Report.

## **B5 pERC Meeting and Deliberation Procedures**

pERC Meeting and Deliberation procedures include all those procedures related to the preparation for and conduct of the pERC meeting and are described in section B5 for Post-NOC or Post-NOC/c Submissions. pERC meeting and deliberation procedures for Pre-NOC or Pre-NOC/c Submissions are described in section C5 and for Resubmissions are described in section D5.

More details related to pERC Meeting and Deliberation Procedures can be found in the *pERC Terms of Reference*, the *pERC Deliberative Framework*, the *pCODR Conflict of Interest Guidelines*, the *pCODR Code of Conduct*, the *pCODR Code of Communications*, and the *pCODR Pre-Submission, Submission and Resubmission Guidelines*, which are available on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

**Note:** Before a Submission is placed on the pERC agenda, all Submission Requirements must be met. See the *pCODR Pre-Submission, Submission and Resubmission Guidelines* for Submission Requirements.

### **B5.1 The pERC**

- a) pERC is established in accordance with the *pERC Terms of Reference* (see pCODR section of the CADTH website, [www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

- b) All pERC Members must comply with the *pCODR Conflict of Interest Guidelines*, the *pCODR Code of Conduct* and the *pCODR Code of Communications* (see pCODR section of the CADTH website, [www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

## **B5.2 The pERC Brief**

The pCODR program compiles the materials for the pERC meeting into the pERC Brief for delivery to pERC and to the PAG and which can be used by the pERC in its deliberations on a Submission. The pERC Brief includes the following information upon which pERC will deliberate:

- Clinical and Economic Guidance Reports which include a summary of the patient group input, registered clinician input and the Provincial Advisory Group input
- The original patient group and clinician submissions
- Summary report about key implementation issues, including information about the provisional algorithm
- May or may not include key published studies summarized in the Clinical Guidance Report and Economic Guidance Report

## **B5.3 Preparation for the pERC Meeting**

- a) The pERC agenda is set by the pCODR program and the pERC Chair.
- b) Before a Submission is placed on the pERC agenda, all Submission Requirements must be met. See the *pCODR Pre-Submission, Submission and Resubmission Guidelines* for Submission Requirements. All information in a submission is considered final six (6) business days prior to the targeted pERC meeting.
- c) The pERC Brief will be delivered to pERC Members (with copies to F/P/T Ministries of Health, Provincial Cancer Agencies and to the Canadian Association of Provincial Cancer Agencies (CAPCA) and through CAPCA to its Board of Directors) before the date scheduled for consideration of such pERC Brief.
- d) Although the full Submission, as applicable will be available at the pERC meeting, it will not routinely be sent to pERC Members in advance, but will be available upon request.

## **B5.4 pERC Meeting**

- a) The pERC meets in-person on a monthly basis on a pre-specified day of each month.
- b) pERC Members declare all conflicts of interest prior to deliberations on each Submission, in accordance with the *pCODR Conflict of Interest Guidelines*.
- c) Attendees at the pERC meeting will be in accordance with the *pERC Terms of Reference*.
- d) At the pERC meeting, pERC Members consider and discuss the pERC Brief for each Submission on the meeting's agenda so as to make a Recommendation. pERC Members who represent their various areas of expertise (e.g. oncologists, economists, patient members) will, respectively, summarize the clinical

information (including registered clinician input, where available), the economic information and the patient input for each Submission.

- e) The PAG Chair and/or PAG members may attend the pERC meeting and will be provided an opportunity on the agenda to summarize the PAG input on the Submission (Note: No New Information will be allowed at this time, as defined in Appendix A).
- f) The pERC Chair may invite members of the Review Team, including Clinical Guidance Panel members or Economic Guidance Panel members and/or External Experts to provide input in person at a pERC meeting and other observers, as applicable. (Note: No New Information will be allowed at this time, as defined in Appendix A).
- g) If pERC needs Additional Information, either from the Review Team or from the Sponsor, or from External Experts, the pERC Chair will determine if the Additional Information may be impactful and if the deliberations should be deferred. If the deliberation is deferred, the matter will be sent back to the pCODR program to collect the Additional Information and the deliberation upon the Submission will be deferred to a subsequent pERC meeting, pending the collection of such information. (Note: No New Information will be allowed at this time, as defined in Appendix A).
- h) If the pERC Brief is complete, pERC will consider the pERC Brief and make a Recommendation.
- i) In making its Recommendation, the pERC will follow *the pERC Deliberative Framework* (see pCODR section of the CADTH website, [www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)), which includes assessing:
  - overall clinical benefit of the Drug in appropriate populations, taking into consideration information on effectiveness, safety, burden of illness and need.
  - alignment with patient values based on patient group input
  - cost-effectiveness relative to current accepted therapy
  - Federal drug plan, P/T Ministry of Health and Provincial Cancer Agency perspectives on enablers and barriers to implementation of a recommendation as obtained through PAG input, as well as information about the provisional algorithm

## **B5.5 pERC Recommendations**

- a) A Recommendation by pERC shall be made for each Submission in the manner set out by the pCODR Advisory Committee.
- b) A Record of Decisions will be taken of the pERC deliberations so that there is a record of the meeting, of attendance at the meeting, of Recommendations made and of any pERC-related decisions. A transcript of the meeting will also be kept by the pCODR program.
- c) pERC Recommendations will, in every case, be accompanied by reasons for the recommendation and key messages. The pCODR program may be tasked with the responsibility of preparing a draft of the reasons for the recommendation and key messages, for detailed review and approval by pERC.
- d) The Recommendation, reasons for the recommendation and key messages shall contain a sufficient explanation as to address the main issues and be

sufficiently detailed to demonstrate that pERC has considered all the material before it and applied the *pERC Deliberative Framework*. It is important to note that a provisional algorithm will only be included as part of the implementation consideration in the Recommendation if pERC recommends to reimburse or reimburse with clinical criteria and/or conditions.

## B6 Procedures for Preparation of Public Posting of Initial Recommendations and Guidance Reports

Procedures for the preparation of public posting of Initial Recommendations and Guidance Reports are described in section B6 for Post-NOC or Post-NOC/c Submissions, section C6 for Pre-NOC or Pre-NOC/c Submissions and section D6 for Resubmissions.

For more details related to procedures associated with the public posting of Initial Recommendations and guidance reports see the *pCODR Disclosure of Information Guidelines*, which is available on the pCODR section of the CADTH website, [www.cadth.ca/pcodr](http://www.cadth.ca/pcodr).

### B6.1 Redaction of Non-Disclosable Information in the Initial Recommendation and Guidance Reports

- a) If the Clinical Guidance Report or Economic Guidance Report includes Non-Disclosable Information, this will be handled as decided at the Checkpoint Meeting with the Sponsor and in accordance with the *pCODR Disclosure of Information* guidelines. If any Non-Disclosable Information was included in the Clinical Guidance Report or the summary of the Economic Guidance Report to be publicly disclosed, and has been redacted, it will be noted that the Sponsor requested that this information not be disclosed and the reason why it was redacted, pursuant to the *pCODR Disclosure of Information* guidelines. The timeframe for which this redaction will remain in place will also be stated.
- b) If the pERC Initial Recommendation includes Non-Disclosable Information, this will be handled as decided at the Checkpoint Meeting with the Sponsor and in accordance with the *pCODR Disclosure of Information* guidelines. If Non-Disclosable Information is redacted from the pERC Recommendation, the pCODR will indicate that Non-Disclosable Information was used to make the funding recommendation and that the Sponsor requested that this information not be disclosed and the reason why it was redacted, pursuant to the *pCODR Disclosure of Information* guidelines. The timeframe for which this redaction will remain in place will also be stated.
- c) pCODR recognizes that the information owner retains the right to make a final decision in relation to the release of information into the public domain. pCODR reserves the right to determine how Non-Disclosable Information is used in the pCODR review process, including pERC deliberations, if at all. Under certain circumstances, information that the owner has decided not be allowed into the public domain will be accepted for inclusion in the pCODR review process and pERC deliberations under agreement not to disclose such information, once it has been agreed mutually by pCODR and the Sponsor to be Non-Disclosable (see *pCODR Disclosure of Information Guidelines*, section 3.4). In other circumstances, information that the owner has decided not be allowed into the public domain will be accepted for inclusion in the pCODR review process and pERC deliberations under agreement not to disclose such

information for a defined time-limited period [see pCODR Disclosure of Information Guidelines, section 3.3b)iii)]. pCODR will always strive for the shortest time period of non-disclosure possible.

- d) If agreement on the handling of Non-Disclosable Information cannot be reached, pCODR will not use the information in the Clinical Guidance Report and/or Economic Guidance Report or pERC deliberations. Only in rare circumstances, where pCODR is of the view that the inclusion of such information in the Clinical and/or Economic Guidance Reports is necessary for the integrity of pERC recommendations (e.g., important safety/harms information), pCODR reserves the right to use such information and pCODR will note that while the Sponsor refused to propose a means of disclosure of the information that was acceptable by pCODR, the information was nonetheless used to preserve the integrity of the pERC recommendations.
- e) Three (3) Business Days prior to the posting of the Initial Recommendation and Guidance Reports, the Sponsor and/or the Manufacturer of the drug under review (if not the Sponsor) will be provided with the Clinical Guidance Report and the summary of the pCODR Economic Guidance Report to be publicly posted. Reports will also be provided to the Manufacturer of the drug under review (if not the Sponsor) if the Manufacturer contributed substantive clinical or economic information to the Submission and if they attended the Checkpoint Meeting. The Clinical Guidance Report and Economic Guidance Report to be publicly posted will be made available to the Sponsor via secure electronic transmission. An email notification will be sent to the Submission contact with a unique, time-limited and user-specific link to the Clinical Guidance Report and the summary of the Economic Guidance Report.
- f) Reports are provided to the Sponsor and/or Manufacturer of the drug under review for the following purposes only:
  - to verify that Non-Disclosable Information has been handled in the manner agreed upon at the Checkpoint Meeting with the Sponsor, and as documented in the *Record of Decisions* and the *Addendum* to the Record of Decisions;
  - to understand the disposition of any Additional Information provided by the Sponsor after the Checkpoint Meeting that is Non-Disclosable;
  - to identify any gross factual errors prior to the public posting of the reports.

Interpretative comments provided by the Sponsor and/or Manufacturer would not be considered.

- g) If during the review of the report, the Sponsor and/or Manufacturer of the drug under review identify any discrepancies or errors, they should be submitted in writing to pCODR within the three (3) Business Day period, in accordance with the format outlined in the *pCODR Disclosure of Information Guidelines*. The pCODR program will consider the proposed discrepancies and errors and make revisions or additional redactions to the Clinical Guidance Report, the Economic Guidance Report and the pERC Initial Recommendation as deemed necessary by the pCODR program and prior to public posting of these documents.



## **B6.2 Public Posting of the Initial Recommendation**

- a) The pERC Initial Recommendation will be publicly posted on the pCODR website ten (10) Business Days following the pERC Meeting at which the pERC Initial Recommendation was made. Notification will be sent via e-mail to stakeholders indicating the posting and calling for stakeholder feedback on the pERC Initial Recommendation.
- b) If a Submission is withdrawn (either because of withdrawal of market authorization by Health Canada or voluntary withdrawal by the Sponsor) but a pERC Initial Recommendation has been made, the pCODR program will proceed to publicly post the pERC Initial Recommendation.

## **B6.3 Public Posting of Guidance Reports**

The Clinical Guidance Report and a summary of the Economic Guidance Report will be publicly posted on the pCODR website ten (10) Business Days following the pERC Meeting at which the associated pERC Initial Recommendation was made.

## **B7 Procedures for Feedback on Initial Recommendations**

These procedures relate to stakeholders providing and pCODR using feedback on the pERC Initial Recommendation and are described in section B7 for Post-NOC or Post-NOC/c Submissions, in section C7 for Pre-NOC or Pre-NOC/c Submissions and in section D7 for Resubmissions.

More details related to providing feedback on recommendations can be found on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)) and in the *pCODR Stakeholder Feedback on a pERC Initial Recommendation* template, and the *pCODR Disclosure of Information Guidelines*.

