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# pan-Canadian Pharmaceutical Alliance Negotiation Guidelines

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## Executive Summary

The pan-Canadian Pharmaceutical Alliance (pCPA) was established in 2010 by the Council of Federation (COF) for the purpose of conducting joint provincial/territorial negotiations for brand name drugs in Canada.

Although the purpose is well-defined, the pCPA recognizes that the process and framework to guide the negotiations has been more “organic”. Stakeholders have expressed a need for greater transparency and communication around the process, decisions, criteria, and timelines. Now that it has completed approximately 50 negotiations, the pCPA is in a better position to outline what they believe is required to ensure a more effective and efficient interaction with manufacturers. It is with this end in mind that PDCI Market Access contacted the pCPA to seek their participation in an interview to discuss useful approaches related to negotiations.

Given the complexity and uniqueness of each product’s negotiation, it is important to note that this document is not a definitive guide to the process or policies of the pCPA, but is a general summary that can inform stakeholders on improving their interaction with the pCPA. The key points summarized below are PDCI’s interpretation of the discussion and have been vetted by all jurisdictions within the pCPA.

### **Pre-Negotiation Stage (prior to receiving a recommendation from Health Technology Assessment [HTA] Agency)**

- The pCPA does not currently have a formal process for pre-negotiation discussions, but is open to communicating with companies in advance of an HTA recommendation if a company has:
  - never negotiated with the pCPA and requires clarification on the process.
  - a breakthrough drug, orphan drug, or drug that has the potential to change the treatment landscape in a particular disease area.
- For any company that has a pre-negotiation meeting, the pCPA finds it useful to receive a high level summary of the clinical information, the current place in therapy, treatment options, public funding of alternative therapies, cost of the new therapy and how it compares to other similar products, budget impact analysis (BIA), and if possible, an offer.

### **Negotiation Stage**

**Representation** - The key element of effective representation is an individual who understands the dynamics of government and the drug funding process. The pCPA believes that it is essential that company representation has a solid understanding of the reimbursement landscape and what it is that the pCPA is looking for. Ideally, company representatives should be open and honest in their dialogue and at the same time, be neutral, flexible, and listen to what it is that jurisdictions need in the negotiation process.

**Proposal Structure and Format** - Although the pCPA is flexible on the proposal format, PowerPoint presentations are preferred. The length of the proposal is contingent on the complexity of the situation but generally speaking, if a company is looking at a straight forward negotiation, the pCPA suggests no more than 4–5 key content slides to express the company’s perspective. The pCPA is open to innovative solutions, but if companies are making such

suggestions, it is important to ensure that the proposals consider how such an approach can be implemented.

**Proposal Information** - What the pCPA finds to be the most helpful is a clear, concise overview of the situation including: the summary of the HTA recommendation; review of current treatment landscapes across participating jurisdictions (what/how comparators are funded); summary of the Common Drug Review (CDR) or pan-Canadian Oncology Drug Review (pCODR) recommendations; what the key concerns are; and an explanation of how the proposal addresses the concerns. The BIAs are not required in the initial offer, but a high level snapshot is appreciated because pCPA may not have the BIA information during the initial phase of the negotiation. It should be noted that an executable BIA is eventually required during the discussions with the pCPA. Negotiations are informed by the national HTA review and recommendation for the product; therefore, it is important to put the proposal within this context. There is no need to provide extensive background on clinical or economic material.

Significant challenges may occur during the pCPA negotiations if companies try to revisit a point of disagreement they had with the HTA agency in terms of the clinical or economic value recommendation. Another major issue encountered during negotiations is when there are substantial changes in the BIA model submitted to the pCPA compared with the BIA model submitted to the HTA agency.

