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pCPA Brand Process Guidelines



Version 1.0

RECORD OF UPDATES TO pCPA BRAND PROCESS GUIDELINES

Version Number	Details	Date
1.0	Original Version	May 2018
<i>Next</i>	<i>Anticipated Updated Version</i>	<i>6-12 Months</i>

INQUIRIES

All inquiries related to the pCPA Brand Process Guidelines should be submitted in writing.

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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 Office, 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 Office in Toronto is open for business during regular business hours.
CADTH	Canadian Agency for Drugs and Technologies in Health - 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 CADTH composed of individuals with expertise in drug therapy, drug evaluation and drug utilization, and public members (for a lay perspective).
CDIAC	Cancer Drug Implementation Advisory Committee - CDIAC's role is to provide advice about how New Drugs can be integrated into existing treatment pathways and to achieve greater consistency in Drug funding decisions across Canada.
CDR	Common Drug Review – through the CDR process, CADTH 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 Office 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 Office 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 of Canada (CSC), Veterans Affairs Canada (VAC).
Hold Letter	A letter, issued by the pCPA Office 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 CADTH and INESSS). CADTH 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 CADTH 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.

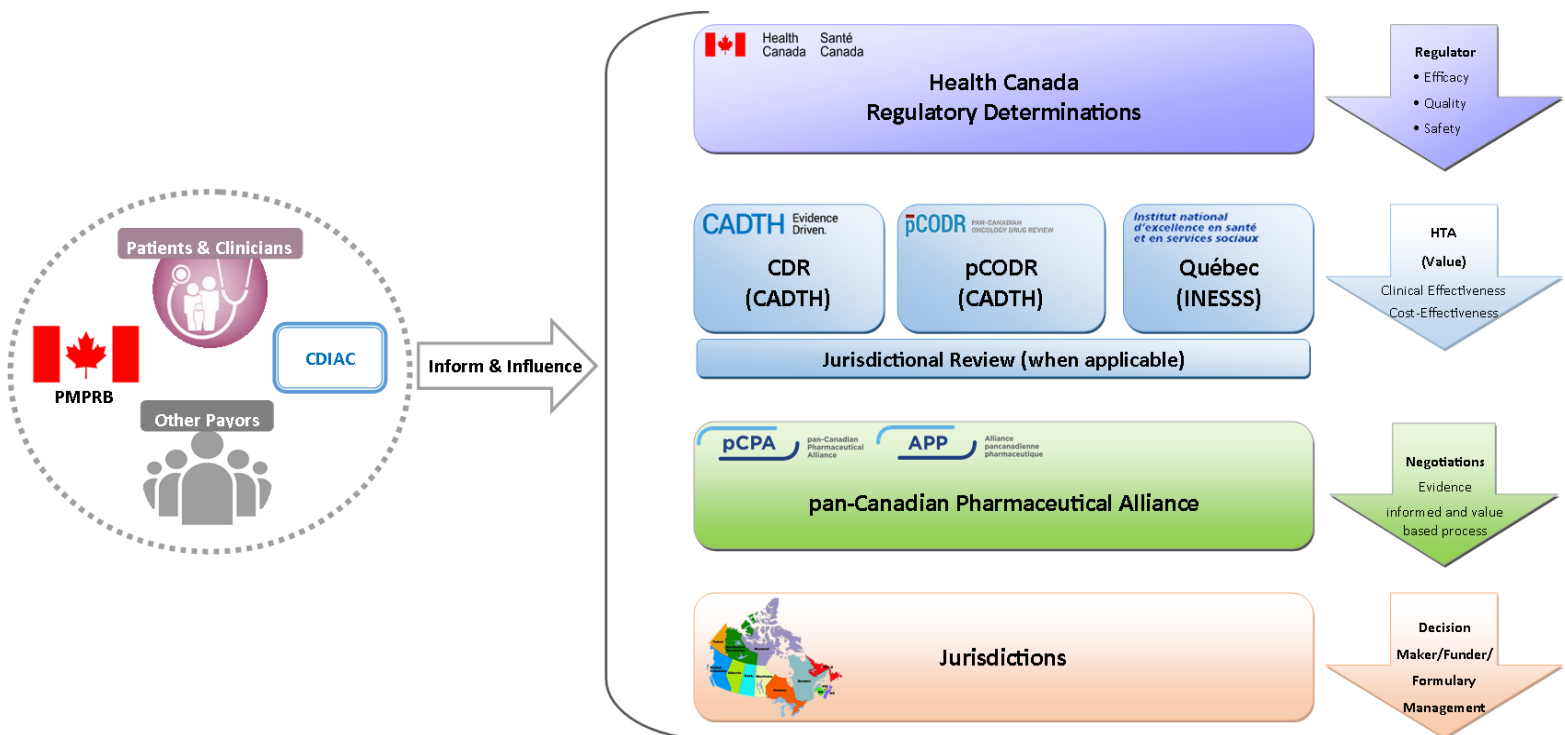
pCODR	pan-Canadian Oncology Drug Review - through the pCODR process, CADTH conducts thorough and objective evaluations of clinical, economic, and patient evidence on cancer drugs, and uses this evaluation to provide reimbursement recommendations and advice to provincial and territorial public drug plans (with the exception of Quebec) and provincial cancer agencies.
pCPA	pan-Canadian Pharmaceutical Alliance – All Jurisdictions and the pCPAO.
pCPAO	pan-Canadian Pharmaceutical Alliance Office.
pERC	pan-Canadian Oncology Drug Review Expert Review Committee (of CADTH) - 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.

