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pCPA brand process guidelines

Record of updates to pCPA brand process guidelines

Version Number	Details	Date
1.0	Original Version	May 2018
1.1	Updated Vision and Mandate	April 2022
1.2	Updated Contact and Overview	August 2023
1.3	Updated email address, federal drug plan membership	January 2025
1.4	Updated pCPA visual identity; updated references to CDA-AMC	February 2025

Inquiries

All inquiries related to the pCPA Brand Process Guidelines should be submitted to brands@pcpa-app.ca.

About

The pCPA was originally established as the pan-Canadian Pricing Alliance in August 2010.

In 2015, the alliance was formalized with the new name pan-Canadian Pharmaceutical Alliance, a mandate and objectives were developed, a governance structure was implemented, and an office was created to provide support to the member jurisdictions.

An organizational review conducted in 2019 to assess pCPA's current and future roles recognized the importance of this rare collaboration of provincial, territorial and federal governments, which has enabled the sharing of resources and expertise to achieve its objectives. It also recommended that the pCPA become a standalone organization to better respond to the demands of the rapidly evolving pharmaceutical landscape.

The standalone pCPA organization was established in late 2022, and the transition was completed in 2023. The new organizational structure, along with an increase in internal capacity, will allow the pCPA to lead and support more product negotiations on behalf of member jurisdictions in the years ahead.

Table of contents

Common terms and abbreviations

The following are high-level definitions for common terms as well as abbreviations used in the pCPA Brand Process Guidelines and associated Frequently Asked Questions (FAQs).

Acknowledgement Letter	A letter issued to the Manufacturer, by the pCPA, confirming that the pCPA is aware of the recent HTA recommendation(s) related to a Drug and that the Drug has entered the pCPA process.
Business Day	Any day (other than a Saturday, Sunday, or statutory holiday) on which the pCPA is open for business during regular business hours.
CDA-AMC	Canada's Drug Agency - An independent, not-for-profit organization responsible for providing health care decision-makers with objective, evidence to help make informed decisions about the optimal use of health technologies, including: drugs, diagnostic tests, medical, dental, and surgical devices, and procedures.
CDEC	Canadian Drug Expert Committee - pan-Canadian advisory body to CDA-AMC composed of individuals with expertise in drug therapy, drug evaluation and drug utilization, and public members (for a lay perspective).
CDR	Common Drug Review – through the CDR process, CDA-AMC conducts thorough and objective evaluations of the clinical, economic, and patient evidence on Drugs, and uses this evaluation to provide reimbursement recommendations and advice to Canada's Federal, Provincial, and Territorial public drug plans, with the exception of Québec.
Close letter	A letter issued by the pCPA to the Manufacturer indicating that the pCPA is not opening a negotiation for a Drug or indicating that an open negotiation for a Drug is closed.

Drug	According to the Food and Drugs Act (Canada), a drug includes any substance or mixture of substances manufactured, sold, or represented for use in: a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof in man or animal, b) restoring, correcting or modifying organic functions in man or animal, or c) disinfection in premises in which food is manufactured, prepared, or kept.
Engagement letter	A letter issued by the pCPA to the Manufacturer indicating that the pCPA has decided to engage in negotiation for a Drug and identifying the Lead (s) and Participating Jurisdiction(s) that will lead the negotiation.
Existing Drug	A Drug that does not have a new HTA recommendation.
Federal Drug Plans	Non-Insured Health Benefits (NIHB), Correctional Service Canada (CSC), Veterans Affairs Canada (VAC), Department of National Defence (DND).
Hold Letter	A letter, issued by the pCPA to the Manufacturer, indicating that the pCPA has decided not to engage in the negotiation for a New Drug for an identified period of time.
HTA	Health Technology Assessment (including CDA-AMC and INESSS). CDA-AMC formulary listing recommendations are used as a guide for pCPA negotiations by the following jurisdictions: British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland & Labrador, Yukon Territory, Nunavut, and Northwest Territories. INESSS formulary listing recommendations are used as a guide for pCPA negotiations by the following jurisdiction: Québec. Federal drug plans, with beneficiaries in all jurisdictions in Canada, use both CDA-AMC and INESSS as a guide for pCPA negotiations, as required.

INESSS	Institut national d'excellence en santé et en services sociaux – Assesses, in particular, the clinical advantages and the costs of the technologies, medications and interventions used in health care and personal social services. It issues recommendations concerning their adoption, use and coverage by the Québec public drug plan, and develops guides to clinical practice in order to ensure their optimal use.
Jurisdiction	pCPA member jurisdictions include public drug plan participation from: British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Québec, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland & Labrador, Yukon Territory, Northwest Territories, Nunavut, and Federal Drug Plans.
Lead(s)	Identified representative(s) acting on behalf of the pCPA during a negotiation.
Line Extension	Includes, but is not limited to, new dosage forms with the same route of administration as a marketed Drug and new strengths of the same dosage form as a marketed Drug.
LOI	Letter of Intent — A document which details the agreed upon terms and conditions for funding reached between the Lead(s) and a Manufacturer. The terms stated in the LOI are then reflected in a Product Listing Agreement (PLA) between a Jurisdiction and the Manufacturer.
Manufacturer	An entity which submits or resubmits a proposal to the pCPA in respect of a Drug.
Negotiation	The time between the issuance of an Engagement Letter and the completion of a negotiation concluding with either an LOI or a Close Letter.
New Drug	A Drug that has received a new final HTA recommendation.
Participating Jurisdiction	A Jurisdiction participating in a Negotiation as identified in the Engagement Letter.
pCPA	pan-Canadian Pharmaceutical Alliance – All Jurisdictions and the pCPA.

