Pan Canadian Drugs Negotiations Report

Draft v1

December 31, 2013

Draft V2

February 18, 2014

Draft v3

February 24, 2014

Final version

March 22, 2014

Table of Contents

1.0 Executive Summary **3**
2.0 Introduction **12**
3.0 Objectives and Approach **15**
4.0 Environmental Scan **16**
5.0 Stakeholder consultation and feedback **24**
6.0 PCPA Process considerations **32**
7.0 PCPA Governance **37**
8.0 Results of Targeted survey across Government stakeholders **62**
9.0 Recommendations **66**
APPENDIX 1: List of stakeholders **71**
APPENDIX 2: Details on feedback from stakeholder interviews **73**
APPENDIX 3: Environmental Scan Details **80**
APPENDIX 4: Survey tool **92**
APPENDIX 5: Interview Guide - Government **93**
APPENDIX 6: Interview Guide – Industry **94**

1.0 Executive Summary

Introduction

Healthcare expenditures are on the rise globally. Canada is no exception with national implications on the sustainability of healthcare. The three levers in a healthcare system (cost, quality and access) are threatened by increasing costs, reduced access and the pressure of maintaining a sufficient quality of care. Obtaining better value for healthcare is an increasing necessity for the sustainability of our healthcare system. Drugs are an important component of a healthcare system. In Canada, total drug expenditure reached $32.0 billion in 2011 and $33.0 billion in 2012, representing annual growth rates of 4.0% and 3.3%, respectively[1]. Drugs' share of total health expenditure remained constant at 15.9% in both 2011 and 2012. For drugs that are funded through the publicly funded health system, obtaining better value and providing better and more consistent access across Canada is important for the health of its citizenry. For example, until 2002, each public plan decided on payment independently with input from different expert groups that evaluated drug benefit and harm. In 2002, in an attempt to standardize input to public drug plan listing decisions, the Ministers of Health established a national Common Drug Review (CDR) process for new brand name drugs.

The **Pan-Canadian Pricing Alliance (PCPA)** was first announced by Premiers in August 2010, at a meeting of the Council of the Federation (COF). The PCPA is a pan-Canadian initiative consisting of the following jurisdictions: Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Nova Scotia, Ontario, Prince Edward Island, Saskatchewan, and the Yukon. These jurisdictions conduct joint negotiations for brand name drug products being considered for reimbursement through their respective public drug plans. This approach is intended to capitalize on the combined purchasing power of public drug plans across multiple jurisdictions, improve the consistency of drug listing decisions across the country, ensure benefits are cost effective, and increase access to drug treatment options.

The PCPA was introduced to address issues faced by the jurisdictions, stemming from their old policies of each jurisdiction making individual decisions. This often resulted in different drug coverage across the country. Jurisdictions struggled with increasing budget costs and dealt with this in different ways through policy, formulary restrictions, product listing agreements (PLAs), etc. Different jurisdictions were at different points in terms of negotiating and implementing PLAs leading to inconsistencies in access and pricing across the country. The different Provinces / Territories (P/Ts) realized that working collaboratively on drug funding could help improve the balance of access and pricing across the country. This would also help the smaller P/Ts which were at a distinct disadvantage to negotiate pricing given their population size.

When the PCPA was first announced, its purpose was to examine opportunities to conduct joint P/Ts negotiations for brand name and generic drug products. The PCPA was not intended to bypass existing evidence-based drug reviews or the development of new listing approaches.

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[1] *http://www.cihi.ca/CIHI-ext-portal/internet/EN/SubTheme/spending+and+health+workforce/spending/cihi015954*

The goals of the PCPA, as set by COF are:

- To increase access to drug treatment options
- To improve the consistency of drug listing decisions across the country
- To capitalize on combined buying power of jurisdictions
- To achieve consistent pricing and lower drug costs
- Reduce duplication of negotiations and improve utilization of resources

Ontario and Nova Scotia are the current lead provinces for the PCPA for brand name drugs. Nova Scotia and Saskatchewan are the leads for the generic initiative.

Objectives of the project

The specific objectives for this engagement included:

- Recommending options for the development of a permanent model that will facilitate negotiations for brand name drugs and approaches to achieving better value for money for generic drugs. The options had to consider feasibility of implementation, including joint versus separate governance and administration of the two initiatives.
- Performing a detailed analysis of the current process, regulatory barriers within each jurisdiction, operational considerations and resource requirements.

Approach

IBM's approach included:

(i) A detailed environmental scan with research into best known practices, including international IBM expert opinion and/or input to validate these findings,

(ii) Conducting strategic interviews with key senior stakeholders, and

(iii) Conducting a targeted survey with provincial drug programs to determine timelines taken for the reimbursement of drugs negotiated through the PCPA process and the future expected human resource effort requirement based on the PCPA experience.

Although the focus was on brand drugs, the recommended governance and process pieces could also be applied to generics.

Key Findings

1) Environmental Scan:

Canada has a unique publicly funded system. The current mechanisms required for drugs to be approved for sale and subsequent public reimbursement in Canada have generated significant interest among manufacturers who have to go through a series of regulatory and assessment steps in order to obtain:

(i) Health Canada approval,

(ii) A Common Drug Review (CDR) or pan-Canadian Oncology Drug Review (pCODR) recommendation,

(iii) A successful PCPA negotiation among participating jurisdictions, resulting in a signed Letter of Intent (LOI) when applicable and ultimately,

(iv) A Product Listing Agreement (PLA) with each province.

In comparison to other publicly funded systems, the uniqueness of Canada's health system becomes apparent as you consider the steps above. The most comparable systems for single drug approval mechanisms include the United Kingdom and Australia. With the UK recently undertaking a significant overhaul of its system, the best comparison for the PCPA is Australia, with interesting aspects of other systems being relevant for this analysis.

∗A detailed analysis of the nine jurisdictions is included in the environmental scan included in Appendix 3.

2) Interviews with stakeholders:

The following groups of stakeholders were interviewed for this project:

- Provincial and Territorial Drug Program Branches
- Provincial Cancer agencies
- Manufacturers (brand name)
- Industry Groups (Rx&D, BIOTECanada)
- Regulatory bodies (pCODR, CADTH, PMPRB)
- Patient Groups
- Cross Sector Alliance (CGPA, CACDS, CAPDM, CpHA)

∗ A complete list of stakeholders interviewed is included in the Appendix 1.

The following overarching themes emerged from the stakeholder interviews. This is followed by a description of areas in common and areas of divergence between manufacturers and P/Ts, and cancer agencies. Section 5 provides additional details on the stakeholder consultation feedback.

Common themes among PCPA stakeholders

- **The PCPA goals are acceptable including non-price goals:**

All stakeholders agreed that the PCPA goals were acceptable but specified that there is an underlying focus on price which should be one of the stated goals. The acronym "PCPA" also suggests the negotiations have been "all about price". Stakeholders felt that the goals of PCPA needed to be clearly articulated without an undue focus on price.

- **In principle, a single pan-Canadian negotiation is better than multiple parallel negotiations:**

Stakeholders did not want duplication and redundancy in processes and hence believed that the premise of having a single pan-Canadian negotiation was better than multiple individual negotiations.

- **No current government body is seen as a "fit" for PCPA:**

When asked if there was an existing organization that would be a good “fit” for the PCPA in terms of absorbing the PCPA as part of its governance structure, most stakeholders felt there was no current entity that was appropriately positioned to take on this role without compromising their existing (and distinct) mandates. For example, a body such as CADTH bases its recommendations on independent evidence-based evaluations according to pre-established guidelines and procedures. In contrast, the PCPA process incorporates a wider array of relevant factors, including individual jurisdictional considerations - which are more appropriate to an informed negotiation between various parties. International leading practices reflect a clear separation between evidence-based health technology assessments (HTAs) and complex price negotiations in order to achieve the goals that the PCPA is striving to achieve. Most concerns about existing government organizations included providing sufficient role clarity for the PCPA vis-à-vis an existing organization and mixing negotiation with HTA creating a possible conflict of interest.

- **Provincial subject matter expertise key to success of the PCPA:**

The drug program branches and cancer agencies are comprised of true subject matter experts in regards to scientific, technical and policy related matters pertaining to drugs. This includes market access, regulatory affairs, reimbursement, cost effectiveness, drug specific technical details such as efficacy and effectiveness data from clinical trials, etc. Most stakeholders stated that the provincial drug expertise should be strongly considered when evaluating various governance models and leveraged accordingly.

- **Resource constraints coping with the PCPA volume (now and in the future):**

The PCPA activities across the country are time consuming and the amount and types of resources available to perform such tasks falls short of what is required given the volume of drugs that will be negotiated through the PCPA. Concerns were raised at how increasing numbers and complexity of drugs negotiated through the PCPA will affect how negotiations can be performed in a timely and effective manner with the existing resources at the P/T level.

- **The PCPA is evolving and is a young alliance:**

Many stakeholders agreed that the PCPA is an evolving and young alliance that needed additional structure and consistency in processes.

- **The PCPA needs to improve their communication and be more transparent:**

Most stakeholders felt that communications from the PCPA regarding timelines and overall process were minimal. More collaborative, consistent, open and transparent communications were felt to be necessary.

- **The PCPA process is still informal and requires more consistency:**

The PCPA stakeholders felt that the PCPA process was informal. A more consistent and transparent process with some additional clarity around average timelines for each stage would be helpful to keep stakeholders, particularly manufacturers, informed about the status of negotiations. The simple analogy of a courier company, where the customer has visibility into the location of their package, can be adopted by the PCPA-by informing its stakeholders where in the process a particular negotiations lie.

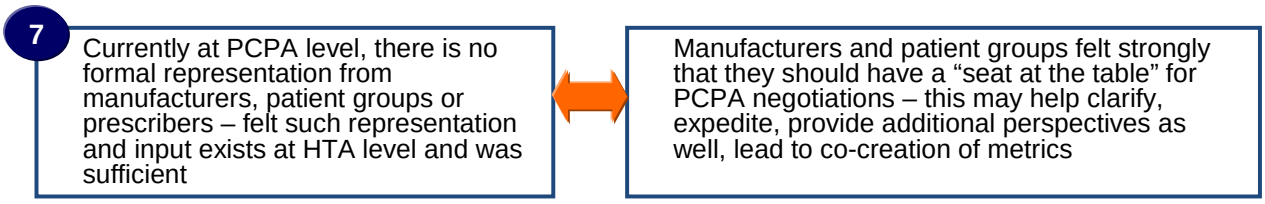
- **Metrics are required to evaluate and benchmark the PCPA performance:**

All stakeholders would like to see the development and use of metrics to evaluate the PCPA performance going forward and to benchmark its performance. Manufacturers and some drug program branches were open to the idea of "co-creating" certain metrics such that both manufacturers and the government had an incentive and vested interest in achieving such performance measures.

Divergent themes among stakeholders

As there were themes that were common among stakeholders, there were also a number of themes where there were clear differences between P/Ts and brand name manufacturers. These differences were important to consider when evaluating various governance models.

1	Provinces / Territories value autonomy to make drug listing decisions on their formularies	Manufacturers (brand name) felt that if a province participates in a PCPA negotiation, they should in good faith list the drug as opposed to delay listing or not list post PCPA LOI
2	Goals of PCPA are widely understood and accepted by provinces and cancer agencies	Would like to see a broader focus on value and overall health system view as opposed to a focus on price – the role of PCPA vis-à-vis other national bodies requires clarity
3	Overall consistency, transparency and timeliness of PCPA process and decisions appears to have less of an impact although it is recognized that the process could be made more formal and with success metrics linked to timelines, process etc.	There is a lack of consistency with PCPA process and inconsistencies in dealing with different lead provinces – Industry does not feel that a positive experience with one product will replicate with others – Lack of transparency regarding a) timelines b) specific criteria on which a product is evaluated c) PCPA process – Lack of timeliness of decisions with certain products – A sense that this is not a negotiation as the ultimate "negotiator" is still the province which decides whether to list or not and when to list on their formulary – PCPA is perceived as another step/ layer in a myriad of steps that manufacturers have to go through – No articulated clear feedback on PCPA decisions – positive and negative
4	Open to a centralized or federated governance model with PCPA as a new entity	Opposed to new entity – prefers the current model with a lead province but would like clarity on role of PCPA, greater transparency on expectations, timelines, communications
5	All products coming out from CDR and pCODR should still go through PCPA process for decision (not all drugs will be negotiated)	Would like to see CDR/ pCODR 'list" decisions (the "gold stars") bypass PCPA. To encourage innovation, PCPA should not commoditize all drugs
6	Differences in opinion on the use of "value demonstrating initiatives"	See huge upside for the health system to include value demonstrating initiatives such as registries for diseases, research, evidence generation, clinical trials. See this as vital to innovation and health system sustainability



Summary of themes

General: The PCPA goals need to explicitly demonstrate broader health system focus, including price as one, but not the only component.

Experience: Overall from the manufacturer's perspective, it has been a negative experience. However much of the negativity revolves around the growing pains of a new process initiated with little stakeholder input. The PCPA has an opportunity to turn this into a positive through:

- Greater transparency around process, decisions, criteria, and timelines

- Greater communications, e.g. dynamic web site

- Greater engagement with manufacturers – an opportunity to co-create in areas such as mutually beneficial metrics

- Improved consistency of approach across jurisdictions

Process: The PCPA process can be streamlined in certain areas but will require additional thinking around redundancy involving other national review bodies. For example, stakeholders question whether all drugs post-CDR and/or -pCODR need to be negotiated through the PCPA

Governance: A separate entity is not favoured by external stakeholders. They feel the present structure with a lead province can work provided there is adequate resourcing (potentially, a Secretariat), as well as a review of resources available in each province. There was appetite for a more centralized model from a number of jurisdictions.

Significant area of concern: If a PCPA negotiation is successful and a LOI is signed, brand name manufacturers have a significant concern when a P/T does not list the drug or takes a long time before listing. This has been strongly presented as being "not in good faith". P/Ts, on the other hand, feel very strongly about retaining their autonomy around listing and when to list.

Generics industry: Similar issues were identified through limited interviews with the generic drug business. Our governance and process work may be applicable to the generic industry as well. It is, however, recommended that based on our limited interactions with the generic pharmaceutical business, a more detailed analysis be undertaken with generic pharmaceutical industry stakeholders.

3) Governance

The following five governance options were considered: Extension of Status Quo, a Secretariat Model, an Extension of an Existing Body, a Net New Entity under the Existing System, and a Net New Autonomous Entity. Section 7 provides additional details on governance.

Based on the above analysis, the two governance options that were selected by the Steering Committee[2] for further analysis included:

- **Option 2: Secretariat model**
  - In this option, drug negotiations with a manufacturer would happen as they are now, but with significant support from a dedicated "Secretariat". A Secretariat would need to be created and funded to perform administrative coordination of the PCPA activities, the PCPA marketing and communications activities, standardizing of templates, formats, tracking of submissions, compiling developed performance metrics and other project management functions. This would leave the specific tasks related to the PCPA negotiations, drug related expertise and secondary review processes to the P/Ts.
- **Option 5: Net New Autonomous Entity**.
  - Create a new independent entity which will act as the single entity responsible for the negotiation process. Decisions made by this entity regarding drugs will be binding for all provinces. Any secondary review process required will be conducted through this entity. There would be a single listing, although provincial formularies would still play a key role in the administration of contracts. This option would require significant legislative policy and/or structural change; most importantly legal implications of delegating provincial authority to this net new autonomous entity.

4) Process

A net new process was created for Option 5: Net New Autonomous Entity structure. For Option 2: Secretariat model, specific opportunities for process improvement with the addition of a secretariat were recommended. Section 6 provides more details on the process

5) Recommendations

General Recommendations

The following general recommendations were made which apply regardless of the governance model adopted.

- Enhance communications:

  a) Website which provides standard templates, PCPA information, processes, timelines, past drug negotiations statistics, and benchmarks

  b) Annual report detailing the progress of the PCPA

  c) Playbook to act as a guide that helps provide consistency and direction for the process.
- Consider changing name of Pan-Canadian Pricing Alliance to "Pan-Canadian Pharmaceutical Alliance". It is understood that additional evaluation of the impact of such a

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[2] *The steering committee is a group comprised of Senior Management from a number of the Provincial Health Ministries of Canada, who support the ADMs. They include members from the Health Ministries of British Columbia, Alberta, Ontario and Nova Scotia*

name change would need to be conducted before formally deciding to rename PCPA as suggested. Pan Canadian Pharmaceutical Alliance is only provided here as a sample new name

- Standardize templates e.g. PLAs, Letter of Intent (LOI)
- Adopt a single common non-disclosure agreement (NDA) that would cover the jurisdictions and manufacturer(s).
- Consider a Tiered structure, such as that seen in Australia, of classification of drugs based on dollar value which will allow for segmentation of drugs into categories which can be appropriately supported by a rigorous process. (See Section 5 – Environmental Scan under Australia for additional details on tiering)
- For larger dollar value submissions, consider a pre-negotiation briefing led by PCPA to review process, timelines, expectations – stakeholders to include PCPA lead province, Health Technology Assessment (HTA) bodies, manufacturers and patient group representatives from patient group organizations of specific diseases for which a particular drug is being considered.
- Develop metrics related to the negotiation for each drug – definition of metrics, reporting of metrics and reporting in aggregates. This requires balancing consistency and flexibility to accommodate unique nature of different drug products. Consider some joint development of metrics with manufacturers and patient groups.
- Complete a review and analysis of the performance and listing dates of the drugs that have been completed through the existing PCPA negotiation process. (e.g. Drug utilization review)

Governance model recommendation:

- Based on our analysis, the optimal governance model in the short to medium term (1-3 years) to consider would be Option 2 – Secretariat Model. Reasons for recommending this model are:
  - This model will address the key pain points identified by stakeholders
  - This model can be achieved relatively quickly without significant expenditures
  - The model would be relevant for both brand and generic side of the drug business
  - The model can still provide flexibility to evolve into Option 5 – Net New Autonomous Entity, which requires significant legislative and structural change
  - Provides lead province with additional focus with various public relations administrative, coordinating and marketing and communications and project management tasks being done by the Secretariat

Process Recommendations:

PCPA process improvements were recommended upon documenting the current PCPA process and identifying issues and problems at specific points in the process. These included:

- Standardization of templates where possible e.g. NDA across provinces
- Greater transparency of PCPA process through:

- Establishing of clear time estimates, benchmarks and targets for the PCPA process and publishing historical timelines, targets and benchmarks on the same

- Developing integrated marketing, branding and multi channel communications
- Establishing clear time lines for exchange of proposals between manufacturer and lead province

In summary, PCPA is at a crucial phase in its evolution as a pan Canadian entity. The aforementioned general recommendations, governance recommendations and process recommendations would allow for PCPA to achieve its immediate next goals in terms of formalizing the PCPA process and addressing key governance questions that have arisen in the past.

2.0 Introduction

Canada has a publicly funded health system. As part of this publicly funded system, each Canadian province and territory operates its own publicly funded drug plan, which primarily covers seniors, welfare recipients, and other groups for whom drug costs represent a significant financial burden. The federal government has established drug plans for First Nations (Non-Insured Health Benefits), veterans, penitentiary inmates, armed services personnel, and the federal police. Altogether, approximately 10 million Canadians are covered by publicly funded drug plans, nine million through the provincial plans and another million through the federal plans, while 10 percent of Canadians lack basic drug coverage. This excludes private insurance drug plans or supplemental insurance drug plans which are either purchased privately or are provided through an employer as part of supplemental health benefits. Even though Canada has a publicly funded health system, in reality, each of the provinces and territories are funded to run their own health systems guided by the principles of the *Canada Health Act, 1984*. While this provides considerable autonomy to the provinces and territories, it can also lead to significant differences in how healthcare is delivered across the country. For example, prescribing patterns for medications for osteoporosis can vary depending on the different types of branded medications approved by formularies in some provinces versus others.[3] Similarly, generic drug pricing as a percentage of the brand equivalent can vary across the country.[4] The approval and subsequent funding of drugs is highly regulated compared to other health care technologies. This adds significant complexities in terms of the rigour and time that it takes for drugs submitted by manufacturers to go through extensive evaluation of evidence as well as cost effectiveness and budgetary impact analysis before their approval and funding respectively.

Health Canada is responsible for product licensure while provincial/territorial bodies control healthcare funding. The federal government provides money to the provinces, which are responsible for providing health care as per the principles of the *Canada Health Act*. Each P/T has its own drug formulary which includes a list of drugs that are reimbursed under their respective publicly funded drug plans. Formulary decisions are rendered P/T by P/T, hospital by hospital and in some cases, separately for diseases such as cancer and HIV/AIDS.

National review bodies for drugs are important in advising formulary decision-making. This process was aided in 2003 by the creation of The Common Drug Review (CDR). The CDR, at the Canadian Agency for Drugs and Technologies in Health (CADTH), is a pan-Canadian process for conducting objective, rigorous reviews of the clinical, cost-effectiveness, and patient evidence for oral non-oncology drugs. The CDR provides formulary listing recommendations to Canada's publicly funded drug plans (except Quebec). The CDR was created to remove inefficiencies and duplication by consolidating the submission filing process for pharmaceutical manufacturers, reduce duplication of reviews by jurisdictions, where each P/T would, prior to

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[3] Osteoporos Int. 2012 April; 23(4): 1475–1480. Published online 2011 September 8. doi: 10.1007/s00198-011-1771-2; http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3304053/

[4] *Canadian Pharmacists Association: http://blueprintforpharmacy.ca/resources/resource-article/2013/05/30/generic-drug-pricing-by-province*

this process, have to go through its own review process, and to provide equal access to timely, evidence-based information and expert advice.

Acknowledging the complexity and types of medications involved in cancer treatment, the pan-Canadian Oncology Drug Review (pCODR) was established in 2010, to assess the clinical evidence and cost-effectiveness of new cancer drugs and to provide recommendations to the P/Ts (except Quebec) to guide their drug funding decisions. Along with the Ministries of the provinces and territories, with the exception of Quebec, pCODR partners are the provincial cancer agencies, the Canadian Partnership Against Cancer (CPAC) and the Canadian Agency for Drugs and Technology in Health (CADTH).

Any drug submitted to Health Canada first receives a Notice of Compliance. The drug then goes through a national review process (CDR or pCODR) where the respective expert advisory committee provides a recommendation regarding listing the drug. Each provincial and territorial formulary then has the autonomy to decide whether to list a drug on their provincial / territorial formulary. This led to differing consistency of across provinces where drugs listed in one province or territories were not listed in another. The time to list a drug also varied. In addition, differing pricing arrangements were seen across the country for a given drug. Realizing this, the PCPA was announced by the Premiers in August 2010, at a meeting of the COF. The PCPA is a pan-Canadian initiative consisting of the following jurisdictions: Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Nova Scotia, Ontario, Prince Edward Island, Saskatchewan, and the Yukon. These jurisdictions conduct joint negotiations for brand name drug products being considered for reimbursement through the public drug plans. This approach capitalizes on the combined purchasing power of public drug plans across multiple jurisdictions, improves the consistency of drug listing decisions across the country, ensures benefits are cost effective and increases access to drug treatment options.

The PCPA was introduced as a response to the issues being faced by the jurisdictions, stemming from their old policies of each jurisdiction making individual decisions. This often resulted in different drug coverage across the country. Jurisdictions were struggling with increasing budget costs – dealing with this in different ways through policy, formulary restrictions, product listing agreements, etc. Different jurisdictions were at different points in terms of negotiating and implementing PLAs leading to inconsistencies in access and pricing across the country. Realizing that working collaboratively on drug funding could help improve the balance of access and pricing across the country, and prevent some P/Ts getting worse deals than others – when all could get a better price if they worked together. Smaller jurisdictions were at a distinct disadvantage to negotiate pricing given their population size.