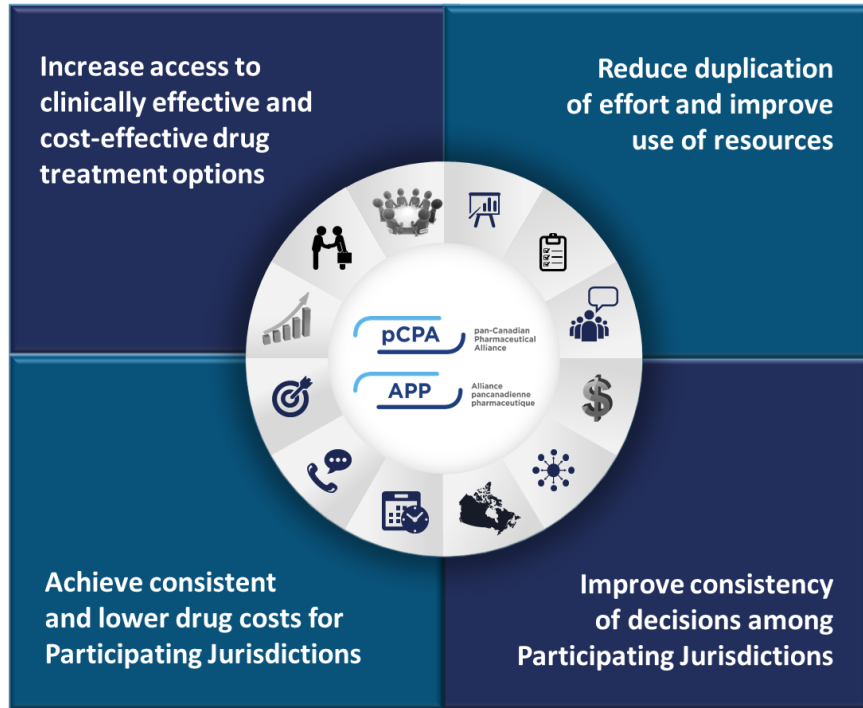


pCPA BACKGROUND

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.

The pCPA’s mandate is to enhance patient access to clinically relevant and cost-effective drug treatment options. It serves this mandate by conducting collective, expert-informed, negotiations for Drugs.

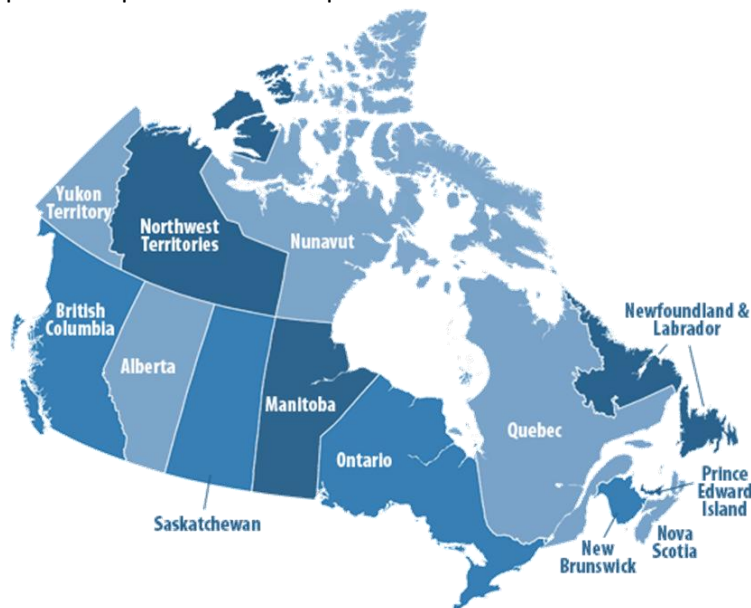
pCPA OBJECTIVES



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 Services of Canada (CSC) and Veterans Affairs Canada (VAC).