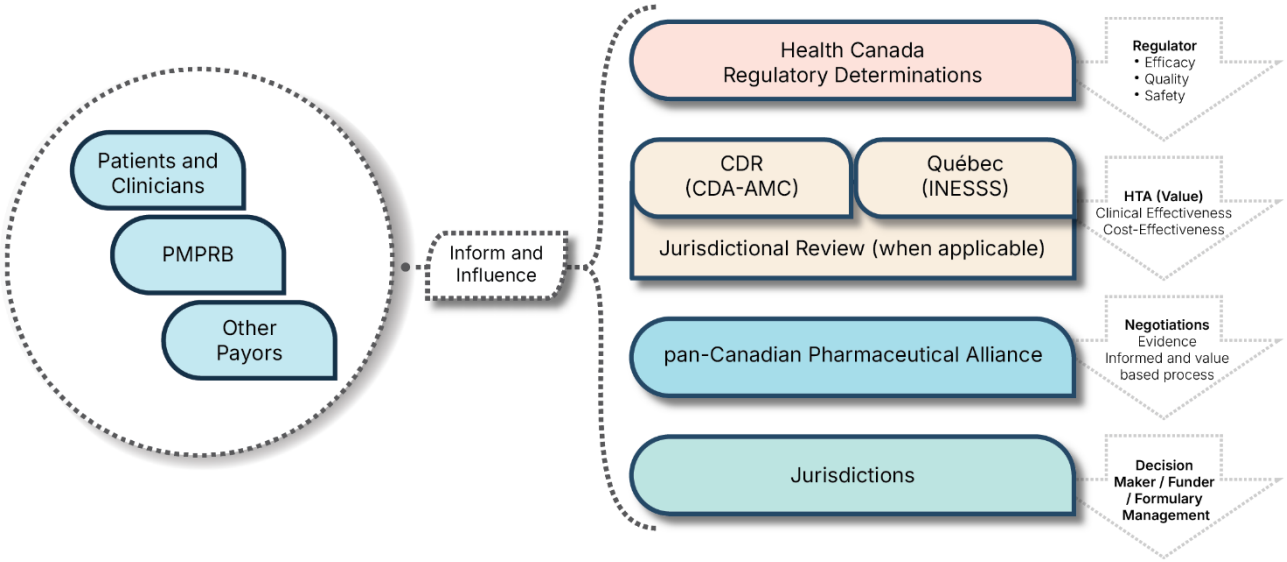
pERC	pan-Canadian Oncology Drug Review Expert Review Committee (of CDA-AMC) - the role of the pERC is to assess the clinical evidence and cost-effectiveness of cancer Drugs in order to make recommendations to the provinces and territories (except Québec) to help guide their Drug funding decisions.
PLA	Product Listing Agreement – An agreement between a Manufacturer and Participating Jurisdiction regarding the public funding of a Drug in the Jurisdiction consistent with the LOI.
PMPRB	Patented Medicine Prices Review Board.
Proposal	An offer outlining terms for funding a Drug in the Participating Jurisdictions submitted by the Manufacturer to the Lead(s) during a Negotiation.
Unsolicited Proposal	An offer from a Manufacturer, for a New or Existing Drug that is submitted to the pCPA outside of a Negotiation.

Introduction

The objective of this document is to promote common understanding of the pCPA process. This document is meant to be a guide only and the pCPA reserves the right to update the contents of this document as necessary to maintain its currency and accuracy.

pCPA context

Drugs come to the pCPA as a part of the overall Canadian drug approval and reimbursement process, as depicted below (accessible version available).



pCPA background

The pCPA, formerly the pan-Canadian Pricing Alliance, was established by the Provinces and Territories in August 2010 as part of work underway by the Council of the Federation's Health Care Innovation Working Group (HCIWG) to achieve greater value for publicly funded drug programs and patients through the use of combined negotiating power of Participating Jurisdictions.

pCPA vision and mandate

The pCPA's vision is to demonstrate collective leadership through value-driven investments in effective treatments that improve the health of Canadians and preserve a sustainable publicly funded health system in Canada.

