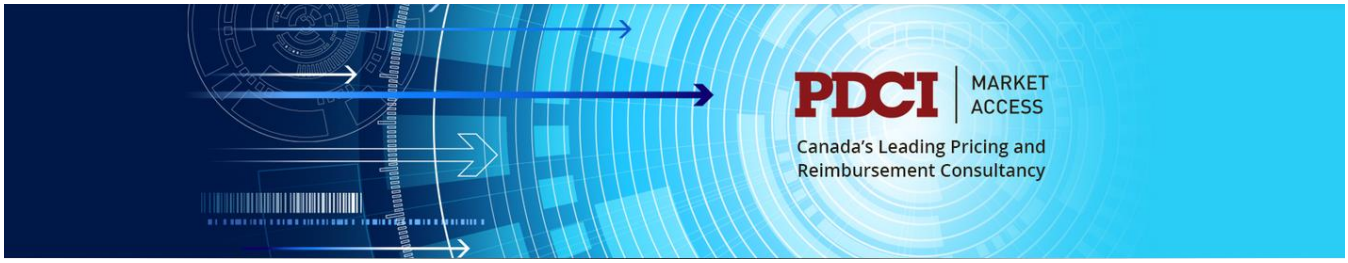

pan-Canadian Pharmaceutical Alliance:

Context, Best Practices, Trends and Outlook

June 2016

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Table of Contents

1.0 Introduction

The pan-Canadian Pharmaceutical Alliance (pCPA), formerly known as the pan-Canadian Pricing Alliance, was established in 2010 by the Council of Federation (CoF) for the purpose of conducting joint public drug plan negotiations for brand drugs in Canada. The goal of these negotiations was to achieve "greater value for publicly funded drug programs and patients". Over the past six years, the pCPA has successfully negotiated agreements for more than 100 products and established itself as a significant component in the Canadian pharmaceutical reimbursement environment.

In February 2015, PDCI Market Access (PDCI) released a report entitled ***pCPA Negotiation Guidelines***. This report, which was a collaboration between the pCPA and PDCI, was meant to provide guidance to manufacturers on pCPA's expectations surrounding negotiations. Although the pCPA Negotiation Guidelines report outlines how manufacturers should deal with the pCPA pre-negotiation, negotiation and post-negotiation stages, it does not provide guidance on understanding the payers' environment and best practices to deal with negotiations.

The purpose of this report is to:

- provide context on process, structure, negotiations, and agreements;
- outline strategic and tactical best practices for engaging with the pCPA;
- clarify some of the recent emerging trends; and
- offer an outlook as to how the environment may evolve in the future.

2.0 Context

2.1 Evolution of Public Drug Plan Collaboration on Pharmaceuticals Negotiations

The pCPA was announced by the CoF in August, 2010 and is currently led by Nova Scotia and Ontario. This alliance was initially focused on brand drugs with a goal of increasing access to drugs, improving consistency of decisions, achieving consistent and lower drug costs, and reducing duplication and improving use of resources.

In July of 2012, the CoF announced the Generic Value Price Initiative, which is currently led by Nova Scotia and Saskatchewan, with the goal of achieving better prices for generic drugs, and improving consistency in pricing and approach.

Combined, the brand and generic initiatives have resulted in published savings to the provinces and territories of approximately $490 million annually at the end of March 2015. Since that time, over 40 additional brand negotiations have been completed and another 4 generic molecules have had their prices reduced to 18% of brand price, resulting in additional savings.

There have been many milestones for the pCPA over the past year: the pCPA Office has been established and staffed, Quebec and the federal drug plans have officially joined the alliance, "First Principles" have been issued for Subsequent Entry Biologics (SEBs), and a formal engagement between the Canadian

Agency for Drugs and Technologies in Health (CADTH) and the pCPA Office has been announced (see Figure 1).