- a) The Sponsor, the Manufacturer of the drug under review (if not the Sponsor), the PAG, registered patient groups (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician(s) who submitted input on the Submission at the beginning of the review process, may provide feedback on the Initial pERC Recommendation.
- b) Feedback must be provided within ten (10) Business Days of the pERC Initial Recommendation being posted on the pCODR section of the CADTH website.
- c) Feedback must be provided in conformity with the templates provided on the pCODR section of the CADTH website and should relate only to the pERC Initial Recommendation.
- d) New Information should not be provided in the feedback by any of the stakeholders and will not be considered by the pERC in their Reconsideration of the Initial Recommendation. New Information may be appropriate for a Resubmission (see section D for more details on Resubmissions).
- e) Any information provided in the feedback will be managed according to the *pCODR Disclosure of Information Guidelines*. To ensure that the pCODR review process is transparent and accountable, the pCODR program considers it essential that information that is within scope provided in the feedback is fully disclosable.

## **B7.1 Feedback from Sponsor and/or Manufacturer**

The Sponsor and the Manufacturer of a drug under review and that is the subject of a pERC Initial Recommendation (if not the Sponsor) can provide feedback on a pERC Initial Recommendation.

## **B7.2A Feedback from PAG**

PAG can provide feedback on a pERC Initial Recommendation. Feedback may include the perspectives of individual PAG members and/or the perspective of the group.

## **B7.2B Feedback from Board of Directors of the Canadian Association of Provincial Cancer Agencies**

The Board of Directors of the Canadian Association of Provincial Cancer Agencies can provide feedback specifically on implementation considerations submitted by PAG, including confirming their support of the recommendation specific to the provisional algorithm.

## **B7.3 Feedback from Patient Group (or registered individual patient or caregiver in cases where there is no patient group)**

Each registered patient group (or registered individual patient or caregiver in cases where there is no patient group) that provided patient input on a Submission to pCODR at the outset of a review on the Drug that is the subject of a pERC Initial Recommendation can provide feedback on the pERC Initial Recommendation.

## **B7.4 Feedback from Registered Clinician**

Registered clinician(s) that provided input on a Submission to pCODR at the outset of a review on the Drug that is the subject of a pERC Initial Recommendation can provide feedback on the pERC Initial Recommendation.

## **B7.5 Review of Feedback on the Initial Recommendation and Eligibility for Early Conversion**

Upon receipt of the feedback on the pERC Initial Recommendation, the pCODR program, in consultation with the pERC Chair and pERC Members, will review the feedback provided on the pERC Initial Recommendation. Where the feedback relates specifically to the provisional algorithm, the pCODR program will share the feedback with the PAG Chair and PAG members for their review and consideration.

### **B7.5.1 Scope of Feedback**

- a) Feedback will be screened by the pCODR program, in consultation with the pERC Chair and PAG Chair (if the feedback is specific to the provisional algorithm) to ensure that it is within the scope of the feedback that was solicited, as outlined in the guidelines and templates for providing feedback on the Initial Recommendation.
- b) If feedback is out of scope, it will not be considered in the decision of whether or not early conversion criteria are met and will be redacted from the posted feedback. A notation will be made in the posted

feedback that the redaction was due to a determination that the feedback was out of scope.

- c) If feedback, from any of the stakeholders includes New Information, the information will not be considered and will be redacted from the posted feedback. A notation will be made in the posted feedback that the redaction was due to New Information being submitted which may be eligible for a Resubmission. It is up to the stakeholder who provided the New Information to determine if a Resubmission will be pursued.

### **B7.5.2 Early Conversion of an Initial to a Final Recommendation**

- a) An assessment will be made by the pERC chair and pERC members to determine if criteria for early conversion of a pERC Initial Recommendation to a pERC Final Recommendation are met.
- b) Criteria for early conversion are as follows:
  - i. No feedback on the Initial Recommendation was provided that was within the scope of the feedback requested; or
  - ii. There is unanimous consensus from stakeholders on the recommended clinical population outlined in the Initial Recommendation; or
  - iii. The Initial Recommendation is an unequivocal positive recommendation, and there are no substantive comments from eligible stakeholders, including no substantive comments regarding the proposed place in therapy of the drug under review in the provisional algorithm.
- c) If any of these conversion criteria are met, editorial changes to the recommendation may be made, and the Final Recommendation will be posted on the pCODR section of the CADTH website two (2) Business Days after the end of the Recommendation feedback deadline date.
- d) There shall be no right to provide further feedback on a pERC Final Recommendation.
- e) If none of these conversion criteria are met, the Initial Recommendation will be returned to pERC for further deliberation and reconsideration at the next possible pERC meeting. The next possible pERC meeting may be the next chronological meeting date or the pERC meeting subsequent to that one, depending on the volume and/or complexity of the reconsideration.

### **B7.5.3 Changes to pCODR Reports Following Feedback on Initial Recommendation**

If it is decided that the Initial Recommendation will be returned to pERC for further deliberation and reconsideration, prior to a pERC meeting, the pCODR program, in consultation with the pERC Chair, may decide the revisions to the Clinical Guidance Report or Economic Guidance Report are required. Revisions may address factual errors or clarifications but will not contain any New Information.

## B8 Procedures for Summarizing and Reviewing Feedback on the Initial Recommendation with pERC and PAG

These procedures include those procedures related to summarizing and reviewing feedback on the Initial Recommendation with pERC and PAG are described in section B8 for Pre-NOC or Pre-NOC/c Submissions, in section C8 for Post-NOC or Post-NOC/c Submissions and in section D8 for Resubmissions.

More details related to summarizing and reviewing feedback on the Initial Recommendation can be found in the *pERC Terms of Reference*, the *pERC Deliberative Framework*, the *pCODR Conflict of Interest Guidelines*, the *pCODR Code of Conduct*, and the *pCODR Code of Communications*, which are available on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

If criteria for early conversion of a pERC Initial Recommendation to a pERC Final Recommendation are not met, the Reconsideration is placed on the agenda of the next possible pERC meeting. The date of the target pERC meeting at which the feedback will be considered will be posted on the pCODR section of the CADTH website two (2) Business Days after the end of the Recommendation feedback deadline date.

### B8.1 Information Provided to pERC on Reconsiderations of Initial Recommendations

- a) The pCODR program prepares the pERC Reconsideration Brief, which includes the following information upon which the pERC will deliberate:
  - The pERC Initial Recommendation
  - Feedback received on the Initial Recommendation, including information about the provisional algorithm that is within the scope of the feedback requested. Where the feedback relates specifically to the provisional algorithm, the pCODR program will share the feedback with the PAG Chair and PAG members for their reconsideration.
  - If required, a revised Clinical Guidance Report and/or revised Economic Guidance Report.
  - The pERC Brief from the initial deliberations (see section B5.2).
- b) The pERC Reconsideration Brief is delivered to pERC Members and the PAG before the scheduled pERC meeting at which the Initial Recommendation is reconsidered.

### B8.2 pERC Consideration of Feedback on the Initial Recommendation

See sections B5.3, B5.4 and B5.5 for procedures for preparation for the pERC Meeting, the pERC Meeting and pERC Recommendations.

In addition:

- a) pERC shall review and consider the pERC Reconsideration Brief. It may view the Submission afresh and consider and decide whether, based on the evidence and with regard to the *pERC Deliberative Framework*, the pERC Initial Recommendation should be maintained or changed.
- b) There shall be no right to provide further feedback on a pERC Final Recommendation.

## B9 Procedures for Preparing & Publicly Posting Final Recommendations, Reports and Feedback

These procedures include all those procedures related to the preparation and public posting of Final Recommendations, Guidance Reports and Feedback are described in section B9 for Post-NOC or Post-NOC/c Submissions, section C9 for Pre-NOC or Pre-NOC/c Submissions and section D9 for Resubmissions.

For more details related to publicly posting Final Recommendations, reports and feedback see the *pCODR Disclosure of Information Guidelines*, the *pCODR Patient Engagement Guide*, the *pCODR Patient Group (or registered individual patient or caregiver in cases where there is no patient group) Conflict of Interest Declaration*, the *pCODR Registered Clinician Conflict of Interest Declaration*, the *pCODR Conflict of Interest Guidelines*, and the *pCODR Procedural Review Guidelines*, which are available on the pCODR section of the CADTH website, [www.cadth.ca/pcodr](http://www.cadth.ca/pcodr).

### B9.1 Finalizing Recommendations

- a) A final determination of a Submission shall be deemed to have taken place when:
  - A pERC Initial Recommendation has been made, early conversion criteria are met (See section B7.5) and the pERC Final Recommendation is publicly posted on the pCODR section of the CADTH website.
  - A pERC Initial Recommendation has been made, the pERC has considered stakeholder feedback on the pERC Initial Recommendation (see section B7.1, B7.2, B7.3 and B7.4) and made a pERC Final Recommendation that is publicly posted on the pCODR section of the CADTH website.
- b) There shall be no right to provide further feedback on a pERC Final Recommendation and a Submission may not be withdrawn following public posting of the pERC Final Recommendation.
- c) A Procedural Review of a publicly posted pERC Final Recommendation may be requested as outlined in section B10.2 and in the *pCODR Procedural Review Guidelines*.
- d) A *Notification to Implement a pERC Final Recommendation* will be issued via email by the pCODR program, as outlined in section B10.1, and participating P/T Ministries of Health or Provincial Cancer Agencies may then proceed to implement the pERC Final Recommendation.

### B9.2 Public Posting of Final Recommendation

- a) If a Final Recommendation is a result of meeting early conversion criteria, it will be publicly posted on the pCODR section of the CADTH website two (2) Business Days after the end of the Recommendation feedback deadline date.
- b) If a Final Recommendation is a result of a Reconsideration by pERC based on feedback provided on an Initial Recommendation, the Final Recommendation will be publicly posted on the pCODR website ten (10) Business Days after the pERC Meeting at which the Final Recommendation was made.
- c) When a pERC Final Recommendation is posted on the pCODR section of the CADTH website, a notification will be sent via email to stakeholders indicating the posting has occurred.

- d) If a Submission is withdrawn (either because of withdrawal of market authorization by Health Canada or voluntary withdrawal by the Sponsor) but a pERC Final Recommendation has been made, the pCODR program will proceed to publicly post the pERC Final Recommendation.

### **B9.3 Public Posting of Final Guidance Reports**

- a) If Clinical or Economic Guidance Reports were revised as a result of feedback that was provided on the Initial Recommendation, the Guidance Reports posted at the time of the Initial Recommendation will be replaced with Final Guidance Reports. The Final Guidance Reports are publicly posted ten (10) Business Days after the pERC meeting at which the Final Recommendation was made or, for those meeting the criteria for early conversion, two (2) Business Days after the end of the Recommendation feedback deadline date.
- b) When the Final Clinical Guidance Report and the Final Economic Guidance Reports are publicly posted on the pCODR section of the CADTH website, a notification will be sent via email to stakeholders indicating the posting has occurred.

### **B9.4 Public Posting of Feedback Received**

- a) Feedback that was received on the Initial Recommendation by eligible stakeholders and which was in scope of the feedback that was solicited, will be posted on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)). If feedback is provided that is not in scope of the feedback that has been solicited, it will be redacted prior to posting and the reason for the redaction, i.e. that it was out of scope, will be stated. To ensure that the pCODR review process is transparent and accountable, the pCODR program considers it essential that information that is within scope provided in the feedback is fully disclosable.
- b) When the stakeholder feedback on the pERC Initial Recommendation is publicly posted on the pCODR section of the CADTH website, a notification will be sent via email to stakeholders indicating the posting has occurred.

### **B9.5 Public Posting of Conflict of Interest Declarations**

- a) Patient group (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician conflict of interest declarations providing input on a Submission or feedback on a pERC Initial Recommendation will be publicly posted on the pCODR section of the CADTH website, as described in the *pCODR Patient Engagement Guide*, in accordance with the *pCODR Patient Group (or registered individual patient or caregiver in cases where there is no patient group) Conflict of Interest Declarations* template and *pCODR Registered Clinician Conflict of Interest Declaration* template.
- b) Conflict of interest declarations of pERC Members and of PAG members are publicly posted on the pCODR website and updated on an annual basis or as needed, in accordance with the *pCODR Conflict of Interest Guidelines*.

### **B9.6 Time-Limited Redactions in Final Recommendations and Final Guidance Reports**

- a) Final Recommendations and Final Guidance Reports posted on the pCODR website will be reviewed by the pCODR program from time to time and Non-

Disclosable Information that is redacted in reports and recommendations will be publicly disclosed at the expiration of the Sponsor/pCODR agreed upon period for time-limited redactions.