Our mandate is to collect collective, expert-informed negotiations and achieve pCPA objectives:

- Increase access to clinically relevant and cost-effective treatments
- Achieve consistent and lower drug costs
- Reduce duplication and optimize resource utilization
- Improve consistency in funding decisions

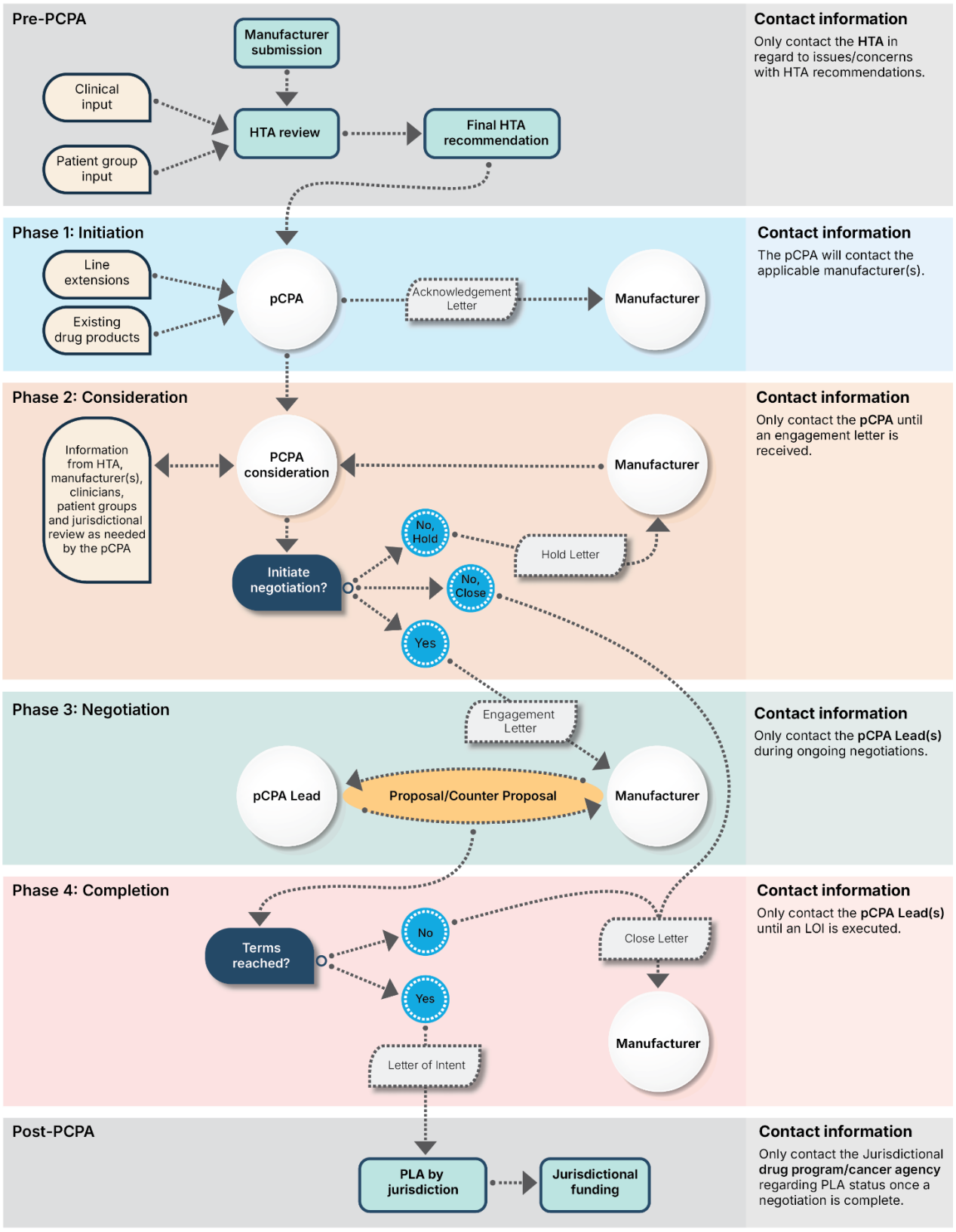
pCPA membership

pCPA member jurisdictions include public drug plan participation from: British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Québec, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland & Labrador, Yukon Territory, Northwest Territories, Nunavut, Non-Insured Health Benefits (NIHB), Correctional Service Canada (CSC), Veterans Affairs Canada (VAC) and Department of National Defence (DND).