**Proposal Expectations** - One of the key messages the pCPA is trying to communicate to stakeholders is that the basis of all negotiations is typically product specific and informed by the recommendation issued by national HTA agencies and provincial bodies. For example, if the 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. The pCPA suggests companies be realistic with their pricing expectations when entering a mature market. There have been situations where a product is priced higher than the public prices within the relevant therapeutic category, and in the absence of a clear therapeutic advantage, prices of comparators will be used as a benchmark for determining whether or not negotiations will occur. The pCPA also examines the cost effectiveness analysis and HTA review to help determine relative value. In other words, price, in and of itself, is only one of the factors considered when reviewing the manufacturer's proposal.

#### **The "Offer"**

**Rebates** - The pCPA does not always want to negotiate a rebate – in fact, they have negotiated transparent price reductions, expenditure caps, utilization reviews, etc. They do not operate with any minimum expectation for a rebate as negotiation parameters vary. Companies should ideally provide some rationale (e.g. some of the economic modeling that has been done in comparison to other products) to justify the level of rebate. The HTA recommendation informs the pCPA's rebate expectations—it is starting point of the economic value equation.

**Expenditure Caps** - When a company is proposing an expenditure cap, the pCPA would prefer that the budget impact figures are provided for each participating jurisdiction, taking into consideration any relevant rebates. In addition, the pCPA requires executable BIAs where the assumptions are clearly outlined and referenced. The BIAs are essential when expenditure caps are offered, and it is important that companies provide reasonable and accurate forecasts of drug expenditures since the BIA forms the basis of such negotiations.

**Outcome-Based Solutions** – The pCPA is open to outcome-based options for certain products taking into consideration the administrative burden. Several types of outcome-based terms are already in place in a number of jurisdictions.

**Highlighting Investment Contributions** – Some manufacturers highlight their investment contributions (e.g. research and development investment, manufacturing, number of employees, etc.) in their proposal and the pCPA does not have any issue with manufacturers providing such information. However, the level of investment made by a company in a particular therapeutic area will not impact the negotiated terms under the pCPA.

**Duration of Agreement** - The duration of the agreement varies between jurisdictions and products. Agreements are typically 3 years in length, but some have been negotiated for shorter (2 years) or longer (no end) duration. However, it is a necessity to provide greater clarity on duration for utilization caps given the nature of such agreements.

**Other Considerations** - There are two other elements that manufacturers need to be aware of when making their initial offer to the pCPA. The first deals with the need for a confidential fixed price. If the manufacturer negotiates a confidential price with the pCPA, the expectation is that the confidential price is fixed for the duration of the agreement. The second element relates to markups. It is important that each jurisdiction pay the SAME net effective price – irrespective of the markup. That is, jurisdictions do not want to pay the difference between the list price and the confidential price on the markups and pCPA expects the manufacturer to rebate that difference in the markup payments between those two prices.

**Reducing the Time of Negotiations** - While offering a steep rebate up front has been helpful in reducing the time of negotiations, ultimately a robust proposal based on the HTA recommendation that addresses concerns raised by the pCPA is most helpful in driving faster negotiations. Setting up touch point meetings with the lead jurisdiction can also streamline the negotiation process. In addition, companies should strive to reduce their own response time. Overall, open and honest dialogue from the start of the process and flexibility from both sides typically leads to fewer rounds of negotiation.

#### **Post-Negotiation Stage**

- Once the letter of intent (LOI) has been finalized, companies move on to negotiating the actual agreement in each jurisdiction. This should be done in a timely manner, without revising any clauses in the LOI.

## 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). The purpose of the pCPA is to conduct joint provincial/territorial negotiations for brand name drugs in Canada “to achieve greater value for publicly funded drug programs and patients.”<sup>1</sup> In January 2013, the COF’s Health Care Innovation Working Group expanded the pCPA’s scope to include generic drugs through the Value Price Initiative. The focus of this article will be on the pCPA’s negotiations related to brand name products.

The pCPA released a report in October 2014 developed by IBM Consulting Inc. which outlined recommendations on, among other matters, a governance structure. One of the developments emerging from this report is an agreement by the provinces/territories to create a permanent and formal structure for the pCPA.