- b) If Non-Disclosable Information was redacted and included in the publicly posted Clinical Guidance Report, Economic Guidance Report or pERC Final Recommendation with the agreement between pCODR and the Sponsor that the redaction was time-limited; in exceptional circumstances such as the Sponsor and/or Manufacturer providing evidence of imminent publication, the pCODR program may grant a brief extension of no greater than one month to the expiry of the time-limited redaction.

## B10 End of pCODR Drug Review Process

These procedures relate to relevant activities following the end of the pCODR drug review process and are described in section B10 for Post-NOC or Post-NOC/c Submissions, in section C10 for Pre-NOC or Pre-NOC/c Submissions and in section D10 for Resubmissions.

More details related to these procedures can be found in the *pCODR Procedural Review Guidelines*, the *pERC Deliberative Framework*, and the *pCODR Disclosure of Information Guidelines*.

### B10.1 Recommendation Implementation and Funding Decisions

- a) Until the pCODR program has issued a *Notification to Implement* a pERC Final Recommendation, the pERC Final Recommendation will not be implemented by participating F/P/T Ministries of Health or Provincial Cancer Agencies.
- b) Ten (10) business days following posting of the pERC Final Recommendation, if a request for a procedural review has not been submitted to the CADTH President and Chief Executive Officer, the pCODR program will issue a *Notification to Implement* a pERC Final Recommendation and indicate on the pCODR section of the CADTH website that this has been issued. Each of the participating F/P/T Ministries of Health and Provincial Cancer Agencies may then proceed to implement the pERC Final Recommendation.
- c) Fifteen (15) business days following the submitted date of an application for a procedural review, if a request for a procedural review has been submitted to the CADTH President and Chief Executive Officer, and the request has not been accepted, the pCODR program will issue a *Notification to Implement* a pERC Final Recommendation and indicate on the pCODR section of the CADTH website that this has been issued. Each of the participating F/P/T Ministries of Health and Provincial Cancer Agencies may then proceed to implement the pERC Final Recommendation.
- d) If a procedural review request is submitted to the CADTH President and Chief Executive Officer and is accepted, a pERC Final Recommendation will only be implemented when the procedural review is complete and a *Notification to Implement* a pERC Final Recommendation has been issued by the pCODR program.

## B10.2 Procedural Review

### B10.2.1 Grounds for a Procedural Review

- a) A procedural review is a determination of whether pCODR and/or pERC have complied with review processes and procedures. A procedural review may be requested on the basis that:
  - i. pCODR failed to act in accordance with its procedures in conducting the review, as described in the *pCODR Procedures*; or
  - ii. pERC failed to apply its deliberative framework in formulating its recommendation, as outlined in the *pERC Deliberative Framework*.
- b) These grounds relate only to whether or not the pCODR drug review process was followed and not to the content of the pERC Final Recommendation. Differences in the interpretation and use of data during the review do not constitute grounds for a procedural review, e.g. the selection of comparators, the use of data sets, the place in therapy. In addition, disagreement with pCODR's approach to managing Non-Disclosable Information that was provided in the Submission, including use or non-use in the review process, does not constitute grounds for a procedural review, provided processes were followed as outlined in the *pCODR Disclosure of Information Guidelines*. It is also important to note that the establishment of an ad hoc clinical panel for the purposes of discussing implementation issues on selected oncology drug products, including the development of a provisional algorithm is at the sole discretion of the pCODR program. For greater certainty, by including or not including an ad hoc clinical panel for a specific Submission or Resubmission will not constitute grounds for a procedural review.

### B10.2.2 Requesting a Procedural Review

- a) A procedural review can be requested within ten (10) Business Days of a pERC Final Recommendation being publicly posted on the pCODR section of the CADTH website, by any one of the parties who participated in the pCODR review of that drug, which could include: the Sponsor, the Manufacturer of the drug under review (if not the Sponsor), the PAG, a registered patient group (or registered individual patient or caregiver in cases where there is no patient group) or registered clinician(s) who provided input on the review or feedback on the pERC Initial Recommendation.
- b) If a review participant wishes to request a procedural review, the *pCODR Procedural Review Request Form* (see the *pCODR Procedural Review Guidelines* for the template) must be completed and submitted, along with all supporting documentation, within ten (10) business days of a pERC Final recommendation being posted. Intent to submit supporting documentation after the ten (10) day period will not be considered sufficient.



- c) Multiple review participants may submit a request for a procedural review of a pERC Final Recommendation but each participant may only submit one request.
- d) A request for a procedural review of a pERC Final Recommendation can only be submitted once. If the Submission is re-deliberated upon, as a result of a procedural review, once the pERC Final Recommendation is posted no further requests for an additional procedural review of the associated recommendation can be made. A *Notification to Implement* a pERC Final Recommendation will be issued.

### **B10.2.3 Screening a Request for a Procedural Review**

- a) The CADTH President and Chief Executive Officer, on the advice of the pCODR Advisory Committee (PAC) Chair and Vice-Chair, will review the *pCODR Procedural Review Request Form* and supporting documentation and determine if grounds for a procedural review exist. The decision of whether to accept or not accept the request for a procedural review will be made within fifteen (15) days of the submitted date of an application for a procedural review. This decision will be communicated to the requestor and posted on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).
- b) While screening the request for a procedural review, the CADTH President and Chief Executive Officer, on the advice of the pCODR Advisory Committee (PAC) Chair and Vice-Chair, may determine that additional clarification is required from the party who made the request. Clarification must be provided by the procedural review requestor, as outlined by the CADTH President and CEO, within 15 days of a Final Recommendation being posted on the pCODR section of the CADTH website, otherwise the request for a procedural review may be rejected.
- c) If the request for a procedural review is not accepted, the party who made the request will be notified by the CADTH President and Chief Executive Officer and the pCODR program will issue a *Notification to Implement* a pERC Final Recommendation so that F/P/T Ministries of Health or Provincial Cancer Agencies can proceed to implement the pERC Final Recommendation
- d) If the request for a procedural review is accepted, the party who made the request will be notified by the CADTH President and Chief Executive Officer and a procedural review will be conducted as outlined in section B10.2.4 of this document and in the *pCODR Procedural Review Guidelines*.

### **B10.2.4 Conducting a Procedural Review**

- a) The CADTH President and Chief Executive Officer will appoint three (3) to five (5) members from the PAC, as needed. The PAC panelists will consider the evidence and make a recommendation to the CADTH President and Chief Executive Officer. In certain circumstances, the panel conducting the procedural review may determine that additional expertise is required and may request advice from external experts while conducting the procedural review.

- b) The Procedural Review Panel will review the *pCODR Procedural Review Request Form* and supporting documentation provided by the requestor. As may be required throughout the procedural review, the Panel may request additional information from the requestor, the pERC, or the pCODR program or other participants in the review process.
- c) At the beginning of the procedural review, the pERC or the pCODR program has the option to provide a provisional response to the Procedural Review Panel.
- d) For the duration of the procedural review, it will be indicated on the pCODR section of the CADTH website that a procedural review is being conducted.
- e) The CADTH President and Chief Executive Officer will make the decision based on PAC's recommendation, and will determine the outcome(s) of the procedural review. This determination will be communicated to the requestor, the pCODR Advisory Committee and the pCODR program.

### **B10.2.5 Outcomes of a Procedural Review**

- a) The Procedural Review Panel may determine that:
  - i. No changes are required and the pCODR program issues a *Notification to Implement* a pERC Final Recommendation.
  - ii. Steps in the pCODR review process must be revisited and/or the pERC Recommendation must be re-deliberated by pERC at the next possible pERC meeting. A re-deliberation may result in the pERC Final Recommendation being maintained or being changed.
- b) If steps in the pCODR review process must be revisited and/or the Submission re-deliberated, the submission would receive priority placement on the pERC meeting agenda at which it will be re-deliberated and work on the Submission would be prioritized as per section B3.1.5 of this document.
- c) If the Submission is re-deliberated by the pERC, details and outcomes of the procedural review will be communicated in the pERC Final Recommendation.

### **B10.3 Disposition of Submission Documents**

The issuance of the *Notification to Implement* a pERC Final Recommendation by the pCODR program signals the completion of the pCODR review process. The pCODR program then undertakes the steps detailed in this section regarding the disposition of documents associated with the review. The pCODR program follows the same steps in the disposal of documents associated with a withdrawn Submission.

#### **B10.3.1 Retrieval**

The pCODR program retrieves all paper and electronic copies of the Submission documents from the Review Team.

### B10.3.2 Archiving

Archiving of Submission documents is carried out as follows:

- The pCODR program retains one (1) complete CD/DVD set of the Submission, where available, and one complete set of all documents (paper and/or electronic) associated with the review of a Drug, on file in secure storage for as long as there may be a need to consult the documents.
- The pCODR program undertakes regular reviews of archived material. Any material that the pCODR program determines to be no longer required is disposed of as described in section 10.3.3
- All other extra copies of paper and electronic documents associated with the review of a Drug are disposed of as described below in section 10.3.3.

### B10.3.3 Disposal

- a) The pCODR program disposes of any paper documents associated with the Submission by confidential shredding. Any additional CD/DVD sets provided in the Submission are destroyed.
- b) The pCODR program advises the Sponsor, in writing, that it has disposed of the extra copies of documents.

## C PRE-NOC and PRE-NOC/c SUBMISSION PROCEDURES

Procedures described in section C of this document are those associated with Pre-NOC or Pre-NOC/c Submissions. Procedures associated with Post-NOC or Post-NOC/c Submissions are described in section B of this document, procedures associated with Resubmissions are described in section D of this document, procedures associated with Requests for Advice are described in section E of this document and procedures associated with Manufacturer Non-Submission are described in section F.

For Pre-NOC or Pre-NOC/c Submissions, refer to procedures associated with Post-NOC and Post-NOC/c Submissions (section B) with the following exceptions outlined in this section, section C.

### C1 Pre-submission Procedures

Pre-submission procedures include all those procedures related to the period before an anticipated Submission is filed with the pCODR program.

More details related to the Pre-submission process can be found in the *pCODR Pre-Submission, Submission and Resubmission Guidelines*, the *pCODR Disclosure of Information Guidelines*, the *pERC Deliberative Framework* and the *pCODR PAG Input on a Review* template, which are available on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

See Section B1. Procedures applied to Pre-submission procedures for Post-NOC or Post-NOC/c Submissions also apply to Pre-submission procedures for Pre-NOC or Pre-NOC/c Submissions.

## C2 Procedures for Preparing and Submitting a Submission

Submission procedures include all those procedures relating to preparing and submitting a Submission to pCODR for review and are described in section C2 for Pre-NOC or Pre-NOC/c Submissions. Procedures for preparing Post-NOC or Post-NOC/c Submissions are outlined in section B2 and procedures for preparing Resubmissions are outlined in Section D2.

More details on the types of Submissions, Submission Requirements and procedures related to preparing and filing a Submission can be found in the *pCODR Pre-Submission, Submission and Resubmission Guidelines* and the *pCODR Disclosure of Information Guidelines*, which are located on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

### C2.1 Initiating a Submission

See Section B 2.1. Procedures applied to the initiation of a submission for Post-NOC or Post-NOC/c Submissions also apply to initiation of a submission for Pre-NOC or Pre-NOC/c Submissions.

### C2.2 Eligible Sponsors

#### C2.2.1 Manufacturers

Pre-NOC or Pre-NOC/c Submissions from Manufacturers include those for New Oncology Drugs, for an Oncology Drug with a New Indication.

#### C2.2.2 PAG

Pre-NOC or Pre-NOC/c Submissions for New Oncology Drugs **cannot** be initiated by the PAG.

The PAG may submit an Oncology Drug with a New Indication that has not received a NOC or NOC/c, if the Oncology Drug is already authorized for marketing in Canada for other indication(s).

#### C2.2.3 Tumour Groups

Pre-NOC or Pre-NOC/c Submissions for New Oncology Drugs **cannot** be initiated by the Tumour Groups.

Provincially-recognized clinician-based Tumour Groups may submit an Oncology Drug with a New Indication that has not received a NOC or NOC/c, if the Oncology Drug is already authorized for marketing in Canada for other indication(s).