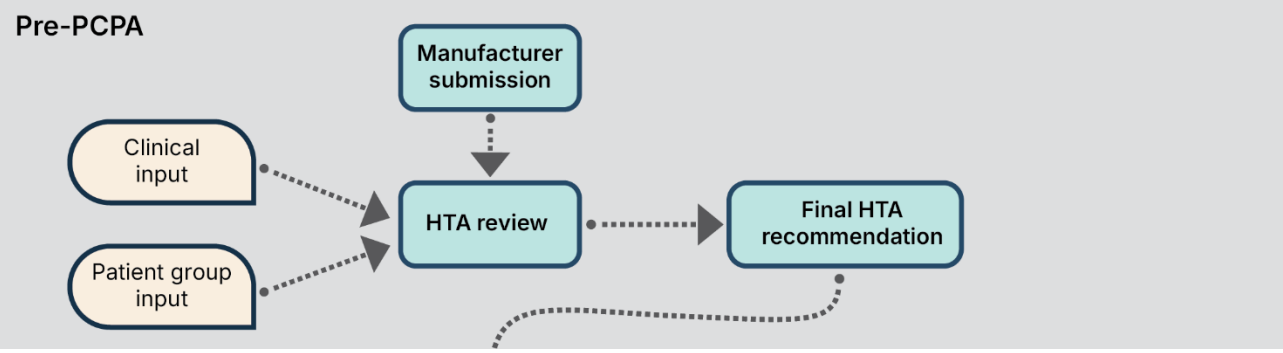
pCPA process overview

The process undertaken by the pCPA occurs in four phases, as illustrated in the following diagram (accessible text is available). For timely responses to inquiries about the process and its phases, Manufacturers are asked to direct queries to the contacts noted for each phase. Manufacturer inquiries related to HTA assessment or individual jurisdictional listing/PLAs will not receive a response from the pCPA.

pCPA process overview



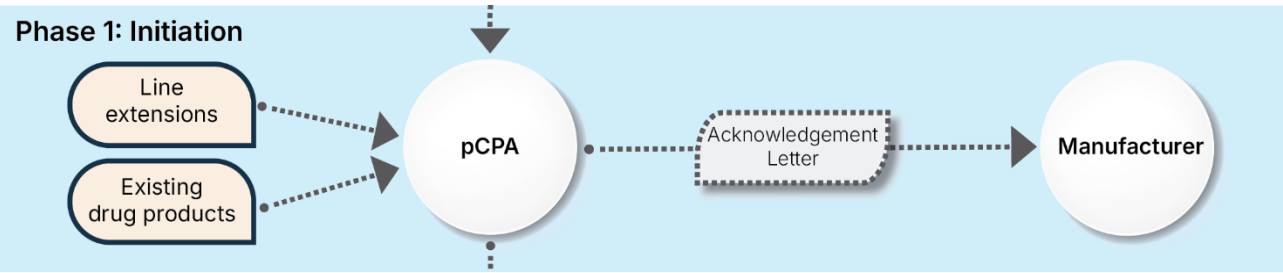
Pre-pCPA



To facilitate timely product awareness, preparation, and to reduce duplication of effort, the pCPA has partnered with CDA-AMC to receive any materials Manufacturers choose to share at CDA-AMC pre-submission meetings. Relevant information from INESSS is incorporated into pCPA process as required.

Prior to Phase 1 of the pCPA process, contact should only be made with the HTA bodies.

Phase 1 – Initiation



1. New drugs

For the majority of New Drugs, the pCPA process begins once a recommendation is published by CDA-AMC and/or INESSS. The pCPA then issues an Acknowledgment Letter to the Manufacturer.

Note: Manufacturers do not need to notify the pCPA about new recommendations.

2. Existing drugs

For Existing Drugs which are currently publicly funded in one or more jurisdictions (pCPA LOI and/or jurisdictional PLA and/or jurisdictional funding), the pCPA process may be initiated by the pCPA upon review of funded drug products.

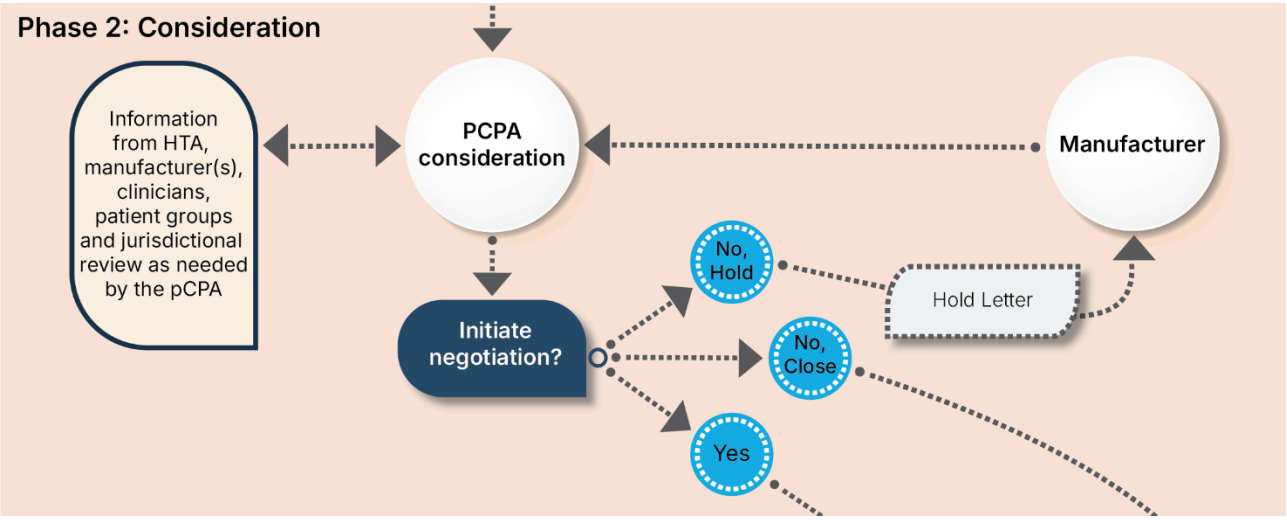
Negotiations for Existing Drugs may be initiated as a result of:

- Clinical landscape changes created by New Drugs entering the same therapeutic space as the Existing Drug;
- Line extensions of the Existing Drug;
- CDA-AMC therapeutic reviews involving the Existing Drug;
- PLA review;
- Formulary review;
- Jurisdictional needs; and
- Any unforeseen circumstance that the pCPA believes warrants initiation of negotiation.

3. Line extensions

Manufacturers should contact the pCPA for inquiries about Line Extensions. Line Extensions are subject to jurisdictional submission review, processes, and approvals and the collective pCPA process may also apply.

Phase 2 – Consideration



Once New and Existing Drugs have been identified in the Initiation Phase, they are considered by the pCPA for negotiation.

Factors that may influence this consideration include the following:

- HTA recommendation, which provides clinical and pharmacoeconomic review (e.g., QALY, ICER)
- Therapeutic gaps
- Budget Impact Analysis (BIA)

- Affordability
- Therapeutic landscape
- Current coverage of alternatives
- Upcoming therapeutic options
- Jurisdiction-specific needs
- International information

Common pan-Canadian objectives and jurisdictional interest to participate in a negotiation are established for the drug product in the Consideration phase of the pCPA process. Collective consideration by all Jurisdictions is coordinated by the pCPA. If needed, the pCPA may contact a Manufacturer to coordinate a meeting and/or to discuss next steps.

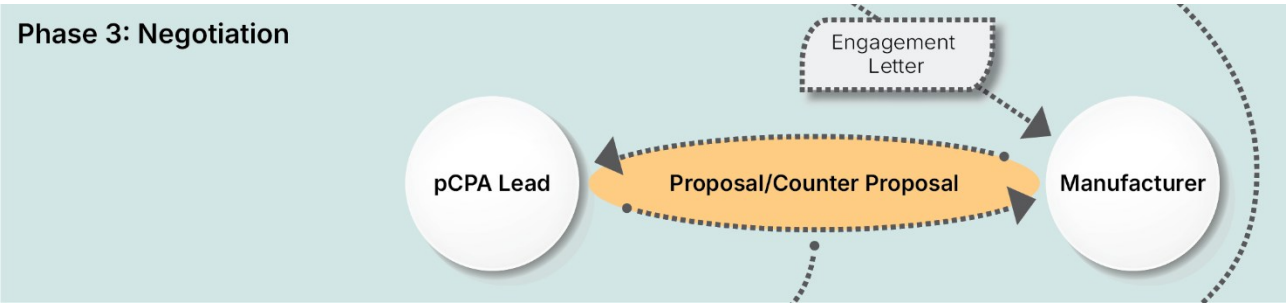
At the discretion of the Participating Jurisdiction(s), information may be sought by the pCPA from stakeholders including HTA bodies, Manufacturers, clinicians, patient groups, Jurisdictional review(s), and others.

- Clarification with the HTA bodies may be sought with regard to recommendation(s)
- Clarification with the Manufacturer, prior to engagement, may be sought to indicate the desired value in circumstances where the negotiation may not seem viable due to the magnitude of value required to achieve cost-effectiveness, according to the HTA recommendation
- Clarification with clinicians and/or patient groups may be sought to further define reimbursement criteria and/or address implementation
- Additional information may also be sought from individual Jurisdictional reviews

At the end of the Consideration Phase, the pCPA may:

- Express interest in opening negotiations through an Engagement Letter to the Manufacturer. The Engagement Letter indicates activation of Phase 3: Negotiation, identifies the Lead(s), and identifies the Participating Jurisdiction(s) in the negotiation; or
- Issue a Hold Letter to the Manufacturer to communicate that the pCPA has decided not to engage in the negotiation for a specific New Drug for an identified period of time in order to await additional HTA information, other products that are relevant to the negotiation, etc.; or
- Issue a Close Letter to the Manufacturer, to indicate that the pCPA will not open a negotiation.

Phase 3 – Negotiation



A Drug enters the Negotiation Phase once the Manufacturer receives the Engagement Letter. The Lead(s) will then reach out to the Manufacturer to outline next steps and may request that the Manufacturer submit a Proposal.