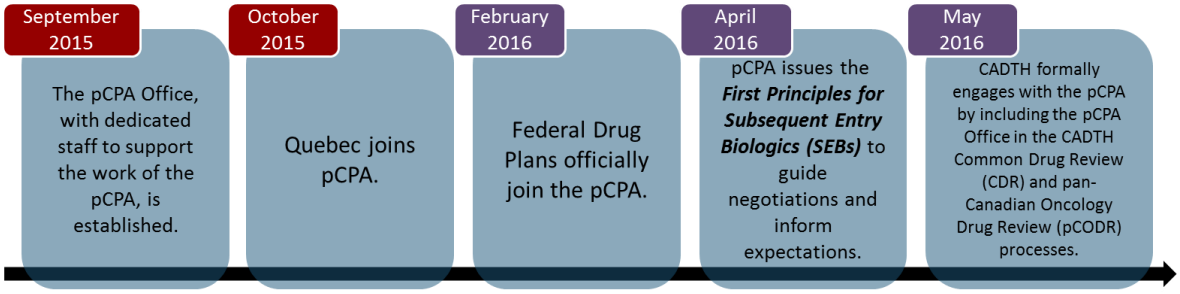

Figure 1. Summary of Recent Developments at the pCPA

The pCPA is now an initiative comprised of all Provincial, Territorial and federal drug plans who conduct joint negotiations for brand name and generic drug products being considered for public reimbursement in Canada.

2.2 pCPA Process

The process by which a drug flows from the health technology assessment (HTA) review through the pCPA is well understood by stakeholders and has been clearly articulated by the pCPA at numerous forums (see Figure 2). The pCPA is currently engaged in public consultations on several topics discussed later in this document; one of these is the development of "Process Guidelines". A revised version of the process may follow.

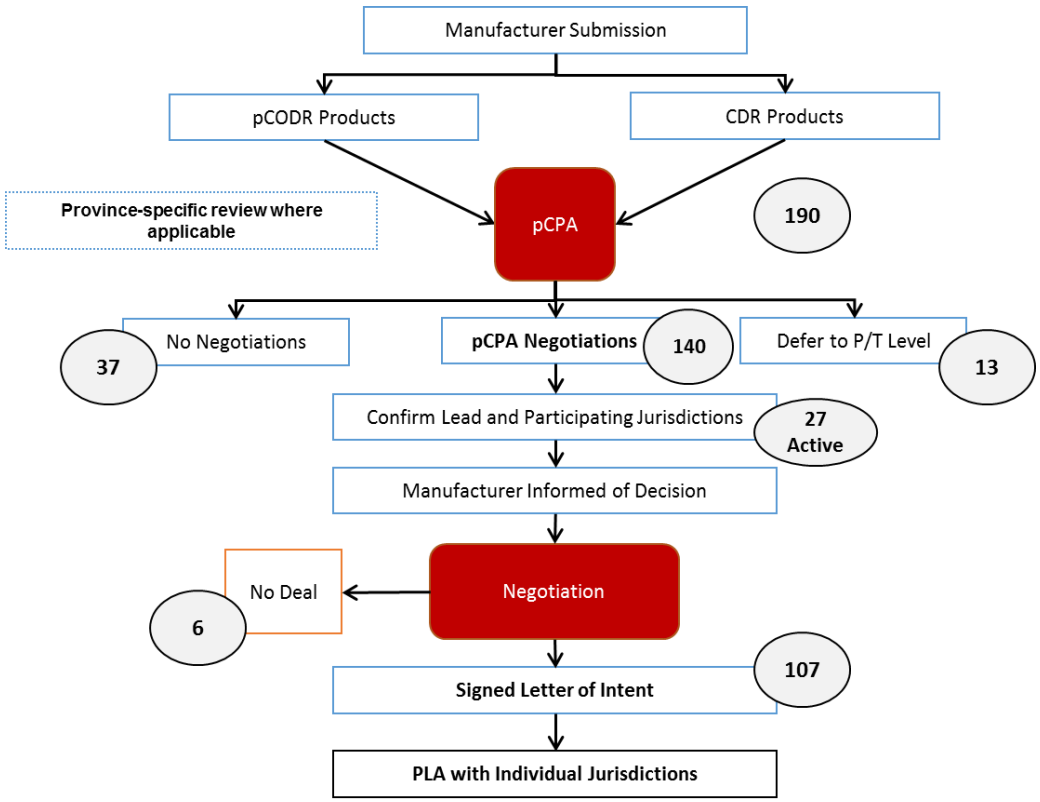

Figure 2. The pCPA Process (*Numbers are indicative of the files that fall into each step of the process)*