In July 2012, the COF directed Health Ministers to identify options to obtain better value for generic drugs. This follows on the work completed for brand name drugs and looks for opportunities to better value for money. With these announcements, participating P/Ts have continued to discuss the development of a formal process to support this pan-Canadian approach for both brand and generic drug reimbursement through the public drug plans (“initiatives”).

Since P/Ts do not directly purchase drug products under the public drug plans, the focus has been on developing a common approach to drug product listing negotiations. The initial work has broadened to include identifying immediate and long-term approaches and opportunities to obtain better value for money for generic drugs. Ontario and Nova Scotia are the current lead provinces for the PCPA for brand name drugs. Nova Scotia and Saskatchewan are the leads for

the generic initiative. Individual product listing agreement (PLA) negotiations have been led by multiple jurisdictions, including both Ministries as well as participating Cancer Agencies on behalf of participating jurisdictions.

PCPA Context

Healthcare expenditures are on the rise globally, and Canada is no exception. With national implications on the sustainability of healthcare, the three levers in a healthcare system are threatened by increasing costs, reduced access and the pressure of maintaining a sufficient quality of care. Obtaining better value for healthcare is an increasing necessity for the sustainability of our healthcare system; whether this is the type and setting where healthcare is provided or the types of drugs used to treat patients.

The original purpose of the PCPA was to examine opportunities to conduct joint P/T negotiations for brand name and generic drug products. The goals of the PCPA as directed by COF include:

- To increase access to drugs treatment options
- To improve the consistency of drug listing decisions across the country
- To capitalize on combined buying power of jurisdictions
- To achieve consistent pricing and lower drug costs
- Reduce duplication of negotiations and improve utilization of resources

The PCPA has largely developed processes based on strong collaboration amongst member P/Ts and a governance model which is relatively informal. A “lead province” takes the onus of conducting the negotiation and works with the manufacturers until a Letter of Intent (LOI) is signed.

Given P/Ts have autonomy over their drug listing decisions, a signed LOI does <u>not</u> mean that a drug will automatically get listed on the P/T Formularies. Provinces may conduct their own due diligence in the form of a secondary review process / Expert Committee review which usually is intended to provide province specific analysis, including relevance of the drug to the specific population in the province (e.g., social factors, specific population needs), cost-benefit analysis, clinical data, etc. Such secondary reviews and Expert Committee reviews can add to the timelines around reviews. Thoroughness and/or transparency of manufacturer’s submission materials may minimize these activities. P/Ts have their own processes to ultimately decide whether a drug that has gone through a PCPA negotiation and has resulted in a signed LOI ultimately gets added to their respective formulary. Provinces also have their own PLAs with manufacturers for specific drugs. PLAs are used to support reimbursement of drug products through the P/T formularies and often include financial and clinical components. PLAs are reached through negotiation between the parties, and often include confidential prices and arrangements achieved between a province and a manufacturer, usually rebate structures that may or may not be tied to drug expenditures, utilization patterns or health outcomes.

3.0 Objectives and Approach

Under the direction of the Ontario Ministry of Health and Long-Term Care and the other partnering P/Ts, specific objectives for this engagement included:

- Recommending options for the development of a permanent model(s) that will facilitate negotiations for brand products and approaches to achieving better value for money for generic drugs. The options must consider feasibility of implementation, including joint versus separate governance and administration of the two initiatives.
- Performing a detailed analysis of the current process, regulatory barriers within each jurisdiction, operational considerations and resource requirements.

IBM's approach included:

(i) A detailed environmental scan with research into best known practices, including international IBM expert opinion and/or input to validate these findings,

(ii) Conducting strategic interviews with key senior stakeholders, and

(iii) Conducting a targeted survey with P/T drug programs to determine timelines taken for approving drugs and the future expected human resource effort requirement based on PCPA experience.

While the results of this work, with respect to governance model and process implications, may be applicable to both the brand name and generic pharmaceutical industry, due to time and resource constraints, the scope of this work focussed on brand name drugs and did not sufficiently cover an analysis of the generic pharmaceutical industry.

4.0 Environmental Scan

An environmental scan of best known practices across international jurisdictions was conducted using literature searches as well as validating the findings with international IBM colleagues in those jurisdictions. The environmental scan was useful in determining best known practices and leveraging these for the PCPA. A detailed environmental scan report and a comparison of different publicly funded health systems and their drug purchasing and regulatory systems is included in Appendix 3. In this section, the key highlights of the environmental scan for Canada and Australia (which was deemed most appropriate for comparison) are reviewed.

Nationally

Canadian Overview

Canada's population is over 34 million people, about 75 percent of whom live within 100 miles (161 kilometers) of the US border. Over 60 percent of the population lives in the central provinces of Ontario and Quebec, the two largest of the 10 provinces.

Canada has Medicare, a universal (publicly funded) healthcare since the 1960s; however, medication, except drugs administered in hospitals and for certain special populations, is not covered through the universal, publicly funded, Medicare program. Thus, the majority of the population (about 66%) obtains drug coverage through private insurers, either through their employers or purchased individually. For public funding, each Canadian province and territory operates its own drug plan, which primarily covers seniors, welfare recipients, and other groups for whom drug costs represent a significant financial burden. Some provinces (such as Alberta, British Columbia, Saskatchewan and Quebec) make their drug plans available to all residents who choose to join the plan (Alberta, British Columbia, Saskatchewan) or lack private drug coverage (Quebec). Moreover, the federal government has established drug plans for First Nations (Non-Insured Health Benefits), veterans, penitentiary inmates, armed services personnel, and the federal police. Altogether, approximately 10 million Canadians are covered by publicly funded drug plans, nine million through the provincial plans and another million through the federal one while 10 percent of Canadians lack basic drug coverage.

Health Canada (the federal health body) is responsible for product licensure while provincial bodies control healthcare funding. However, national bodies are important in advising formulary decision-making. Quebec does not, for the most part, participate in such pan-Canadian processes that serve the rest of the country. Formulary decisions are rendered P/T by province/T, hospital by hospital and in some cases, separately for diseases such as cancer and HIV/AIDS.

Decision-Makers and Influencers

Health Canada: The federal health department is responsible for approving new drugs for sale based on their safety and efficacy, among other factors. Health Canada releases a formal marketing and distribution authorization, known as a Notice of Compliance (NOC), if the new drug's profile conforms to the Food and Drugs Act and Regulations. Health Canada is also responsible for promoting healthy living to Canadians by communicating information on disease prevention, drug safety, and other health-related issues.

The Patented Medicine Prices Review Board (PMPRB): The PMPRB is an independent body within the federal health portfolio, responsible for regulating drug prices for all prescription and non-prescription patented drugs sold in Canada. PMPRB submits to the federal parliament, through the Federal Minister of Health, an annual report including analyses of patented drug prices, price trends, and research and development expenditures of patent-holding drug manufacturers.

The Canadian Agency for Drugs and Technologies in Health (CADTH): CADTH is an independent, not-for-profit agency funded by federal, provincial, and territorial governments, to provide evidence-based information about the effectiveness of drugs and other health technologies to Canadian healthcare decision makers. *The Common Drug Review (CDR)*: Under CADTH's mandate, the CDR process accepts drug submissions from manufacturers, conducts systematic drug reviews, and provides participating public drug plans (federal, territorial, and all Canadian provinces/territories except Quebec) with evidence-based clinical and economic information, and expert advice, to support their formulary listing decisions.

Canadian Drug Expert Committee (CDEC): CDEC is an appointed, national, independent body of physicians, pharmacists and other health care professionals and public members. They use the Clinical and Pharmacoeconomic Drug Reviews to evaluate the comparative benefits and costs of the Drugs under consideration and Patient Input to make common formulary listing recommendations to participating F/P/T Drug Plans. As of September 2011, CDEC replaced the Canadian Expert Drug Advisory Committee (CEDAC). In addition to making listing recommendations, CDEC also provides other drug-related recommendations or advice, based on CADTH reviews, to inform decisions and strategies, including the optimal use of drugs in Canada.

Pan-Canadian Oncology Drug Review Process (pCODR): Assesses cancer drugs and makes recommendations to the provinces and territories to guide their drug funding decisions. Established in 2010 by the provincial and territorial Ministries of Health, pCODR is designed to bring consistency and clarity to the assessment of new cancer drugs by looking at both clinical evidence and cost-effectiveness. pCODR is formally transferring under CADTH in two phases in 2014-2015.

Decision-Making Process

The Common Drug Review (CDR) process (all provinces except Quebec): Until 2002, separate submissions for formulary listing were made to each regional health plan. Submission requirements varied between drug plans. However, all economic evaluations had to comply with either the Ontario economic guidelines or those developed under the auspices of the Canadian Coordinating Office for Health Technology Assessment (CCOHTA, now CADTH) in 1994.

In 2002, Canada initiated the CDR to harmonize the drug review process across the country to optimize the use of healthcare resources and reduce duplication of effort. A CDR submission represents a submission to all participating institutions, including all federal (this covers Non-Insured Health Benefits, the Department of National Defense, Veterans Affairs Canada, the Royal Canadian Mounted Police and Correctional Service Canada), provincial (all provinces, except Quebec) and territorial (Northwest Territories, Yukon, Nunavut) drug plans.

The current CDR process in brief:

- A drug manufacturer, or one or more of the participating drug plans, files a drug submission to CADTH for review.
- A call for patient input is posted on the Patient Input page of the CADTH website and sent to subscribers via an e-alert.
- A review team is established. Typically, the team consists of clinical reviewers, economic reviewers, clinical experts, information specialists, methodologists, and administrative support. All reviewers must abide by the CADTH Conflict of Interest Guidelines.
- A systematic review of the clinical evidence and a critique of the economic evaluation are prepared by the review team. The reviews are based on the drug submission, information retrieved through independent literature searches, any patient group input received. Guidelines and templates are used in preparing the reviews to ensure a consistent, rigorous approach.
- Reviews are sent to the manufacturer for comment.
- Reviewers prepare a reply to the manufacturer's comments on the reviews. A dossier is prepared for the Canadian Drug Expert Committee (CDEC), a CADTH advisory body.
- CDEC meets to consider the submission. Deliberations are based on the CDEC dossier, and may also include input from other experts or the review team.
- The initial CDEC formulary listing recommendation, and the reasons for the recommendation, are sent to the manufacturer and the drug plans in confidence.
- During the embargo period:
    - Drug plans may request clarification of the recommendation.
    - CDEC may recommend a drug (a) be listed, (b) be listed with restrictions, or (c) not be listed at all. The manufacturer may request, based on specified criteria, that CDEC reconsider the drug; if the request is granted, CDEC reconsiders the submission at a subsequent meeting.
- The final recommendation and reasons for the recommendation are released publicly on the CADTH website.

The pan-Canadian Oncology Drug Review (pCODR) process: *(all provinces except Quebec):* Submissions for drug products for active treatment of cancer that may potentially be funded by the participating provincial and territorial drug plans (i.e., federal, provincial and territorial drug plans, except Quebec) are directed to pCODR who will make a listing recommendation. pCODR is a newly established evidence based cancer drug review process with the role of assessing clinical evidence and cost-effectiveness of new cancer drugs. Manufacturers submit a dossier to the pCODR expert review committee (pERC), which also takes into account input by patients and clinician-based tumor groups. pCODR will get transferred back to CADTH. This transfer of will occur in two phases:

- Phase 1: pCODR staff, processes, funding, and expertise will remain intact as a program, with continued operations in Toronto, Ontario, under the governance of CADTH.

- Phase 2: Scheduled for April 2015, will explore better alignment of pCODR and CADTH Common Drug Review evaluation criteria, while taking advantage of the best practices of both review processes.

Hospitals: Hospitals maintain their own formularies through Pharmaceuticals and Therapeutics Committees. Dossiers must be submitted to individual hospitals or hospital consortia.

Private Payers: Private payers in Canada may cover all Health Canada approved drugs, establish their own formularies, or follow the public drug plan in their province. In Quebec, private insurers are required to cover at least all drugs listed in the provincial formulary. Many private drug plans ask for submission dossiers and specific requirements vary by plan.

Reimbursement and Pricing Approval Process

Pricing approval for brand pharmaceuticals in Canada is regulated by the federal government, through the PMPRB, which acts in a regulatory capacity to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive. The price of non-patented drugs, such as generics, is not regulated by the PMPRB. Patentees are required, for each strength of each dosage form of each patented medicine sold in Canada, to file price and sales information twice a year for price regulation purposes.

The reimbursement process in Canada is governed by a combination of federal, provincial and private plans. Through the publically-funded Medicare system, all Canadians and residents have free access to coverage for drugs, procedures, and physician services provided in hospitals. Hospital drug formularies are under provincial purview. Outside the hospital setting, drugs are reimbursed to the majority of Canadians by private health insurance plans, either to employees and their families through employer group insurance, or to other persons and their families on an individual basis. Some vulnerable groups, such as seniors, welfare recipients, and native persons, are covered by specific provincial, territorial, or federal plans. Most plans involve copayments and deductibles so that patients contribute to the costs of reimbursed medicines.

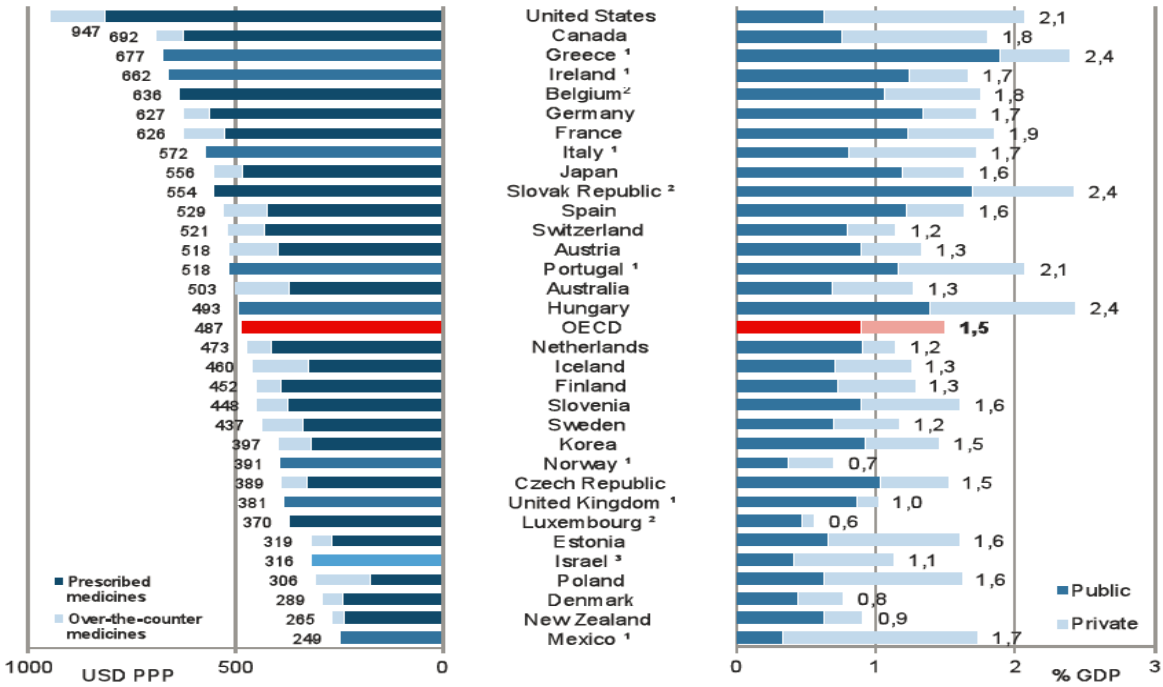
∗The details of specific provincial processes are shown in Appendix 3

Globally

Pharmaceutical policies are geared towards health policy objectives: promoting public health, containing cost growth to sustainable levels, obtaining good value for money in public expenditure, and promoting future innovation in medicine. Figure 1 depicts the expenditure on pharmaceuticals per capita and as a share of GDP globally. Figure 2 depicts global prescription prices.

Some countries regulate prices of on-patent drugs to protect consumers against the risk of manufacturers exploiting their monopoly position. Many public purchasers set or limit the prices of reimbursed medicines in exchange for subsidy (*de facto* regulation). Manufacturers have the option of not submitting their products for reimbursement, but instead marketing their products directly to consumers (at the cost of losing insurance subsidy). Free or market-based pricing is often the rule for over the counter (OTC) products and for products that are not reimbursed, rarely also for products that are reimbursed. Public payers and regulators often have objectives other than cost-containment (e.g., ensure prompt access to effective medicines, support national industry, encourage future innovation, etc.) and do not always seek to obtain the lowest possible price.

Expenditure on pharmaceuticals per capita and as a share of GDP



Information on data for Israel: http://dx.doi.org/10.1787/888932315602

1. Cannot be separated and includes medical non-durables. 2. Prescribed medicines only. 3. Total medical goods.

Source: OECD Health Data 2011 (Published in OECD Health at a Glance, 2011)

Figure 1: Drug expenditures globally

Global Prescription Drug Prices

	Prices for 30 most commonly prescribed drugs, (US set at 1.00)*		
	Brand name	Generic	Overall
Australia	0.40	2.57	0.49
Canada	0.64	1.78	0.77
France	0.32	2.85	0.44
Germany	0.42	3.99	0.76
Netherlands	0.39	1.96	0.45
New Zealand	0.33	0.90	0.34
Switzerland	0.51	3.11	0.63
United Kingdom	0.46	1.75	0.51
United States	1.00	1.00	1.00
Median (countries shown)	0.43	1.96	0.51

*Analysis by G. Anderson of IMS Health Data.
Source: Squires, 2012: 6. Reproduced with permission.

Figure 2: Global prescription drug prices

<u>Scan of drug systems internationally:</u>

The following countries were researched for their health systems, their drug approval and reimbursement mechanisms and especially if a single body comparable to the PCPA existed that could serve as a direct point of reference for comparison:

Australia, China, Denmark, Finland, New Zealand, Singapore, Switzerland, UK and United States of America. The example of Australia is shown below. **Please see Appendix 3 for additional details on environmental scan on the above countries**

Australia

(please see Appendix 3 for additional details on Australia's health system and on Pharmaceutical Benefits Advisory Committee [PBAC])

- Australia achieves universal coverage through Medicare, a tax-funded public insurance program that covers most medical care, including physician and hospital services and prescription drugs.
- The Pharmaceutical Benefits Scheme (PBS) provides subsidised medications to patients.
- A new medicine may only be added to the PBS formulary on the recommendation of an expert advisory panel, the Pharmaceutical Benefits Advisory Committee (PBAC) – for details on PBAC process see Appendix 3
- Any drug that is recommended but which would cost more than $10 million AUD annually must be approved by the government.
- Most prescription medicines in Australia are made available to patients under the PBS, which acts both as an insurer, and as a sole purchaser negotiating prices for medicines with suppliers.
- The PBAC is responsible for providing advice to the Minister of the Department of Health and Ageing regarding which drugs to include on the Schedule of Pharmaceutical Benefits (SPB), the reimbursable drug list.
- Specifically, it recommends maximum usage quantities and restrictions on prescribing indications.
- The PBAC also informs the Pharmaceutical Benefits Pricing Authority (PBPA) of a drug's comparability with existing alternative therapies and its cost-effectiveness.
- For example, when a drug is proven to be substantially more costly than an alternative therapy, the PBAC recommends that it only be offered to patients for whom a significant improvement in efficacy or reduction in toxicity over the alternative therapy is expected.
- The PBAC's membership includes health economists, pharmacists, general practitioners, clinical pharmacologists, specialists in clinical medicine, and consumers.
- In addition, it has two (2) sub-committees: the Economics Sub-Committee (ESC) and the Drug Utilization Sub-Committee (DUSC).
- The ESC assesses and interprets economic evaluations for drugs under review by the PBAC and establishes criteria for their submission.
- The DUSC collects and analyses data on drug utilization trends in Australia and compares them with those in other countries. It also assists with generating information regarding the rational prescribing and use of drugs.
- Before a drug is assessed by the PBAC, it must be registered by the Therapeutic Goods Administration, indicating that it has met acceptable levels of quality, safety, and efficacy, and, thus, may be marketed in Australia.
- The PBAC then makes listing recommendations based on the effectiveness, cost-effectiveness, and the clinical place of a drug compared with alternative therapies. It considers whether the drug is:

  (1) needed for the prevention or treatment of significant medical conditions not already covered or inadequately covered by drugs on the existing SPB and is of acceptable cost-effectiveness,

(2) more effective and/or less toxic than a drug already listed for the same indication(s) and is of acceptable cost- effectiveness, or
(3) at least as effective and safe as a drug already listed for the same indications and is of similar or better cost-effectiveness. As mandated by the Minister, the PBAC also reviews.
(4) the community's need for the drug,
(5) the setting in which the drug would be administered (since Australia's PBS was created to serve community-based patients, drugs for in-hospital use are given low priority), and
(6) the significance of the condition for which the drug is indicated (drugs for minor conditions are given low priority).

- In general, the PBAC does not recommend listing:
  (1) a fixed combination of drugs,
  (2) a drug that may create abuse or dependence problems, or
  (3) a drug intended to treat an individual patient whose response or need is viewed as unique.
- The PBAC may also decide to remove a drug from the PBS if
  (1) a more effective or equally effective and less toxic drug becomes available,
  (2) subsequent evidence indicates that the drug's effectiveness is not satisfactory,
  (3) subsequent evidence indicates the drug's toxicity or potential for abuse outweighs its therapeutic value,
  (4) the drug is either no longer used or available, or (5) when compared with alternative therapies, the drug is no longer cost-effective.

Tiering status for PBAC applications[5]

- The PBAC applications are classified according to their 'Tier' status (as recommended by the 'post-PBAC review')
- For example, straight forward cost minimisation applications where pricing is in accordance with the PBPA's usual pricing methodologies will be classed as Tier 1.
- Tier classification is undertaken by the PBPA Secretariat prior to the PBAC deliberation of the submission.
- Advice is then given to the responsible person about the status and details the dates for providing documentation for listing and these are usually due prior to the PBAC meeting.
- If all of the submission's claims are accepted by the PBAC and there are no significant changes resulting from this recommendation then an expedited listing may proceed without formal price consideration by the PBPA.

The following table depicts the Tier status

There are five categories of submission to the PBAC:		
Type	**Status**	**Description**
Major Submissions	Tier 1	Applications for the listing of new drugs where the claim is one of cost minimization (or 'at least no worse than' according to the PBAC guidelines), where pricing is based on a nominated dosage relativity,

[5] Ref: http://www.health.gov.au/internet/publications/publishing.nsf/Content/health-pbs-pbpa-pricing-policiesdoc~pbac-pbpa

		and where the prices to pharmacist proposed are in accord with the PBPA methods of price calculations.
	Tier 2	Submissions for new drug listing where the claim is one of acceptable incremental cost effectiveness (or new drug listings where the claim is one of cost minimization but where pricing is not in accord with the PBPA criteria) and applications for changes to listings, both cost minimization and cost effectiveness, and where the estimated net cost to the PBS is less than $20 million per annum in any of the first four years of listing.
	Tier 3	Any submission where the estimated net cost to the PBS is estimated to be $20 million or more in any of the first four years of listing.
Minor Submissions	Secretariat	These are minor changes to existing items and can be listed within two months of PBAC meetings. In these cases, there is no need for PBAC to consider efficacy, price is not affected and there is no substantive financial impact on the PBS.
	Other	These are minor changes to existing items that do not have significant financial implications but do require consideration by PBAC because of their potential impact on the PBS. These are listed no earlier than two months after PBAC meetings.