*Note: if a Submission is made for a Oncology Drug with a New Indication for a drug that already has received market authorization in Canada, and sufficient clinical and economic evidence exists to make a Submission, it is not required that the indication currently be under review by Health Canada.*

### C2.3 Content of the Submission

See Section B2.3. Procedures applied to the content of a Submission for Post-NOC or Post-NOC/c Submissions also apply to the content of a Submission for Pre-NOC or Pre-NOC/c Submissions.

## **C2.4 Filing of Submission**

Pre-NOC or Pre-NOC/c Submissions may be filed by the Manufacturer up to six months in advance of anticipated receipt of an NOC or NOC/c. Notwithstanding, a pre-NOC submission will not be placed on the pERC meeting agenda until NOC is granted by Health Canada and the Category 2 requirements are satisfied.

The Manufacturer is responsible for advising Health Canada of the intent to file a Pre-NOC or Pre-NOC/c Submission with the pCODR program and for providing Health Canada with the necessary authorization to share information about the Submission with the pCODR program, through a signed Letter of Authorization. The Letter of Authorization sets out the conditions for information sharing. A template for the Letter of Authorization is included in the pCODR Pre-Submission, Submission and Resubmission Guidelines.

See also Section B2.4. Procedures applied to filing Submissions for Post-NOC or Post-NOC/c Submissions also apply to Pre-NOC or Pre-NOC/c Submissions.

## **C2.5 Submission Tracking**

See Section B2.5. Procedures applied to submission tracking for Post-NOC or Post-NOC/c Submissions also apply to submission tracking for Pre-NOC or Pre-NOC/c Submissions.

In the event of a Submission being reviewed by pCODR that is a Pre-NOC Submission under review by Health Canada, pCODR will not post product strength, product format and NOC date, until such time as regulatory approval has been issued.

## C3 Procedures for Screening Submissions, Initiating the Review Process and Collecting Patient Group (or registered individual patient or caregiver in cases where there is no patient group) and Registered Clinician Input

Procedures relating to screening Pre-NOC or Pre-NOC/c Submissions, initiating the review process for Pre-NOC or Pre-NOC/c Submissions and collecting patient group input for Pre-NOC or Pre-NOC/c Submissions are outlined in section C3. These procedures are outlined in section B3 for Post-NOC or Post-NOC/c Submissions and are outlined in section D3 for Resubmissions.

More details related to these procedures can be found in the *pCODR Pre-Submission, Submission and Resubmission Guidelines*, the *pCODR Disclosure of Information Guidelines*, the *pCODR Procedural Review Guidelines*, the *pCODR Conflict of Interest Guidelines*, *Guidelines for Manufacturers on Application Fees for CADTH Pharmaceutical Reviews*, the *pCODR Patient Engagement Guide*, the *Patient Input Template for CDR and pCODR (or registered individual patient or caregiver in cases where there is no patient group) and Registered Clinician Input on a Drug Review* template, which are located on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

### C3.1 Screening Submissions and Initiating the Review Process

#### C3.1.1 Receipt of a Submission

See Section B3.1.1. Procedures applied to receipt of a submission for Post-NOC or Post-NOC/c Submissions also apply to receipt of a submission for Pre-NOC or Pre-NOC/c Submissions.

#### C3.1.2 Screening a Submission

- a) Submission screening is conducted to determine if a Submission is complete or incomplete. Submissions will be screened in the order in which they were received at pCODR. The pCODR program will determine whether the Submission is complete, in accordance with the *pCODR Pre-Submission, Submission and Resubmission Guidelines*, within ten (10) Business Days of its receipt (Note: The date of receipt for a Submission is considered day zero for the purpose of calculating timelines).
- b) For Pre-NOC or Pre-NOC/c Submissions, Category 1 requirements must be met for the Submission to be deemed complete and to be entered into the review queue and for the review to proceed. For Pre-NOC or Pre-NOC/c Submissions Category 2 information must be provided to the pCODR program as soon as the NOC or NOC/c has been issued, and at least six (6) 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. Details on Category 1 and Category 2

Submission Requirements are outlined in the *pCODR Pre-Submission, Submission and Resubmission Guidelines*.

### **C3.1.3 Deeming a Submission Incomplete**

See Section B3.1.3. Procedures applied to deeming a Submission incomplete for Post-NOC or Post-NOC/c Submissions also apply to deeming a Submission incomplete for Pre-NOC or Pre-NOC/c Submissions.

### **C3.1.4 Deeming a Submission Complete**

See Section B3.1.4. Procedures applied to deeming a Submission complete for Post-NOC or Post-NOC/c Submissions also apply to deeming a Submission complete for Pre-NOC or Pre-NOC/c Submissions.

### **C3.1.5 Prioritization and Order of Review**

See section B3.1.5 for procedures on the prioritization and order of review.

### **C3.1.6 Withdrawal Process**

Anytime after a Submission is deemed complete, and before a pERC Final Recommendation is posted on the pCODR section of the CADTH website, a Submission may be withdrawn from the pCODR review process.

#### **C3.1.6.1 Withdrawal or Non-issuance of Market Authorization by Health Canada**

- a) Subject to section C3.1.7, if in the case of a Pre-NOC Submission that is under review by pCODR, Health Canada decides that it cannot issue an NOC or NOC/c (i.e., market authorization) for the Drug, the provisions of section B3.1.6.1 shall apply. This will occur in cases when the Manufacturer has received a Notice of Non-Compliance, Notice of Non-Compliance Withdrawal Letter, Notice of Deficiency, or Notice of Deficiency Withdrawal Letter.
- b) In the case of a Manufacturer Pre-NOC Submission, the Manufacturer must advise the pCODR program, in writing, within five (5) Business Days and must provide the following information:
  - the date on which Notice of Non-Compliance, Notice of Non-Compliance Withdrawal Letter, Notice of Deficiency, or Notice of Deficiency Withdrawal Letter was issued.
  - the reason why the market authorization was withdrawn or the NOC or NOC/c was not issued
- c) The pCODR will stop the review of a Pre-NOC Submission immediately upon being notified of, or learning about Health Canada's decision to withdraw market authorization or to not issue an NOC or NOC/c.
- d) If and when Health Canada issues an NOC or NOC/c or reinstates the market authorization and the Sponsor wants

the Drug to be reviewed by pCODR, the Sponsor will be required to file a complete Submission in accordance with the *pCODR Pre-Submission, Submission and Resubmission Guidelines*. The Resubmission must contain information, including Health Canada information, which addresses the reason(s) for the withdrawal or non-issuance of an NOC or NOC/c and reinstatement of market authorization. It will be assessed on a case-by-case basis as to whether the Resubmission goes to the end of the review queue or if it resumes at the stage where it was stopped. This assessment will depend upon factors such as: (1) the timing of the resolution with Health Canada (2) the point in the pCODR review at which the withdrawal occurred and how much work was completed (3) the availability of pCODR resources (4) the nature of the Notice of Non-Compliance, Notice of Non-Compliance Withdrawal Letter, Notice of Deficiency, or Notice of Deficiency Withdrawal Letter.

- e) For Pre-NOC Submissions of a New Indication that is not currently under review by Health Canada, the provisions of section B3.1.6.1 shall apply.

#### **C3.1.6.2 Voluntary Withdrawal of a Submission**

See section B3.1.6.2. Procedures associated with the voluntary withdrawal of a Submission for Post-NOC or Post-NOC/c Submissions also apply to Pre-NOC or Pre-NOC/c Submissions.

In addition:

- a) If the Submission withdrawn is a Pre-NOC Submission, information sharing between Health Canada and the pCODR program regarding the Pre-NOC Submission will stop immediately.
- b) If the Sponsor wishes to reinitiate the review of a voluntarily withdrawn Pre-NOC or Pre-NOC/c Submission for a Drug, which has subsequently received an NOC or NOC/c, the Sponsor is required to file a Resubmission in accordance with the *pCODR Pre-Submission, Submission and Resubmission Guidelines* for a regular Post-NOC or Post-NOC/c Submission in order for the review to proceed.

#### **C3.1.7 Temporary Suspension of Review**

See section B3.1.7. Procedures associated with the temporary suspension of a Post-NOC or Post-NOC/c Submission also apply to the temporary suspension of a Pre-NOC or Pre-NOC/c Submission. In addition:

- a) Where a submission is filed on a pre-NOC basis and received a Notice of Non-Compliance (NON) or a Notice of Deficiency (NOD) from Health Canada, the pCODR program may allow the Submission to be temporarily suspended if it meets the set of requirements under this section. In order to be eligible for a temporary suspension, a Sponsor must have consented to the information sharing process between CADTH and Health Canada. The pCODR program will also consider the



following factors when determining if a temporary suspension is warranted, including but not limited to:

- i. Health Canada's rationale for the NOD or NON (e.g., clinical versus quality issues)
  - ii. The anticipated timelines for addressing the issues raised by Health Canada
- b) The decision to allow for a temporary suspension will be made solely at the discretion of the pCODR program on a case-by-case basis. If the pCODR program determines that a temporary suspension is not eligible, the Submission will have to be withdrawn in accordance with section C3.1.6.1.
- c) For greater certainty, the pCODR program does not have any authority with respect to the determination of the NOD or NON that is the subject of the Pre-NOC or Pre-NOC/c Submission. Only Health Canada can determine how its review of the Drug proceeds in accordance with the Food and Drugs Act and Regulations, and Health Canada's guidance documents and policies.
- d) The following information will be required in order for the pCODR program to lift the temporary suspension:
  - i. A brief summary of the issue and how the manufacturer has or is planning to resolve the issue
  - ii. Any new clinical data filed with Health Canada to address the issue
  - iii. Advance notification of a minimum of six weeks from the Sponsor when the issue is likely to be resolved and anticipated timelines that a NOC or NOC/c will be issued by Health Canada
- e) Once the issue is resolved, and depending on the availability of resources, the review by pCODR will resume at the stage where it was suspended. The Sponsor, the Manufacturer of the drug under review (if not the Sponsor) and Health Canada will be advised, in writing, when the review process resumes along with the anticipated target dates for the steps of the review process, and it will be posted on the website when the review process resumes along with the anticipated target dates for the steps of the review process.

### **C3.1.8 Initiation of Review Process**

See Section B3.1.8. Procedures applied to initiating the review process for Post-NOC or Post-NOC/c Submissions also apply to initiating the review process for Pre-NOC or Pre-NOC/c Submissions.

### **C3.1.9 Composition of the Review Team**

See section B3.1.9. Procedures applied to determining composition of the review team for Post-NOC or Post-NOC/c Submissions also apply to determining composition of the review team for Pre-NOC or Pre-NOC/c Submissions.

### **C3.1.10 Disclosure of the Review Team**

See section B3.1.10. Procedures applied to disclosure of the Review Team for Post-NOC or Post-NOC/c Submissions also apply to disclosure of the Review Team for Pre-NOC or Pre-NOC/c Submissions.

### **C3.2 Collect Patient Group (or registered individual patient or caregiver in cases where there is no patient group) and Registered Clinician Input**

See section B3.2. Procedures applied to collecting patient group (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician input for Post-NOC or Post-NOC/c Submissions also apply to collecting patient group (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician input for Pre-NOC or Pre-NOC/c Submissions.

## **C4 Clinical and Economic Review Procedures**

Clinical and economic review procedures include all those procedures related to preparing the Clinical Guidance Report and Economic Guidance Report and are described in section C4 for Pre-NOC or Pre-NOC/c Submissions. Clinical and economic review procedures for Post-NOC or Post-NOC/c Submissions are described in section B4 and clinical and economic review procedures for Resubmissions are described in section D4.

More details related to procedures for clinical and economic reviews can be found in the *pCODR Clinical Guidance Report* template, the *pCODR Economic Guidance Report* template, the *pCODR Disclosure of Information Guidelines*, the *pCODR Clinical Guidance Panel Terms of Reference* and the *pCODR Economic Guidance Panel Terms of Reference*.