2.3 Structure & Process

The role of the pCPA Office is focused initially on providing centralized administration, coordination and operational support to the lead and participating jurisdictions. The Office is the primary point of contact for all queries on the status of negotiations that have yet to commence and may provide assistance to jurisdictions as required during the course of a negotiation. While the pCPA Office plays key administrative and operational functions, at this time, participating drug plans retain responsibility for leading negotiations with manufacturers.

The pCPA Office is focused on establishing rules and structures for operation – first between the Office and the participating drug plans and then tackling the interaction between the pCPA and manufacturers. The integration of Quebec, with its own independent HTA process, into the pCPA will be a key priority and will take time. In addition, the fact that not all the federal drug plans have the capacity to negotiate PLAs will be another matter for the Office's consideration.

The pCPA has weekly teleconferences to discuss the assignment of new negotiations and the status of ongoing negotiations. When a product receives its final recommendation from CADTH, the pCPA will ask for a volunteer to assume the role of lead negotiator – essentially, the first to "raise their hand". Although the selection of this negotiator may be influenced by past experience in the therapeutic area, resource capacity or familiarity with the manufacturer, there is no systematic process on how the lead is determined for each negotiation. It is not uncommon that two jurisdictions will "co-lead" a negotiation, often when a particular drug or therapeutic space is highly complex.

Although confidentiality has been raised as a potential area of concern for manufacturers, participating drug plans are bound by jurisdictional legislation which prevent the disclosure of confidential information from past provincial agreements at the pCPA table.

With regard to pCPA's linkages with other federal and pan-Canadian organizations such as the Patented Medicine Prices Review Board (PMPRB) and CADTH, there already is a great deal of communication between the HTA organizations and public payers. Overall, the pCPA Office is an observer to CADTH's deliberations and will not share any confidential information on the details surrounding any past or current PLA negotiations. As far as the PMPRB, it has been providing informal support to pCPA's activities for a number of years.

2.4 Negotiations

The pCPA relies heavily on the review and recommendation provided to them by their HTA body. Concerns raised through the review need to be addressed within a product's negotiation. For example, if the HTA recommendation indicates a product is not cost effective at the current price, the expectation is that the company's proposal to the pCPA will address this concern. If manufacturers have concerns with the HTA recommendation itself, it is crucial that this is dealt with at CDR or pCODR and not at the pCPA.

At its inception, the pCPA was not reviewing *all* products that had undergone a HTA review and there was less congruence on the approach to negotiations between the jurisdictions. As a result, a number of

products were categorized as "Defer to P/T Level" for resolution. However, as the pCPA became more established, provincial drug plans decided that all products reviewed by CADTH must go through the process. Further, pCPA strove for a greater level of consensus on which drugs will be negotiated and as such, the practice of deferring to P/T level became less common.

A review of the most recently available data from the pCPA (as of May 31, 2016) reveals that of the 190 products reviewed by the HTA organizations, 140 proceeded to pCPA negotiations. Twenty-seven of these are currently in active negotiations. Another thirty-seven products did not go through the process and are not listed because the majority of these products received a "do not list" recommendation based on a clinical rationale. It is important to note that of the 113 products that have completed the pCPA process, 107 resulted in successful negotiations – this signals that there is significant interest on the part of payers to arrive at an agreement once the process is initiated.

The duration of the negotiation process is contingent on a number of factors. Proposals from manufacturers that address the key concerns raised in the HTA review and provide substantial value to drug plans are likely to face an expeditious process for a successful agreement. However, using the pCPA negotiation to dispute elements of the HTA review and substantially adjusting the budget impact analysis (BIA) model from the time it was originally submitted is certain to complicate negotiations. Some companies have successfully incentivized drug plans to expedite the implementation of the letter of intent (LOI) and listing.