The pCPA Office (pCPAO) supports the pCPA membership.



pCPA OFFICE

The decision to establish a pCPA Office was informed by a review of international best practices and broad consultation with both internal and external stakeholders¹. In September 2015, the pCPAO was officially launched and is now in place to support the pCPA in delivering on its objectives.

The pCPAO is currently being hosted by the Ontario Ministry of Health and Long-Term Care.

The pCPAO supports the work of the pCPA by providing administrative, analytical, negotiations, measurement, policy, and communications support.

pCPA OFFICE TEAM

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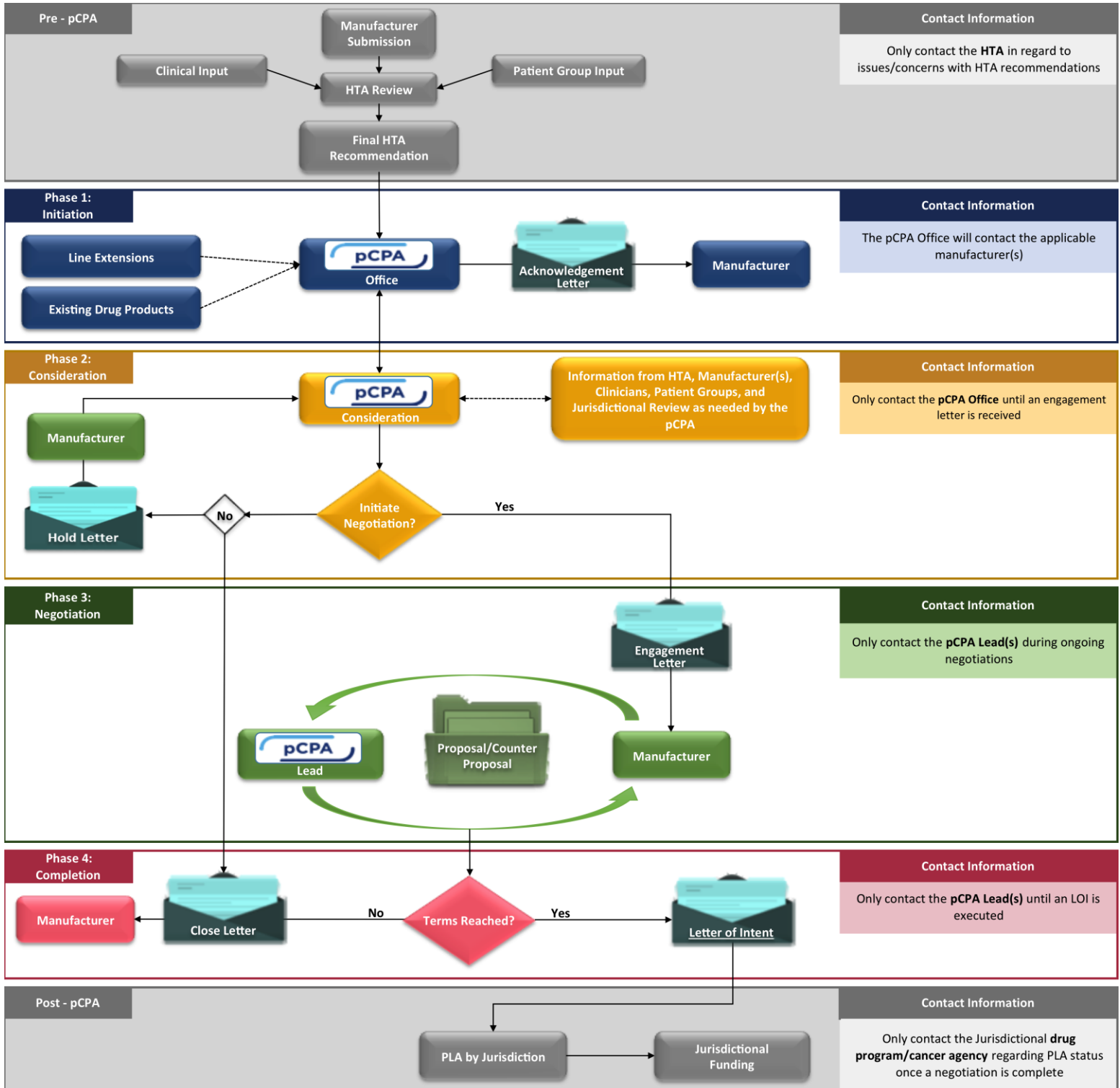
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¹IBM's final "[Pan Canadian Drugs Negotiations Report](#)" is published on the pCPA webpage on the Canada's Premiers website.