A complete, well-organized, and comprehensive Proposal will facilitate the pCPA Negotiation Phase and sharing of information with the Participating Jurisdiction(s). The minimum expected content is as follows[1]; *a checklist is provided in Appendix 1*:

Manufacturer proposal content expectations

Proposal Requirements:

- The submission must be PDF or Word documents that are not scanned images.
- All BIAs must be in an unlocked Excel file with a description of formulae and assumptions.
- When applicable, address any issues raised in the HTA recommendation related to the criteria, conditions, concerns, uncertainties, etc. and reflect the impact of the recommendation on the BIA.
- Cost-effectiveness estimates and total cost/budget impact for each Jurisdiction.
- When applicable, international product pricing and availability.

The Following Examples Do Not Meet Proposal Requirements:

- Detailed clinical information is not required by the pCPA as part of the proposal given that the HTA recommendation for a product informs negotiations.
- Scanned/locked images.
- PowerPoint documents as the official proposal document (Note: the Manufacturer may use PowerPoint to supplement the proposal).

[1] The lists provided are not exhaustive, and the Lead(s) may provide further guidance specific to each negotiation.

- Email proposals (Note: attachments are acceptable but proposals should not be solely within the body of email).
- Verbal proposals without documentation.

Negotiator expectations – lead(s) and manufacturer

Negotiators representing the pCPA and Manufacturers alike are expected to have a strong understanding of the following:

1. Drug funding process and reimbursement landscape in Canada
2. pCPA negotiations role
3. Federal/Provincial/Territorial government decision-making structures and processes
4. Canadian healthcare environment

Negotiators are expected to maintain an open, honest, respectful, and transparent culture throughout negotiations.

Confidentiality and disclosure

pCPA negotiations are confidential. Pricing information, budget impact estimates, and other sensitive information exchanged amongst the pCPA, Participating Jurisdictions, and a Manufacturer during the negotiation process will be held in confidence and will not be disclosed, except in accordance with applicable law or with the consent of the parties. The pCPA and Manufacturers are expected to respect the standard provisions regarding confidentiality obligations specified in the LOI and PLA.

During negotiations, discussions are expected to remain between the identified contacts from pCPA and the Manufacturer. In support of efficiency, effectiveness, and integrity of process, negotiations are not to include any undue external influence from political, media, or patient channels.

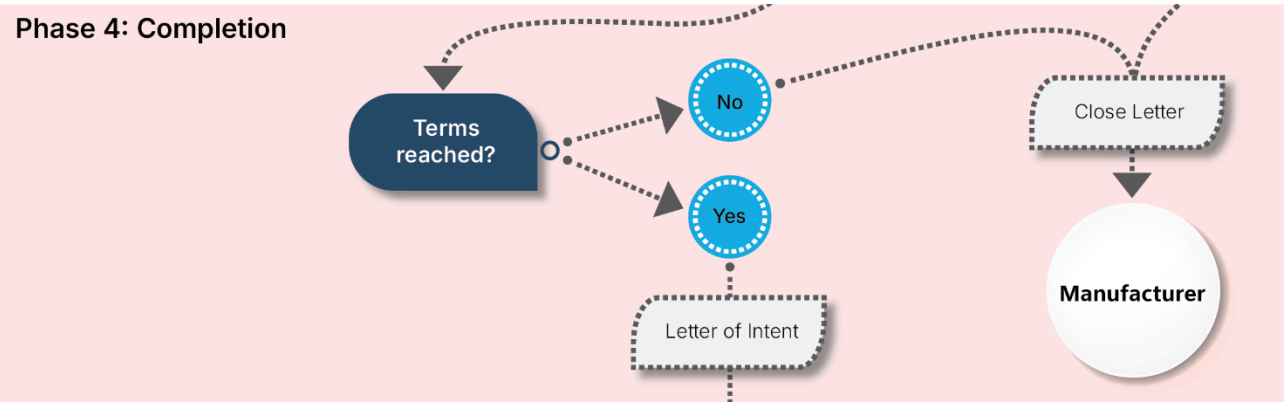
Negotiation format

The negotiation format is determined by a combination of contributing factors including the Drug, the Manufacturer, and Lead(s). Negotiations typically take place in person or via teleconference. Meeting frequency is directed by specific product requirements and it is recommended that new information is available for discussion when meetings are scheduled.

Communication

During negotiations (Phase 3), the Manufacturer should not communicate with any member of the pCPA, including senior officials of drug plans, other than the Lead(s).

Phase 4 - Completion



The pCPA process is considered complete once the negotiation has resulted in mutually agreed upon terms and a fully executed LOI, or, if mutually agreed upon terms are not reached, the pCPA has issued a Close Letter to the Manufacturer, indicating that the negotiation is closed.

Letter of Intent

Upon reaching mutual agreement on terms for a Drug, the pCPA Lead(s) populate the Standard LOI Template and share it with the Manufacturer for review and execution.

Participation of every pCPA Jurisdiction is sought for every Drug; however, there may be circumstances in which agreement among all Jurisdictions is reached to allow a subset of Jurisdictions to proceed to an LOI. Typically, these circumstances are a result of the inability of specific Jurisdictions to achieve sufficient value through negotiation of the product at hand.