Although it has a well-defined purpose, the pCPA recognizes that the process and framework to guide the negotiations has been more “organic”. Stakeholders have expressed a need for greater transparency and communication around the process, decisions, criteria, and timelines. The creation of the pCPA Office may be an important step to addressing some of the feedback from stakeholders. While the pCPA embarks on the creation of its Office, there is a need for greater clarity on what they expect from manufacturers in their proposals. Now that it has experience with approximately 50 completed negotiations, the pCPA is in a better position to outline what they believe is required to ensure a more effective and efficient interaction with manufacturers.

It is with this end in mind that PDCI Market Access contacted the pCPA to seek their participation in an interview to discuss useful approaches related to negotiations. A discussion guide was prepared by PDCI and shared with the representative of a lead province prior to the interview (see Appendix A). Given the complexity and uniqueness of each product’s negotiation, it is important to note that this document is not a definitive guide to the process or policies of the pCPA, but is a general summary that can inform stakeholders on improving their interactions with the pCPA. The key points summarized below are PDCI’s interpretation of the discussion and have been vetted by all jurisdictions within the pCPA.

The interview with the pCPA focused on three broad areas:

- Pre-Negotiation Stage
- Negotiation Stage
- Post-Negotiation Stage

The purpose of this document is to provide meaningful insights to manufacturers to better understand the pCPA’s perspective and to highlight strategies to improve negotiations in the future for all parties involved.

## 2.0 Pre-Negotiation

The pCPA does not currently have a formal process for pre-negotiation discussions. Typically, preliminary discussions or meetings with the pCPA regarding a negotiation approach do not occur before the HTA recommendation is released. This is because the details of the recommendation, and

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<sup>1</sup> <http://www.canadaspremiers.ca/en/initiatives/358-pan-canadian-pharmaceutical-alliance>

hence the advice required for negotiations, are not available and as a result the discussions may not be as productive as the public plans and the manufacturer may want. Another reason why a pre-negotiation process has not been formalized is that not all products will be negotiated through the pCPA. Members of the pCPA are cognizant of the resources required for such meetings and hence, a pre-negotiation meeting is not a requirement. In addition, there are often meetings between drug plan managers/staff and the manufacturer when new submissions are filed.

However, the pCPA is open to communicating with companies in advance of an HTA recommendation if the company has never engaged in negotiations with the pCPA and require clarification on the process. In addition, the pCPA believes it may be a beneficial to engage in pre-negotiation discussions prior to receiving a final HTA recommendation for certain drug products. For instance, the pCPA is open to meeting with companies about breakthrough drugs, orphan drugs, or drugs that have the potential to change the treatment landscape in a particular disease area.

For any company that has a pre-negotiation meeting, the pCPA finds it useful to receive a high-level summary of the clinical information, the current place in therapy, current treatment options, public funding of alternative therapies, cost of the new therapy and how it compares to other similar products, budget impact analysis (BIA), and if possible, an offer. Other pCPA jurisdictions not involved directly in the negotiations, may also find this high-level information (without the offer) useful to provide some context on the drug, so that they are better prepared when the manufacturers contacts them after signing the Letter of Intent (LOI) with the pCPA.

The Pan-Canadian Drugs Negotiation Report completed by IBM Canada Inc. for the pCPA recommended that pre-negotiation briefings be considered for larger dollar value submissions. The pCPA indicated that these recommendations are currently being considered with the implementation of the Office of the pCPA. It seems clear that as the pCPA moves forward with establishing the Office, they will be looking for opportunities to engage manufacturers earlier in the process.

## 3.0 Negotiation

### 3.1 Representation

In general, the pCPA finds it beneficial for the company to have a government relations representative and senior management representation for additional input if necessary. The key element of effective representation is an individual who has understands the dynamics of government and the drug funding process. The pCPA believes that it is essential that company representation has a solid understanding of the reimbursement landscape and what it is that the pCPA is looking for. Ideally, company representatives should be open and honest in their dialogue and at the same time, be neutral, flexible, and listen to what it is that jurisdictions need in the negotiation process. Negotiations can become lengthy and difficult when company representatives are not familiar with the Canadian context and how government decisions are made across jurisdictions.