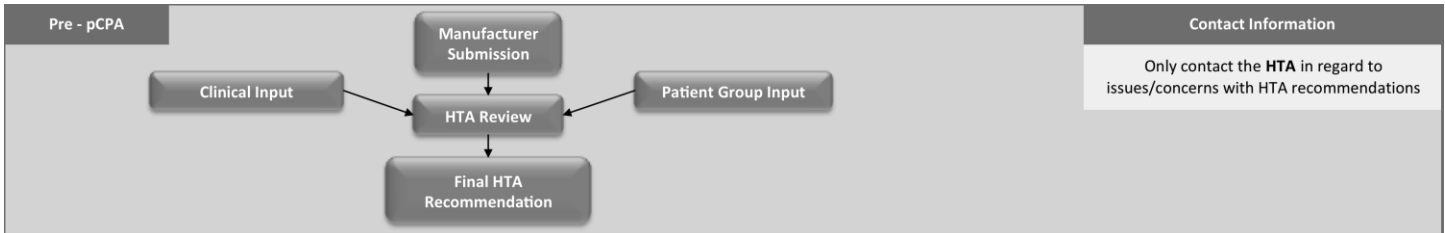
pCPA PROCESS OVERVIEW

The process undertaken by the pCPA occurs in four phases, as illustrated in the following diagram.

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 pCPAO.



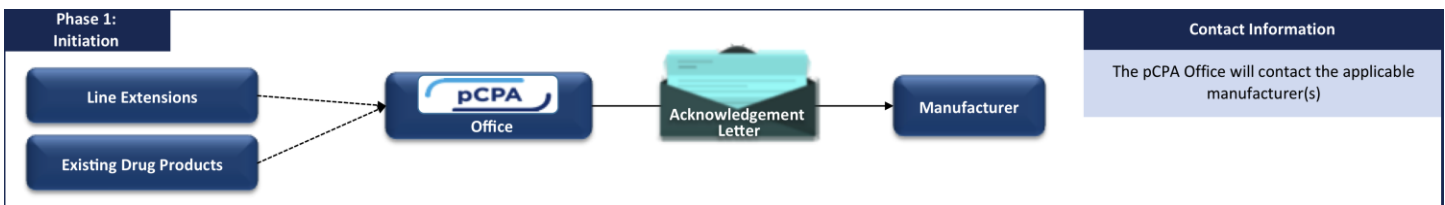
PRE-pCPA



To facilitate timely product awareness, preparation, and to reduce duplication of effort, the pCPA has partnered with CADTH to receive any materials Manufacturers choose to share at CADTH 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 CADTH and/or INESSS. The pCPAO then issues an Acknowledgment Letter to the Manufacturer.

Note: Manufacturers do not need to notify the pCPAO 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.

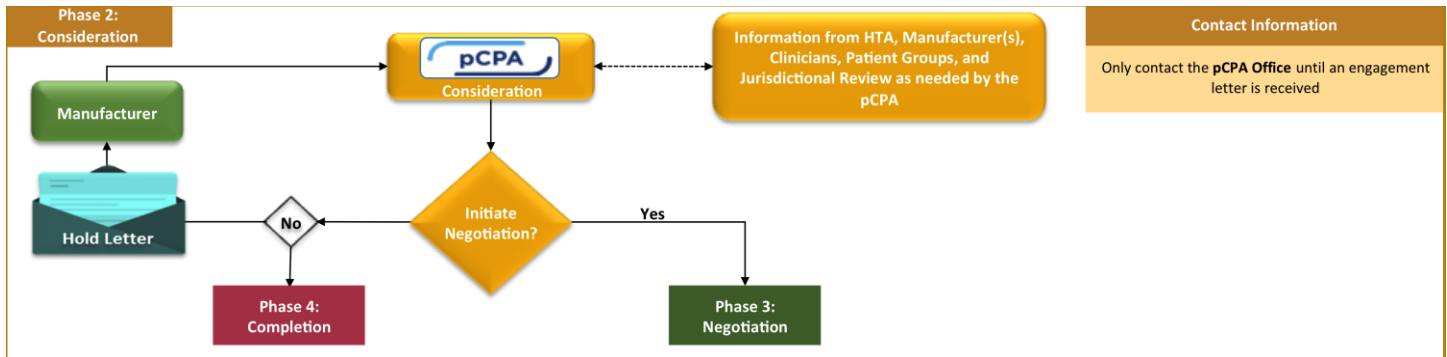
Negotiations for Existing Drugs may be initiated as a result of:

- Clinical landscape changes created by New Drugs entering the same therapeutic space as the Existing Drug;
- Line extensions of the Existing Drug;
- CADTH 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 pCPAO 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 pCPAO. If needed, the pCPAO may contact a Manufacturer to coordinate a meeting and/or to discuss next steps.