Relevance to PCPA: This concept of prioritizing file types could be helpful in PCPA work load management but requires thoughtful set up, and clear and consistent communication to industry, to be sustainable

Key Takeaway from environmental scan:

Canada has a unique publicly-funded system. The current mechanisms of drug approval in Canada have generated significant interest among manufacturers who have to go through a series of regulatory steps in order to obtain first Health Canada approval, a positive CDR and/or pCODR recommendation, now a successful PCPA negotiation among participating jurisdictions resulting in a signed LOI and ultimately, a PLA individually with each province. In comparing other publicly funded systems, the uniqueness of Canada's health system becomes apparent. The most comparable systems for single drug approval mechanisms included the UK and Australia. With the UK recently undergoing a significant overhaul of its system, the best comparison for the PCPA would appear to be Australia, with interesting aspects of other systems being used for the analysis.

5.0 Stakeholder consultation and feedback

Stakeholder consultation: Conducting strategic interviews

IBM conducted interviews (one-on-one interviews, group interviews, in-person interviews) with the following segments of stakeholders:

- Provincial and Territorial Drug program branches
- Provincial cancer agencies,
- Health technology assessment groups,
- Manufacturers (brand name)
- Patient Groups and Industry organizations,
- PMPRB.

A semi-structured interview guide was developed, approved by our Steering Committee and pre-circulated with the stakeholders that we interviewed (see Appendix 5 and 6). The interview guide was divided into four sets of questions: (a) Introductory questions (b) PCPA experience questions; (c) Process questions; and (d) Governance questions.

The stakeholder interviews were used to obtain feedback on the present PCPA process, the PCPA experience, their thoughts and recommendations on governance and the PCPA process. The interviews helped in determining what some of the barriers and challenges are with the present PCPA process, communication and governance. The interview findings were used to identify key themes; those that were common among stakeholders as well as those where the greatest divergence was noted. Based on the interview findings, various governance model options were proposed. From the various options, two governance model options were selected for further analysis, including opportunities for process improvement. Due to limitations with time, several manufacturers also provided written feedback which was analyzed for key themes. The overall level of stakeholder engagement was very high as all groups of stakeholders made themselves readily available and provided candid feedback about their experience with PCPA, regulatory approval of drugs, the PCPA process, and their thoughts on the future governance of PCPA.

Independent of the choice of governance model, a set of recommendations broadly applicable to PCPA has been made based on the themes identified during the stakeholder interviews.

Results of Stakeholder Consultations:

The stakeholder consultation sessions were divided into three key groups: A. Government, B. Manufacturers, and C. Patient groups

- **A. Government –** These included drug program branches, cancer agencies from provinces and territories across Canada and national review bodies like CADTH and pCODR.
- **B. Manufacturers** – These included senior staff from various branded drug pharmaceutical companies, with different experiences with the PCPA, as well as pharmaceutical associations representing a number of companies.

- **C. Patient Groups** – Representative members of various Patient Groups attended one or both of an in person interview held in Toronto on October 7th, 2013; or a national teleconference on October 18th, 2013.

* A complete list of stakeholders who were interviewed or gave written feedback is provided in Appendix 1. Detailed feedback from each of the stakeholder groups is provided in Appendix 2. This section has synthesized the feedback shown in this appendix to key common and divergent themes among stakeholders.

Summary of Stakeholder interview themes:

A number of themes were identified from stakeholder interviews and written responses provided by some manufacturers. It was important to identify areas where stakeholders had themes in common as well as where they diverged. This analysis became the basis upon which various governance options and areas for process improvement were considered.

Common themes among PCPA stakeholders

The following diagram depicts key themes that were common among the PCPA stakeholders that we interviewed and/or obtained written responses from.

Figure 3: Common themes identified among PCPA stakeholders

The PCPA goals accepted including non-price goals: All stakeholders agreed that the PCPA goals were acceptable but specified that there is an underlying focus on price which should be one of the stated goals. The acronym "PCPA" also suggests the "negotiations were all about price". Stakeholders felt that the goals of PCPA needed to be clearly articulated without an undue focus on price.

In principle, a single pan-Canadian negotiation is better than multiple individual negotiations: Stakeholders did not want duplication and redundancy in processes and hence believed that the premise of having a single pan-Canadian negotiation was better than multiple.

No current government body is seen as a "fit" for PCPA: When asked if there was an existing organization that would be a good "fit" for the PCPA in terms of absorbing the PCPA as part of its governance structure, most stakeholders felt there was no currently existing entity that was appropriately positioned to take on this role without compromising their existing (and distinct) mandates. For example, a body such as CADTH bases its recommendations on independent evidence-based evaluations according to pre-established guidelines and procedures. In contrast, the PCPA process necessarily incorporates a wider array of relevant factors, including individual jurisdictional considerations which are more appropriate to an informed negotiation between various parties. Best practices internationally reflect a clear separation between evidence-based HTA assessments and complex price negotiations in order achieve the goals that the PCPA is striving to achieve. Most concerns about existing government organizations included providing sufficient role clarity for the PCPA vis-à-vis an existing organization and mixing negotiation with health technology assessment creating a possible conflict of interest.

Provincial subject expertise key to success of the PCPA: The drug program branches and cancer agencies are comprised of true subject matter experts in regards to scientific, technical and policy related matters pertaining to drugs. This includes market access, regulatory affairs, reimbursement, cost effectiveness, drug specific technical details such as efficacy and effectiveness data from clinical trials, etc. Most stakeholders stated that the provincial drug expertise should be strongly considered when proposing various governance models and should be leveraged accordingly.

Resource constraints coping with the PCPA volume (now and in the future): The PCPA activities across the country are time consuming and the amount and types of resources available to perform such tasks falls short of the existing and future volume of drugs that will be negotiated through the PCPA. Concerns were raised at how increasing number and complexity of drugs negotiated through the PCPA can be performed in a timely and effective manner with the existing resources at the P/T level.

The PCPA is evolving and is a young alliance: Many stakeholders agreed that the PCPA is still an evolving and young alliance that needed additional structure and consistency in processes.

The PCPA needs to improve their communication and be more transparent: Most stakeholders felt that communications from the PCPA regarding timelines and overall process were minimal. More collaborative, consistent, open and transparent communications were felt to be necessary.

The PCPA process is still informal and requires more consistency: The PCPA stakeholders felt that the PCPA process was informal. A more consistent and transparent process with some additional clarity around average timelines for each stage would be helpful to keep stakeholders, particularly manufacturers, informed about the status of negotiations. The analogy of a process

similar to that of a courier company was stated where just as in a courier company, the customer has visibility into where their package is, so too; the PCPA could adopt similar principles and inform its stakeholders where in the process a particular negotiation was.

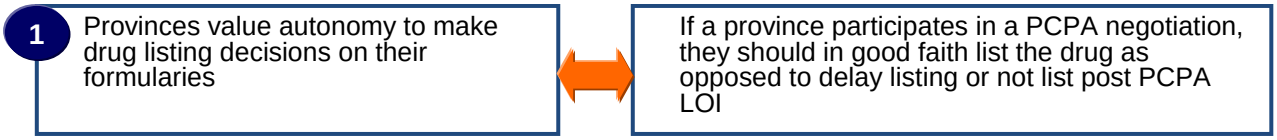
Metrics required to evaluate and benchmark the PCPA performance: All stakeholders would like to see the development and use of metrics to evaluate the PCPA performance going forward and benchmark its performance. Manufacturers and some drug program branches were open to the idea of "co-creating" certain metrics such that both manufacturers and the government had an incentive and vested interest in achieving such performance measures.

Some examples of metrics suggested by stakeholders include the following:

- Time from HTA recommendation (pCODR, CDR) to confirmation from the PCPA that process has been initiated
- Time for manufacturer to respond to the PCPA with a written proposal
- Period for the PCPA to respond to manufacturer offers
- Time for the manufacturers to respond to PCPA responses
- Time for the PCPA to issue signed LOI post-verbal agreement to terms
- Time to listing post-LOI signing versus mutually-agreed benchmark,
- Time from the HTA recommendation to access to drug by patients
- Time from the PCPA recommendation to proceed to access to drug by patients
- Limitation periods for participating jurisdictions to conclude PLAs, list and reimburse a medication to ensure applicability of LOI terms and conditions
- Number of listings through the PCPA
- Number of resources (i.e. FTEs) used by the PCPA to conduct negotiations from post-HTA to LOI

Divergent themes among stakeholders

As there were themes that were common among stakeholders, there were also a number of themes where there were clear differences. These differences are important to consider when evaluating various governance models.



Most P/Ts stated that they needed to retain the autonomy to make drug listing decisions post-LOI and that a signed LOI did not guarantee that a drug would be listed, since in most P/Ts this is dependent on approval by the Minister. E.g. the Minister in Alberta

Manufacturers strongly opposed the view that a province would participate in the PCPA negotiation, sign a LOI and, yet, not list or delay listing on their provincial formulary. Manufactures felt such uncertainty presented significant concern particularly in business planning and trying to forecast sales of drugs to their head office. Manufacturers felt that provinces signing a LOI should be bound to list the drug versus there being another "out".

2 Goals of PCPA are widely understood and accepted by provinces and cancer agencies

Would like to see a broader focus on value and overall health system view as opposed to a focus on price – the role of PCPA vis-à-vis other national bodies requires clarity

Government stakeholders felt that the goals of the PCPA were largely understood by provincial drug program branches (albeit there being some difference in opinion regarding a focus on price).

Manufacturers felt that there should be an even broader focus on value and the overall benefits to the health system when considering the acceptance of a drug versus focusing on the cost of a drug. For example, if a targeted drug therapy in pill form for non-small cell lung cancer has a higher cost but provides other benefits such as saving chemotherapy costs, other infusions, hospital stays, laboratory investigations, then such broader health benefits accrued to the health system need to be considered when evaluating whether a drug should be approved.

3 Overall consistency, transparency and timeliness of PCPA process and decisions appears to have less of an impact although it is recognized that the process could be made more formal and with success metrics linked to timelines, process etc.

There is a lack of consistency with PCPA process and inconsistencies in dealing with different lead provinces

- Industry does not feel that a positive experience with one product will replicate with others
- Lack of transparency regarding a) timelines b) specific criteria on which a product is evaluated c) PCPA process
- Lack of timeliness of decisions with certain products
- A sense that this is not a negotiation as the ultimate "negotiator" is still the province which decides whether to list or not and when to list on their formulary
- PCPA is perceived as another step/ layer in a myriad of steps that manufacturers have to go through
- No articulated clear feedback on PCPA decisions – positive and negative

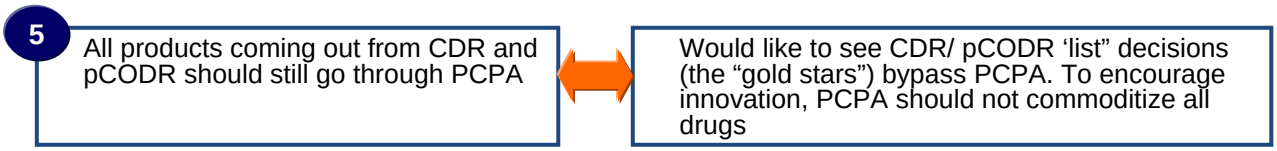
Government stakeholders acknowledged that a more formal governance model would help in defining a process that would support the governance model. In addition, the need for developing appropriate metrics linked to timelines and processes was felt to be critical to hold the PCPA accountable for specific performance measures. Similarly government stakeholders also felt that manufacturers should also be held accountable for high quality and complete drug submissions

Manufacturers felt strongly that there is a lack of consistency with the PCPA processes as well as dealing with different lead provinces. Specifically, product to product experiences varied, there was felt to be a lack of transparency regarding process, timelines, feedback on submission, expectations and timeliness of decisions. The strongest feedback was the overall sense amongst manufacturers that the PCPA negotiation was not a true negotiation since even after a signed LOI, individual provinces and territories decided whether to list a drug or not. This has led to the perception that the PCPA was another layer in an already complicated myriad of steps that manufacturers have to go through.

4 Open to a centralized or federated governance model with PCPA as a new entity

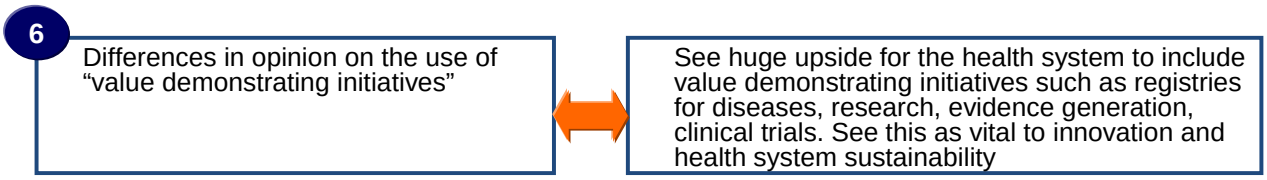
Opposed to new entity – prefers the current model with a lead province but would like clarity on role of PCPA, greater transparency on expectations, timelines, communications

Government stakeholders were open to a centralized or federated governance model. Consideration was given to the creation of a new entity for the PCPA. Manufacturers were opposed to the creation of a new entity with concerns stated regarding funding such an entity, the value it would bring, and potential duplication. Manufacturers were in favour of the current model but with significant clarity on the role of the PCPA, greater transparency around timelines, communications and feedback.



Government expects that all branded drug products that receive a positive recommendation from CDR or pCODR would go through the PCPA for a harmonized decision on whether negotiations should occur with the manufacturer. Those that do not require further negotiation based on CDR recommendations and/or initial analyses are deferred to the individual jurisdictions for listing decisions.

Manufacturers felt that not all products needed to go through the PCPA; that those products which received a "List" recommendation from CDEC did not need to demonstrate additional evidence to be listed. Manufacturers also felt that not all drugs have to receive a discount; that in the case of certain drugs, government should expect a specific price to remain in effect with no additional discounting.



There were considerable differences in opinion among government stakeholders regarding the use of "value demonstrating initiatives" – these were felt to be difficult to manage, onerous to administrate, difficult to structure, and hard to truly demonstrate the value for which they were intended. Thus, a straight discount was preferred. Other stakeholders were open to the idea of carefully chosen value demonstrating initiatives which could help in specific related health projects and had made use of these in the past. Conflict of interest, where a pharmaceutical company was seen to fund specific research and health activity was also noted as a concern. It was also felt that it was important to consider the administrative burden of these activities on provincial governments and how they would have to be appropriately structured to be meaningful.

Manufacturers, on the other hand, felt that value demonstrating initiatives allowed them to use funds earmarked for research and innovation, and saw such incentives as vital to the health system's sustainability and innovation. With rising fiscal healthcare expenditures and budgetary cuts across governments, manufacturers saw value demonstrating initiatives in areas such as disease registries, evidence generation or specific disease related research projects as other ways of demonstrating value.

7

Currently at PCPA level, there is no formal representation from manufacturers, patient groups or prescribers – felt such representation and input exists at HTA level

Manufacturers and patient groups felt strongly that they should have a "seat at the table" for PCPA negotiations – this may help clarify, expedite, provide additional perspectives as well, lead to co-creation of metrics

Government stakeholders felt there was no specific need for patient group representation for individual negotiations at the PCPA level given the opportunities for input during the review process at the national HTA levels, as well as at the jurisdictional level in some cases. Both manufacturers and patient groups strongly felt that they should be formally included in the PCPA discussions. In the case of patient groups, it was felt that additional patient perspectives that may not disseminate from the HTA level could be provided that may aid negotiations. Manufacturers felt that those drugs that had gone through negotiations could have used upfront meetings and communications to clarify expectations, timelines, and processes. Similarly, top down decisions from government with no consultation or discussion with industry (e.g., generic pricing as a percentage of brand drugs) were unpopular.

Some areas where there are opportunities for more transparency with patient groups include:

- Confirming how PCPA uses CDR/pCODR work will aid in understanding that those perspectives are considered
- Improve understanding about why P/Ts are adhering to recommendations

Overall key takeaways from stakeholder interviews

General: The PCPA goals need to explicitly demonstrate broader health system focus, including price as a component.

Experience: Overall from the manufacturer side, it has been a negative experience. The PCPA has an opportunity to turn this into a positive one through:

- Greater transparency around process, decisions, criteria, and timelines

- Greater communications, e.g., dynamic web site

- Greater engagement with manufacturers – an opportunity to co-create in areas such as mutually beneficial metrics

Process: The PCPA process can be streamlined in certain areas but will require additional thinking around redundancy involving other national review bodies; there are questions around whether all drugs post CDR and/or pCODR need to go through the PCPA.

Governance: Creating a separate PCPA entity was supported by some stakeholders (mostly from Provinces and Territories) and opposed by others (mostly manufacturers). The present structure with a lead province can work provided there is adequate resourcing (potentially, a Secretariat).

Significant area of concern: If a PCPA negotiation is successful and a LOI is signed, there is significant concern with manufacturers when a province does not list the drug or takes a long time before listing. This has been strongly deemed to be "not in good faith". Provinces, on the other hand, feel very strongly about retaining their autonomy for listing decisions.

Generics industry: Similar feedback was expressed in the limited interviews with the generic pharmaceutical industry. Our governance and process work is applicable to both the brand and generic industry. It is, however, recommended that based on our limited interactions with the generic pharmaceutical business, a similar analysis be undertaken with generic pharmaceutical industry stakeholders.

6.0 PCPA Process considerations

PCPA Process

A. Current Process of Drug Approval

The flow chart below depicts the end-to-end process starting with the submission of a file for a particular drug to Health Canada. The purple box depicts the high level PCPA process which is the focus of this report.

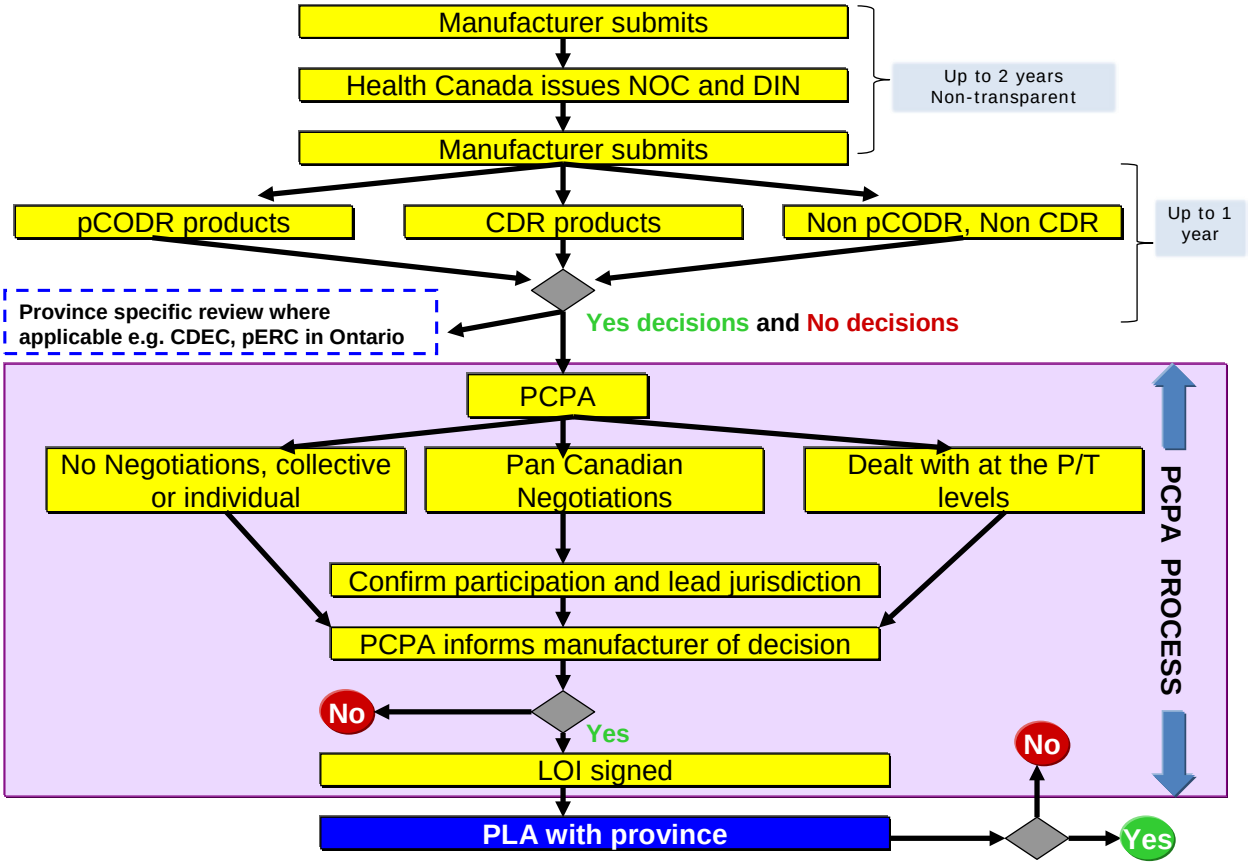


Figure 4: High level process from NOC to the listing of a drug in a province

The PCPA process is one portion of the entire process of approval of a drug with the PCPA process officially ending with a signed LOI. However, it should be noted, that the "process" will still be judged by end to end timelines from the time a drug submission is made to a drug being listed. For example, based on the results of the survey we administered to the P/Ts regarding drug approval timelines, the overall time it takes for a drug to go from NOC to listing on a provincial formulary can vary. The following figure depicts the end-to-end timeline for Pradaxa where it took approximately 17 months for a drug to go from the NOC being provided by Health Canada to a LOI being signed between the PCPA and the manufacturer. The PCPA portion of the time was approximately 8 months which included an impasse in negotiations for approximately one month. Post-LOI signing, while most provinces listed the drug within two months of LOI execution, others took longer. It is important to note that for every drug, there may be a variety of factors that either expedite or delay the timelines.

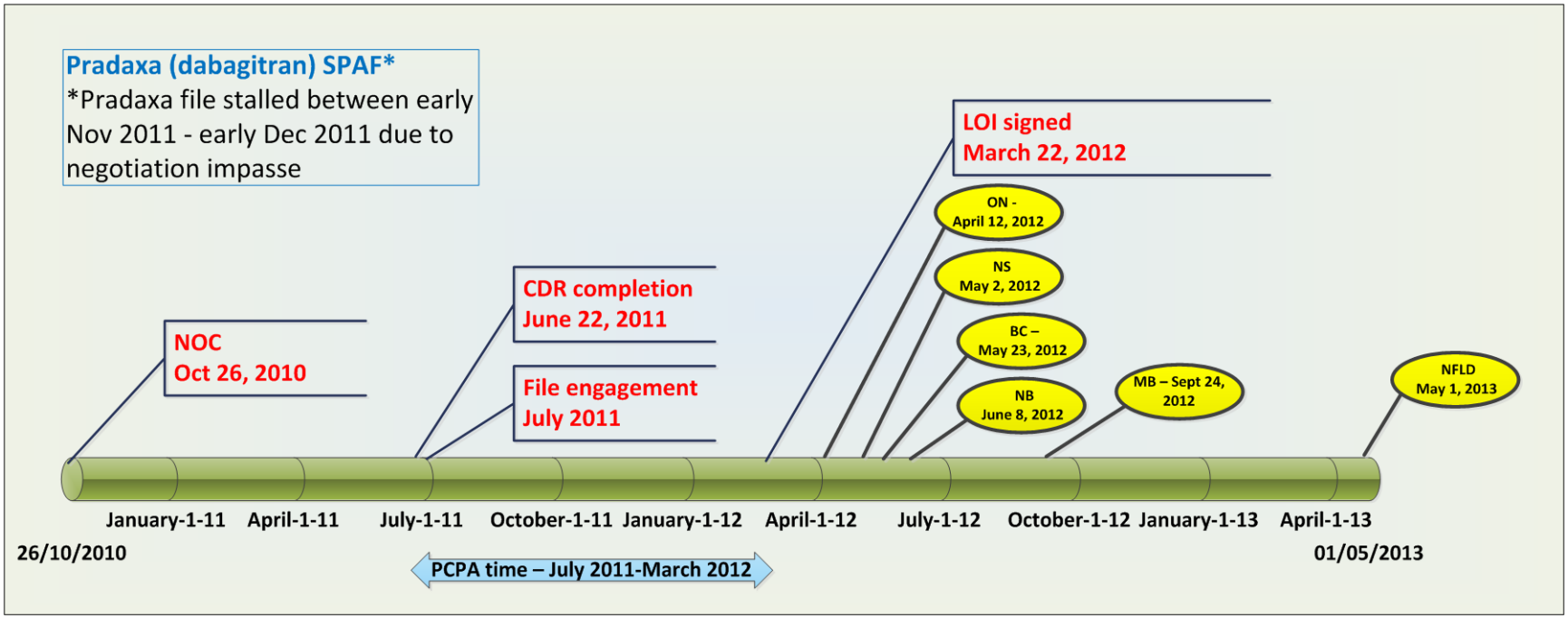


Figure 5: Timeline showing approval of Pradaxa from NOC to provincial listing (Pradaxa used as an example from survey data)

Note Impasse in negotiations from early November 2011 to early December 2011

B. Current PCPA negotiation Process

The flow chart below depicts the current PCPA negotiation process in more detail.