Representation is contingent on the issues in question and the negotiation stage between the pCPA and the manufacturer. For instance, BIAs are an important component of the negotiations and other parties may become involved in the negotiations. If there are questions about the BIAs, the pCPA may have their lead jurisdiction representative meet with the financial analyst at the company to ensure that all parties understand the BIA baseline estimates.

Negotiations with the pCPA can take place as either teleconferences or face-to-face meetings, but the pCPA does not have a strong preference either way. It is often dependent on logistics and complexity of the discussions required. When it comes to a face-to-face meeting, the pCPA generally finds meetings can be better managed with a smaller group of individuals. In the pCPA's experience, they find that three to four representatives is generally a reasonable number. The pCPA does not have any issues with a larger group listening via teleconference, but recommends that to keep discussions focused, phone negotiations should be led by one or two key company spokespeople.

### 3.2 Proposal Structure & Format

Although the pCPA is flexible on the proposal format, PowerPoint presentations are preferred. Even if the pCPA does not have a face-to-face meeting, PowerPoint offers an effective visual means of presenting the information in a simple way that is easy to understand. The length of the proposal is contingent on the complexity of the situation. Generally speaking, if a company is looking at a straight forward negotiation, the pCPA suggests no more than 4–5 key content slides to express the company's perspective.

The proposals that the pCPA find difficult to interpret are those where the offer is unclear. There have been instances where companies have put forward conceptual ideas that are not accompanied by recommendations surrounding implementation into the current system. The pCPA is open to innovative solutions, but if companies are making such suggestions, it is important to ensure that the proposals consider how such an approach can be implemented.

### 3.3 Proposal Information

The pCPA finds a clear, concise overview of the situation to be the most helpful, including: the summary of the HTA recommendation; review of current treatment landscapes across participating jurisdictions (what/how comparators are funded); what the Common Drug Review (CDR) or pan-Canadian Oncology Drug Review (pCODR) recommendations are; what the key concerns are; and an explanation of how the proposal addresses the concerns. BIAs are not required in the initial offer, but a high level snapshot is appreciated because the pCPA may not have the BIA information during the initial phase of the negotiation. It should be noted that an executable BIA model is required at some point in the negotiations. It is also helpful to include the "value" of the proposal for each participating jurisdiction. For example, if a company is proposing a 20% volume discount, the pCPA would like to know what that means to the budget impact compared to what was originally submitted. It is important to ensure that both the offer and the proposed implementation process are clearly explained. Overall, the pCPA receives many files for consideration and they find it helpful to "tell the story" of the product.

The company may wish to focus the detailed BIA information for the lead jurisdiction as it is this jurisdiction's expertise that is most pertinent to the negotiation at hand, however the BIA must be available (and relevant) for all jurisdictions to review. The pCPA also suggests that companies include a simple chart with drug expenditure impact by province. In the case of drugs for rare diseases, they have also found it helpful for companies to include patient numbers to help drug plan managers understand the impact on their jurisdiction.

Negotiations with the pCPA are informed by the national HTA review and recommendation for the product; therefore, it is important to put the proposal within this context. There is no need to provide extensive background on clinical or economic materials. It is important to note that many jurisdictions have agreements in place with manufacturers, particularly for products in more mature markets. The

pCPA recognizes that manufacturers do not have information on effective prices of comparators, due to confidentiality requirements. As a result, manufacturers should be aware that the pCPA will provide feedback on proposals including the presence of listing agreements which will impact a proposed price and/or recommendation provided by the CDR or pCODR.

Significant challenges may occur during the pCPA negotiations when companies try to revisit a point of disagreement they had with the HTA agency in terms of the clinical or economic value recommendation. The pCPA can appreciate that the company may not agree with all aspects of the HTA recommendation, but a detailed document in the pCPA proposal outlining the company's grievances is not productive to the negotiations. Such discussions need to occur directly with the HTA bodies.