The jurisdictional value assessment may be impacted by:

- Alternatives that are funded or may be funded; and/or
- PLAs for the comparators executed prior to pCPA negotiations; and/or
- Affordability within a Jurisdiction's budget; and/or
- Unique jurisdictional circumstances.

Note: Jurisdiction(s) which opt out of the LOI will not negotiate with the Manufacturer for the Drug independently. Should any Jurisdiction(s) that is not listed as a Participating Jurisdiction in the LOI (the "New Jurisdiction") wish to fund the Drug at a later date, the pCPA will issue a notification letter, on behalf of the Participating Jurisdictions, to the Manufacturer in order to amend the LOI and either:

1. Extend the material terms specified in this agreement; or
2. Extend the material terms specified in this agreement with less restrictive clinical criteria at the request of the New Jurisdiction; or

3. Extend the material terms of this agreement insofar as they align with the clinical criteria set forth by INESSS if Québec is the New Jurisdiction.

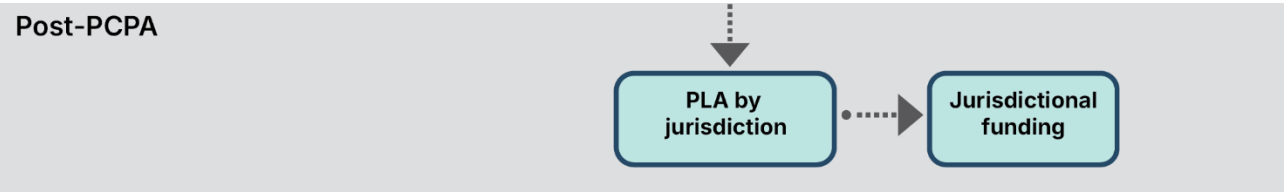
The New Jurisdiction may then enter into its own Product Listing Agreement (PLA) with the Manufacturer. This process will be managed through the pCPA, and a formal notification letter to the Manufacturer will serve as an amendment to the LOI to add the New Jurisdiction as a "Participating Jurisdiction" in the LOI.

pCPA website updates

The pCPA Website is updated monthly. Drugs fall under the following four negotiation categories:

- **Active Negotiations:** Negotiations currently underway
- **Completed Negotiation:** A joint negotiation for a Drug and indication for which an LOI has been signed between the Lead(s) and the Manufacturer OR a negotiation that has been closed without an LOI. The decision to close a negotiation is made when agreement is not reached between the pCPA and the Manufacturer.
- **Considered by Individual Jurisdiction:** Certain negotiations are conducted at a jurisdictional level following pCPA decision to proceed in this manner. Factors considered by Jurisdictions in pursuing individual drug negotiations include CDEC, pERC, or INESSS recommendations, listing status of alternatives, and the overall value of joint negotiations for the particular Drug.
- **No pCPA Negotiation:** Each Drug is considered individually based on a number of factors, including the recommendation from the CDEC, pERC, or INESSS patient perspective, clinical need and considerations. The majority of Drugs for which the pCPA does not pursue negotiations have received negative recommendations from CDEC, pERC, and/or INESSS due to clinical concerns, such as uncertainty regarding the clinical benefit of the drug. This may also occur when the Manufacturer and the pCPA have engaged in discussions regarding criteria and conditions, as recommended through the HTA review, and both recognize that an LOI could not be reached at this time for the Drug(s).

Post-pCPA



Upon full execution of an LOI, it is the responsibility of the individual Jurisdictions and the Manufacturer to transfer the terms into a PLA.

Process timelines

The pCPA is committed to continuous improvement of process predictability and standardization. The target timelines below are aspirational and aim to improve the current pCPA process timelines over the course of the coming years for New Drugs.

The transition from the current state, in which the proposed target completion times are not being met, is outlined below through target expectations for Year 1 (commencing within fiscal year 2018/19) and Year 2 (fiscal year 2019/20).

Phase	Associated Deliverable	Target Completion Time	Frequency of Meeting Target Completion Time
1 - Initiation	Acknowledgment Letter	**≤ 10** Business Days from HTA recommendation[2]	**100%**
2 - Consideration	Engagement/Close/Hold Letter	**≤ 40** Business Days from HTA recommendation[2]	Year 1: **80%** Year 2: **90%**
3 - Negotiation	Proposals/Counterproposals	**≤ 90** Business Days from Engagement Letter	Year 1: **80%** Year 2: **90%**
4 - Completion	LOI/Close Letter		

While the deliverables for Phase 1 and Phase 2 can be managed through pCPA internal processes, it is noted that Phase 3 and Phase 4 deliverables are dependent on all negotiating parties and therefore should be considered as joint targets. Variations and perspectives on causes for deviation from targets will be tracked to assist the parties in further improving process efficiency.

[2] First HTA recommendation, either CDA AMC or INESSS

Appendix I - Checklist for proposal submission

The lists provided are meant to facilitate the submission of proposals by the Manufacturer to the pCPA[3].