2.5 Agreements

The pCPA is open to negotiating a variety of different agreements with manufacturers but place considerable value on simplicity and the ease of implementation. The types of agreements negotiated include:

1. **Transparent Price Reduction** - Given the complications associated with maintaining a multitude of confidential prices and the issue of reconciling HTA pharmacoeconomic evaluations with pCPA negotiations, the pCPA sees clear value in negotiating transparent price reductions where possible.

2. **Rebate** – The pCPA does not operate with any minimum expectation for a rebate, as negotiation parameters vary. However, in some cases jurisdictions are pragmatic regarding the administrative burden of undergoing negotiation and implementing a listing agreement versus the value of a rebate. The pCPA strongly recommends that manufacturers provide the basis for their proposed rebate. Companies should provide some rationale (e.g. some of the economic modeling that has been done in comparison to other products) to justify the level of proposed rebate.

3. **Price-volume** – Price-volume agreements provide an option with limited administrative burden and help to mitigate financial risks if expenditures exceed pre-defined thresholds.

4. **Expenditure caps** – Generally, expenditure caps should be clearly defined and should be set using the same approach and similar assumptions across all participating jurisdictions. The BIA models are essential when expenditure caps are negotiated with the pCPA, and it is important that

companies provide reasonable and accurate forecasts of drug expenditures since the BIA forms the basis of such negotiations.

5. **Annual Expenditure Per Patient Caps** – For certain conditions where patient data is readily available and can be tracked, the pCPA is open to negotiating expenditure caps on a per patient basis. These agreements are typically better suited for certain high-cost specialty products.

6. **Data Collection/Utilization Reviews** – The pCPA has expressed an openness to negotiating data collection and utilization reviews with manufacturers. However, it is important to note that such agreements can be complex and time-consuming to negotiate, particularly if the outcomes of the reviews are tied to financial terms.

7. **Performance-Based Agreements** - The pCPA is willing to negotiate performance-based terms for certain products if it addresses their concerns, feasibility and the administrative burden. Performance-based agreements can be difficult to administer and based on the pCPA's past experience, even options that all parties consider to be good ideas at the outset can ultimately become problematic when it comes to the actual implementation of the agreement. As more specialty products enter the market and more robust health care information data sets become available, there may be a role for realworld evidence to facilitate the development of such agreements.

3.0 Ten Strategic & Tactical Negotiation Best Practices

3.1 Strategic Practices

1. ***Relationships*** - Public drug plans are facing an increasingly challenging fiscal reality with limited year-over-year budgetary growth. It is advisable for the manufacturer to establish and maintain good working relationships with all drug plan managers to build a strong foundation for negotiation success. **Understand the objectives & challenges of the pCPA and maintain a trusting, respectful relationship with all the drug plans.**

2. ***HTA Primacy*** – It is imperative to understand that the pCPA views the HTA recommendation as the cornerstone of the negotiation. Jurisdictions have invested considerable resources in building a national HTA capacity and there is significant emphasis placed on the analysis produced by these organizations. **Understand the importance of the HTA recommendation and how it will impact negotiations.**

3. ***Openness*** – Negotiations can be complex – particularly when some manufacturers require approval from global head offices before finalizing agreements. There are certain options that the pCPA may be interested in pursuing but may be considered "non-starters" from the manufacturer's perspective. Rather than expend valuable negotiation time exploring such options that will ultimately be rejected by head office, it is advisable to be clear on the bounds of the negotiation. **Be transparent with what the organization will and will not do in the Canadian context.**

4. ***Preparedness*** - The discussion between the pCPA and manufacturer can sometimes be a long and drawn out process as the environment may shift during the course of the negotiation as new products enter the market or unexpected challenges arise. It is important to be prepared, to be flexible and creative if needed, and come with solutions that can be implemented. **Consider PLA/pCPA strategy prior to HTA review and be prepared to bring in any helpful international experiences to help inform the discussions.**