Another major issue encountered during negotiations is when there are substantial changes to the BIA model submitted to the pCPA compared with the BIA model submitted to the HTA agency. The pCPA recognizes that there may be some shifts within the market and is open to adjusting the BIA as new information becomes available. However, it is not reasonable from the pCPA's perspective if the new information changes the entire value proposition that was originally submitted to the HTA agency. It is important to recognize that the CDR and pCODR recommendations do consider the financial impact on public plans and a significant variation in the BIA after a recommendation raises questions about the accuracy of information that was reviewed leading to the final HTA recommendation.

### 3.4 Proposal Expectations

Whether the product is reviewed by CDR or pCODR has no impact on the pCPA's expectations of the proposal. One of the key messages the pCPA wishes to communicate to stakeholders is that the basis of all negotiations are typically product specific and informed by the recommendation of the national HTA agencies and provincial bodies. For example, if the 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. The pCPA does not want to enter into detailed clinical discussions during the negotiations because they rely on the clinical expertise/review from the HTA agencies.

The pCPA suggests companies be realistic with their pricing expectations when entering a mature market. There have been situations where a product is priced higher than the public prices within the relevant therapeutic category, and in the absence of a clear therapeutic advantage, prices of comparators will be used as a benchmark for determining whether or not negotiations will occur. For example, if the price is considerably higher, the pCPA will question whether or not an agreement can be achieved given the differential in pricing and may decide not to proceed with negotiations.

From the pCPA's perspective, although price is one of a number of factors considered, the key is the potential value the product brings to the health system. They will consider the type of product, the current treatment alternatives, whether the drug fills a therapeutic gap, affordability and other province-specific issues. The pCPA also examines the cost effectiveness analysis and HTA review to help determine relative value. In other words, price, in and of itself, is only one of the factors considered when reviewing the manufacturer's proposal.

### 3.5 "The Offer"

When manufacturers are preparing their offers to the pCPA, it is important to note that regardless of the type of offer being proposed (e.g. rebate, expenditure cap, etc.), the pCPA considers numerous factors beyond cost effectiveness and product price in their deliberations. Other elements include

comparator products covered by the drug plan, the treatment landscape, comparators' prices and affordability. There may be situations where therapeutic value and cost effectiveness are well established and agreed upon but the overall affordability to the drug plan may be a crucial component that drives the negotiations. Manufacturers are encouraged to not exclusively focus on price and cost effectiveness and think about the broader implications for the drug plan when formulating their offer to the pCPA.

### 3.5.1 Rebates

The pCPA does not always want to negotiate a rebate – in fact, they have negotiated transparent price reductions and also considered other options such as expenditure caps, utilization reviews, etc. They do 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.

The HTA recommendation informs the pCPA's rebate expectations—it is the starting point of the economic value equation. The pCPA recognizes that it may be criticized for negotiating with a company that received a positive recommendation on clinical and cost effectiveness. The rationale for conducting these negotiations is that companies are submitting public list prices to HTA bodies and are likely not aware of the confidential prices for their comparators. In addition, certain issues such as sustainability and affordability must be dealt with at the level of each jurisdiction.

### 3.5.2 Expenditure Caps

When a company is proposing an expenditure cap, the pCPA would prefer that the budget impact figures are provided for each participating jurisdiction, taking into consideration any relevant rebates. In addition, the pCPA requires executable BIAs where the assumptions are clearly outlined and referenced. The BIAs are essential when expenditure caps are offered to 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.

### 3.5.3 Outcome-Based Solutions

The pCPA is open to outcome-based options for certain products taking into consideration the administrative burden. Several types of outcome-based terms are already in place in a number of jurisdictions.

Innovative options, such as outcome-based solutions, can be difficult to administer. 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 execution. Most manufacturers seem to prefer price rebate options over novel solutions because they too recognize that price rebates are the simplest and most timely way to arrive at a mutually agreed upon value for the product under negotiation.