### **C4.1 Conduct Clinical Review**

In addition to those procedures described in section B4.1, the following procedures apply:

- a) If available at the time of protocol development, relevant information from the Health Canada Product Monograph meetings may be used when developing the review protocol.
- b) The pCODR program may attend the Health Canada Product Monograph meetings as observers at the invitation of Health Canada. The Manufacturer informs pCODR of the meeting date and time and provides copies of all documents required for the meeting (e.g., relevant Clarifaxes, Product Monograph, presentations) to the pCODR program. Documents provided at the meeting will be handled in accordance with the *pCODR Disclosure of Information Guidelines*.
- c) The pCODR and Health Canada communicate only as required regarding the Pre-NOC or Pre-NOC/c Submission by email, telephone or teleconference. In certain cases, the Manufacturer may be included in communications between the pCODR and Health Canada. The Manufacturer has the responsibility of communicating to the pCODR program any relevant issues raised by Health Canada or changes in direction that occur in the Health Canada review as soon as the Manufacturer is aware and a decision has been made during the time that a pre-NOC or NOC/c Submission is under review by pCODR.

#### **C4.1.1 Clarify Clinical Information with Sponsor at Checkpoint Meeting**

See section B4.1.1. Procedures associated with clarifying clinical information with the Sponsor at the Checkpoint Meeting for Post-NOC or Post-NOC/c Submissions apply to clarifying clinical information with the Sponsor at the Checkpoint Meeting for Pre-NOC or Pre-NOC/c Submissions.

##### **C4.1.1.1 Additional Information and Clarification of the Submission**

See section B4.1.1.1. Procedures associated with Additional Information and clarification of the Submission for Post-NOC or Post-NOC/c Submissions apply to Additional Information and Clarification of the Submission for Pre-NOC or Pre-NOC/c Submissions. In addition:

If the Review Team considers that Additional Information is required, the pCODR program will contact the Manufacturer and/or Health Canada.

##### **C4.1.1.2 Review of Non-Disclosable Information in the Submission**

See section B4.1.1.2. Procedures applied to the review of Non-Disclosable Information for Post-NOC or Post-NOC/c Submissions also apply to the review of Non-Disclosable Information for Pre-NOC or Pre-NOC/c Submissions.

#### **C4.1.2 Delay in the Clinical Review**

See section B4.1.2. Procedures applied to a delay in the clinical review for Post-NOC or Post-NOC/c Submissions also apply to a delay in the clinical review for Pre-NOC or Pre-NOC/c Submissions.

#### **C4.1.3 Completing the Clinical Guidance Report**

See section B4.1.3. Procedures applied to completing the Clinical Guidance Report for Post-NOC or Post-NOC/c Submissions also apply to completing the Clinical Guidance Report for Pre-NOC or Pre-NOC/c Submissions. In addition:

The Methods Team and/or the Clinical Guidance Panel may revise the Clinical Guidance Reports to reflect the final Product Monograph or other information that is received when the NOC or NOC/c becomes available.

### **C4.2 Conduct Economic Review**

See section B4.2. Procedures applied to the conduct of the economic review for Post-NOC or Post-NOC/c Submissions also apply to the conduct of the economic review for Pre-NOC or Pre-NOC/c Submissions.

#### **C4.2.1 Clarify Economic Information with Sponsor at Checkpoint Meeting**

See section C4.1.1. Procedures applied to clarifying clinical information with the Sponsor at the Checkpoint Meeting for Pre-NOC or Pre-NOC/c Submissions also apply to clarifying economic information with the Sponsor at the Checkpoint Meeting for Pre-NOC or Pre-NOC/c Submissions.

#### C4.2.2 Delay in the Economic Review

See section C4.1.2. Procedures applied to the delay in the clinical review for Pre-NOC or Pre-NOC/c Submissions also apply to the delay in the economic review for Pre-NOC or Pre-NOC/c Submissions.

#### C4.2.3 Completing the Economic Guidance Report

See section C4.1.3. Procedures applied to completing the Clinical Guidance Report for Pre-NOC or Pre-NOC/c Submissions also apply to completing the Economic Guidance Report for Pre-NOC or Pre-NOC/c Submissions. In addition:

The Economic Guidance Panel may revise the Economic Guidance Reports to reflect any changes in the Clinical Guidance Report that occur as a result of the final Product Monograph or other information that is received when the NOC or NOC/c becomes available.

## C5 pERC Meeting and Deliberation Procedures

pERC Meeting and Deliberation procedures include all those procedures related to the preparation for and conduct of the pERC meeting and are described in section C5 for Pre-NOC or Pre-NOC/c Submissions. pERC meeting and deliberation procedures for Post-NOC or Post-NOC/c Submissions are described in section B5 and for Resubmissions are described in section D5.

More details related to pERC Meeting and Deliberation Procedures can be found in the *pERC Terms of Reference*, the *pERC Deliberative Framework*, the *pCODR Conflict of Interest Guidelines*, the *pCODR Code of Conduct*, the *pCODR Code of Communications*, and the *pCODR Pre-Submission, Submission and Resubmission Guidelines*, which are available on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

See section B5 for pERC Meeting and Deliberation Procedures for Post-NOC or Post-NOC/c Submissions, which also apply to Pre-NOC or Pre-NOC/c Submissions.

In addition:

- Pre-NOC or Pre-NOC/c Submissions will not be placed on the pERC Meeting agenda until the Drug has Canadian market authorization and the pCODR program has received all Category 2 Submission Requirements for a Pre-NOC or Pre-NOC/c Submission including a copy of the NOC or NOC/c and a final Health Canada approved product monograph. 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. If the review is a Pre-NOC or Pre-NOC/c Submission for an Oncology Drug with a New Indication that has not been submitted to Health Canada for review, this requirement would be waived.

## C6 Procedures for Preparation of Public Posting of Initial Recommendations and Guidance Reports

See section B6 for Procedures for Preparation of Public Posting of Initial Recommendations and Guidance Reports for Post-NOC or Post-NOC/c Submissions, which also apply to Pre-NOC or Pre-NOC/c Submissions. Procedures for the preparation of public posting of Initial Recommendations and Guidance Reports for Resubmissions are described in section D6.

For more details related to procedures associated with the public posting of Initial Recommendations and guidance reports see the *pCODR Disclosure of Information Guidelines*, which is available on the pCODR section of the CADTH website, [www.cadth.ca/pcodr](http://www.cadth.ca/pcodr).

## C7 Procedures for Feedback on Initial Recommendations

These procedures relate to stakeholders providing and pCODR using feedback on the pERC Initial Recommendation and are described in section B7 for Post-NOC or Post-NOC/c Submissions, in section C7 for Pre-NOC or Pre-NOC/c Submissions and in section D7 for Resubmissions.

More details related to providing feedback on recommendations can be found on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)) and in the *pCODR Stakeholder Feedback on a pERC Initial Recommendation* template and the *pCODR Disclosure of Information Guidelines*.

See section B7 for Procedures for Feedback on Initial Recommendations for Post-NOC or Post-NOC/c Submissions, which also apply to Pre-NOC or Pre-NOC/c Submissions.

## C8 Procedures for Summarizing and Reviewing Feedback on the Initial Recommendation with pERC and PAG

These procedures include all those procedures related to summarizing and reviewing feedback on the Initial Recommendation with pERC and PAG are described in section B8 for Pre-NOC or Pre-NOC/c Submissions, in section C8 for Post-NOC or Post-NOC/c Submissions and in section D8 for Resubmissions.

See section B8, Procedures for Summarizing and Reviewing Feedback on the Initial Recommendation with pERC for Post-NOC or Post-NOC/c Submissions, which also apply to Pre-NOC or Pre-NOC/c Submissions.

More details related to summarizing and reviewing feedback on the Initial Recommendation pERC can be found in the *pERC Terms of Reference*, the *pERC Deliberative Framework*, the *pCODR Conflict of Interest Guidelines*, the *pCODR Code of Conduct*, and the *pCODR Code of Communications*, which are available on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

## C9 Procedures for Preparing & Publicly Posting Final Recommendations, Reports and Feedback

These procedures include all those procedures related to the preparation and public posting of Final Recommendations, Guidance Reports and Feedback are described in section B9 for

Post-NOC or Post-NOC/c Submissions, section C9 for Pre-NOC or Pre-NOC/c Submissions and section D9 for Resubmissions.

For more details related to publicly posting Final Recommendations, reports and feedback see the *pCODR Disclosure of Information Guidelines*, the *pCODR Patient Engagement Guide*, the *pCODR Patient Group (or registered individual patient or caregiver in cases where there is no patient group) Conflict of Interest Declaration*, the *pCODR Registered Clinician Conflict of Interest Declaration*, the *pCODR Conflict of Interest Guidelines*, and the *pCODR Procedural Review Guidelines*, which are available on the pCODR section of the CADTH website, [www.cadth.ca/pcodr](http://www.cadth.ca/pcodr).

See section B9, Procedures for Preparing & Publicly Posting Final Recommendations, Reports and Feedback for Post-NOC or Post-NOC/c Submissions, which also apply to Pre-NOC or Pre-NOC/c Submissions.

## C10 End of pCODR Drug Review Process

These procedures relate to relevant activities following the end of the pCODR drug review process and are described in section B10 for Post-NOC or Post-NOC/c Submissions, in section C10 for Pre-NOC or Pre-NOC/c Submissions and in section D10 for Resubmissions.

More details related to these procedures can be found in the pCODR Procedural Review Guidelines, the pERC Deliberative Framework, and the pCODR Disclosure of Information Guidelines, which are available on the pCODR section of the CADTH website at [www.cadth.ca/pcodr](http://www.cadth.ca/pcodr).

See Section B10, Procedures for the end of the pCODR drug review process for Post-NOC or Post-NOC/c Submissions, which also apply to Pre-NOC or Pre-NOC/c Submissions.

## D RESUBMISSION PROCEDURES

### Assessment of Eligibility for Resubmissions

Prior to initiating a Resubmission, a Sponsor is required to file a completed *pCODR Resubmission Eligibility Form* and provide copies of one or more new studies that addresses the specific issues identified in a pERC recommendation, if available, at least 120 calendar days in advance of the anticipated Resubmission filing date. If the anticipated submission received date falls on a weekend or statutory holiday, the following business day will be applied. This information must be sent to [pcodrsubmissions@cadth.ca](mailto:pcodrsubmissions@cadth.ca)

If this information is not provided in accordance with the stipulated timelines, there may be a delay in the processing and review of the Resubmission by pCODR.

A Resubmission will be assessed to determine if the information provided by the Sponsor meets the definition of New Information and that it addresses the specific issues identified in a pERC recommendation. This assessment will be conducted by a three to five-person pERC panel as determined appropriate based on the type of New Information being submitted, and will include the pERC Chair and/or Vice Chair.

The assessment of eligibility for a Resubmission will typically be completed within 30 calendar days. A Sponsor will be notified by the pCODR program if additional time is required to complete the assessment.

A Sponsor will be notified in writing if the Resubmission is eligible for review through the pCODR process. If the panel decides that the Resubmission is eligible for review through the

pCODR process, a Sponsor will be required to follow the procedures applicable to a Resubmission. If the panel decides that the Resubmission is not eligible for review through the pCODR process because it does not meet the eligibility requirements, the Sponsor will have five (5) business days from the date of notification from the pCODR program that the Resubmission did not meet the eligibility to identify in writing any discrepancies or errors with the decision. The pCODR program will have five (5) business days to consider the proposed discrepancies or errors, and will communicate in writing the final decision regarding whether or not a Resubmission will be eligible for review to the Sponsor. A Sponsor may refile a Resubmission if New Information becomes available at a later date without prejudice.

For all anticipated Resubmissions made to the pCODR program, pCODR will post the decision to indicate if the Resubmission is eligible or not eligible for filing with pCODR and the date of the decision on the pCODR section of the CADTH website. For Resubmissions that are not eligible, the eligibility assessment decision will be posted once the final decision has been issued. For Resubmissions that are eligible, the eligibility assessment decision and details of the pending Resubmission will be posted one month prior to the anticipated Resubmission being filed on the pCODR section of the CADTH website.

The assessment of eligibility for a Resubmission may be waived if the New Information for an Oncology Drug and indication is from a randomized controlled trial and that it address the specific issues identified in a pERC recommendation. In cases where pERC has issued an initial or a final recommendation, New Information must address the specific issues identified in the pERC recommendation. Notwithstanding, a Sponsor will be required to provide a minimum of 120 day advanced notification of an anticipated Resubmission for the purposes of resource planning, and provide a completed *pCODR Resubmission Eligibility Form*.