5. ***Realistic*** – Manufacturers often spend many years developing a treatment and developing the clinical and pharmacoeconomic package aimed at achieving regulatory approval and a positive HTA recommendation. Although the manufacturer may have a strong belief in the value proposition offered by their new treatment and bold commercial expectations surrounding the product launch, it is advisable to carefully test these assumptions to the fiscal situation facing public payers. **Ensure that negotiation expectations are realistic and feasible.**

3.2 Tactical Practices

6. ***Awareness*** – Given the volume of submissions being sent to drug plans, it is advisable for the manufacturer to consider proactively communicating with individual public drug plans based on their jurisdictional preferences. Pre-submission meetings are one such way of engaging. **Ensure drug plans are aware of status of your drug prior to pCPA.**

7. ***Timeliness*** – Although there is a well-established process whereby reimbursement submissions are provided to HTA organizations, there is benefit to making sure that participating jurisdictions receive their submission in a timely fashion. **Ensure submissions are provided to the drug plans prior to the initiation of pCPA negotiations.**

8. ***Respect*** – Individual pCPA-participating jurisdictions may be amenable to maintaining communication on a specific product with a manufacturer prior to the commencement of formal negotiations with the lead jurisdiction. **Once the negotiations have started, respect the process by communicating with the appropriate individuals (leads) throughout the negotiation process.**

9. ***Touch Points*** – Once the negotiations with the lead jurisdiction are initiated, the manufacturer is encouraged to help move the process forwarded by organizing regular meetings. Although there may not always be meaningful progress to discuss at such meetings, it establishes regular touch points to keep the communications channels open between the negotiating parties. **Set up regular meetings with the lead negotiating jurisdiction**.

10. ***Robust Proposal*** – Include the rationale for the proposal and address any issues raised in HTA recommendation and/or by pCPA in initial meetings. In presenting the proposal, aim to "tell the story"—highlight key elements of the review and recommendation and how the product fits in the Canadian reimbursement landscape. Furnish the same executable BIA models for each participating drug plan that was originally submitted updated to reflect the HTA recommendation (if applicable) and with elements from the offer if relevant. **Develop a clear, concise, and understandable proposal.**

4.0 Trends

The Canadian reimbursement landscape as it relates to the pCPA is rapidly evolving. Please find below some observations on recent trends.

Delayed Negotiation Initiation

- Over the last few months there is a trend towards a longer wait time from CADTH Recommendation to pCPA negotiation initiation (estimated 4-6 months). This is likely due to a number of factors including increased volume of products, time and resource required to establish and staff the new pCPA Office and evolving procedures surrounding the development of negotiation mandates prior to initiation of negotiations. It is expected that this upfront work will lead to more efficient and timely negotiations in the future.

Adapting Resources

- Increasing use of co-leads for larger, complex, or potentially contentious negotiations. In addition, the pCPA Office is doing more of the background analysis and "pre" work-up for negotiations.

Negotiation Expectations

- Increased development of the negotiation objectives and mandate prior to initiation of active negotiations. The initial pCPA engagement letter may contain more detail regarding pCPA's expectations for an initial offer from the manufacturer (including specific percentage price reduction in some cases).

Proactive Communication

- On February 16, 2016, the Executive Officer of the Ontario Public Drugs Program issued a press release on behalf of the pCPA indicating that they had ended negotiations on Soliris®(eculizumab). Although such communication will likely only be done in very unique circumstances where the media has already been engaged, it signals a new proactive approach to pCPA's communication. This approach was supported by the release of the pCPA's First Principles for Subsequent Entry Biologics on April 1, 2016.

5.0 Outlook

The current reimbursement environment is quite challenging for both manufacturers and public payers. More submissions are going through the HTA process which is increasing the number of product launches, and impacting the volume of pCPA negotiations. Given the importance of securing reimbursement funding, manufacturers are submitting unsolicited proposals earlier in the process to try to speed up time to active negotiations and there is considerable uncertainty as to when and how long the negotiations will take.