### 3.5.4 Highlighting Investment Contributions

Manufacturers have been known to highlight their investment contributions (e.g. research and development investment, manufacturing, number of employees, etc.) in their proposal and the pCPA

does not have any issue with manufacturers providing such information. However, the level of investment made by a company in a particular therapeutic area will not impact the negotiated terms under the pCPA. Given that the pCPA negotiations are a national process, it is difficult to measure these investments at a national level if this information is provided for only one jurisdiction. Generally, manufacturers make business decisions about the value added programs, which may not be created to support payer recommendations.

### **3.5.5 Duration of Agreement**

The duration of the agreement varies between jurisdictions and products. Agreements are typically 3 years in length but there have been some that have been negotiated for shorter (2 years) or longer (no end) duration. Even if there is a fixed term, the expectation is that the agreement is not in place to address the payer's shorter financial situation and will stay in effect until the jurisdiction deems otherwise. However it should be noted that for utilization caps there is a necessity for greater clarity on the duration term given the nature of such agreements.

### **3.5.6 Other Considerations**

There are two other elements that manufacturers need to be aware of when making their initial offer to the pCPA. The first deals with the need for a confidential fixed price. If the manufacturer negotiates a confidential price with the pCPA, the expectation is that the confidential price is constant for the duration of the agreement. Although various jurisdictions may have provisions for price increases on their publicly available formulary, the confidential fixed net price will not be adjusted irrespective of whether the formulary's published list price changes.

The pCPA recognizes that the allowable markups vary between jurisdictions. However, for the purposes of the negotiations, it is important that each jurisdiction pay the SAME net effective price – irrespective of the markup. That is, jurisdictions do not want to pay the difference between the list price and the confidential price on the markups and pCPA expects the manufacturer to rebate that difference in the markup payments between those two prices. In essence, the actual rebate payment back to each jurisdiction may be different (because one jurisdiction's markup is higher than another's) but since jurisdictions are responsible for paying different markup payments, rebating the difference in markup payments will result in a situation where each jurisdiction pays the same net effective price.

## **3.6 Reducing the Time of Negotiations**

While offering a steep rebate up front has been helpful in reducing the time of negotiations, ultimately a robust proposal based on the HTA recommendation which addresses concerns raised by the pCPA is most helpful in driving faster negotiations. As previously discussed, a major hindrance to a timely negotiation process occurs when companies make substantial changes to the BIA.

Another factor that is important to keep in mind is that not all negotiations are created equally. It often occurs that the pCPA and the company are close to agreeing on an appropriate discount at the outset, and these negotiations tend to move quickly. Other times the initial proposal from the manufacturer is quite different from what the pCPA considers appropriate. These negotiations tend to be longer in duration as it can be hard to reach that middle ground that satisfies both parties.

Setting up touch point meetings with the lead jurisdiction can also streamline the negotiation process, and companies should strive to reduce their own response time. Overall, open and honest dialogue from the start of the process and flexibility from both sides typically leads to fewer rounds of negotiation.

## 4.0 Post-Negotiation Stage (after Letter of Intent has been signed)

Once the LOI has been finalized, companies move on to negotiating the actual agreement in each jurisdiction. This should be done in a timely manner, without revising any clauses within the LOI. Ultimately, the listing decision lies with each jurisdiction, and even though they are part of the pCPA process, the LOI is nonbinding. The pCPA recognizes that the nonbinding aspect of the LOI is a source of contention for manufacturers, but it remains up to each individual province or territory to make their own funding decisions.

## 5.0 Conclusion

The pCPA was created more than 4 years ago and now has a significant impact on both the generic and brand pharmaceutical market. Stakeholders have looked for greater transparency and communication around the pCPA's process, decisions, criteria, and timelines. The organization is in the process of taking its first steps to create a formal Office with dedicated resources which will allow for improved communication and clearer direction from the pCPA in the future. Until such an Office is established, this article is meant to provide some much needed guidance on how manufacturers should best deal with the pCPA to ensure a smoother negotiating process.