Resubmissions may be for New Oncology Drugs, Oncology Drugs with New Indications and Pre-NOC Submissions that are undergoing review through the pCODR process or for which a Final Recommendation has been issued by the pCODR program. The pCODR may accept Resubmissions under the following circumstances:

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

### **Requirements for New Information**

New Information is either (1) new clinical information (not previously submitted) in support of improved efficacy or safety or (2) new cost information (not previously submitted) that significantly impacts the cost-effectiveness of the Drug. In cases where pERC has issued an initial or final recommendation, New Information must address the specific issues identified in the pERC recommendation.

If the New Information is in support of improved efficacy and/or in support of improved safety, it should be from a randomized controlled trial. Notwithstanding, New Information may be from a non-randomized study when a randomized controlled trial is not available.

If a Resubmission is for a withdrawn Submission or Resubmission, New Information may not be required. For greater clarity, if a withdrawal is because Health Canada decides that it cannot issue an NOC or NOC/c (i.e., market authorization) for the Drug at the time of the Submission, the Resubmission must contain information, including Health Canada information, which addresses the reason(s) for the withdrawal or non-issuance of an NOC or NOC/c and reinstatement of market authorization. A Sponsor is required to include a list of changes since the Submission was withdrawn. In this case, the assessment of eligibility for a Resubmission may be waived. Notwithstanding, a Sponsor will be required to provide a minimum of 120 day advanced notification of an anticipated Resubmission for the purposes of resource planning.

Sponsors are invited to contact the pCODR program for direction whenever there is a question as to whether or not a Resubmission should be made to the pCODR program.

Refer to all procedures associated with Post-NOC and Post-NOC/c Submissions (section B) and with Pre-NOC or Pre-NOC/c Resubmissions (section C) unless otherwise stated in the sections that follow.

## D1 Pre-submission Planning for Resubmissions

Pre-submission procedures include all those procedures related to the period before an anticipated Submission or Resubmission is filed with pCODR and are described in section D1 for Resubmissions. Pre-submission procedures for Post-NOC or Post-NOC/c Submissions are described in section B1 and Pre-submission procedures for Pre-NOC or Pre-NOC/c Submissions are described in section C1.

More details related to the Pre-submission process can be found in the *pCODR Pre-Submission, Submission and Resubmission Guidelines*, the *pCODR Disclosure of Information Guidelines*, the *pERC Deliberative Framework* and the *pCODR PAG Input on a Review* template, which are available on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

### D1.1 Notification of an Anticipated Resubmission by the Sponsor

If a Resubmission is because new information became available during the review process but before the pERC Final Recommendation was issued, the Pre-submission Requirements outlined in the *pCODR Pre-submission, Submission and Resubmission Guidelines* may be waived although advanced notification of an anticipated Resubmission is requested as soon as possible for the purposes of resource planning.

For all other Resubmissions, procedures outlined in section B1.1 for notification of an anticipated Submission by the Sponsor apply.

### D1.2 Pre-submission Information for Resubmissions

- a) Sponsors should complete the Pre-submission Information Requirements Form - Resubmissions to the greatest extent possible in anticipation of a Resubmission as set out in the *pCODR Pre-submission, Submission and Resubmission Guidelines*. While some allowance will be made where information is not available to complete the form, pCODR reserves the right to request further information be provided. If Pre-submission Information is not provided as outlined in the *pCODR Pre-submission, Submission and Resubmission Guidelines*, there may be a delay in the processing and review of the Submission by pCODR.



- b) If a Resubmission is because new information became available during the review process but **before** the pERC Final Recommendation is publicly posted on the pCODR section of the CADTH website, Pre-submission Information does not need to be provided to pCODR.

### **D1.3 Pre-submission Meetings for Resubmissions**

At the time of requesting the meeting, Sponsors must provide a completed Pre-submission Information Requirements Form for Resubmissions (see pCODR Pre-submission, Submission and Resubmission Guidelines on the pCODR section of the CADTH website, [www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)). All other procedures associated with Pre-submission meetings outlined in section B1.3 apply to Resubmissions.

### **D1.4 Disclosure of Pre-submission Information**

See section B1.4. Procedures applied to the disclosure of Pre-submission Information for Post-NOC or Post-NOC/c Submissions also apply to the disclosure of Pre-submission Information for Resubmissions.

### **D1.5 Public Notification by pCODR of a Pending Resubmission**

See section B1.5. Procedures applied to the public notification by pCODR of a pending submission also apply to the public notification by pCODR of a pending Resubmission.

### **D1.6 Pre-submission Planning**

See section B1.6. Procedures applied to Pre-submission planning for a Submission also apply to procedures for a Resubmission.

### **D1.7 Notifying the PAG and Collecting PAG Input**

See section B1.7. Procedures applied to notifying the PAG and collecting PAG input for a Submission also apply to procedures for notifying PAG and collecting PAG input for a Resubmission.

## **D2 Preparing and Submitting a Resubmission**

Resubmission procedures include all those procedures relating to preparing and submitting a Resubmission to pCODR for review and are described in section D2. Procedures for preparing a Post-NOC or Post-NOC/c Submission are outlined in section B2 and procedures for preparing a Pre-NOC or Pre-NOC/c Submission are outlined in section C2.

More details on the types of Submissions and Resubmissions, Submission Requirements and procedures related to preparing and filing a Resubmission can be found in the *pCODR Pre-Submission, Submission and Resubmission Guidelines* and the *pCODR Disclosure of Information Guidelines*, which are located on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

### **D2.1 Initiating a Resubmission**

A Resubmission is initiated by the Manufacturer, PAG or a provincially-recognized clinician-based Tumour Group filing a Resubmission with the pCODR program. A Resubmission is assessed by the pCODR program to determine its eligibility prior to

its initiation. A Sponsor must provide a completed *pCODR Resubmission Eligibility Form* and that the pERC panel has deemed it to be eligible before a Resubmission can be initiated.

## **D2.2 Eligible Sponsors**

See sections B2.2 and C2.2. Procedures related to eligible Sponsors for Post-NOC or Post-NOC/c Submissions and Pre-NOC or Pre-NOC/c Submissions also apply to Resubmissions.

In addition, the Sponsor of the New Information does not need to be the same as the Sponsor of the original Submission or Resubmission.

## **D2.3 Content of the Resubmission**

See section B2.3. Procedures applied to the content of a Submission also apply to procedures for the content of a Resubmission.

## **D2.4 Filing of Resubmission**

See section B2.4 and section C2.4. Procedures applied to filing a Submission also apply to procedures for filing a Resubmission.

## **D2.5 Resubmission Tracking**

See section B2.5 and section C2.5. Procedures applied to Submission tracking also apply to procedures for Resubmission Tracking.

## D3 Procedures for Screening Resubmissions, Initiating the Review Process and Collecting Patient Group (or registered individual patient or caregiver in cases where there is no patient group) and Registered Clinician Input

Procedures relating to screening Resubmissions, initiating the review process for Resubmissions and collecting patient group (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician input for Resubmissions are outlined in section D3. These procedures are outlined in section B3 for Post-NOC or Post-NOC/c Submissions and in section C3 for Pre-NOC or Pre-NOC/c Submissions.

More details related to these procedures can be found in the *pCODR Pre-Submission, Submission and Resubmission Guidelines*, the *pCODR Disclosure of Information Guidelines*, the *pCODR Procedural Review Guidelines*, the *pCODR Conflict of Interest Guidelines*, the *pCODR Patient Engagement Guide*, the *Patient Input Template for CDR and pCODR (or registered individual patient or caregiver in cases where there is no patient group) and Registered Clinician Input on a Drug Review* template, which are located on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

### D3.1 Screening Resubmissions and Initiating the Review Process

#### D3.1.1 Receipt of a Resubmission

- a) Upon receipt of the Resubmission, the pCODR program will apply a date and time stamp to identify the order in which it is screened.
- b) If the Resubmission is received by pCODR more than ten (10) Business Days after the target Resubmission date that was confirmed with pCODR one month prior to the Resubmission being filed, there may be a delay in the processing and review of the Submission, as previously secured review resources may need to be released to complete other reviews.
- c) In addition, if a Resubmission is filed Before a Final Recommendation is publicly posted on the pCODR section of the CADTH website, the following will apply:
  - Upon receipt of the Resubmission, the pCODR program suspends all work on the original Submission and the Resubmission is placed at the back of the review queue.
  - If the Resubmission is filed after the pERC Brief for the original Submission has been issued, the pCODR program, in consultation with the pERC Chair, will remove the pERC Brief from the pERC agenda.
  - If at the time the Resubmission is filed, a pERC Initial Recommendation or pERC Final Recommendation has been made by pERC but has not yet been publicly posted, the pCODR program will proceed to publicly post the pERC Recommendation.

#### D3.1.2 Screening a Resubmission

- a) Screening is conducted to determine if a Resubmission is complete or incomplete. Submissions and Resubmissions will be screened in the order in which they were received at pCODR. For all Resubmissions, the pCODR program determines within ten (10) Business Days of

receiving the Resubmission, whether the Resubmission is complete, in accordance with the *pCODR Pre-Submission, Submission and Resubmission Guidelines*.

### D3.1.3 Deeming a Resubmission Incomplete

- a) If the Resubmission is incomplete, the pCODR program will send a notice to the Sponsor advising what information is needed to complete the Resubmission.
- b) If the Resubmission is incomplete, the Resubmission does not enter the review queue, regardless of when it was received by the pCODR program.
- c) If the deficiencies in the Submission are not resolved within ten (10) Business Days from the date it is deemed incomplete, either the Resubmission will be rejected or there may be a delay in further processing of the review, as previously secured review resources may need to be released to complete other reviews.
- d) If the information in the Resubmission does not comprise New Information, the following will apply:
  - a) If a Resubmission is Filed Before an Initial Recommendation is made by pERC:
    - The pCODR program will send a notice to the Sponsor informing them that the Resubmission has been rejected and it will be posted on the pCODR website that the Resubmission was rejected because New Information was not provided.
    - The pCODR program will resume review of the original Submission from the point in the review process at which the review was suspended.
    - It will be noted in the Clinical Guidance Report and the Economic Guidance Report that a Resubmission had been received but that it did not contain New Information.
    - If a pERC Brief was issued for the original Submission, the pERC Brief will be placed on the next available pERC agenda by the pCODR program, in consultation with the pERC Chair.
  - b) If a Resubmission is Filed Before a Final Recommendation is made by pERC:
    - The pCODR program will send a notice to the Sponsor informing them that the Resubmission has been rejected and it will be posted on the pCODR website that the Resubmission was rejected because New Information was not provided.
    - The pCODR program will resume review of the original Submission from the point in the review process at which the review was suspended.
    - It will be noted in the Clinical Guidance Report and the Economic Guidance Report that a Resubmission had been received but that it did not contain New Information.

- If a pERC Brief was issued for the original Submission, the pERC Brief will be placed on the next available pERC agenda by the pCODR program, in consultation with the pERC Chair.
- c) If a Resubmission is Filed After a Final Recommendation is publicly posted on the pCODR section of the CADTH website:
- The pCODR program will send a notice to the Sponsor informing them that the Resubmission has been rejected and it will be posted on the pCODR website that the Resubmission was rejected.
  - The pCODR program will retain one copy of the rejected Resubmission on file.

#### **D3.1.4 Deeming a Resubmission Complete**

- a) If the information in the Resubmission does comprise New Information and the Resubmission Requirements are met, the Resubmission is deemed complete.
- b) If New Information is not required for the Resubmission (i.e., Resubmissions filed for a withdrawn Submission or Resubmission), the Resubmission is deemed complete when the Resubmission Requirements are met.
- c) If the Resubmission is deemed complete, the pCODR program will send an acknowledgement via email to the primary contact provided in the Resubmission and inform them of the target pERC meeting date and the target Checkpoint Meeting date. This information will also be posted on the pCODR section of the CADTH website (see Figure 2).
- d) When the Resubmission is deemed complete, it is entered into the review queue as described in section B3.1.5, Prioritization and Order of Review.
- e) When the Sponsor receives acknowledgement that the Resubmission Requirements are satisfied, the Sponsor must ensure that each participating F/P/T Ministry of Health and Provincial Cancer Agency is provided with one or more copies of the Resubmission, or part thereof, as directed by the Ministries of Health and Provincial Cancer Agencies in Appendix B of the *pCODR Pre-Submission, Submission and Resubmission Guidelines*.