Affordability concerns are colouring all negotiations that come with budget impact and there is a desire for payers to more actively manage their current formularies. In addition, lack of human resources at the individual drug plan level continues to be an issue despite increased resources centrally at the pCPA Office.

Against this backdrop, the following points reflect how the environment may evolve over the coming months and years:

- **Improvement in Consistency and Definition of Process** – The pCPA Office is having more external presence now that they are firmly established – conferences, meetings with manufacturers, patient groups and associations. With the development of a pCPA "Process Guidelines" document, manufacturers may see an improvement in the level of consistency and clarity surrounding the negotiation process.

- **Earlier Defined Engagement** – The pCPA Office is working with drug plans to provide background research and help develop mandates for negotiation. As such processes become more firmly entrenched, this may address some of the timing issues surrounding the initiation of negotiations.

- **Stakeholder Consultation** – Consultations are expected imminently on "Process Guidelines" and SEB First Principles. Further, the development of performance metrics will be another matter that will be discussed with stakeholders. Similar to other established HTA and regulatory bodies such as CADTH and the PMPRB, the pCPA Office is developing a stakeholder engagement plan which may assuage manufacturers' concerns surrounding transparency.

- **Negotiation of Entire Categories –** Public drug plans are reaching a limit on the level of savings they can extract from new therapies entering the market and are increasingly intent on re-negotiating previously listed products – as a class, or individually. For example, the dipeptidyl peptidase-4 (DPP-4) inhibitors were negotiated through the pCPA in 2015 and manufacturers should expect that other therapeutic classes will be targeted.

- **Prioritization** – The approach of "First In - First Out" – where the sequence of the negotiations is based on when it is received by the pCPA - appears to be increasingly untenable given the volume of negotiations, the available drug budgets, and limited resources. Manufacturers can expect more discussions about the need to prioritize files and call for consultation with industry and patient groups to help inform the pCPA on how this can be implemented.

- **Continuing evolution as needs of payers change** - On May 26th, 2016, CADTH announced that the pCPA Office will be "Observer" at CADTH pre-submission meetings, Canadian Drug Expert Committee (CDEC) & pCODR Expert Review Committee (pERC) meetings and Formulary Working Group (FWG), Drug Policy Advisory Committee (DPAC), and Provincial Advisory Group (PAG) meetings. Although a linkage between pCPA and CADTH are moving forward, developing concrete linkages with the PMPRB and the Canadian Institute for Health Information (CIHI) may be slower to evolve.

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Sherry O'Quinn is the Director of Reimbursement Strategy, responsible for leading PDCI's product listing agreement (PLA) services and related strategic reimbursement advice. She brings unparalleled experience and insights into the negotiation of PLAs and the needs of public payers.

Sherry has a broad knowledge of the entire pharmaceutical landscape, including experience working in government, industry, hospital, and the retail sector. Prior to joining PDCI in January 2016, she spent the past 13 years in the Ontario Public Drug Program Division, Ministry of Health and Long-Term Care where she was involved in the evaluation of drug submissions, policy development, stakeholder management, contract negotiation, strategic planning, and the management of multiple complex and contentious files. Sherry's roles over the last 9 years have been focused on negotiation of PLAs, supporting drug funding decisions and most recently, acting as operational co-lead to the pan-Canadian Pharmaceutical Alliance (pCPA) brand initiative. She was integrally involved in the creation of the Office of the pCPA, established in 2015.

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At PDCI, he provides strategic advice in the development of reimbursement submission dossiers that help clients demonstrate clinical- and cost-effectiveness to payers and health technology assessment agencies. Arvind has expertise on emerging market access topics related to product listing agreements (PLAs), biosimilars, and drugs for rare diseases. He has published on a wide range of subjects from companion diagnostics to healthcare policy reform. Arvind's payer research project work has helped establish a solid relationship with both public and private payer stakeholders in Canada and allows him to offer clients strategic advice to help negotiate PLAs. Aside from facilitating advisory board meetings and conducting training sessions on topics related to the Canadian market access environment, he also presents/moderates sessions at market access conferences and academic institutions.