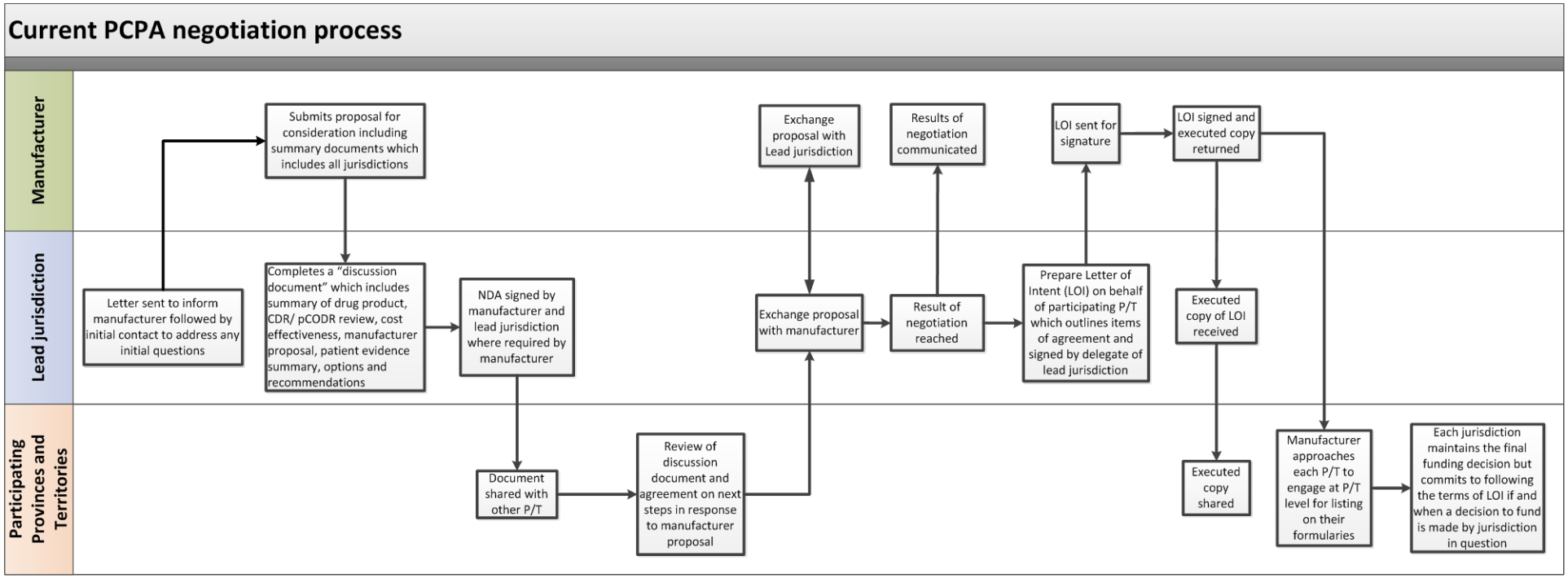


Figure 6: Current PCPA negotiation process

C. Suggested guiding principles for the PCPA process based on stakeholder feedback

The following guiding principles are proposed when considering the PCPA process and making it more efficient. These were developed from the interview feedback and the environmental scan. The future PCPA process should incorporate the following guiding principles:

- **Holistic** – full value of a therapy in the PCPA negotiations needs to be considered, including benefits to patients and caregivers, the health system and society.
- **Predictable** – the overall PCPA process should be predictable in terms of steps, timelines, past experiences with specific drug classes, and the number of provinces participating.
- **Consistent** – the attributes of value applied to drug negotiations are consistently applied to the PCPA negotiations.
- **Transparent** – the information is readily available on timelines, where a particular drug is in the PCPA process, and what it means for stakeholders to provide the PCPA with input and feedback.
- **Timely** – to have clearly communicated timelines and measures to meet timelines, and make access to funding available so as to get medicines to patients in a timely fashion and that is in-line with clinical evidence.
- **Efficient** – to reduce duplication in processes and sub-processes, where possible.
- **Collaborative** – the engagement and dialogue with industry and other stakeholders on all dimensions of the health enterprise (doctors, nurses, hospitals, etc.) and not just pharmaceuticals and pharmacotherapy.
- **Representative** – A process that is multidisciplinary, cross-jurisdictional and collaborative in nature, and includes appropriate input from key stakeholders and links to other key national initiatives.
- **Ethical** – Should reflect ethical principles such as validity, veracity, and autonomy.

D. Process Impact:

The following is a representation of the current PCPA process shown earlier with specific opportunities to improve process based on feedback from the interviews. In the governance analysis, the below process is referenced with specific opportunities for improvement listed.

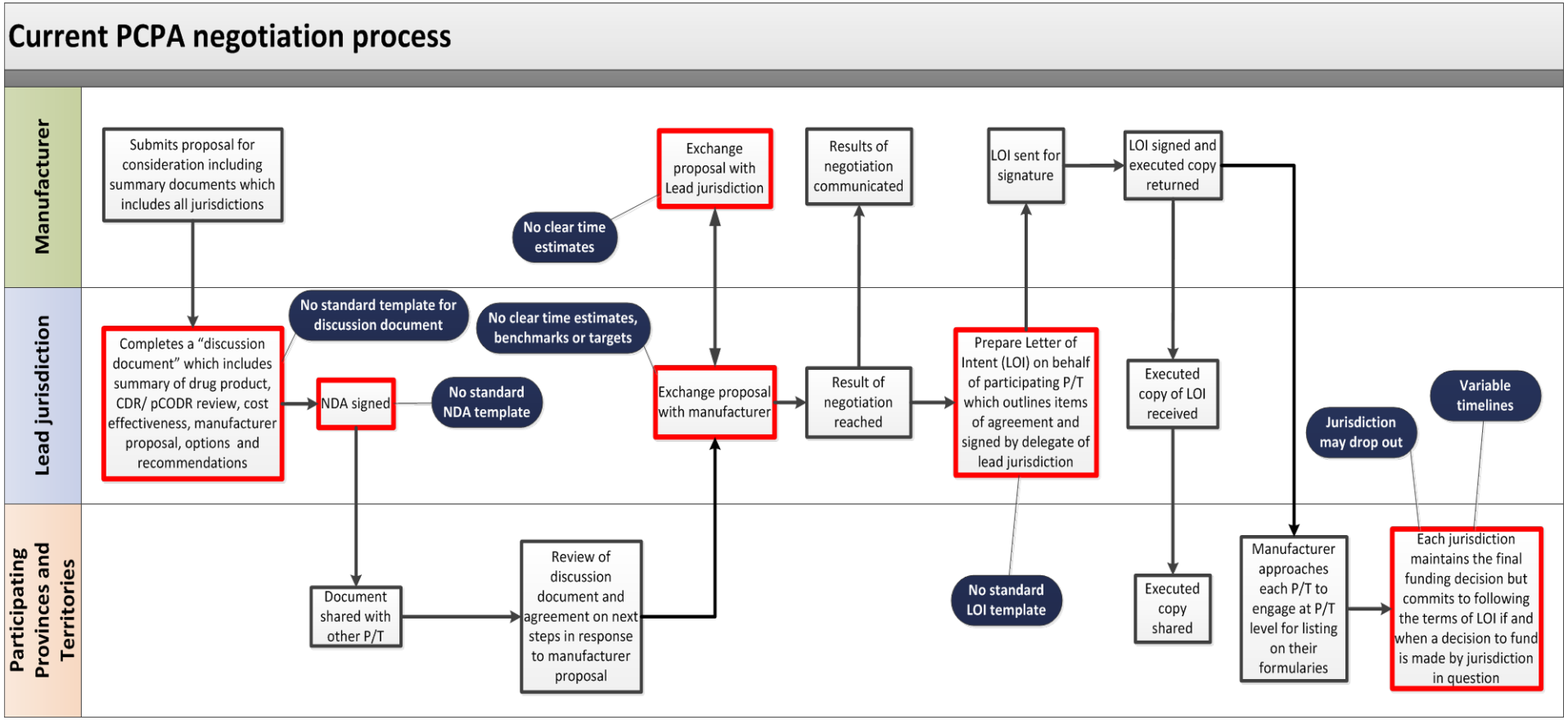


Figure 7: Current PCPA negotiation process with suggested areas for improvement

7.0 PCPA Governance

Implications of stakeholder consultations on Governance

Governance establishes the chains of responsibility, authority and communication to empower people (decision rights). It also establishes measurement, policy and control mechanisms to enable people to carry out their roles and responsibilities.

Elements of governance

For any governance model, in addition to the above definition, the following four elements[6] as depicted in figure 9 are considered relevant:

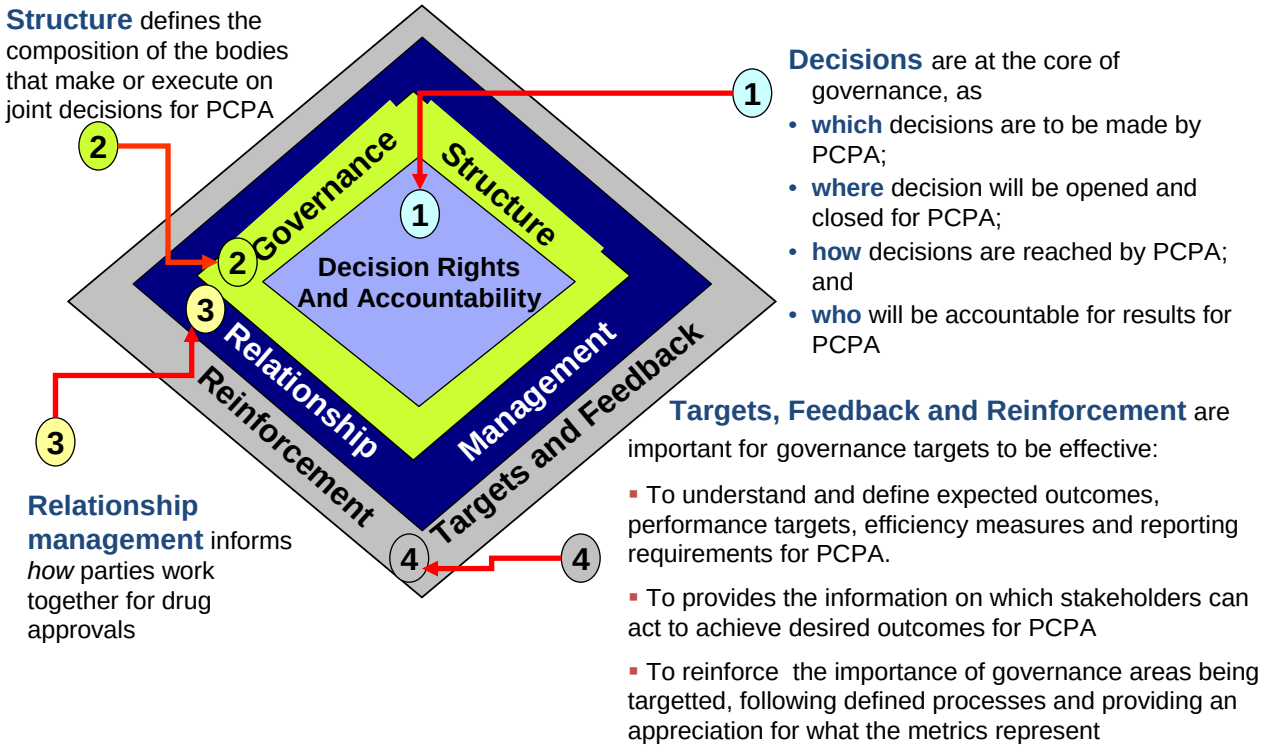


Figure 8: elements of Governance

1. **Decisions:** These are at the core of governance. The following questions were asked during interviews to determine which governance model option would be the most suitable:
   - **Which** decisions are to be made by PCPA?

[6] *Adapted from "GTEC presentation on IT Governance - October 15, 2007 Gale Blank, IBM and Chuck Henry, Chief Information Officer Branch, TBS*

- **Where** will a decision be opened and closed for PCPA?
- **How** are decisions reached by PCPA regarding pricing negotiations for generic and brand name drugs? and
- **Who** will be held accountable for negotiations for brand and products and approaches for achieving better value for money for generic drugs?

2. **Structure** defines the composition of the bodies that make or execute on negotiations relating to the brand name products and approaches for achieving better value for money for generic drugs. The preferred governance model for the PCPA should offer a structure that facilitates negotiations.
3. **Relationship management** informs us about how parties that have a stake in drug reimbursement work together. The preferred governance model should enable successful relationship management.
4. **PCPA performance targets, feedback** received on PCPA and reinforcement of PCPA performance measures with stakeholders are important aspects of governance for the following reasons:
   - To understand and define expected outcomes, performance targets, efficiency measures and reporting requirements relevant to the PCPA. (targets)
   - To provide the information on which project stakeholders can act to achieve desired outcomes. (feedback)
   - To reinforce the importance of governance areas being targeted, following defined processes and providing an appreciation for what the metrics represent (reinforcement of PCPA performance measures with stakeholders)
   - The preferred governance model should be able to incorporate the above targets, feedback and reinforcement which would make the preferred governance more effective.

The above generic elements of governance will be used to build a draft governance model and in stakeholder interviews along with a RACI (**R**esponsible, **A**ccountable, **I**nformed, **C**ommunicated) analysis.

The figure below depicts three typical governance models that are seen in the health industry: Centralized, Decentralized, Federated. The advantages and disadvantages of the three models are depicted in the diagram[7] below.

Note: In the below figure BU = Business Unit

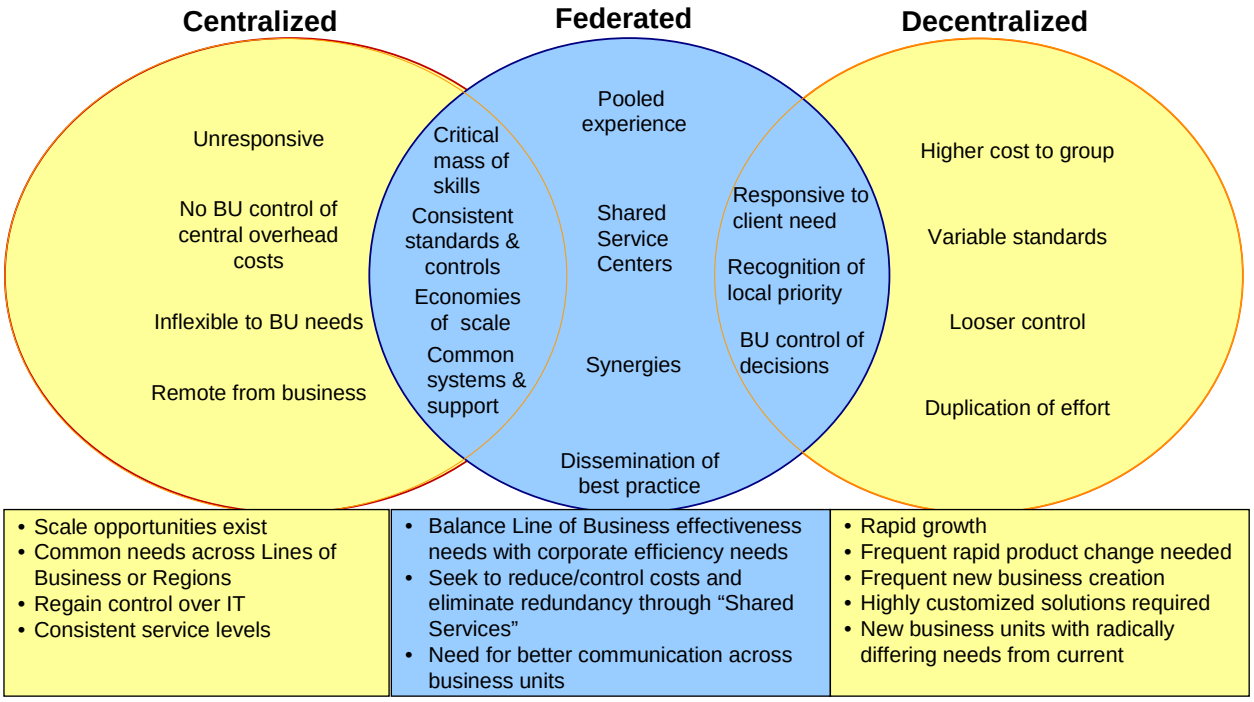


Figure 9: Centralized versus Decentralized versus Federated models of governance

[7] *"Report on Impact of Conceptual Architecture on Member Departments and a Conceptual Framework for Governance for the Design and Build Phases"*

Options for Governance

The table below depicts the various proposed governance model options with the two models that were selected for further evaluation. The complexities of the models are also depicted below with the least complex model on the left and the most complex model on the right.

Complexity of model

Low → High

	Extension of Status Quo	✓ Secretariat	Extension of Existing Body	Net New Entity under existing system	✓ Net new autonomous entity
✓ = two options for drill down	Commitment to develop a playbook depicting timelines, standardized processes and templates and an annual report providing data regarding drug approvals and rejections against set benchmarks. A letter of inter-Jurisdictional agreement specifying roles. This will have no centralization.	Create a new entity or house the entity within a Province, responsible for the secretariat work and leaving the negotiations to the Jurisdictions. This will include only a centralized secretariat. Will allow the provinces to focus on negotiations, drug related expertise and secondary review processes.	Extend the role and responsibility of an existing entity to include the negotiation duties on behalf of all the Jurisdictions. This will include both a centralized secretariat and negotiation process.	Create a new independent body that will undertake the negotiation duties on behalf of all of the Jurisdictions. This will include both a centralized secretariat and negotiation process.	Create a new independent entity which will act as the single entity responsible for the negotiation process – decisions made by this entity regarding drugs will be binding for all provinces. Any secondary review process required will be conducted through this entity. Instead of provincial listing a single national formulary. Can only occur with legislative and structural change.
Ease of Deployment	+ Easy	++	+++	++++	+++++ Difficult
Degree of sustainable funding required	+ Minimal	++ Medium	++ Med-High	+++ High	+++++ v. High
Degree of structural change required	+ Minimal	++ Medium	++ Medium	++++ High	+++++ V. High
Degree of Legislative change required	none	none	none	++ Medium	+++++ V. High
Acceptance by stakeholders	low	high	medium	low	high
Degree of change	+ Minimal	++ Medium	++ Medium	+++ High	+++++ V. High

Extension of Status Quo	Secretariat	Extension of Existing Body	Net New Entity under existing system	Net new autonomous entity

<u>Governance model Option 1:</u> Extension of Status Quo

In this model, the current governance model stays as is but with some augmenting around communications and process. The feedback from stakeholders indicated that keeping the status quo with no changes was not an option. However, with changes to communications, standardizing existing processes, some improvements can still be achieved. This will have no centralization.

At a minimum, the following activities are recommended:

- Develop a playbook depicting timelines, forms, templates, and a sample of a submission to PCPA.
- Standardized processes and templates.
- An annual report providing data regarding drug approvals and rejections on products which PCPA 'approved' to proceed with against set benchmarks.
- A letter of inter-jurisdictional agreement specifying roles.

The following are the pros and cons of this option:

Pros	Cons
Minimal change but still opportunity to standardize existing process, enhance communications, and transparency.	Status quo has already raised concerns with challenges pertaining to communications, transparency and process inconsistency.
	Risk of continued or increasing negative sentiment and frustration amongst players may continue to grow.
	Activities listed to standardize processes, enhance communications and transparency will require time and work effort. Unless such activities are funded, there is a risk that the current model will not be able to cope with these additional activities given the current resource constraints.

Extension of Status Quo	Secretariat	Extension of Existing Body	Net New Entity under existing system	Net new autonomous entity

<u>Governance model Option 2:</u> Secretariat

In this option, drug negotiations with a manufacturer would happen as they are now, but with significant support from a dedicated "Secretariat". A Secretariat would need to be created and funded to perform administrative coordination of the PCPA activities, the PCPA marketing and communications activities, standardizing of templates, formats, tracking of submissions, compiling developed performance metrics and other project management functions.

This would leave the specific tasks related to the PCPA negotiations, drug related expertise and secondary review processes to the P/Ts. The following are the pros and cons of this option:

Pros	Cons
Allows provinces to retain the expertise required for negotiations while the secretariat will focus on coordination, communication, and process standardization.	Will require role clarity in terms of what secretariat does versus provinces.
Adds a level of independence or neutrality to the negotiations role.	Where the Secretariat is housed (e.g., province) may lead to perceived bias regarding its role and function.
Centralized coordination, communication, process standardization will lead to more clarity around timelines, set benchmarks and consistency of process.	
Ease of implementation	
Lower cost compared to other options	
Negotiations will be carried out by the lead provinces (as done now) except with more consistent centralized processes, timelines, and benchmarks.	

<u>Governance model Option 3</u>: Extension of Existing Body

Extension of Status Quo	Secretariat	Extension of Existing Body	Net New Entity under existing system	Net new autonomous entity

In this option, the role and responsibility of an existing entity would be extended to include the negotiation duties on behalf of all the jurisdictions. This would include both a centralized secretariat and negotiation process and would fall under the governance structure of an existing body. No existing agencies appeared to be appropriately positioned to take on the added role of the PCPA without compromising their existing (and distinct) mandates. For example, an organization such as CADTH provides recommendations on independent scientific and evidence based evaluations according to pre-established guidelines and procedures. In contrast, the PCPA process has a broader mandate and incorporates a wider set of relevant factors including individual jurisdictional considerations which are more appropriate to an informed negotiation between various parties. Best practices internationally reflect a clear separation between evidence-based HTA assessments and complex price negotiations.

The following are the pros and cons of this option:

Pros	Cons
Provides an established structure under which the PCPA can operate.	Legislative impact in terms of jurisdictions still having the final decision in making listing decisions.
Will allow for standardized processes spanning from clinical benefit and safety review through to price negotiations as a result of centralization.	Separation of duties becomes blurry – drug negotiations and price versus drugs expertise being done by two distinct bodies and agencies instead of a single body and agency.
Opportunity to reduce the time-lag between CDR and negotiations.	Achieving consensus on which existing body would serve to also incorporate the PCPA.
Potential for administrative efficiencies.	Issues with lack of dedicated resourcing in the long run.

<u>Governance model Option 4:</u> Net New Entity under existing system

Extension of Status Quo	Secretariat	Extension of Existing Body	Net New Entity under existing system	Net new autonomous entity

Create a new independent body that will undertake the negotiation duties on behalf of all of the jurisdictions. This will include both a centralized secretariat and negotiation process but the decision to list a drug on a province's formulary will still remain with the province.