### About the Author



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*Arvind provides strategic solutions to clients on market access-related issues throughout the entire product lifecycle. He leads the development of reimbursement submission dossiers that help clients effectively communicate the value proposition of new technologies to payers/ health technology assessment agencies. Arvind offers clients advice to help negotiate product listing agreements with the pan-Canadian Pharmaceutical Alliance (pCPA) and public drug plans and executes direct payer research projects through primary research interviews with current and former payers across Canada.*

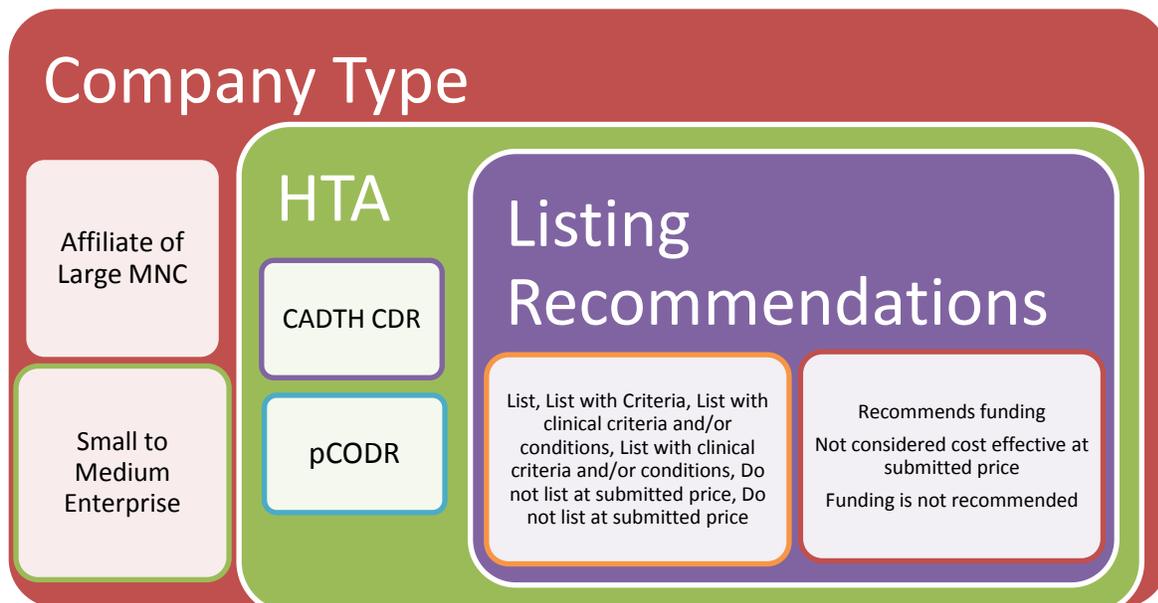
## Appendix A: Discussion Guide for Interview with pCPA Representative

The purpose of this interview is to solicit feedback from the pan-Canadian Pharmaceutical Alliance (pCPA) on some of the **best practices** representatives have observed from companies that have successfully negotiated Letters of Intent (LOI) with pCPA. We are also looking for pCPA's perspective on companies' approaches that have been counter-productive to the negotiation process and factors that pCPA believes contribute to delayed or unsuccessful negotiations. PDCI is not seeking any confidential company or product specific information, but would appreciate specific examples of practices that have contributed to arriving at a successful outcome for all parties.

The interview will be structured into the following sections:

1. **Pre-negotiation (prior to final recommendation issued from health technology assessment [HTA] agencies)**
2. **Negotiation**
3. **Post-negotiation (after LOI signed)**

As shown in the figure below, we recognize that each negotiation with pCPA is unique in terms of the type of company submitting the proposal, the HTA organization which reviewed the product, and the listing recommendation the product received.



In addition, pCPA needs to consider factors such as the likely therapeutic benefit offered by the product, the magnitude of unmet clinical need, and the listing price suggested by the manufacturer.