#### **D3.1.5 Prioritization and Order of Review**

See section B3.1.5 for procedures associated with prioritization and order of review.

In addition, when a Resubmission is deemed complete:

- If that Drug is under review with the pCODR program as a Submission, at any stage of the review process, that Submission will be stopped.
- A Resubmission during any stage of the review process results in the Resubmission being placed at the back of the review queue.

### **D3.1.6 Withdrawal Process**

See sections B3.1.6 and C3.1.6. Procedures applied to the withdrawal process for Submissions also apply to the withdrawal process for Resubmissions.

### **D3.1.7 Temporary Suspension of Review**

See section B3.1.7 and C3.1.7. Procedures applied to the temporary suspension of review for Submissions also apply to the temporary suspension of review for Resubmissions.

### **D3.1.8 Initiation of Review Process**

See section B3.1.8 and C3.1.8. Procedures for initiating the review process for Submissions also apply to Resubmissions.

In addition:

- a) the pCODR program determines the nature of the Resubmission, that is, if it is based on new cost information or new clinical information.
- b) The pCODR program reviews the Resubmission and relevant documents that relate to the previous Submission or Resubmission reviewed for that Drug, including the Review Reports, if any, and the pERC Final Recommendation, if issued.
- c) If the Resubmission is for a withdrawn Submission or Resubmission, the pCODR program considers the nature of the Resubmission and determines the appropriate approach for reviewing it. The Sponsor is apprised of the program's determination.

### **D3.1.9 Composition of the Review Team**

- a) The Review Team is established based on the nature of the Resubmission (i.e. new cost information or new clinical information) and in consideration of the proposed team members' qualifications, expertise and compliance with the *pCODR Conflict of Interest Guidelines*. The Review Team may include individuals with methodological expertise from either the PEBC or from CADTH, i.e., the Methods Team, members of the pCODR Clinical Guidance Panels and members of the pCODR Economic Guidance Panels.
- b) Additional expertise may be required as determined by the pCODR program and/or the pERC Chair.

### **D3.1.10 Disclosure of the Review Team**

See section B3.1.10. Procedures applied to the disclosure of the Review Team for Submissions also apply to procedures for disclosure of the review team for Resubmissions.

## **D3.2 Collect Patient Group (or registered individual patient or caregiver in cases where there is no patient group) and Registered Clinician Input**

- a) Depending on how much time has passed since the original Submission or previous Resubmission had been filed with the pCODR program and the nature of the Resubmission, patient groups (or registered individual patient or

caregiver in cases where there is no patient group) and registered clinician(s) may be notified of the receipt of the Resubmission and invited to provide input, in accordance with the procedures outlined in section B3.2 for Submissions.

- b) If patient groups (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician(s) are not notified and invited to provide input (e.g., in the event that only new cost information has been submitted), the most recent and relevant patient group (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician(s) input given on a previous Submission related to the drug and indication under review will be provided to the Review Team to incorporate into the Clinical and Economic Guidance Reports and to pERC for the purposes of their deliberations.

## D4 Clinical and Economic Review Procedures

Clinical and economic review procedures include all those procedures related to preparing the Clinical Guidance Report and Economic Guidance Report and are described in section D4 for Resubmissions. Clinical and economic review procedures for Post-NOC or Post-NOC/c Submissions are described in section B4 and clinical and economic review procedures for Pre-NOC or Pre-NOC/c Submissions are described in section C4.

More details related to procedures for clinical and economic reviews can be found in the *pCODR Clinical Guidance Report* template, the *pCODR Economic Guidance Report* template, the *pCODR Disclosure of Information Guidelines*, the *pCODR Clinical Guidance Panel Terms of Reference* and the *pCODR Economic Guidance Panel Terms of Reference*.

If the Resubmission is based on new cost information that significantly impacts the cost-effectiveness of the Drug and does not form part of the original Submission or previous Resubmission, an Economic Guidance Report will be prepared but a Clinical Guidance Report may not be prepared.

If the Resubmission is based on new clinical information that will affect the cost-effectiveness of the Drug, the Sponsor must also provide a new appropriate pharmacoeconomic evaluation and the pCODR program will prepare an Economic Guidance Report and a Clinical Guidance Report.

### D4.1 Conduct Clinical Review

See section B4.1 and C4.1. Procedures applied to conducting the clinical review for Submissions apply to conducting the clinical review for Resubmissions. In addition:

- a) The Review Team determines if a new systematic review is required and determines the appropriate approach to assess the New Information.
- b) An independent literature search is conducted to identify any new relevant information and to supplement the data provided by the Sponsor.

### D4.2 Conduct Economic Review

See section B4.2 and C4.2. Procedures applied to conducting the economic review for Submissions apply to conducting the economic review for Resubmissions. In addition:

If a Clinical Guidance Report is not prepared because the Resubmission is based only on new cost information, the Economic Guidance Panel refers to the results

and conclusions reported in the previous Clinical Guidance Report on that Drug in the assessment of the submitted pharmacoeconomic information.

## D5 pERC Meeting and Deliberation Procedures

pERC Meeting and Deliberation procedures include all those procedures related to the preparation for and conduct of the pERC meeting and are described in section D5 for Resubmissions. pERC meeting and deliberation procedures for Post-NOC or Post-NOC/c Submissions are described in section B5 and for Pre-NOC or Pre-NOC/c Submissions are described in section C5.

More details related to pERC Meeting and Deliberation Procedures can be found in the *pERC Terms of Reference*, the *pERC Deliberative Framework*, the *pCODR Conflict of Interest Guidelines*, the *pCODR Code of Conduct*, the *pCODR Code of Communications*, and the *pCODR Pre-Submission, Submission and Resubmission Guidelines*, which are available on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

See sections B5 and C5. pERC Meeting and Deliberation procedures for Submissions also apply to Resubmissions.

## D6 Procedures for Preparation of Public Posting of Initial Recommendations and Guidance Reports

See section B6 and C6. Procedures for the preparation and public posting of Initial Recommendations and Guidance Reports for Submissions also apply to Resubmissions.

For more details related to procedures associated with the public posting of Initial Recommendations and Guidance reports see the *pCODR Disclosure of Information*, which is available on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

## D7 Feedback on Initial Recommendations

These procedures relate to stakeholders providing and pCODR using feedback on the pERC Initial Recommendation and are described in section B7 for Post-NOC or Post-NOC/c Submissions, in section C7 for Pre-NOC or Pre-NOC/c Submissions and in section D7 for Resubmissions.

More details related to providing feedback on recommendations can be found on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)) and in the *pCODR Stakeholder Feedback on a pERC Initial Recommendation* template and the *pCODR Disclosure of Information Guidelines*.

See sections B7 and C7. Procedures for feedback on Initial Recommendations for Submissions also apply to Resubmissions.

In addition:

For Resubmissions, if registered patient groups (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician(s) are not notified during the review process to provide input on the Resubmission and input given by registered patient groups (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician(s) on a previous Submission related to the drug and indication under review is provided to the Review Team to incorporate into the Clinical and Economic Guidance Reports, the registered patient groups (or registered individual patient or caregiver in cases where there is no patient group) and registered clinician(s) that provided that original input will be contacted and informed that they are eligible to provide feedback on the Initial Recommendation for the Resubmission.



## D8 Summarize and Review Feedback on the Initial Recommendation with pERC and PAG

These procedures include all those procedures related to summarizing and reviewing feedback on the Initial Recommendation with pERC and PAG are described in section B8 for Pre-NOC or Pre-NOC/c Submissions, in section C8 for Post-NOC or Post-NOC/c Submissions and in section D8 for Resubmissions.

More details related to summarizing and reviewing feedback on the Initial Recommendation pERC can be found in the *pERC Terms of Reference*, the *pERC Deliberative Framework*, the *pCODR Conflict of Interest Guidelines*, the *pCODR Code of Conduct*, and the *pCODR Code of Communications*, which are available on the pCODR section of the CADTH website ([www.cadth.ca/pcodr](http://www.cadth.ca/pcodr)).

See sections B8 and C8 for procedures for summarizing and reviewing feedback on the Initial Recommendation with pERC for Submissions, which also apply to Resubmissions.

## D9 Prepare & Publicly Post Final Recommendations and Feedback

These procedures include all those procedures related to the preparation and public posting of Final Recommendations, Guidance Reports and Feedback are described in section B9 for Post-NOC or Post-NOC/c Submissions, section C9 for Pre-NOC or Pre-NOC/c Submissions and section D9 for Resubmissions.

For more details related to publicly posting Final Recommendations, reports and feedback see the *pCODR Disclosure of Information Guidelines*, the *pCODR Patient Engagement Guide*, the *pCODR Patient Group (or registered individual patient or caregiver in cases where there is no patient group) Conflict of Interest Declaration*, the *pCODR Registered Clinician Conflict of Interest Declaration*, the *pCODR Conflict of Interest Guidelines*, and the *pCODR Procedural Review Guidelines*, which are available on the pCODR section of the CADTH website, [www.cadth.ca/pcodr](http://www.cadth.ca/pcodr).

See section B9 and C9 for Procedures for the preparation and public posting of Initial Recommendations and Guidance Reports for Submissions, which also apply to Resubmissions.

## D10 End of pCODR Drug Review Process

These procedures relate to relevant activities following the end of the pCODR drug review process and are described in section B10 for Post-NOC or Post-NOC/c Submissions, in section C10 for Pre-NOC or Pre-NOC/c Submissions and in section D10 for Resubmissions.

More details related to these procedures can be found in the *pCODR Procedural Review Guidelines*, the *pERC Deliberative Framework*, and 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).

See sections B10 and C10 for procedures for the end of the pCODR drug review process for Submissions, which also apply to Resubmissions.

## E REQUEST FOR ADVICE

A Request for Advice is a written request made by the pCODR Advisory Committee (PAC) or by the Provincial Advisory Group (PAG), to the pERC for advice on specific therapeutic, clinical, pharmacoeconomic or implementation issues, regarding a pERC Recommendation, which may result in a new Recommendation. PAC or PAG will set out the issue(s) or question(s) that is needed to be addressed by pERC. This information will be published on pCODR section of the CADTH website. An overview of the Request for Advice process and estimated timelines are presented in Figure 3.

In the case of a Request for Advice filed by PAC or PAG, the following provisions will apply:

- a) The Request for Advice will be regarding a previous pERC Final Recommendation.
- b) A Request for Advice will not be assigned to the review queue.
- c) The date on which the pCODR program receives a Request for Advice is considered day zero for the purpose of calculating the time frame for determining the approach for the request.
- d) The pCODR program determines the appropriate approach for responding to the Request for Advice and develops a workplan for its review within 10 business days of receipt.
- e) The pCODR program may seek direction from the pERC chair and members on how to proceed with the Request for Advice.
- f) The pCODR program establishes a review team, based on the nature of the request for advice and in consideration of the proposed team members' qualifications, expertise, and compliance with the *pCODR Conflict of Interest Guidelines*. The names of the review team members will not be disclosed to the manufacturer.
- g) The steps in the review of a Request for Advice are as follows:
  - i. stakeholders, including the Sponsor/manufacturer(s) of the drug(s) in question, patient groups and registered clinician(s) will be apprised that a request is being undertaken and the reasons for the review, and those stakeholders who provided input on the original submission in question are invited to comment or provide information using *pCODR's feedback on a Request for Advice* template to help inform the question(s) or issue(s) raised by PAC or PAG within ten (10) business days of the posting of the request for advice.
  - ii. the Request for Advice is assigned to a Review Team.
  - iii. a protocol to address the question or issue is established.
  - iv. the Review Team conducts a literature search. The studies and material identified through the literature search and any information or data provided by the stakeholder(s) are supplied to the review team to consider as part of the review. To ensure that the pCODR review process is transparent and accountable, the pCODR program considers it essential that any information provided to inform the Request for Advice is fully disclosable.

The pCODR program publishes on the website the targeted pERC meeting date upon which a Request for Advice may be deliberated. See section B3.1.5.4 for procedures on Placement on pERC Meeting Agenda.

When considering a Request for Advice, pERC may address the request by providing one of the following:

- a) a revised pERC recommendation that would supersede a previous pERC Final Recommendation
- b) a pERC Record of Advice document containing additional context and/or clarifications regarding a pERC Final Recommendation.