The following are the pros and cons of this option:

Pros	Cons
Will allow for standardized processes for price negotiations as a result of centralization.	Provincial expertise in drugs subject matter may be lost due to centralization.
Dedicated entity that can carve a niche for itself in a pan-Canadian capacity.	Legal implications of creating a new entity.
The sole purpose of being for this new entity would be centralized drugs negotiations and other functions such as communications, and coordination.	Will need to deal with the Legislative impact of provinces still having the final say in listing decisions. This may raise concerns regarding creating a new agency. Perception by manufacturers of new agency adding "another layer" which will require role clarity to avoid notion of "duplication" of effort and process.

	Cost of implementing this option – set up cost and ongoing operational cost (obtaining sustainable funding)

<u>Governance model Option 5:</u> Net new autonomous entity

Extension of Status Quo	Secretariat	Extension of Existing Body	Net New Entity under existing system	Net new autonomous entity

Create a new independent entity which will act as the single entity responsible for the negotiation process. Decisions made by this entity regarding drugs will be binding for all provinces. Any secondary review process required will be conducted through this entity. There would be a single listing, although provincial formularies would still play a key role in the administration of contracts. This option would require significant legislative and structural change; most importantly legal implications of delegating provincial authority that binds provinces to negotiations conducted by this net new autonomous entity.

The following are the pros and cons of this option:

Pros	Cons
A single entity for decision-making regarding drugs for the entire country versus participating provinces/territories each with their own decision-making.	Requires a significant legislative change in how provinces operate and the autonomy they currently possess with regards to decisions on what drugs are listed on their formularies.
Enables consistency and efficiency of listing with single contract for a drug (one entity versus ten).	Province/territory specific population drug needs may be lost unless carefully designed.
Clear separation of roles and responsibilities – independent of the HTA agencies.	Most disruptive of options and will take longer to implement.
Enables standardization of templates, submissions, and communications.	Several operational tasks related to administration and contracting are carried out at provincial formulary level. Need to clearly delineate national versus provincial responsibilities.

All five governance options were considered. Based on the above analysis, the two governance options that were selected by the Steering Committee for further analysis included:

Option 2: Secretariat model

Option 5: Net New Autonomous Entity.

Further analysis on these two options is discussed next.

Option 2: Secretariat model

Figure 11 depicts the proposed governance model for the Secretariat option with corresponding roles. This model has been socialized with the Steering Committee and at the Assistant Deputy Minister levels and includes a strategic layer, a management (Direction) layer and an Execution (Tactical) layer.

- In this governance model, the role of existing HTA bodies does not change and will continue to make recommendations on drug submissions to the PCPA. The PCPA will liaise with the PMPRB appropriately as required. Similarly, the role of the provinces with a lead province being appointed for each drug submission will continue as organized presently.
- However, in this model a specific PCPA Secretariat is recommended to perform the following tasks:
    - Handle the public relations of the PCPA to enhance clarity and transparency regarding the role and mandate of PCPA
    - Communications in multi channel format, including web, email, newsletters, and annual report. The web channel in particular provides an opportunity to raise the level of transparency and communications through its dynamic use in providing information on the PCPA process, templates, information on the PCPA, and summaries of timelines for successfully negotiated drugs. The web also offers an opportunity to evolve into a "courier-like" tracking mechanism for manufacturers who could securely log into a website / portal to determine the status of a PCPA negotiation. In addition, a web site targeted for public consumption should be strongly considered to make the public aware especially with drugs that have been successfully negotiated. This would provide another layer of transparency and address the feedback we received regarding the same from stakeholders interviewed.
    - Standardization of templates where possible recognizing that across provinces, specific legal language may differ. Examples of this include, where possible, standardize templates for a PCPA submission, a standard NDA agreements, and across provinces for a specific manufacturer, a standard LOI template. This could be very helpful depending on level of technical support provided and would require a degree of technical skill within Secretariat
    - Process queries: Where there are questions pertaining to the PCPA process, the Secretariat will serve as the single point of contact to respond to such queries by the manufacturer.
    - Compiling, organizing and presenting data collected by the PCPA as per specific performance metrics.
    - Providing administrative support to the lead province in preparing for a negotiation.
    - Pre negotiation evaluation and research with ability to direct manufacturer to listing statuses of comparator products across the country
- By creating a PCPA Secretariat, the lead provinces will be able to focus on more specific PCPA negotiation tasks. By virtue of having a centralized Secretariat, more standardization in process and communications is expected and thus the work effort saved from these activities can be used for specific negotiating tasks.
- The role of the secondary review process that takes place in various capacities across the country could remain the same. However, it is the experience of some jurisdictions that such reviews, while useful, may in fact contradict recommendations made by the HTA bodies

leading to more discussion to resolve such conflicts. In order to make the PCPA process more efficient, the PCPA could use this as an opportunity to:

- Determine if a secondary review or additional expert input was truly needed given the detailed HTA process. If so, develop a set of criteria that define when such a process is needed.
- Develop a more consistent national process of secondary review to enable consistency of drug listing decisions.

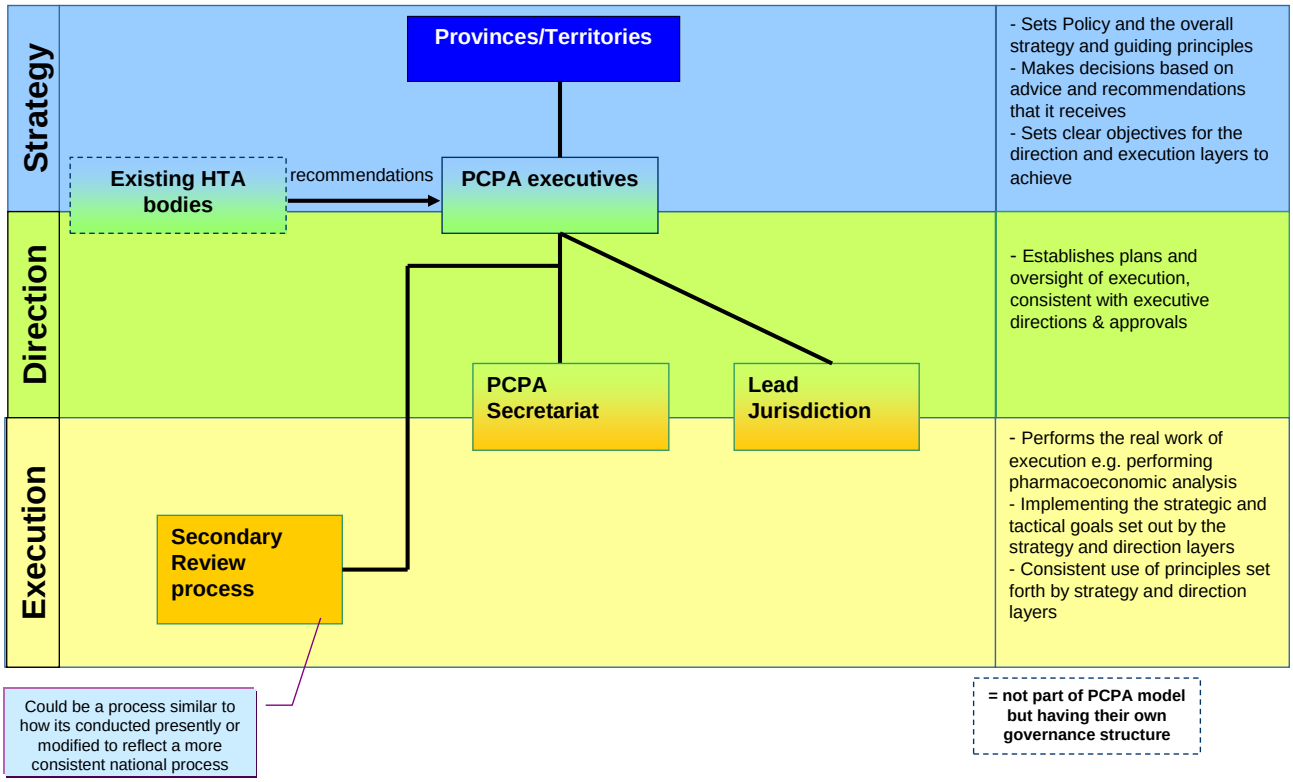


Figure 10: PCPA Secretariat model option: Option 2

The following table depicts the various roles for the various proposed teams under the Secretariat model.

Team	Role
PCPA	• Negotiations with manufacturers as per goals of the PCPA • Recommendations result in a LOI • Utilization reviews
Secretariat	• Standardization of templates • Multi channel communications to internal and external stakeholders (web, email, newsletter, and annual report) • Provides support to the PCPA negotiation (Lead jurisdiction) • Marketing, branding of the PCPA • Compiling data collected by the PCPA as per agreed to performance metrics

HTA bodies	• Role stays as is currently performed
Provinces/ Territories	• Decision-maker regarding whether drug gets listed on P/T formulary • Can undertake secondary review process at jurisdiction's discretion

Funding the PCPA Secretariat:

It is expected that a maximum of three full-time equivalents (FTEs) would need to be funded to perform the outlined tasks of the PCPA Secretariat. When the PCPA Secretariat is put into operation, it is expected that these three FTEs would be fully deployed given a significant amount of work would need to be undertaken in areas of, communication, and standardization of process and templates. It is expected that with the increase in volume of drug negotiations going through PCPA, these three FTEs will continue to be actively deployed in aforementioned tasks, including support of the lead jurisdiction. The skill set that will be required by members of the secretariat should include (collectively or individually) marketing and communications as well as the following::

- Administrative capabilities
- Strong medical/pharmaceutical content knowledge
- Business knowledge
- Industry knowledge
- Public relations
- Project management functions

At a salary of approximately $100,000-$120,000[8] per FTE, the total Secretariat would require approximately $300,000 per year in funding for labour. This cost can be justified on grounds of using lower salaried employees to perform the tasks of the Secretariat compared to more expensive subject matter experts who would then focus only on the negotiations.

[8] *Used as an estimated loaded cost for a FTE with the required skill as stated above*

PCPA Secretariat Model – Governance (with anticipated FTE count)

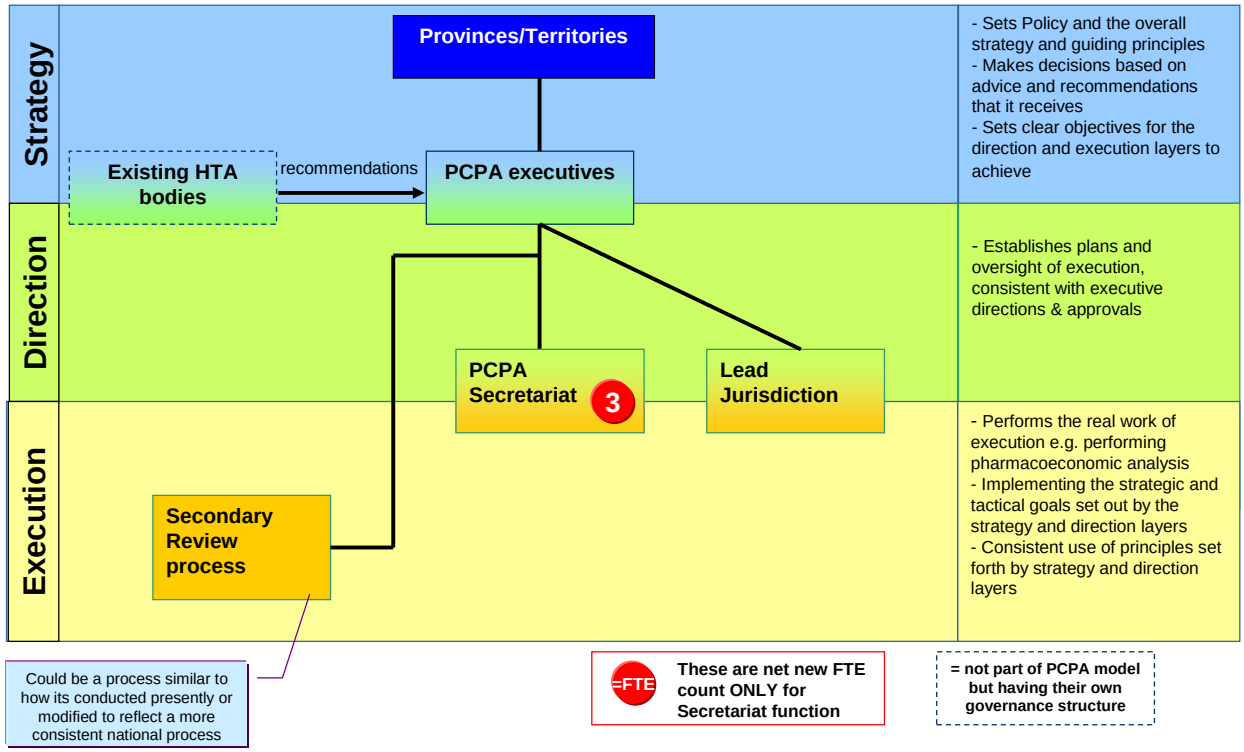


Figure 11: Secretariat Governance model with FTE count

RACI chart

With a governance model, it is also essential to develop a RACI chart. In the chart below, specific activities that are vital to the PCPA process are listed with a RACI chart which assigns responsibilities and accountability appropriately and also identifies who needs to be informed and consulted for specific tasks.

Secretariat

R	A	C	I
Responsible	Accountable	Consulted	Informed

Activities	PCPA (as it stands now with lead prov)	Secretar -iat	PCPA Executive	PCPA Eco Team (PET)	PCPA Drug Util Team (PDUT)	PCPA Negotiations Team (PNT)	Prov	National Pharma Collective	Existing HTA / reg bodies - CDR, Pcodr, PMPRB, CADTH	Drug Manuf	Patient Groups	2° review
Health technology assessment and expert review of the clinical and pharmacoeconomic evidence	I	I					n/a		A	C	I	n/a
Obtaining more expert advice on drug if insufficient clarity on therapeutic claims, evidence, and analyses	C	I					C		C	I	I	A
Decision to list drug or not	I	I					A		I	I	I	I
Negotiating terms and conditions for reimbursement for a particular drug	A	I					I		I	I	I	I
PCPA communications	R	A					C		I	I	I	C
Process, template standardization	R	A					C		C	C	n/a	C n/a

Figure 12: RACI chart for Secretariat governance model

Proposed Secretariat Structure:

The following figures depict two proposed Secretariat structure options using the three proposed FTEs that would need to be specifically part of the PCPA Secretariat.

Option 1:

In this option, the three FTEs would be split in location and specialization across the country. Resource 1 would be in the Western part of Canada, resource 2 in Ontario, and resource 3 in the Eastern part of Canada. The primary role of the three resources would also be specialized. Pros and cons of this option are depicted below. Such a team for the PCPA would need to be virtually organized and would represent a risk in terms of size as one resource would have the know how for their primary role.

Proposed Secretariat Structure — **Option 1**

Number of FTEs	1	1	1
Location	CanWest	Ontario	Atlantic Canada
Primary Role	Cancer Drugs	Brand Drugs	Communications (website, PR,etc)
Responsibilities	Process Cancer drug applications, prepare package and information for lead jurisdiction, ensure NDA's and other relevant documents are signed, respond to manufacturers	Process Brand drug applications, prepare package and information for lead jurisdiction, ensure NDA's and other relevant documents are signed, respond to manufacturers	Maintain website, promote awareness, manage the brand, increase communication, direct inquiries, co-ordinate meetings and manage information.

Pros

- Provides a dedicated spread of FTE's across each location
- Allows for degree of specialization in certain areas e.g. cancer in CanWest

Cons

- Potential for bias for specific primary role to the region the FTE's are located in
- May lead to silos versus foster collaboration

Figure 13: Proposed Secretariat structure – option 1

Option 2:

In option 2, the numbers of FTEs are more centrally organized in that there are no specific roles as in option 1 for each of the resources. The pros and cons of this option are depicted below. The overall risk in having a single resource possessing specialized knowledge is minimized as well; the opportunities for teaming, growth and collaboration are increased with a sharing of responsibilities. This would facilitate the needed consistency between files.

Proposed Secretariat Structure

Option 2

Number of FTE's	3
Location	All three located in one province allowing for teaming, growth, collaboration
Role	Support to the overall portfolio of drugs negotiated by PCPA
Responsibilities	Processing of drug applications, standardizing and developing a standard "package" for every negotiation which can be reviewed by the lead province; communication via a web site, standardized templates and processes, brand promotion and PR, meeting coordination, handling direct inquiries, Administrative support to PCPA lead province

Pros

- 3 FTE's in one location allows for effective teaming and collaboration
- Provide a single point for all administrative, communication, PR, standardization functions which can effectively support a PCPA lead province

Cons

- Location of province may lead to some degree of bias for that province
- Challenging for communications and seamless work

Figure 14: Proposed Secretariat structure – option 2

IBM Recommendation:

We recommend option 2 as the preferred structure for the Secretariat given the opportunities for teaming, growth, collaboration, as well, for a team of three, this option avoids expertise resting on a single person as in option 1.

The PCPA negotiation process with role of the Secretariat

The following process map shows the PCPA process highlighting the role of the Secretariat in those steps identified in Figure 16 with opportunities for process improvement.

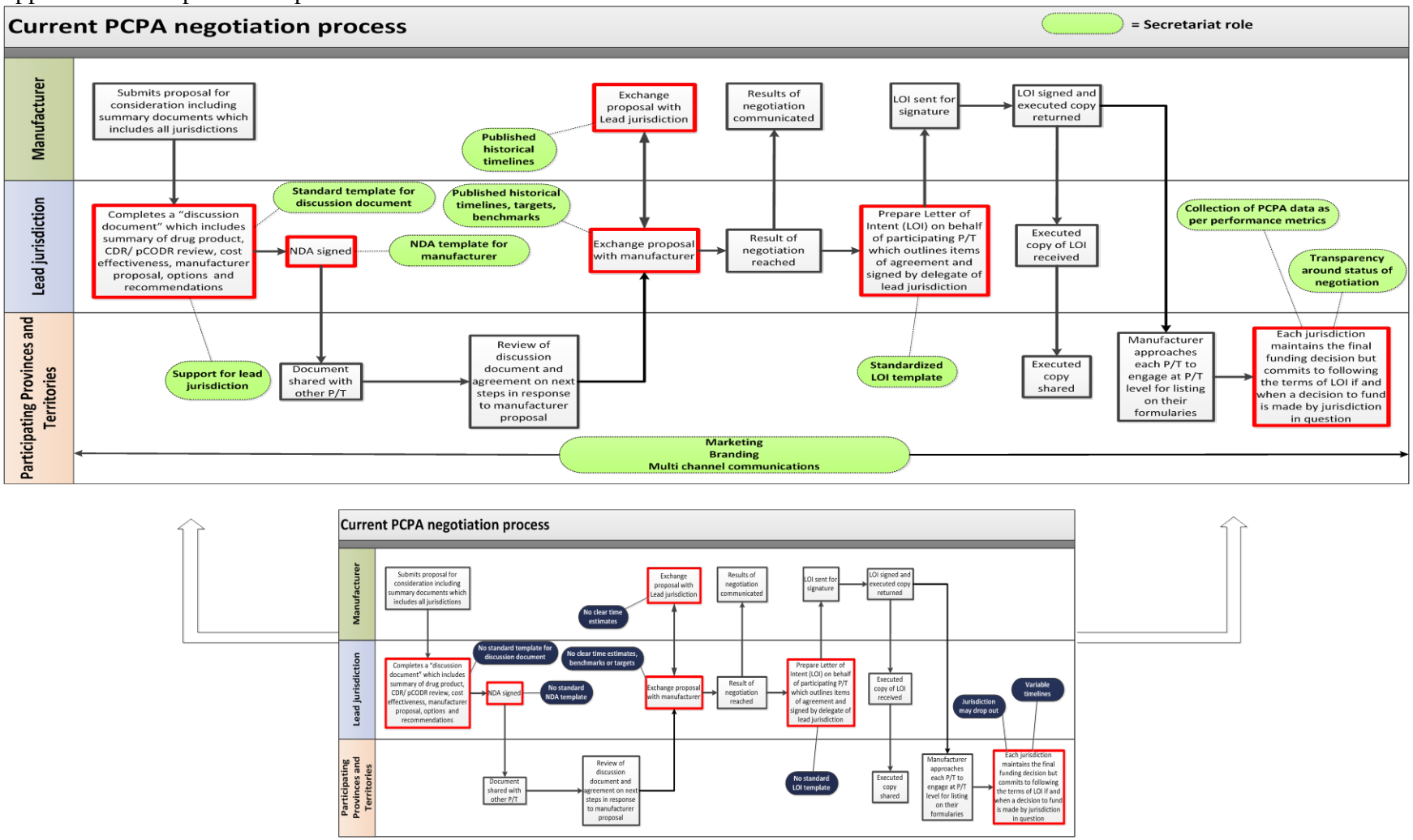


Figure 15: PCPA negotiation process with role of Secretariat

Governance Model Option 5: Net New autonomous entity

The following figure depicts the proposed governance model for the net new autonomous entity option with corresponding roles. This model has been socialized with the Steering Committee and at the Assistant Deputy Minister levels and includes a strategic layer, a management (Direction) layer and an Execution (Tactical) layer.

A very distinct feature of this model is that the net new autonomous entity would make drug listing decisions for all the participating P/Ts thereby binding the P/Ts to their decisions. Such a model would require significant legislative change given provinces hold the autonomy as per the *Canada Health Act* to make their own policy decisions in regards to listing drugs on their formularies. This option was however selected for further consideration as it represents a fundamental change in the status quo and thus examines how the Canadian drugs landscape could look. For this reason, when analyzing the five presented options, this option was the most complex in terms of change required structurally and from a legislation perspective. In this model, a National Pharmaceuticals Collective comprising senior drug program branch leaders would fulfill the role of national decisions makers regarding the negotiation of a PCPA drug submission following a post-HTA recommendation.

This option does not go into the detailed implications of specific P/T level processes such as transfer payments, rebates and contract management responsibilities, for which each P/T has its own processes and sub-processes. It is expected that this option would focus on negotiating with a manufacturer the listing or not of a particular drug as per the principles, goals and mandates of the PCPA. Many of the existing provincial level processes such as rebates and contracts, which are the purview of drug program branches would continue. However, in light of the significant change that this option provides, it is recommended that a detailed listing of all provincial tasks be compiled and examined such that any additional implications of such a model not go unresolved.

- A PCPA Executive Team would be responsible for obtaining more expert advice on a particular drug submission if insufficient clarity on therapeutic claims, evidence, and analyses exists. This team would provide its recommendation to the National Pharmaceuticals collective regarding a particular drug and would play a strategic and management role in the PCPA submissions by its oversight on the PCPA process, as well as liaise with key stakeholders. The team would be supported by three teams:
    - **PCPA Economics Team (PET)** which consolidates pharmacoeconomic analysis, cost benefit data, economic benefits of a particular drug and recommendations provided by the HTA with a national perspective and as required obtain province specific economic analysis. This team would not duplicate any of the HTA efforts but would instead compile, consolidate and appropriately present data to the PCPA Executive Team and the PCPA Negotiations Team (PNT).
    - **Pharmaceutical Drug Utilization Team (PDUT)** clinical experts who would consolidate utilization reviews from a national and provincial perspective and perform due diligence and keep the PCPA Executive Team informed about new drug related information. This team would not duplicate any of the HTA efforts but would instead compile, consolidate and appropriately present data to the PCPA Executive Team and the PNT.
    - **PCPA Negotiations Team** (PNT) which would play a key negotiation role with manufacturers and addresses the principles and goals of the PCPA when negotiating a

drug. The team would be staffed by drug program branch experts who would undertake the negotiation with the manufacturers and provide a recommendation to the PCPA Executive Team for endorsement. This team would be informed by the PDUT and PET.