The following mandatory proposal requirements are included:

- ☐ The submission must be PDF or Word documents that are not scanned images to facilitate sharing information with the Participating Jurisdiction(s).
- ☐ All BIAs must be in Excel with formulae and assumptions to facilitate sharing information with the Participating Jurisdiction(s).
- ☐ When applicable, address any issues raised in the HTA recommendation related to the criteria, conditions, concerns, uncertainties, etc. and reflect the impact of the recommendation on the BIA.
- ☐ Cost-effectiveness estimates and total cost/budget impact for each Jurisdiction.
- ☐ When applicable, international product pricing and availability.

The following are not included in the proposal being submitted:

- ☐ Detailed clinical background information. This is not required by the pCPA as part of the proposal submission given that the HTA recommendation for a product informs negotiations.
- ☐ Scanned/locked images.
- ☐ PowerPoint documents as the formal proposal document (Note: the Manufacturer may use PowerPoint in presentations).
- ☐ Email proposals (Note: attachments are acceptable but proposals should not be solely within the body of email).
- ☐ Verbal proposals without documentation.

[3] The lists provided are not exhaustive, and the Lead(s) may provide further guidance specific to each negotiation.

Appendix II – Brand process FAQs

All inquiries related to the pCPA Brand Process Guidelines should be submitted to brands@pcpacorp.ca.

1. How is a Lead(s) selected?

A Lead(s) is identified based on a combination of factors including:

- Expertise in a given therapeutic area
- Ease of access to required resources
- Jurisdictional negotiation capacity

2. When and how is Lead identification communicated to the Manufacturer?

The Lead(s) is first communicated to the Manufacturer via the Engagement Letter. The Engagement Letter is sent out by the pCPA once the Drug is considered by the Jurisdictions and common pan-Canadian objectives are established for the Drug.

3. Which agencies are included when referring to HTA?

HTA includes CDA-AMC and INESSS. With pCPA representing all of Canada, including Québec, recommendations from both CDA-AMC and INESSS are included in consideration by the pCPA.

4. Does pCPA meet with Manufacturers to discuss specific Drugs prior to HTA Review?

The pCPA will typically not accept meetings from Manufacturers to discuss specific Drugs prior to HTA Review. The pCPA may, however, accept a meeting with a Manufacturer in circumstances where a Manufacturer is unfamiliar with the pCPA negotiation process, in order to address the Manufacturer's process-related inquiries.

5. Can a Proposal for a Drug with an HTA recommendation be considered by the pCPA prior to the pCPA issuing an Engagement Letter?

Unsolicited Proposals will not result in expedited timelines and there is no commitment from Jurisdictions to respond to Unsolicited Proposals. If a Manufacturer wishes to submit an Unsolicited Proposal, the Proposal should be sent to the pCPA to be shared with all Jurisdictions, and not directly to individual Jurisdictions.

Manufacturers may decide to submit an Unsolicited Proposal to:

- Address issue(s) raised by HTA requiring further attention; and/or
- Demonstrate readiness to offer significant value

6. What can impact negotiation timelines?

Some factors include:

- Proposal requirements are not met.
- Complexity of the proposal with more complex proposals usually requiring greater time for understanding and review by Lead(s) and Jurisdiction(s).
- Disagreement with HTA recommendations/concerns and attempts to resolve through pCPA negotiations, which the pCPA process is not meant to address.
- Introduction of new clinical aspects at the time of the negotiations that have not been reviewed by HTA and which the pCPA process is not meant to address.
- BIA issues such as:
    - BIA is not updated to match the HTA recommendation prior to commencing negotiations.
    - BIA assumptions are not explained.
    - Discrepancies between the BIA provided by the Manufacturer and the BIA prepared by the pCPA.
    - No BIA formulae provided, etc.
- Continued significant differences in expected value between the Manufacturer and the pCPA.
- Ambiguity on more detailed implementation issues (i.e. specific clinical criteria).
- Meetings between the parties where no new information is presented.
- Changes in the therapeutic space.
- Requests to amend LOI template provisions.

7. Can negotiations with individual Jurisdictions begin after a Close Letter is sent to the Manufacturer?

Decisions to send a Close Letter are made on a collective pan-Canadian basis. Any interest in pursuing negotiations with one or more jurisdictions should be raised through the pCPA to those jurisdictions.

8. What are the options for a Manufacturer when they receive a Close Letter?

A Manufacturer can request a meeting with the pCPA to discuss possible next steps specific to their Drug.

If the decision to send a Close Letter was based on a negative/no therapeutic value HTA recommendation, the Manufacturer should contact CDA-AMC/INESSS.

9. Can a decision to close negotiations without LOI be reconsidered?

If a Manufacturer wishes to provide a new Proposal after receiving a Close Letter, this may be submitted through the pCPA (not individual Jurisdictions) and will be at the discretion of the pCPA for reconsideration. It should be noted that changes in therapeutic/funding environment may impact the objectives previously sought through negotiations.