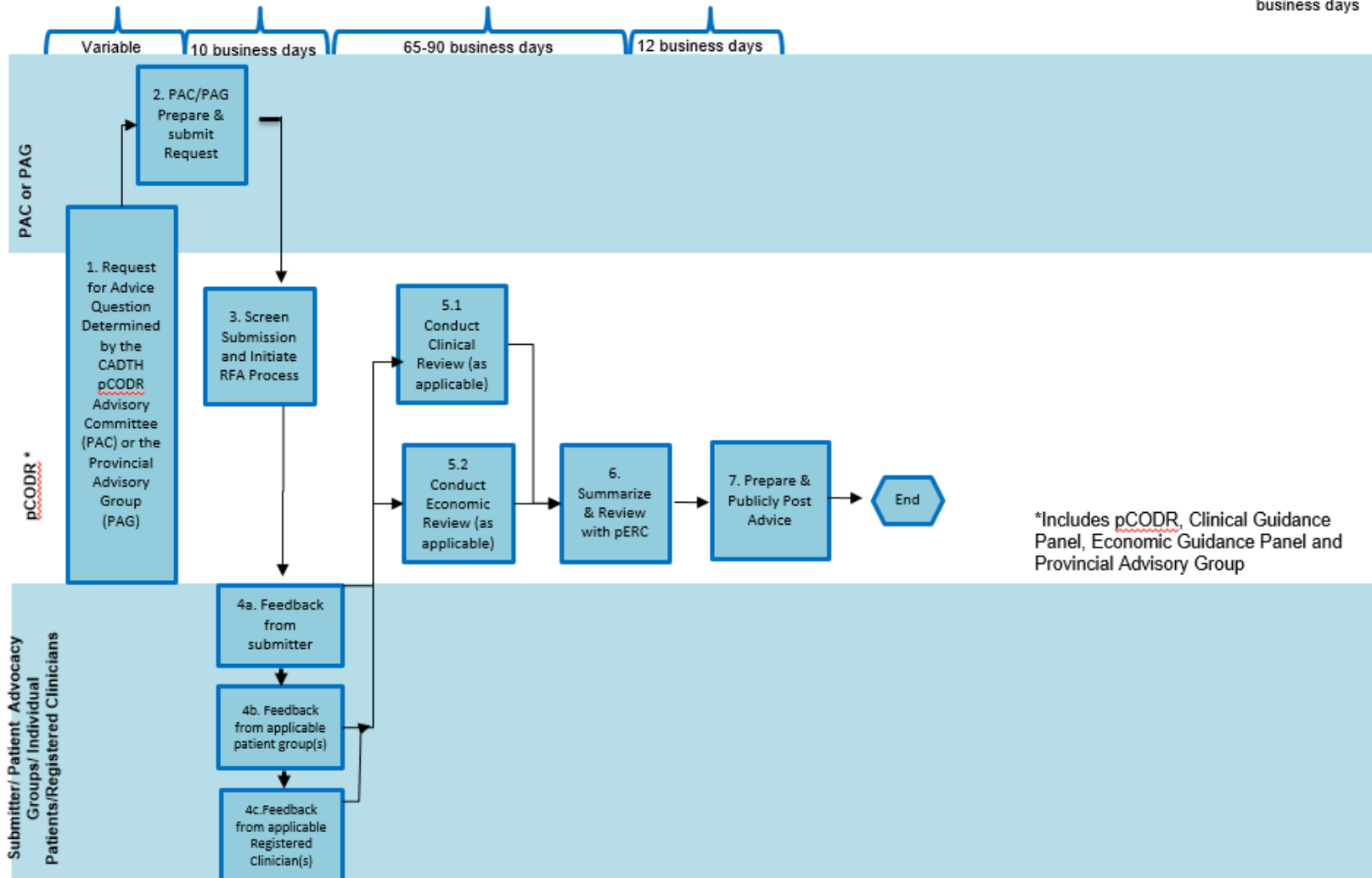
In either case, the pERC Record of Advice or revised pERC recommendation and supporting report will be posted ten (10) Business Days following the pERC Meeting on the pCODR section of the CADTH website.

**Important Notes:**

1. PAC or PAG may withdraw a Request for Advice by submitting to the pCODR program in writing and providing the reason for the withdrawal.
2. For greater clarity, a Request for Advice by PAC or PAG will not be subject to a procedural review as outlined in section B10.2 and the *pCODR Procedural Review Guidelines*.

Figure 3. pCODR Request for Advice Process

Estimated  
87 – 112  
business days



## F MANUFACTURER NON-SUBMISSION

CADTH makes best efforts to ensure timely access of oncology drug products that are submitted to the pCODR program for the issuance of a reimbursement recommendation.

A pCODR submission may be initiated in accordance with clause B2.1 of the pCODR Procedures.

In situations where a manufacturer does not proactively file a submission with CADTH for an eligible product, CADTH, on behalf of the participating jurisdictions, may contact a manufacturer to make a request for a specific oncology drug or indication be submitted for reimbursement consideration.

A manufacturer will have a maximum of 30 business days from the issuance date of the written request to respond to CADTH and the PAG Chair indicating whether or not it is planning to file a submission for the requested oncology drug and indication, as well as its anticipated timelines to file a submission with the pCODR program.

CADTH will advise the participating jurisdictions that CADTH is unable to make a reimbursement recommendation about the requested oncology drug and indication because a submission will not be filed by the manufacturer:

- a. If a manufacturer confirms that it will not be filing a submission,
- b. If, after a request is made by CADTH and no definitive response has been received from the manufacturer by the requested deadline date, or
- c. If a manufacturer indicated that a submission will be filed with the pCODR program, but fails to provide advance notification by providing a completed Pre-submission Information Requirements Form - Submissions, within 12 months of the issuance date as requested by CADTH and the PAG Chair.

In the aforementioned cases, CADTH will publicly post on its website: the drug product name (generic and brand, if applicable), indication, tumour type, name of the manufacturer and clarification that CADTH is unable to recommend reimbursement of the relevant product because a submission to CADTH was not filed by the manufacturer.

The requested oncology drug will receive a non-submission status. If the manufacturer subsequently indicates that it intends to make a submission by filing a completed Pre-submission Information Requirements Form - Submissions to the pCODR program or a Tumour Group files a completed Pre-submission Information Requirements Form - Submissions, then the non-submission status will be removed from the CADTH website and the requirements for filing a submission will apply in accordance with the pCODR Procedures and the pCODR Pre-Submission, Submission and Resubmission Guidelines.

## 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.

**CADTH** - The Canadian Agency for Drugs and Technologies in Health (CADTH) is a national body that provides Canada’s federal, provincial and territorial health care decision makers with credible, impartial advice and evidence-based information about the effectiveness and efficiency of drugs and other health technologies. On April 1, 2014, pCODR was transferred to 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.

**CAPCA** - Canadian Association of Provincial Cancer Agencies. CAPCA is an inter-provincial association of provincial/territorial cancer agencies engaged in cancer control.

**Checkpoint Meeting** - the meeting corresponding to Step 4.1.1 and step 4.2.1 in the pCODR review process map at which there is an opportunity to clarify information with the Sponsor and to discuss the management of Non-Disclosable Information included in the Submission.

**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.

**Clinical Guidance Panel** - Eleven tumour-specific expert panels that ensure the review of each cancer drug draws from the most important, relevant and current clinical information. These panels submit a Clinical Guidance Report for use by the pERC in making recommendations. Additional guidance panels may be created if pCODR review a drug to treat tumours that are not covered by the 11 tumour-specific panels.

**Clinical Guidance Report** - the report written by the Clinical Guidance Panel and other Review Team members after conducting the clinical review and that is provided to pERC for their deliberations on a Submission or Resubmission.

**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.

**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).

**Economic Guidance Panel** - experts who assess the economic evidence provided by the Sponsor for each cancer drug submission filed with pCODR. These panels submit an economic guidance report for use by the pERC in making its recommendations.

**Economic Guidance Report** - the report written by the Economic Guidance Panel after conducting the economic review and that is provided to pERC for their deliberations on a Submission or Resubmission.

**External Expert** - an individual with appropriate qualifications and expertise required to provide some input on some aspect of a Submission or Resubmission during a pCODR review or at a pERC meeting when requested by the pERC Chair.

**F/P/T** - federal, provincial and territorial.

**Final Recommendation** - the Recommendation made by the pERC at the pERC Meeting identified in step 8 of the pCODR review process map or as a result of early conversion of an Initial Recommendation in step 7.4 of the pCODR review process map.

**Guiding Principles** - the eight guiding principles developed for pCODR by the pCODR Advisory Committee that direct the way in which pCODR conduct its work and the pCODR drug review process and which are available on the pCODR section of the CADTH website.

**Initial Recommendation** - the Recommendation made by the pERC at the pERC Meeting identified in step 5 of the pCODR review process map. The Initial Recommendation is publicly posted for stakeholder feedback on the pCODR section of the CADTH website.

**Manufacturer** - a Drug Manufacturer, also known as a Pharmaceutical Manufacturer.

**Methods Team** - individuals with methodological expertise in conducting systematic reviews.

**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 Indication** - a condition or place in therapy for a Drug that has not previously been reviewed by pCODR.

**New Information** - 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.

**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 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 Federal drug plans, 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).

**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 Federal drug plans, each of the provincial Ministries of Health and Provincial Cancer Agencies participating in the pCODR. The PAG is accountable to the pCODR Advisory Committee.

**PAG Chair** - a member of the pCODR Advisory Committee selected to serve on PAG as its Chair as set out in the PAG Terms of Reference.

**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 (pERC) assesses the clinical evidence and cost effectiveness of new cancer drugs, and uses this information to make recommendations to the provinces and territories to guide their drug funding decisions. The pERC is an advisory body



composed of up to 18 individuals with expertise in drug therapy / drug evaluation and patient members.

**pERC Brief** - a brief prepared by the pCODR program that includes the information upon which pERC will deliberate when making an initial recommendation for a drug submission.

**pERC Chair** -The pERC is led by a Chair who reports on pERC's activities to CADTH's President and Chief Executive Officer, as set out in the *pERC Terms of Reference*.

**pERC Member**- a member of the pCODR Expert Review Committee (pERC)

**pERC Reconsideration Brief** - a brief prepared by the pCODR program that includes the information upon which pERC will deliberate when reconsidering an initial recommendation and making an final recommendation for a drug submission.

**pERC Vice-Chair** - the pERC member selected to be Vice-Chair of the pERC with responsibilities as set out in the *pERC Terms of Reference*.

**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 Sponsor filing a Submission with the pCODR. In the case of Pre-NOC or Pre-NOC/c Submissions for New Drugs, the only Sponsor 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 Sponsor type may file the Submission.

**Pre-submission, Submission and Resubmission Guidelines** - the guidelines that have been adopted by pCODR provide guidance to Sponsors on the information required by pCODR prior to a Submission being filed and to provide guidance around Pre-submission meetings between pCODR and the Sponsor; and how Submissions and Resubmissions must be prepared and submitted.

**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. Sponsors are requested to file this information at least 120 calendar days before the anticipated date of filing the complete submission. If the 120th day falls on a weekend or statutory holiday, the following business day will be applied.

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

**Recommendation** - an evidence-based recommendation made by pERC following deliberations on a Submission or Resubmission, as set out in the pERC Deliberative Framework.

**Reconsideration** - the process identified in steps 7 and 8 of the pCODR review process map whereby stakeholders provide feedback on the Initial Recommendation and pERC considers the feedback and reconsiders its Initial Recommendation at a subsequent pERC meeting before making a Final Recommendation

**Record of Decisions** - a written record of the decisions that are made by pCODR and other attendees at a meeting that is part of the pCODR review process.

**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.

**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.

**Request for Withdrawal** - a written request by a Sponsor to withdraw a Submission or Resubmission from the pCODR review process.

**Resubmission** - 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. A Resubmission may also be filed for a withdrawn Submission or Resubmission and, in this case, New Information is not required.

**Review Team** - the team established to complete the pCODR clinical and economic reviews of a Submission or Resubmission and composed of individuals with methodological expertise, members of the Clinical Guidance Panel, members of the Economic Guidance Panel and External Experts as needed.

**Sponsor** - the person, corporation, or entity filing a Submission or Resubmission.

**Submission** - a submission to the pCODR consisting of:

- a CD/DVD provided by the Sponsor 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 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.

**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.