- In this option, there is no specific need for expert input or a secondary review. However, if such a need arises, either the PCPA Executive Team and/or the PNT can request for additional expert input on an *ad hoc* basis.

The following table depicts the roles of the various teams

	Team	Role
	National Pharmaceuticals Collective	• Decision maker regarding national approval of a drug submission
PCPA	**PCPA Executive team**	• Obtaining more expert advice on drug(s) if there is insufficient clarity on therapeutic claims, evidence, and analyses • Providing recommendations to National Pharmaceuticals collective regarding a particular drug • Oversight and leadership over the PCPA • Liaise with key stakeholders
	PCPA Economics Team (PET)	• Consolidating pharmacoeconomic analysis and recommendations performed by the HTA • Consolidating cost benefit analysis data and recommendations provided by the HTA bodies • Liaises with the HTA bodies for cost-effectiveness and economic benefits from a national perspective • Obtains province specific economic analysis where necessary • Liaises with the PMPRB
	PCPA Drug Utilization Team (PDUT)	• Clinical experts • Consolidates utilization reviews from a national and provincial perspective • Due diligence and keeping the PCPA Executive Team informed about new drug related information
	PCPA Negotiations Team (PNT)	• Key negotiation role which addresses the principles and goals of the PCPA • Negotiates terms and conditions for reimbursement of a particular drug with manufacturers • Provides recommendations to the PCPA Executive Team
	Expert Input	• If required by the PCPA Executive team or PNT, can request expert input if required

Funding the Net New Autonomous Entity:

With the overall centralization of PCPA negotiations being undertaken at a national level, when the Net New Autonomous Entity is put into operation, it is expected that approximately 15 to 20 total FTEs would be required to undertake the tasks listed above.

- The majority of these FTEs (4) are allocated to the PNT. This uses information from the provincial interviews and the survey tool which indicated 1 to 2 FTEs per province for the PCPA related tasks.
- Given the PDUT and PET are primarily involved in compiling and presenting data and analysis that has been provided by the HTAs, three (3) FTEs were estimated given that in some cases additional province specific data may be required.
- The PCPA Executive Team will provide an oversight role and will also make final recommendations to the National Pharmaceuticals Collaborative. Three (3) FTEs were recommended based on the complexity that may arise when making national level decisions.
- It is expected that with the increase in volume of drug negotiations going through the PCPA, these FTEs will continue to be actively deployed in aforementioned tasks.

New autonomous entity – Governance model (with FTE count)

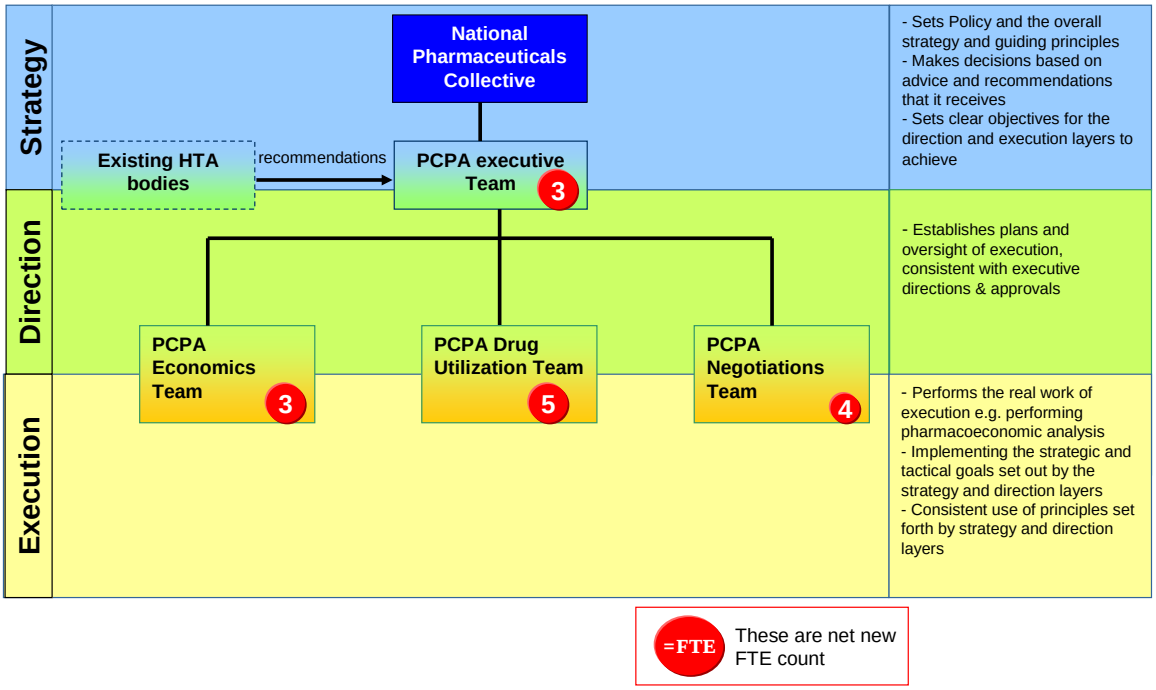


Figure 16: Net New Autonomous Entity Governance model – Option 5

- The overall approximate labour cost of operating the Net New Autonomous Entity would be approximately $1.725 million. This does not account for any offsets realized by redeployment of existing provincial ministry staff which would likely occur versus hiring 15 to 20 new employees.

The breakdown of this labour cost is as follows:

PCPA Executive Team	3 x $175000*[9] = $525,000
PCPA Negotiations Team (PNT)	4 x $150,000 = $600,000
PCPA Drug Utilization Team (PDUT)	3 x $100,000 = $300,000
PCPA Economics Team (PET)	3 x $100,000 = $300,000

[9] ** $ amounts used are approximate based on Ministry salaries*

RACI chart

With a governance model, it is also essential to develop a RACI chart. In the chart below, specific activities that are vital to the PCPA process are listed with a RACI chart which assigns responsibilities and accountability appropriately and also identifies who needs to be informed and consulted for specific tasks.

Net New Autonomous entity

R	A	C	I
Responsible	Accountable	Consulted	Informed

Activities	PCPA (as it stands now with lead prov)	Secretariat	PCPA Executive	PCPA Eco Team (PET)	PCPA Drug Util Team (PDUT)	PCPA Negotiation Team	Prov	National Pharma Collective	Existing HTA / reg bodies - CDR, Pcodr, PMPRB, CADTH	Drug Manuf	Patient Groups	2° review (national)
Health technology assessment and expert review of clinical and pharmacoeconomic evidence			R	A	C	C		I	C	I	I	
Obtaining more expert advice on drug if insufficient clarity on therapeutic claims, evidence, and analyses			A	C	C	C		I	I	I	I	
Decision to list drug or not			C	I	I	I		A	I	I	I	
Negotiating the terms and conditions for reimbursement for a particular drug			I	I	I	A		I	I	I	I	
PCPA communications			A	R	R	R		I	I	I	I	
Process, template standardization			A	C	C	C		I	C	C	n/a	

Figure 17: RACI chart for Net New Autonomous Entity structure governance model

Proposed Net New Autonomous Entity structure:

The following figure depicts the proposed structure of the Net New Autonomous Entity together with pros and cons.

Proposed net new autonomous entity Structure

Option

Number of FTE's	15-20 (3 on Executive Team, 3 for PET, 3 for PDUT, 8 for PNT)
Location	PCPA Executive Team and sub teams located in one province
Role	National body mandated with providing recommendations including price to the National Pharmaceuticals collective
Responsibilities	Provide access to drugs via consistent and expeditious national approval. Obtain a single price for drug nationally. In this model, the 15-20 expected FTE's do not include the need to bring in additional experts as part of working groups e.g. a specific group of experts for carrying out a secondary review.

Pros

- True centralization – a single entity and location allows for effective teaming and collaboration
- Provide a single point for decision making and for all administrative, communication, PR, standardization functions

Cons

- Requires net new FTE count
- FTE needed exceed those in Secretariat model
- Location of province may lead to some degree of bias for that province

Figure 18: Proposed structure for Net New Autonomous Entity structure

The PBAC model applied to Canada (for illustration only)

It is to be noted that the PBAC model in Australia works under a different set of circumstances than in Canada where each province and territory has autonomy in drug funding and listing decisions. The manner in which P/Ts deliver healthcare to its citizens is governed by the principles of the *Canada Health Act*. The below illustration of PBAC applied to Canada requires the creation of a net new autonomous entity that fundamentally acts in a completely different manner than structured in Canada. In effect, this option would require significant legal and structural changes but was selected as an option to consider on account of examining a completely different view of how drug reimbursement decisions would occur in reference to the over arching principles of the PCPA. The follow illustrative steps provide a high level process and structure for this option:

- Assume Health Canada has already issued a NOC
- Upon receiving an application, the PCPA distributes copies to all members within each of the following four teams
  - (1) CDR or pCODR,
  - (2) the PET

- (3) the PDUT, and
- (4) the PNT

∗Note: CDR, pCODR functions, governance stays the same

- CDR or pCODR convene to discuss the application and complete separate comprehensive evaluations and provide a recommendation to the PCPA Executive Team. The role of existing HTA bodies remains unchanged.
- The **PCPA Economics Team (PET)** compiles the results and findings of CDR and pCODR. It consolidates pharmaco-economic analysis, cost benefit data, and economic benefits of a particular drug and recommendations provided by HTA with a national perspective and where required obtain province specific economic analysis. This team would not duplicate any of the HTA efforts but would instead compile, consolidate and appropriately present data to the PCPA Executive Team and the PNT.
- The **Pharmaceutical Drug Utilization Team (PDUT)** consolidates Utilization reviews from a national and provincial perspective and performs due diligence, and keeps the PET informed about new drug related information. This team would also not duplicate any of the HTA efforts but would instead compile, consolidate and appropriately present data to the PCPA Executive Team and the PNT.
- The **PCPA Negotiations Team (PNT)** plays a key negotiation role with manufacturers and addresses the principles and goals of PCPA when negotiating a drug. The team would be staffed by Drug program branch senior managers who would undertake the negotiation with the manufacturers and provide a recommendation to the PCPA Executive Team for endorsement. The PNT would be informed by the PDUT and PET. At the end of the negotiation, a recommendation is made to the PCPA Executive Team.
- This recommendation, which includes a summary of therapeutic claims, evidence, price and analyses, are forwarded to the PCPA Executive Team, who then uses them as the basis for its advice to the National Pharmaceuticals Collective.
- If deemed necessary, the PCPA Executive Team and/or the PNT may seek expert advice from other relevant professional bodies and/or specialists.
- In cases where PCPA recommends that a new drug be listed, the PCPA Executive team notifies the National Pharmaceuticals Collective.
- The PCPA informs applicants of its decisions within 15 days of the meeting at which the application was submitted for consideration.

What Would Change

- Identical formularies (on a go-forward basis) in each province.
- No provincial secondary review process; instead as needed a national secondary review team and process
- Consistent reimbursement criteria across the country
- Decisions taken at national level, not provincial/territorial
- Provinces/territories lose autonomy to add/modify any PCPA negotiated price.
- National teams for the PCPA to consolidate and include national and P/T perspectives to recommendations made by the HTA bodies
    - the PET;

- the PDUT and
- the PNT.

What Would Remain the Same?

- CDR, pCODR functions, governance stay the same
- Legacy prices and agreements will still need to be managed separately
- Health Canada process to NOC stays the same
- Contract management, renewals, transfer payments between federal government and provinces stays the same

The detailed structural changes that would need to occur at the level of each province and territory are out of the scope of this engagement. However, it is recognized that in this option, additional detail would need to be collected regarding how various other drug program branch functions would be impacted (e.g., contract renewals, rebates).

Process for net new autonomous entity

The following process diagram depicts the suggested process to be followed for the Net New Autonomous Entity.

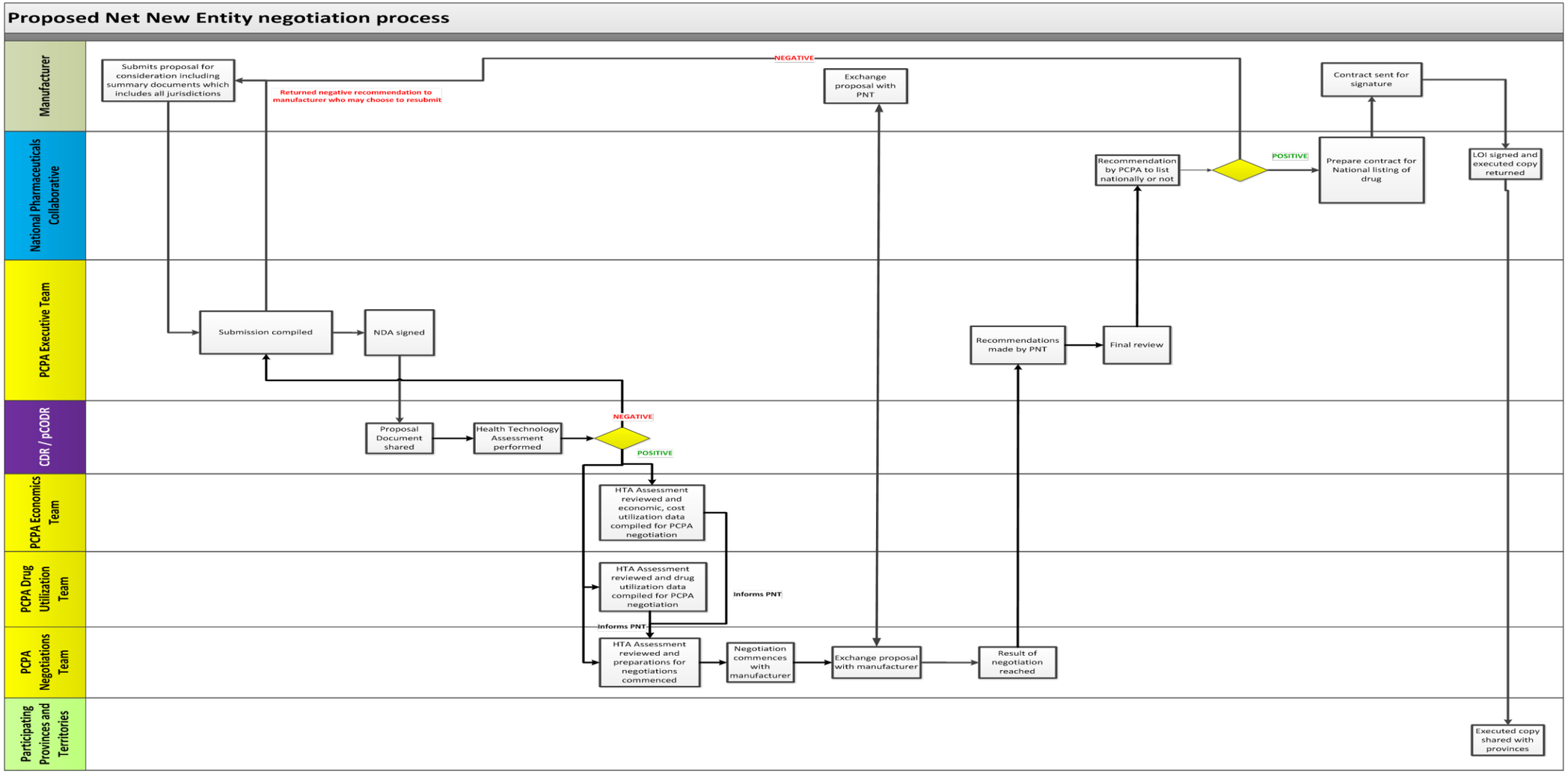


Figure 19: Suggested process for net new autonomous structure governance model. Note that (1) P/T will still need to implement the decisions taken by the net new autonomous entity and (2) a negative" CDEC/pERC recommendation should also go to the PCPA executive team for a decision as well

8.0 Results of Targeted survey across Government stakeholders

We conducted a targeted survey with the participating provincial/territorial public drug programs to:

A. Determine best estimate of the resources required to:

- LEAD and/or
- PARTICIPATE in pan-Canadian files

In some jurisdictions, clinical, business and support functions were not differentiated and were performed by the same staff and team e.g. PEI. Hence the overall results of the survey are high level estimates of the resource effort required to conduct various clinical, business and support functions.

An average of 0.85 FTE for clinical functions, 0.6 FTE for business and 0.6 FTE for support functions for a total of approximately 2 FTE's was identified through the surveys. These were used as inputs for approximate resource estimates when recommending the two governance model options.

Recommendation:

Current resourcing in terms of number of FTE and role is inconsistent and overlapping across clinical, business and support functions. However based on a collective average, 2 FTEs would appear to be an appropriate estimate for performing the various activities.

The survey template is included in Appendix 4.

B. Collect the timeline data for the 19 PCPA drugs negotiated at the time of the survey by the various provinces.

The timeline data for 19 PCPA drugs was amalgamated, including when each province/territory listed the drug following the signing of a LOI by the participating provinces/territory and a manufacturer. The graph in Figure 21 depicts the time each of the 12 drugs for which complete timeline data was available for the following

- Time from obtaining NOC to CDR and/or pCODR
- Time from completion of CDR and/or pCODR recommendations to file engagement by the PCPA
- Time from the PCPA process commencing to a signed LOI

The chart in Figure 22 shows the complete data for the 19 PCPA negotiated drugs

Key Takeaway:

Data from the graph provides metrics on the timelines related to multiple processes, not simply the PCPA process. In addition, there are multiple reasons (such as the type of molecule, quality/strength of the data and CDR/pCODR recommendations, time for manufacturers to respond to PCPA due to global approvals, complexity of the disease being treated, availability of alternatives, etc.) for varying timeframes within the PCPA, many of which are outside of the control of the governments negotiating. However, there is consensus amongst stakeholders, supported by the data, that there may be process inefficiencies that can be improved with further standardization and formalization of the PCPA process. The value of this data is that this still provides an estimate for how long it took drugs in a particular class or a type for a specific condition to to through the process to understand the reasons for the varying timelines across the continuum of the review and approval process. These are the types of metrics that we recommend should be reported publicly going forward.

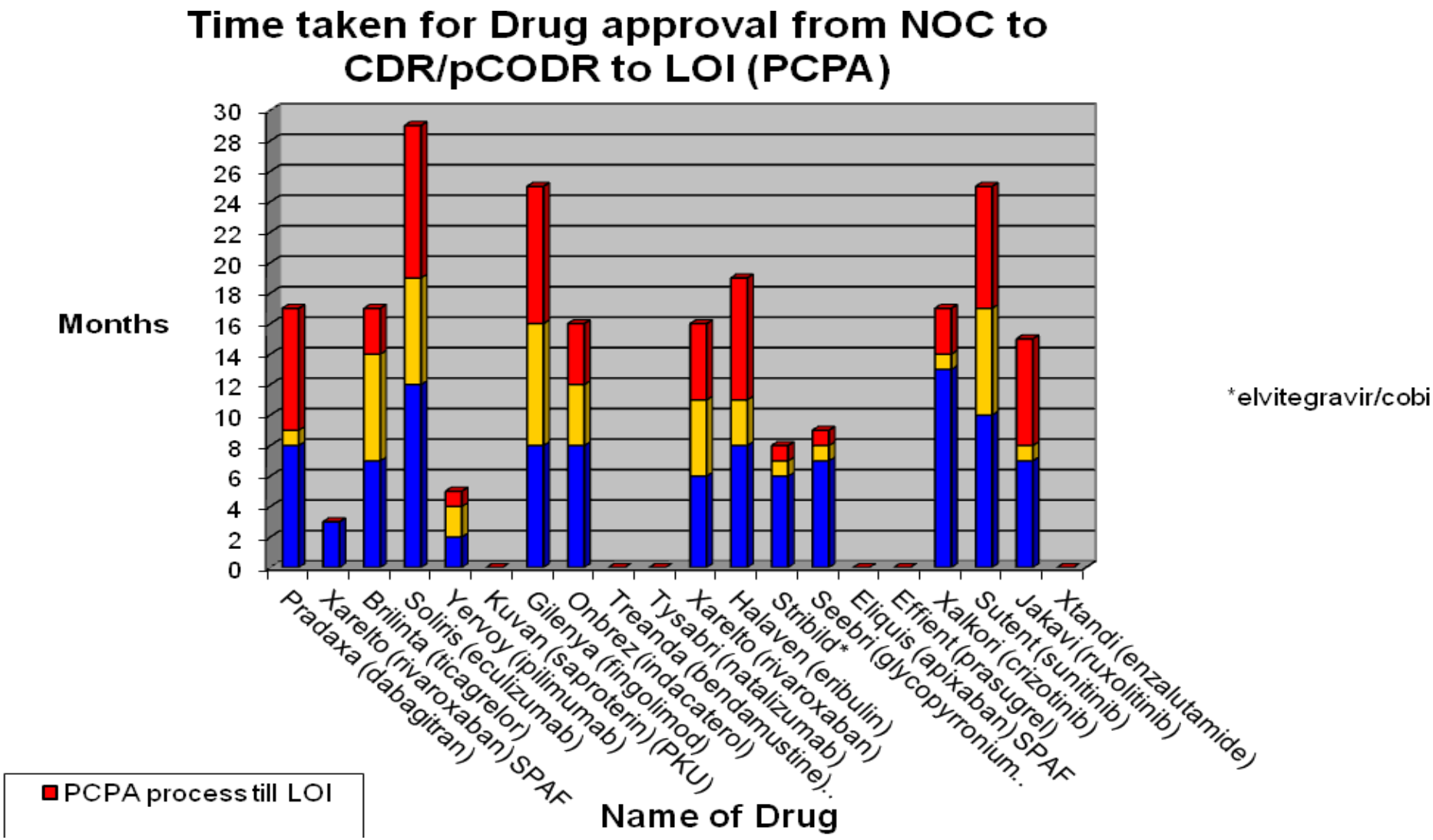


Figure 20: Time taken for PCPA negotiated drugs from NOC to CDR and/or pCODR to LOI (from survey data where complete data was available. Note Kuvan, Treanda, Tysabri, Eliquis, Effient and Xtandi are still under review

Drugs	Lead Jurisdiction	NOC Date	CDR /pCODR Date	File Engagement Date (Est.)	LOI Signed Date	Drug Listing Date										Time taken to complete each of the below steps (approximate time frames)			
						BC	AB (only cancer drugs)	YK	SK (n/a)	MB	ON	NB	NS	PEI (n/a)	NFLD	NOC to CDR/pCODR	CDR/pCODR to file engagement	PCPA process till LOI	Total time: NOC to CDR/pCODR to LOI
Pradaxa (dabagitran) SPAF *	BC	26-Oct-10	22-Jun-11	July 2011	22-Mar-12	[redacted]										8 months	1 month	8 months	17 months
Xarelto (rivaroxaban) SPAF	BC	16-Jan-12	19-Apr-12	Feb-12	19-Jun-12											3 months	n/a	4 months	n/a
Brilinta (ticagrelor) (ACS)	BC	30-May-11	16-Dec-11	June 2012	12-Sep-12											7 months	7 months	3 months	17 months
Soliris (eculizumab) (PNH)	ON	28-Jan-09	19-Feb-10	Sep-10	22-Jul-11											12 months	7 months	10 months	29 months
Yervoy (ipilimumab) (melanoma)	ON	01-Feb-12	19-Apr-12	Jun-12	28-Aug-12											2 months	2 months	1 month	5 months
Kuvan (saproterin) (PKU)	BC	30-Apr-10	26-Jan-11	May 2012												9 months	5 months	n/a	n/a
Gilenya (fingolimod)	ON	09-Mar-11	16-Nov-11	Jul-12	05-Mar-13											8 months	8 months	9 months	25 months
Onbrez (indacaterol)	ON	06-Dec-11	16-Aug-12	Dec-12	12-Apr-13											8 months	4 months	4 months	16 months
Treanda (bendamustine) for NHL/MCL & CLL	NS				25-Apr-13											n/a	n/a	n/a	n/a
Tysabri (natalizumab)	ON			Dec-13	09-May-13											n/a	n/a	5 months	n/a
Xarelto (rivaroxaban) for DVT treatment **	BC	15-Feb-12	16-Aug-12	Jan 2013	06-May-13											6 months	5 months	5 months	16 months
Halaven (eribulin)	MB Cancer	14-Dec-11	02-Aug-12	Nov-12	02-Jul-13											8 months	3 months	8 months	19 months
Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir)	ON	26-Nov-12	15-May-13	Jun-13	11-Jul-13											6 months	1 month	1 month	8 months
Seebri (glycopyrronium bromide)	SK	16-Oct-12	15-May-13	Jun-13	29-Jul-13											7 months	1 month	1 month	9 months
Eliquis (apixaban) SPAF	BC	05-Dec-12	20-Mar-13	Jan 2013	02-Aug-13											3 months	unclear	7 months	n/a
Effient (prasugrel)	ON			Oct-12	07-Aug-13											n/a	n/a	10 months	n/a
Xalkori (crizotinib)	AB Cancer	12-Apr-12	17-May-13	May-13	08-Aug-13											13 months	1 months	3 months	17 months
Sutent (sunitinib) for pNET	ON	05-Jul-11	03-May-12	Dec-12	14-Aug-13											10 months	7 months	8 months	25 months
Jakavi (ruxolitinib)	ON	19-Jun-12	14-Jan-13	Feb-13	03-Sep-13											7 months	1 month	7 months	15 months
Xtandi (enzalutamide)	BC Cancer	29-May-13			17-Sep-13											n/a	n/a	n/a	n/a

Notes:

Pradax file stalled between early Nov 2011 - early Dec 2011 due to negotiation impasse

Xarelto DVT - delay due to Request for Advice from CADTH (Oct 27, 2012)

Tysabri negotiation was based on revising criteria. This was initiated by the mfr and unrelated to new NOC or CDR recommendation (not driven by CDR submission)

Effient negotiation was a subgroup of P/Ts who were interested in reviewing in context of new safety data and given new listing of Brilinta (not driven by CDR submission)

^ Listed for DVT Proph prior to pan-Can negotiation

^^ Projected

^^^ Not listed but re-imbursed.