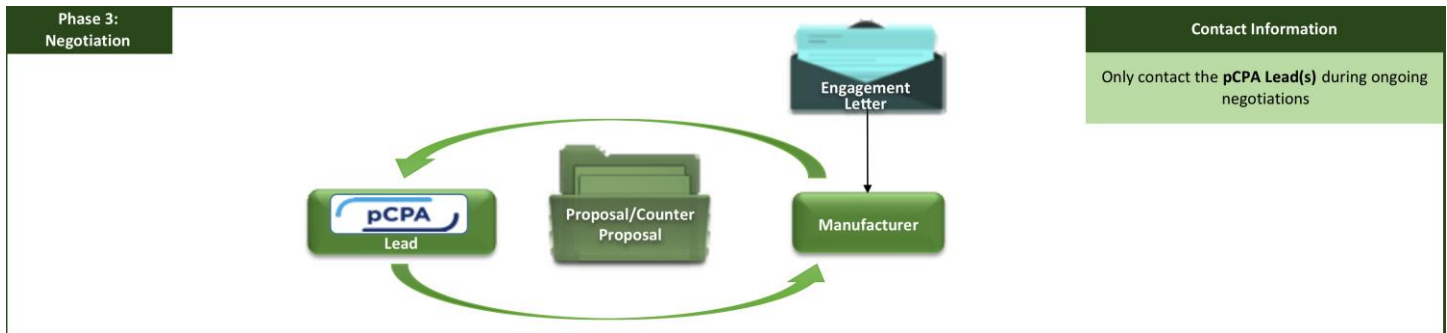
At the discretion of the Participating Jurisdiction(s), information may be sought by the pCPAO from stakeholders including HTA bodies, Manufacturers, clinicians, patient groups, Jurisdictional review(s), and others.

- 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
- 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[†]; *a checklist is provided in Appendix I:*

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

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

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 pCPAO, 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.

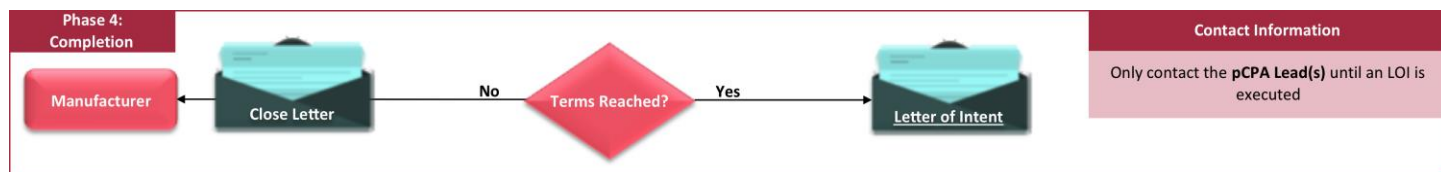
NEGOTIATION FORMAT

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 pCPAO 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 pCPAO 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.

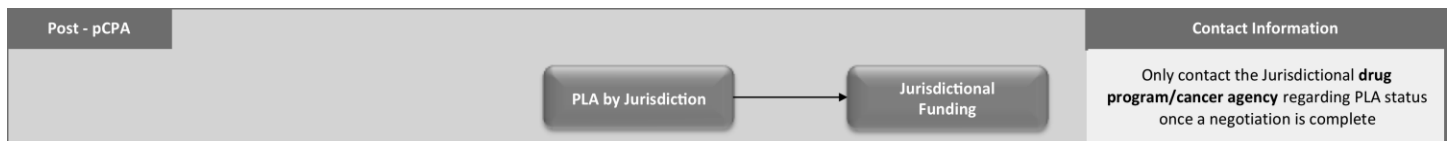
The New Jurisdiction may then enter into its own Product Listing Agreement (PLA) with the Manufacturer. This process will be managed through the pCPAO, and a formal notification letter to the Manufacturer will serve as an amendment to the LOI to add the New Jurisdiction as a “Participating Jurisdiction” 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 [†]	100%
2 - Consideration	Engagement/Close/Hold Letter	≤40 Business Days from HTA recommendation [†]	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.

[†]First HTA recommendation, either CADTH 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^{††}.

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.

^{††}The lists provided are not exhaustive, and the Lead(s) may provide further guidance specific to each negotiation.