With that in mind, we ask that when answering questions for this interview that pCPA try to provide examples that illustrate best practices which can generally apply to different types of situations they face. It would also be appreciated if specific examples can be provided to appreciate some of the unique situations you face as well.

## **I. Pre-Negotiation Stage (prior to final recommendation issued from health technology assessment [HTA] agencies)**

- Have you found the practice of companies contacting pCPA prior to receiving a final recommendation from an HTA agency to be helpful to the overall negotiation?
- If it was helpful:
  - Can you please elaborate on what type of companies or products such early engagement was helpful for?
  - What type of information can companies provide to help pCPA at this stage?
  - How far in advance of the HTA recommendation would you suggest the company contact pCPA?
- Can you provide an example of how a company handled the pre-negotiation stage well?
- Can you provide an example of how a company handled the pre-negotiation stage poorly?

## **II. Negotiation Stage**

### **• Representation**

- When it comes to company representation, what type of experience/knowledge do you find most helpful for effective negotiations?
- How many representatives should participate and what roles should they have (e.g. finance, market access, scientific, etc.)?
- Are pCPA's expectations on representation influenced by the type of product being considered (e.g. orphan, breakthrough, slight/no improvement, oncology)? If so, can you please elaborate on those expectations?
- How often have consultants been involved in the negotiation process to date?
- What has pCPA found useful from the participation of the consultant?
- What would pCPA suggest consultants avoid when representing company interests in negotiations?
- Can you please elaborate on a particularly good example of company representation and what made it good?
- Can you please elaborate on an example of a company whose representation was not effective and factors that contributed to its ineffectiveness?

### **• Proposal**

#### **i) Structure**

- What is the best way to structure the proposal to pCPA?
- Can you please provide an example of a proposal that was structured particularly well?
- Can you please elaborate on a proposal that was not well structured and what pCPA found objectionable?
- What is the preferred format and length for the proposal?

ii) **Information**

- Ideally, what type of information would pCPA like to see in the initial proposal from the manufacturer (e.g. clinical background, value, place in therapy, national BIA, rebate, etc.)?
- What information do you believe is extraneous and should **not** be included in the initial proposal?

iii) **Expectations**

- How are pCPA's expectations about the initial proposal affected by:
  - Which HTA organization reviewed the product?
  - The listing recommendation received?
  - The perceived therapeutic value of the product?
  - The listing price of the product?

iv) **Rebates/Expenditure Cap**

- When it comes to rebates, how best would you like the information presented to pCPA?
- What information would you like to see from the manufacturer to justify the rebate?
- Ideally, what is the minimum rebate you would like to see from the manufacturer?
- How are pCPA's rebate expectations impacted by the HTA recommendation?
- Can you please provide an example of a proposal that presented rebate information particularly well?
- When it comes to an expenditure cap, how best would you like information related to a cap presented to pCPA?
- What data would you like to see from the manufacturer to support an expenditure cap?
- Can you please provide an example of a proposal that presented expenditure cap information particularly well?
- Other than rebates and expenditure caps, what other cost containment options would pCPA be open to?
- Can you please provide an example of a particularly creative (and effective) alternative cost containment option presented by manufacturer?

v) **The "Ideal" proposal**

- Can you please provide specific examples which represent an **ideal** initial proposal for:
  - an Orphan drug
  - a breakthrough drug
  - a drug that offers slight/no improvement
  - an oncology drug

• **Rounds of Negotiation**

- What can companies do (other than provide a steep rebate in the initial proposal) to minimize the rounds of negotiation?
- What are some company practices that have facilitated fewer rounds of negotiation with pCPA?
- What kinds of company practices may create the need for more rounds of negotiation?

### **III. Post-Negotiation Stage (after LOI signed)**

- Can you please describe the key factors that impact the time to listing post LOI and how companies can effectively address these factors?
- What would pCPA recommend manufacturers do to facilitate more timely listing in participating provincial and territorial plans?
- Can you please provide an example of company that was particularly effective post LOI in obtaining listing and why you believe this company was effective?