Figure 21: Amalgamated survey data depicting timelines for Drug approvals and listings

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9.0 Recommendations

The following are the key proposed recommendations. These have been organized into

1. General recommendations that are being made irrespective of choice of governance model and

2. Specific Governance model recommendations and;

3. PCPA process recommendations.

These recommendations are being made based on stakeholder interviews, a detailed environmental scan and the results of the targeted survey results.

1) General Recommendations

The following general recommendations were made which apply regardless of the governance model adopted.

Recommendations	Rationale
Consider changing name of the Pan Canadian Pricing Alliance to the "Pan Canadian Pharmaceutical Alliance".	The term "Pricing" takes the focus away from other PCPA goals and creates the perception that the PCPA is only about securing the lowest possible price. It is understood that a change in name of PCPA would require various approvals
Enhanced communications: a)Website which provides standard templates, PCPA information, status of negotiations, processes, timelines, past drug negotiations statistics, benchmarks b) Annual report providing data regarding drug approvals and rejections on products which PCPA 'approved' to proceed with against set benchmarks. c) Playbook depicting timelines, forms, templates, and a sample of a submission to PCPA	Overall communications can be significantly improved given this was raised by several stakeholders. Need for improved transparency, etc.

Recommendations	Rationale
As much standardization of templates as possible, e.g., PLA, LOI incorporating the following two points: - Include flexibility to adjust LOI to reflect different downstream contracting practises - Identify examples of complicating issues which manufacturers should flag early in discussions. e.g. if co-development deals or distributors are involved and will need to be privy to provincial information, this will require special drafting and is not a last minute change for provinces	Higher standard of submission would help in evaluation and follow up Too much variability and duplication for what should be a common set of standardized templates. It is recognized that definitions and legislation can vary by province. Note: A single PLA for all jurisdictions was felt to be difficult. As provinces move to more firm templates it may be possible to pre-provide substantive terms on the basis that provinces do not deviate from language.
A common Non-Disclosure Agreement (NDA) that would cover jurisdictions and manufacturer.	Avoids a new NDA per manufacturer per province and duplication of effort.

Recommendations	Rationale
Consider a Tier structure of classification similar to that developed in Australia (see below) based on various criteria which will allow for segmentation of drugs into categories which can be supported by adequate rigour of process. This may be relevant for orphan drugs and 'older drugs' that are not coming straight from CDR but may be of interest to negotiate on a broad scale. Tiered structure in Australia: Tier 1: Applications for the listing of new drugs where the claim is one of cost minimisation (or 'at least no worse than' according to the PBAC guidelines), where pricing is based on a nominated dosage relativity, and where the prices to pharmacist proposed are in accord with the PBPA methods of price calculations. Tier 2: Submissions for new drug listing where the claim is one of acceptable incremental cost effectiveness (or new drug listings where the claim is one of cost minimisation but where pricing is not in accord with the PBPA criteria) and applications for changes to listings, both cost minimisation and cost effectiveness, and where the estimated net cost to the PBS is less than $20 million per annum in any of the first four years of listing. Tier 3: Any submission where the estimated net cost to the PBS is estimated to be $20 million or more in any of the first four years of listing.	Different types of drugs may need more or less time, evidence, and evaluation and thus can be segmented into appropriate categories.

Recommendations	Rationale
Assign a lead province early in the process, preferably immediately after HTA. For larger dollar value submissions, consider a pre-negotiation briefing led by PCPA to review process, timelines, expectations – stakeholders to include PCPA lead province, HTA bodies, manufacturers and patient group representative from disease for which drug is being considered.	Allows greater flexibility for organizing the negotiation sooner in the process. Provides clarity and expectations on process, timelines and an opportunity to engage in initial dialogue.
Development and use of metrics around timelines leading to the negotiation for a particular drug. This includes providing a definition of metrics used, how these metrics will be reported (e.g. quarterly, yearly) and reporting in aggregates (e.g. metrics around timelines to approval for therapeutic class of drugs). Consider some joint development of metrics with manufacturers that will be used to evaluate the negotiation process.	An understanding of the areas of the process that work well or not so well (i.e. delays/timeliness) will support (provide evidence for) the recommended options. May also assist with setting standards/targets. This will be important for external stakeholders for reporting and transparency.
Need to complete a review and analysis of the performance and outcomes of the drugs that have been completed through the existing PCPA negotiation process. See Figures 21, 22 E.g. time from HTA recommendation to initiation of PCPA process, time from verbal agreement to signed LOI	An understanding of the areas of the process that work well or not so well (i.e., delays and timeliness) will support (provide evidence for) the recommended options. May also assist with setting standards and targets. This will be important for stakeholders for reporting and transparency.

2) **Specific Governance model recommendation:**

Overall Governance recommendations:

- Based on IBM's analysis, the immediate best governance model to consider would be **OPTION 2 – SECRETARIAT MODEL**. Reasons for recommending this model are:
- This model will address the key pain points identified by stakeholders
- This model can be achieved relatively quickly without significant expenditures
- The model would be relevant for both brand and generic side of the drug business
- The model can still provide a broader view and a starting point that has the flexibility to evolve slowly across the continuum of options into Option 2 – Net New Autonomous

Entity which requires significant legislative and structural change

- Provides lead province with additional focus with various public relations, administrative, coordinating and marketing, project management and communications tasks being done by the Secretariat

3) **PCPA process** recommendations

A proposed future state for the net new autonomous entity option was developed using the below principles. In addition, we also developed the specific areas for process improvement based on the recommended Secretariat option. These included

- Standardization: e.g. templates such as the NDA across provinces
- Greater transparency of PCPA process e.g. Establishing of clear time estimates and benchmarks and targets for the PCPA process
- Integrated marketing, branding and multi channel communications
- Clear time lines for exchange of proposals between manufacturer and lead province

APPENDIX 1: List of stakeholders

Government – Internal
Ontario Ministry of Health and Long Term Care Drug Programs Branch
BC Ministry of Health
Alberta Health
Saskatchewan Ministry of Health
Manitoba Provincial Policy and Programs
New Brunswick Dept of Health
Nova Scotia Dept Health and Wellness
Health PEI
Newfoundland & Labrador Dept of Health and Community Services
Yukon Health Services Branch
Government Agencies – External
CADTH
PCODR
Cancer Agencies – External
BC Cancer Agency
Alberta Health Services
CancerCare Manitoba
Cancer Care Nova Scotia
IBM Team
Strategy and Transformation, Healthcare Practice IBM Global Business Services
Industry - External Interviews
Rx&D
BioteCanada
Novartis
Bristol Myers Squibb
Gilead
Lundbeck Pharmaceuticals
Bayer, Inc., Rexdale
Vertex Pharmaceuticals Canada Inc.
Cross-Sector Alliance
CGPA, CACDS, CAPDM, CPhA
Patient Groups – External

Best Medicines Coalition
Canadian Cancer Action Network
Canadian Treatment Action Council
Carcinoid NeuroEndocrine Tumour Society (CNETS) Canada
Consumer Advocare Network
Health Charities Coalition of Canada
Written Responses
Valeant Canada
Genzyme
Amgen Canada
Novartis
Hoffmann-La Roche Limited
Servier Canada
Canadian Cancer Survivor Network's
Janssen Pharmaceutical Companies of Johnson and Johnson
AstraZeneca Canada
Sanofi
Merck Canada Inc.
AbbVie
Takeda Canada, Inc.
GlaxoSmithKline (Ottawa)
Novo Nordisk
Ferring Pharmaceuticals
Forest Laboraties Canada Inc
InterMune
BioteCanada
CNETS Canada

APPENDIX 2: Details on feedback from stakeholder interviews

Details on feedback from stakeholder interviews

1. General feedback from Government stakeholders:

- Secondary review processes are highly valued in certain provinces and are deemed essential to their provincial and local mandates
- Budget impact analysis and cost effectiveness analysis performed by the PCPA and in some cases provinces is key
- Overall high degree of alignment between national review bodies and the PCPA
- Expanded role for generics represents an opportunity for the PCPA notwithstanding legislative differences (price compared to brand varies from 18 to 35%)
- PLA, LOI templates across provinces vary but could use some standardization, especially LOI
- Role of the PCPA needs to be clearly articulated to avoid confusion regarding what the PCPA can and cannot do
- Role, expertise and leadership of drug program branches has been a critical success factor for the PCPA
- Provincial autonomy is important when it comes to drug listing decisions and secondary review processes
- Varying quality received from manufacturers can lead to significantly different resource requirements for review

2. Feedback from Government stakeholders: Experience with the PCPA

- Overall experience among the PCPA members has been collaborative and positive
- The pCODR model has been praised as a model by cancer agencies and drug manufacturers – strongly recommend emulating pCODR principles where relevant, e.g., transparency, clear role, attributes of value
- The PCPA needs to exert caution about decisions related to expanding indications that a drug has been recommended for by a national review body, a “do Not List” recommendation from CDR will be confirmed by PCPA. If such a recommendation is based on clinical, it should be a hard stop.
- Provinces have a mixed view on manufacturers providing various types of “value demonstrating initiatives” versus providing a straight discount. According to government stakeholders, manufacturers often overlook and underestimate the administrative burden of such value demonstrating initiatives on provinces and territories.

3. Feedback from Government stakeholders: The PCPA process

- Provinces recognized that the PCPA process is evolving
- Process has largely developed on an *ad hoc* basis
- While process was felt to work well, as the volume and complexity of the PCPA submissions increases, more formalizing will be required. For example:
  - Needs clear criteria for fast tracking and prioritization of files

  - Need clear metrics around the PCPA process, e.g., time for approval
- The PCPA process needs to be enabled by dedicated resources within each participating jurisdiction. 1 to 2 FTEs consistently identified as dedicated resource need.
- Process needs to define steps if the PCPA negotiation is a "no" including the formal reconsideration process

4. Feedback from Government stakeholders: Governance

- Provinces favour a centralized governance model with some appetite for a federated model to account for provincial autonomy
- Provinces strongly favour a separate entity versus an existing government body. Legal opinion deemed key if the conclusion is to create a separate entity. Concerns around separate entity include funding, sustainability, duplication
  - Some consideration should be given to a private entity versus solely considering a public entity
- Role of the PCPA is key to articulate. Most provinces felt the role to be that of a "negotiations" body but coupled with a deep expertise around drug recommendations, i.e., consider advisory members from national review bodies on PCPA and vice versa
- Clearer communication of mandate, goals and role of the PCPA needed

B. Manufacturers – These included pharmaceutical companies, biotechnology companies, and industry associations like Rx&D, BIOTECanada, Cross Sector Alliance members, including CGPA, CACDS, CAPDM, and CPhA. A complete list of stakeholders interviewed is provided in Appendix A.

1. General feedback from the manufacturers:

- **Consider adopting a broader definition of "value for money"**
  - Consider <u>overall</u> economic impact to health research capacity investments, expanded clinical trial investments in therapeutic areas. Such value demonstrating initiatives should be considered with partners like the Ministries of Health to address health system challenges, e.g., sustainable and scalable interventions to address complex chronic diseases, patient registries, and health research commitments.
  - Improving quality and value for innovation in the delivery of healthcare to Canadians
  - The full value of innovative drugs should be recognized as it relates to patient outcomes, improving quality of life and productivity as well the brand industry's contribution to R&D and the future development of innovative medications
- **PCPA as a driver of innovation:**
  - A PCPA goal should be to bring more innovative medicines to Canadians in a faster more efficient way that allows the pharmaceutical industry to be a part of providing solutions that ensure health system sustainability
  - The PCPA mandate should be considered in the context of enabling the commercialization of research, the clusters and small or medium-sized enterprises (SME) biotech entrepreneurs that is highly dependent on partnerships and investments from large Canadian and multi-national biotech companies. The PCPA initiative must take into account the interdependency within this ecosystem and avoid diminishing the investment and operating climate for these crucial development partners.
  - Market access and reimbursement play a critical role in determining where global

biotech companies invest. Creating a PCPA process that does not factor this into its development will have significant impact on biotech SMEs across the country.

- **pCODR as a model organization:** Experience with pCODR has been collaborative and the culture of pCODR is one that works with industry, clinicians and patient groups to find, when possible, a "place in therapy" for innovative oncology medications. Consider leveraging some of the pCODR principles for the PCPA

2. **Feedback from Manufacturers: Experience with the PCPA**

- Overall industry experience is negative due to:
  - Lack of consistency with the PCPA process and inconsistencies with dealing with different leads – industry does not feel that a positive experience with one product will replicate with others
  - Lack of transparency regarding (a) timelines, (b) specific criteria on which a product is evaluated, and (c) the PCPA process
  - Lack of timeliness of decisions with certain products
  - A sense that this is not a negotiation as the ultimate "negotiator" is still the province which decides whether to list or not
  - The PCPA is perceived as another step and/or layer in a myriad of steps that manufacturers have to go through
  - No articulated clear feedback on what they are trying to work to, or why they are getting certain responses.

- Time to list after the LOI has been unclear and inconsistent
- If all provinces act in unity then there is value, having Federal bodies involved as well would add some value – however, having some provinces back out or take their own time to decide whether to list is concerning
- Provincial implementation after LOI has been inconsistent
- Process presupposes that every single drug that comes to market merits a discount. PCPA may want to consider deferring some products directly to P/T for decisions if it is cost effective and no other agreements are in place with comparator products
- Commoditizing innovation, or treating innovators as commodity service providers – a threat to innovation in general and R&D
- Consistency in pricing is a challenge - epidemiology and priority by each province result in different value
- Nothing explicitly stated or done in the PCPA goals about improving quality and improving health outcomes
- Achieving province specific fair pricing instead of just pricing
- Rationale when the province refuses the offer is unclear and not made transparent
- Value added agreements are very hard to do on a Pan-Canadian space as different provinces have different situations, and there are no resources to support these.
- When you aggregate buying power it will change industry as it creates an all or nothing environment

3. **Feedback from Manufacturers: The PCPA process – divided into (a) Pre-PCPA Process, (b) PCPA process, and (c) PCPA timelines**

(a) PRE-PCPA NEGOTIATIONS PROCESS: Manufacturers

- Be transparent before negotiations: Who is the provincial lead, who are the participating jurisdictions, target PCPA dates on which a submitted drug will be on agendas, status within PCPA process and target LOI dates
- Manufacturer should have the ability to engage with a lead province during CDR process. It should be noted that until a CDR decision comes out, many jurisdictions will be unable to commit to participating.
- The process should begin with a face-to-face meeting between the manufacturer and the PCPA lead to ensure that the best information from both sides is brought to bear when establishing a fair value proposition.
- Standardize contract templates that every participating province will use with every product
  - A master NDA and then have amendments
- Inclusion criteria of how PCPA decides which products will be selected to go through PCPA
- LOI should clearly define listing criteria and these should be consistently applied.
- Dialogue between manufacturers and provinces regarding whether a product should be negotiated via PCPA or directly with a province
- Very clearly need to outline the terms, conditions and implications of the negotiations at the outset of negotiations
- Consider nominating one province (recommend Ontario) to be the lead for all rare disease products given Ontario has a framework for assessing such drugs and it requires significant expertise
- It is essential that product expertise and benefit be gathered by the PCPA <u>in parallel</u> with the HTA review in order to facilitate timely access to new innovations
- Eliminate duplication, e.g., post-CDR recommendation, additional provincial review; post LOI, manufacturers still have to go to individual provinces which can deviate from LOI
  - On the dimension of improving patient access to innovative medicines, a review of IMS Brogan data published in *CMAJ Journal* found that there was actually a decline in the proportion of new drugs listed after the introduction of CDR. In addition, not one provincial or territorial government has decided to eliminate their drug review/health technology assessment process since the inception of CDR.

(b) The PCPA PROCESS

- For CDR/pCODR "yes list" recommendation (effectively a gold star from CDR and/or pCODR), eliminate need for negotiations via the PCPA –ability to fast track such products
- Determine how the PCPA will handle "CDR or pCODR No recommendations" – products in this category should go through the PCPA. Based on listing recommendations, outright "do not list" (as opposed to "do not list at submitted price" or "list with conditions and/or criteria") is based on clinical merit – or lack thereof.
- If there is a PCPA impasse or reject, manufacturers should have the option to negotiate directly with provinces. This will eliminate need for appeal. Avoid an "all or none" process. Currently, PCPA negotiations can lead to a united "No" or a deferring of the drug in question to a province.

- Consider EAP for life saving, end of life, rare and first in class treatments with understanding that industry members will retroactively rebate to provinces post-LOI
- Once negotiations are concluded, and the LOI is signed, the terms should be implemented across jurisdictions consistently, with no additional concessions required in individual jurisdictions unless they have been negotiated as part of the PCPA process. The only exception to this should be when a province/territory wishes to negotiate for broader criteria than negotiated as part of the PCPA.
- Better alignment between CDR, pCODR and the PCPA needed to avoid redundancy and duplication. United positioning by PCPA helps in upholding CDR/ pCODR recommendations.
- If a jurisdiction believes it is appropriate to proceed on its own in order to best meet its priorities, it should be free to do so. A "good" PCPA framework should not prevent a P/T from benefitting from opportunities or meeting obligations to achieve its local health, investment or innovation priorities
- Governance and process should accommodate for interim access to life saving medications while negotiations are being conducted
- The PCPA should not be used to unilaterally re-open existing listings

(c) **PROCESS TIMELINES**

- Commitment needed by jurisdictions and manufacturers to provide access to patients within a reasonable time (e.g., formal listing between 6 to 12 months post-CDR or -pCODR recommendation)
- Process should include a mechanism for prompt listing once a LOI is signed
  - The lack of timelines around when a province will list post-LOI is unfair as the final price at the LOI is a function of volume. The lack of an obligation to list post-LOI creates a one-sided contracting process
  - Value of discounts should be correlated to the number of beneficiaries covered within 6 to 12 months post CDR or pCODR recommendation
- Need transparency of when products enter the PCPA process, when a LOI is signed and how many provinces are committed to list
- Implementation of listings should be seamless and done within three months of a finalized LOI by all jurisdictions that have participated.
- Need for clear stating of response timelines at every step of the PCPA process
- In the interests of timely access for patients, negotiations should be concluded within three months.
- The PCPA process should include structured and formalized opportunity for patient input

4. Feedback from Manufacturers: Governance

- Need to define the role of the PCPA before we create a governance and formalization.
  - **Role Clarity:** Clearly delineate the roles of the national HTA bodies (CDR, pCODR) versus the PCPA versus the provincial bodies (CED, A/CDR, etc.) is necessary.
- The PCPA negotiation should remain with provinces with lead jurisdiction identified at beginning of CDR review
  - Incorporation of the PCPA into an existing agency, or the creation of a new stand-

alone agency would impede the flexibility individual provincial/territorial decision makers need to ensure decisions are taken based on the local health interest of the patients within their jurisdiction.
  - The pCODR is a good model of a new entity
- Create broad metrics to measure the success of the PCPA in ways that extend to beyond "savings captured" and which are published annually
  - e.g., how fast a province listed drug post-LOI, How has access improved, how quickly were uniform and standard templates created – co-create with industry
- The continued lack of a formal engagement mechanism with industry and Rx&D can be best achieved through a "seat at the table" within the PCPA governance
- The PCPA needs to be adequately staffed to ensure timely reviews and improved access
- Confidentiality of the PLA and the LOI terms is of very high importance - consider an NDA
- Distinguish the PCPA as a process from the PCPA as an organization
- Communications principles need to support the PCPA process and governance structure – there has been virtually no communication directly from the PCPA
- Governance and process should accommodate for interim access to life saving medications while negotiations are being conducted

C. Patient Groups – Nineteen patient group representatives attended a pan-Canadian web conference and in-person session. The patient groups represented a variety of health conditions and chronic diseases.

Overall feedback:

- Physician input is invaluable – consider their perspective. Based on this recommendation, a request for an interview with the Canadian Medical Association was made. However the Canadian Medical Association declined the interview on the basis of not being able to provide a single voice for all physicians across Canada regarding PCPA
- Patient group perspective is key to the PCPA despite other avenues such as CDR and pCODR to provide input
  - Patients can give real time stories
- Every province should list a drug if there is a PCPA deal
- Timelines around negotiations need to be clear
- Use Special Access Program to get drugs to people who need them (charge the PMPRB prices)
- Worry about consecutive processes leading up to the listing of a drug - consider concurrent processes where possible
- Communications via a website that tells us when negotiations start; live person you can call and get information from, information should be available across multiple channels including tablets, smart phones
- Patient submissions should be considered
- Develop an appeal process if drug is turned down
- Price should not be the limiting factor:
  - Do not limit price negotiation to particular drug or formulation – look holistically at impact of drug on health system
- Consider other aspects of value for patients – e.g., delivery systems like infusions

- When are you <u>really</u> saving – other savings to the system as a result, e.g., less monitoring, less doctor visits
- With some drugs you can't save money
- Ethical perspective

- Administrative costs for the PCPA should not wipe out savings
- Guaranteed supply – to avoid drug shortages
  - Preference to Canadian suppliers
- Be mindful to where Canadian regulatory framework is headed
  - e.g., rare disorders, invite all stakeholders to come to the table even at time of clinical trial design
  - Keep issue of ongoing monitoring of patients in mind
- Liaise with genetic testing companies
- Formal monitoring evaluation made transparent

APPENDIX 3: Environmental Scan Details

Environmental scan details on health systems and drugs related information:

The following attached files include:

- **A detailed environmental scan report**

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- **A summary of international countries for comparison with a process similar to CDR**

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IBM_ADMIN\Documer

- **A comparison of drug purchasing across countries**

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IBM_ADMIN\Documer

Canada

Description of CDEC Recommendations[10]

Recommendation Options Description and Considerations

List

A Drug[a] demonstrates comparable or added clinical benefit and acceptable cost/cost-effectiveness relative to one or more appropriate comparators.[b]

List with clinical criteria and/or conditions

Examples that typically fit this listing category include:

- A Drug[a] demonstrates comparable or added clinical benefit and acceptable cost/cost-effectiveness relative to one or more appropriate comparators in a subgroup of patients within the approved indication. In such cases, the subgroup is specified through "clinical criteria."
- A Drug[a] demonstrates added clinical benefit, but the cost/cost effectiveness relative to one or more appropriate comparatorsb is unacceptable. In such cases, a condition may include a reduced price.
- A Drug[a] demonstrates comparable clinical benefit and acceptable cost/cost-effectiveness relative to one or more appropriate comparators. In such cases, a condition may include that the Druga be listed in a similar manner to one or more appropriate comparators. Examples of clinical criteria include, but are not limited to:
    - characteristics that identify a patient subgroup, for example:
    - co morbidity status
    - inadequate response to appropriate comparator(s)
    - intolerance to appropriate comparator(s)
    - inability to use appropriate comparator(s).
    - characteristics of the care setting (e.g., prescribed by or under the care of an experienced clinical team)
    - starting and stopping rules (e.g., response to treatment).
    - Examples of conditions include, but are not limited to:
        - pricing considerations
        - reimbursement limits (e.g., number of doses supported by clinical and cost-effectiveness evidence)

[10] *http://www.cadth.ca/en/products/cdr/cdr-overview*

- current formulary listing status of one or more appropriate comparators (i.e., if a Drug under review is similar to [a] listed appropriate comparator[s], the condition may be to list the Drug in a similar manner to the listed comparator[s]).

Note:

The use of "and/or" in the "List with clinical criteria **and/or** conditions" allows for three subcategories of this listing category:

- clinical criteria and conditions
- clinical criteria only
- conditions only.

Do not list at the submitted price

An example that typically fits this listing category includes:

- A Drug[a] demonstrates comparable clinical benefit, but the cost/cost-effectiveness relative to one or more appropriate comparators[b] is unacceptable.

Note: The "Of Note" section in the Recommendation may provide additional context around price, comparator(s), patient subgroups to whom the Drug might be restricted, and other relevant considerations.

Do not list

- A Drug does not demonstrate comparable clinical benefit relative to one or more appropriate comparators.

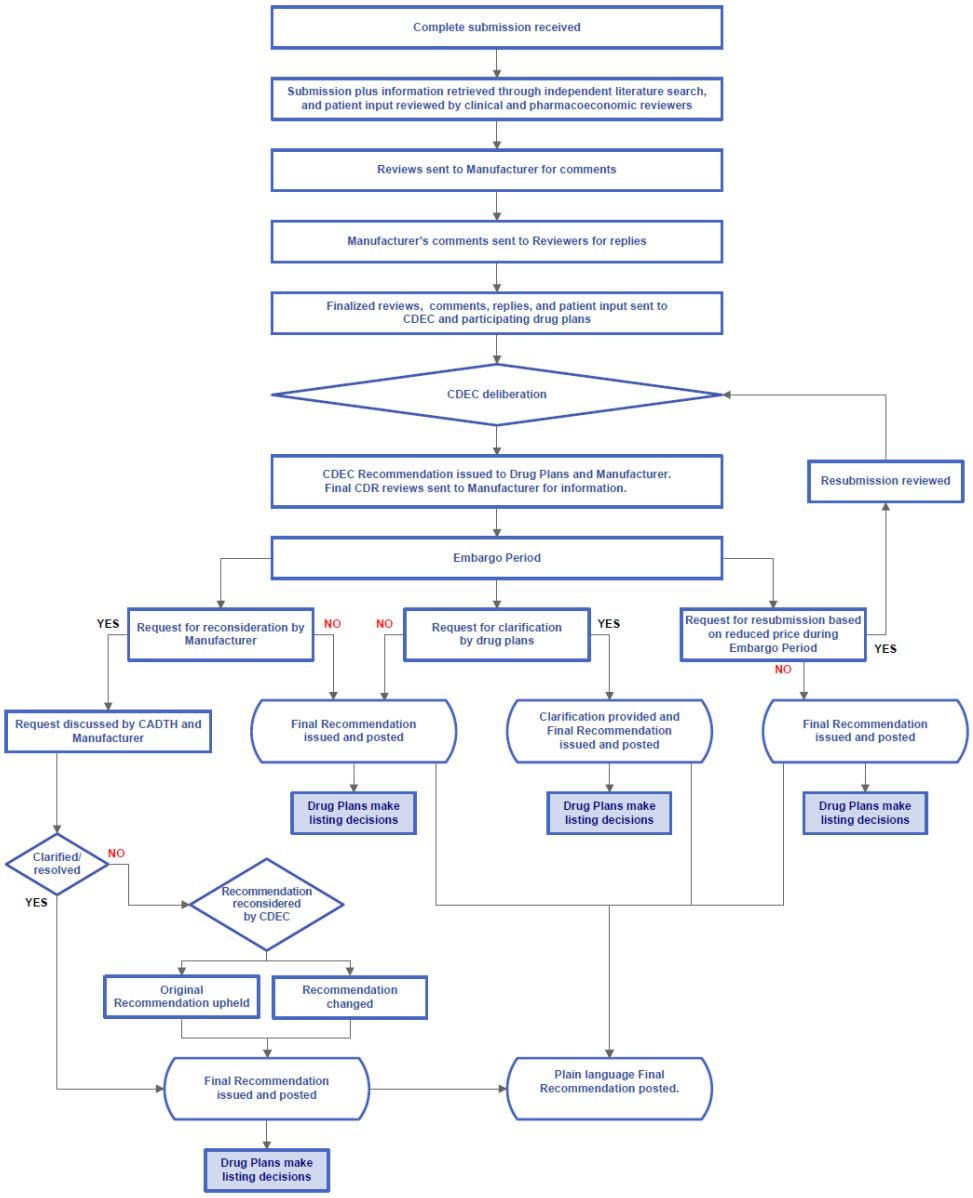
[a] Refers to a Drug under review.

[b] An appropriate comparator is typically a Drug listed by one or more participating Drug Plans for the indication under review.

[c] Although not listed as conditions, evidence gaps and the need for evidence development may be highlighted in the CDEC

Recommendation document as appropriate.

CDR Process[11]



CDR = Common Drug Review; CDEC = Canadian Drug Expert Committee

Figure 22: CDR process

[11] *http://www.cadth.ca/en/products/cdr/cdr-overview*

Generic Drug Pricing across Canada[12]

CANADIAN PHARMACISTS ASSOCIATION | ASSOCIATION DES PHARMACIENS DU CANADA

Generic Drug Pricing – Provincial Policies

February 2013

JURISDICTION*	% of BRAND	GENERIC DRUG REIMBURSEMENT DETAILS**
British Columbia	35%	• July 2010: – 45% of brand name price for new generics (effective July 28, 2010) and 50% for existing generics (effective October 15, 2010) – 40% for all generics (effective July 4, 2011) • April 2, 2012: 35% of brand • April 1, 2013: 25% of brand – Non-solid generics will remain at 35% of brand • April 1, 2014: 20% of brand – Non-solid generics will remain at 35% of brand
Alberta	35%	• October 2009: the price for new generic drugs added to the provincial formulary was reduced to 45% of the brand name price • April 2010: the price for existing generic drugs listed on the provincial formulary was reduced to 56% of the brand name price • July 1, 2012: 35% of brand name price for all generics
Saskatchewan	35%	• Existing generic drugs: – June 2011: lowered the price to 45% of the brand name price – April 2012: lowered to 35% • New generic drugs: – June 2011: 40% – April 2012: 35%
Manitoba		• Since July 2008, generic drug pricing has been subject to Utilization Management Agreements with the manufacturer which declare that the price of the generic is equal to that of other provinces
Ontario	25%	• July 2010: Generic drug price reduced to 25% of brand name price for Ontario Drug Benefit (ODB) public drug plan • For private plans, reduction in generic prices was phased in: – 50% of brand (July 2010) – 35% of brand (April 1, 2011) – 25% of brand (April 2012) • April 20, 2012: 20% of brand price on top 10 products proposed by government (details pending) • Elimination of Professional Allowances (PAs): – ODB plan: As of July 2010, all rebates (PAs) were eliminated (prior to this date, were set at 20%) – PAs for Private Plans to be phased out as follows: July 2010: 50%; April 2011: 35%;April 2012: 25%; April 2013: 0%
Quebec	25%	• Reduction in prices of generics on the provincial formulary to 25% of brand name price, phased in over 3 years: – November 2010: 37.5% – April 2011: 30% – April 2012: 25% • Professional Allowances: – April 2012: reduced from 20% to 16.5%
New Brunswick	35%	• Reductions in generic drug prices phased in: – June 11, 2012: 40% of brand name price – December 1, 2012: 35% of brand name price
Nova Scotia	35%	• Reductions in generic drug prices phased in: – July 1, 2011: 45% of brand name price – January 1, 2012: 40% of brand name price – July 1, 2012: 35% of brand name price
Prince Edward Island	35%	• July 2, 2012: Generic drug price reduced to 35% of brand name price (no phased in reductions)
Newfoundland and Labrador	45%	• Reductions in generic drug prices phased in: – April 1, 2012: 45% of brand name price – October 1, 2012: 40% of brand name price – April 1, 2013: 35% of brand name price

** The Council of the Federation announced, on January 18, 2013, that the price for six of the most common generic medications would be reduced to 18% of the brand name equivalent effective April 1, 2013 across all provinces and territories in Canada (excluding Quebec). The six generic drugs are: atorvastatin, ramipril, venlafaxine, amlodipine, omeprazole and rabeprazole.*

*** Some jurisdictions have processes in place for manufacturers to apply for an exemption for a particular drug to generic pricing policy in exceptional circumstances.*

[12] *Canadian Pharmacists Association, 2013*

Provincial Processes

Ontario Ministry of Health Drug Programs Branch

All negotiations are managed through the Senior Pharmacist. The Senior Pharmacist will liaise with other staff in the Division for input on clinical criteria, place in therapy, budget impact, etc. All final decisions are vetted through Senior Management (Director and Executive Officer). The Senior Pharmacist leads all work with legal and the manufacturers for development of listing agreements and implementation of funding. Much of the same work is completed whether we are participating or leading a file. We would not complete a separate value and options analysis as participants in a file, but would review and consider the analysis put together by the lead jurisdiction. This reduces the workload associated with participating. Implementation of funding requires the same level of resources whether participating or leading.

Alberta

Alberta Health Services – Cancer

As member of PCPA, Alberta Health determines who the lead jurisdiction is on a file. For the lead jurisdiction it means confirming who is participating in the file and confirming with vendor if non-disclosure required. One pCODR notification to implement formal negotiations can begin. The lead jurisdiction will now notify the vendor they are lead and who are all participating. A folder on SharePoint is created and the lead jurisdiction creates a review summary and posts various items. Each company offer is placed there for discussion at papa meeting. If you are not lead you must read the SharePoint file and be prepared to discuss at meeting. Once a deal is struck the lead jurisdiction draft the LOI and posts for comments for at least 2 days. Then it goes to vendor for signature and then the lead jurisdiction signs it off. At that point it is posted to SharePoint and all participating provinces notified. Once PCPA LOI is signed in Alberta we begin our Alberta agreement. We have a template which we populate from the LOI. I have Alberta Health Services legal review and then send to company for their review. If all goes well it is signed off and returned to me for our signatures. If not, after three emails we have Legal at AHS speak with Legal at the company to resolve as it is only the legal clauses at this point that remain a potential issue. Once it is returned signed to AHS I coordinate our signatures and mail original back to company while retaining one original in AHS. This now joins the package for recommending to Minister to list – that package has the pCODR recommendation, the PCPA pricing negotiation, and the cancer drug evaluation committee recommendation from our tumor programs.

Alberta Health

Alberta Health will consider new CDR recommendations prior to discussion with the PCPA group. Alberta Health makes a determination regarding Alberta's participation on a particular file, and if it is a file which they will volunteer to lead – mainly based on the CDR recommendation and any other PLAs that are currently in place in Alberta.

If Alberta decides to lead, a determination regarding which other jurisdictions are participating will be made. Following this, notification is made to the manufacturer regarding PCPA negotiations occur. Alberta requests a manufacturer to consider whether or not it will require an NDA, as not knowing this upfront may result in undue delay. Alberta will then request for the manufacturer to prepare a submission tailored to the participating provinces and present it to the lead jurisdiction. The lead jurisdiction is responsible for evaluating and summarizing the manufacturer's offer, presenting it to the PCPA group and relaying feedback back to the

manufacturer throughout negotiations. When Alberta is not leading they will review materials provided, consider Alberta specific issues and provide feedback in PCPA calls. Alberta may engage with its Expert Committee during discussions and implementation as appropriate.

Once an agreement of the financial terms is reached and Alberta receives support from the PCPA group, Alberta and manufacturer draft an LOI and post it for comment by the other jurisdictions. Usually at least 2 days are allowed for review. It is then signed by the manufacturer, the lead province and provided to all participating jurisdictions for implementation.

Upon receiving a fully executed LOI, Alberta Health will provide any criteria to Alberta Blue Cross to operationalize and then draft a PLA contract on the LOI using Alberta's standard PLA template. The PLA will be internally reviewed by finance and legal than provided to the manufacturer. Alberta Health will correspond with the manufacturer to finalize the contract. Once the contract is finalized and two copies are signed by the manufacturer, it will be packaged with approval documents and submitted to the Assistant Deputy Minister for approval and addition to the Alberta Drug Benefit List.

New Brunswick Dept of Health

The Director, Business Management Pharmaceutical Services participates in all PCPA calls. Sometimes the Executive Director also participates. The Director, Business Management Pharmaceutical Services reviews the posted material prior to the call for all pCODR and CDR drugs. They provide feedback when required until LOI is signed. Once the LOI is signed, the NB PLA template is sent to the manufacturer to complete with the information from the LOI. Once the draft PLA is received, they review with our lawyer. They have several calls/emails with manufacturer to discuss issues and concerns. Once the PLA is agreed upon, it is sent to the contract management staff person who prepares the PLA for signature. The PLA is then sent to the manufacturer by the Administrative Assistant. Once the PLA has been signed by both parties, the PLA data schedule is determined. Data is prepared by our Data Officer and then sent to a Financial Services Officer who issues the invoices and tracks the rebates.

Newfoundland & Labrador Dept of Health and Community Services

Newfoundland and Labrador will identify if they are interested in participating in negotiations for a drug. If so, they will track the progress of the process and provide input as required. Once LOI is signed, they provide the manufacturer with a standard PLA template to incorporate specific Listing Criteria and Financial Information and conduct legal review on the draft PLA. Once finalized, this PLA is signed off by Minister and product listed.

Yukon Health Services Branch

The Yukon Health Services Branch serves as a participant only. They have no access to expertise nor do they conduct a separate review of their own. The Yukon Health Services Branch relies heavily on CDRs and the Pan-Canadian process. They conduct a number of surveys across Canada to look at what the coverage and criteria are in other places to help inform their decisions. Their visiting specialists are mostly from B.C., with some from Alberta and this also influences them to move fairly closely with those jurisdictions when possible. The Yukon Health Services Branch is too small to negotiate on their own with pharmaceutical companies, and hence rely on

the PCPA negotiated deals.

Australia

Australia Overview

Australia's health care system is a partnership between the federal, state and territory governments. Through the Health and Ageing portfolio, the Australian Government works to provide a health care system to meet the health care and ageing needs of all Australians by providing national leadership, determining national policies and outcomes, improving programme management, research, regulation and working in partnership with state and territory governments, stakeholders and consumers.

The vision of the Department of Health and Ageing is of better health and active ageing for all Australians. The department's priorities include to:

- support the government in its reform of the health and hospital system;
- increase the focus of primary health care on people's needs and prevention/early intervention, to help reduce the incidence of chronic illness;
- improve the capacity of the health workforce through education and training and by expanding the roles of non-medical health professionals;
- improve the delivery of health care and early intervention measures for Indigenous Australians, to help close the gap in life expectancy rates between Indigenous and non-Indigenous Australians;
- support people living with mental illness, their families and their carers through integrated, effective and evidence-based mental health care;
- reconfigure health service delivery to achieve better health outcomes for people living in rural and remote communities; and support older Australians with a national health and ageing system responsive to their needs and improved governance arrangements and reforms.

Drug Coverage

- Australia achieves universal coverage through Medicare, a tax-funded public insurance program that covers most medical care, including physician and hospital services and prescription drugs.

- The PBS provides subsidised medications to patients.

- a new medicine may only be added to the PBS formulary on the recommendation of an expert advisory panel, the PBAC – for details on PBAC process see Appendix __

- Any drug that is recommended but which would cost more than $10 million AUD annually must be approved by the government.

- Most prescription medicines in Australia are made available to patients under the PBS, which acts both as an insurer, and as a sole purchaser negotiating prices for medicines with suppliers.

Key Participants in the PBAC process in Australia

Role of PBS – Pharmaceutical Benefits Scheme

- The PBS Schedule lists all of the medicines available to be dispensed to patients at a Government-subsidised price. The Schedule is part of the wider PBS managed by the Department of Health and administered by Department of Human Services.
- This schedule is now on-line and updated on a monthly basis. This on-line searchable version contains:
  - All of the drugs listed on the PBS
  - Information on the conditions of use for the prescribing of PBS medicines
  - Detailed consumer information for medicines that have been prescribed by your doctor or dentist;
  - What you can expect to pay for medicines.
  - The PBS has been in existence since 1948 and is governed by the National Health Act 1953 (Commonwealth).

Role of PBAC

- The PBAC is an independent statutory body established under the National Health Act 1953 to make recommendations and give advice to the Minister about which drugs and medicinal preparations should be subsidised on the PBS. It considers submissions in this context. These submissions are of two types:
  1. to seek listing of a medicine on the Pharmaceutical Benefits Scheme (PBS); or
  2. to change the circumstances through which a medicine is already listed.
  3. Each submission results in one of three outcomes.

1. The PBAC can decide to recommend that:

- the medicine be listed on the PBS; or
- the circumstances through which a medicine is already listed be changed.
- Each recommendation is made to Government. There are other processes that need to be completed before the Government takes a final decision to implement any PBAC recommendation.

2. The PBAC can decide not to recommend that:

- the medicine be listed on the PBS; or
- the circumstances through which a medicine is already listed be changed.
- The government cannot list a medicine on the PBS without a PBAC recommendation to do so. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine and is subject to review whenever a new submission is lodged.

3. The PBAC can defer a decision pending the provision of specific additional information that would be relevant and important to its decision.

- 'PBAC recommendations are in accordance with the indications approved by the Therapeutic Goods Administration, but may not include all such indications.'
- The PBAC considers the medical effectiveness and cost-effectiveness of a proposed benefit compared to alternative therapies. The PBAC recommends maximum quantities and repeats, and may also recommend restrictions for medicines. When recommending listings, the PBAC provides advice to the PBPA regarding comparison of alternatives with the medicine's cost effectiveness.

- The PBAC has three cycles per year, each lasting approximately 17 weeks.
- The PBAC consists of medical experts who meet several times a year and is not a permanent unit in the Department of Health. Because of its structure, the committee is best contacted by writing.

Role of DUSC

- The DUSC of the PBAC assesses estimates on projected usage and financial cost for medicines.
- It also collects and analyses data on actual use (including in comparison with different countries), and provides advice to PBAC.

Role of ESC

- The ESC of the PBAC assesses clinical and economic evaluations of medicines submitted to the PBAC for listing, and advises PBAC on the technical aspects of these evaluations.

Role of PBPA

- PBPA is an independent body appointed by the Australian Government.
- Members include representatives from industry, consumer groups and government. The Authority meets three times a year five to six weeks after PBAC meetings.
- When recommending listings, the PBAC provides advice to the PBPA regarding comparison of alternatives with the medicine's cost effectiveness.

Role of Cabinet:

- Cabinet comprises senior Australian Government ministers. Cabinet makes recommendations to the Minister for Health on all changes to the PBS with financial implications.
- The Department of Health prepares Cabinet submissions for these medicines.

Role of Minister for Health

- If listing of a high cost drug is recommended by Cabinet, the Minister authorises its inclusion on the SPB.
- Currently the Minister delegates approval of the listing of other items on the PBS to the Assistant Secretary, Pharmaceutical Evaluation Branch, Department of Health.

PBAC process

1 Seek advice from PEB (optional but recommended)

* Notify PBAC Secretariat of your intention so you can receive general advice on how to best present information to PBAC and to confirm specific deadlines and other data cut-off dates
* May also be encouraged to start early discussions about any usage and pricing issues with DUSC and ESC secretariats

2 Complete an application and provide a submission that meets the PBAC requirements to the PBAC secretariat by the PBS calendar

* PBAC secretariat confirms receipt
* ESC secretariat evaluates and develops commendatries on major submissions
* DUSC secertariat evaluates and develops commentaries on major submissions that are likely to be identified as Tier 2 or 3
* PBAC secretariat prepares an overview of the submission for the PBAC
* Pharmaceutical Pricing Section allocates provisional tier status to submissions
* Tier status will be advised and the inclusion of submission on PBAC agenda

3 Evaluation report commentary including the PBAC secretariat overview will be sent to the manufacturer for a response

* Manufacturer may provide a written response to the evaluation report and overview to the PBAC Secretariat. Manufacturer may also continue discussions with Pharmaceutical Benefits Pricing Authority (PBPA) secretariat on price
* The ESC and DUSC meet to consider manufacturer's submission, the PBAC Secretariat overview, the evaluation process and the manufacturer's response. Sub-Committees then prepare formal advice for the PBAC meeting

PBAC and the sub-committees all have secretariats

IBM

4

Manufacturer will receive advice regarding considerations from the DUSC and ESC and may respond to their advice to PBAC in writing before the cut-off date

* Manufacturer may choose to request a hearing for the PBAC and should prepare a presentation of no more than 10 minutes

* Manufacturer may also be required to work with the Restrictions working group to develop restrictions and the restrictions wording

5

PBAC Secretariat gives manufacturer verbal advice of the PBAC decision on manufacturer's application

*If the PBAC makes a recommendation to list, then the drug or medicinal preparationis included on agenda for the next PBPA meeting

*If PBAC does not make a recommendation to list, applicant may submit with additional or new information

*Independent review is also available where PBAC did not make recommendation to list and in certain circumstances where the PBAC did not recommend the listing of an additional indication for an already listed drug on the PBS

6

PBPA secretariat will contact manufacturer after the PBAC meeting to initiate formal pricing discussions

*Manufacturer may discuss price and risk sharing arrangements aiming to reach in-principle agreement before the PBPA meeting

7

Confirming the agreed price

*When pricing is agreed, manufacturer must complete the required documentation

*When pricing cannot be agreed, the medicine is not listed and the manufacturer may not put another submission to PBPA or PBAC for reconsideration

8

Agreement on usage estimates

*The Department of Health makes a Cabinet Submission for medicines that will cost the PBS more than $10m per year

*The DUSC and PBPA secretariats will discuss usage estimates with the manufacturer to reach an agreed position. The agreement is confirmed in writing

*Cabinet may endorse the listing and the Minister for Health confirms this decision and lists the medicine or Cabinet rejects recommendation for listing

9

The Minister for Health and Ageing authorises the listing of items on the Schedule of Pharmaceutical Benefits by tabling of legislative instruments which are registered on the Federal Register of Legislative instruments

APPENDIX 4: Survey tool

Activities Performed
Resource Requiremer

APPENDIX 5: Interview Guide - Government

Questions for Interview Guide -Pan

APPENDIX 6: Interview Guide – Industry

Questions for
Interview Guide -Pan