Objective

To provide participants with an understanding of the pan-Canadian Pharmaceutical Alliance (pCPA) and the important role it plays in the Canadian reimbursement process.

To learn about the history of the pCPA and its process, gain insights into the use of product listing agreements and be presented with metrics capturing pCPA’s activities to date.
Overview of the pCPA

What is the pCPA? What was the rationale for the establishment of the pCPA?
There are many stakeholders in the Canadian P&R landscape.

Health Canada asks: Is it safe? Does it work?

PMPRB asks: Is the price excessive compared to other countries?

CADTH/INESSS asks: How does it compare to existing treatment options?

pCPA asks: What is value?

Payers ask: Can we afford it?

The pCPA was created to help public payers achieve value through negotiation.

The pan-Canadian Pricing Alliance (pCPA) was originally established in 2010 by the Council of Federation to determine the feasibility of joint drug negotiations by the public drug plans.

pCPA goals include:

- Increasing access to treatment options;
- Improving consistency of access across the country;
- Capitalizing on combined buying power of jurisdictions;
- Achieving consistent pricing and lower costs;
- Reducing duplication of negotiations; and
- Improving utilization of resources.
Some history as pCPA has continued to evolve...

- In 2012, the Generics Value Price Initiative was announced.
- In late 2012/early 2013, all new drugs began going through pCPA.
- In 2013/14, IBM released the Pan Canadian Drugs Negotiations Report which analyzed the current work to date and provided recommendations on a permanent model going forward.
- Following the release of the IBM report, in 2015:
  - The brand and generic initiatives were amalgamated under the same umbrella and the brand & generic initiatives became collectively known as the pan-Canadian Pharmaceutical Alliance.
  - Establishment of the pCPA Office.
- In late 2015/early 2016, Quebec and the Federal plans also joined the pCPA.

More about the Office that was created to support the pCPA

As of September 2015, an Office (pCPAO) with dedicated staff to support the work of the pCPA is being hosted in Ontario.

**Mandate**
Providing leadership and operational excellence to participating public drug plans to collectively achieve the objectives of the pCPA.

**Focus**
Internally focused on streamlining and providing consistency in the negotiation process and establishing a governance structure for the pCPA.

**Priorities**
Exploring collaborative opportunities with other F/P/T organizations and conducting stakeholder consultations for both brand and generic initiatives.
The pCPA has been busy...some highlights

- Introduction of generic tiered pricing framework and centralized submission process
- 16 generic molecules with lower price points relative to brand (15-18%)
- Development of Biosimilars First Principles
- Negotiations:
  - Completed 142 brand negotiations
  - 33 active negotiations
  - Over 20 under consideration

The total combined savings realized by April 2016, is estimated at $712M.

Product Listing Agreements

What is their overall intention? What are some examples of the different types/formats of PLAs?
The largest tools at the pCPA’s disposal are PLAs

A product listing agreement (PLA):

- Refers to a **negotiated agreement** between a **pharmaceutical manufacturer** and a **payer** (either public or private payer).
- **Outlines specific conditions** related to the drug plan’s reimbursement of a drug product.
- Acts as a way to **mitigate risk** between payers and manufacturers around elements such as:
  - Efficacy (heterogeneity)
  - Real world effectiveness
  - Safety risks
  - Cost-effectiveness
  - Budget impact & affordability
- **Terms are confidential**

There are many different types of PLAs

**PLA Types**

- Rebate
- Price volume
- Utilization caps
- Non-responder rebates
- Manufacturer funded treatment initiation
- Coverage with evidence development
- Outcomes based
Common PLA agreements are financially or clinically based...

<table>
<thead>
<tr>
<th>Financial Agreements</th>
<th>Clinical Agreements</th>
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<tbody>
<tr>
<td>Rebate Agreements</td>
<td>Price–Volume Agreements</td>
</tr>
<tr>
<td>Create two different prices for the same medication: a confidential reduced price for the payer and an official public price (higher) for insurers.</td>
<td>The first simple form of a &quot;risk-sharing&quot; agreement. The price of the medication is reduced according to drug utilization.</td>
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<td>Conditional Coverage Agreements</td>
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<td>Performance-Linked Reimbursement Agreements</td>
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<tr>
<td></td>
<td>Drug coverage is tied to a specific clinical aspect of the drug:</td>
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<tr>
<td></td>
<td>i) Outcome guarantee agreements</td>
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<td>ii) Process of care agreements</td>
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...and each has different advantages and disadvantages

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<td>[+ Simple to implement.</td>
<td>[+ Improve budget certainty.</td>
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<td>[+ Generate savings for payers.</td>
<td>[+ Greater transparency compared to rebate agreements.</td>
</tr>
<tr>
<td>[- High opacity.</td>
<td>[+ Simple to implement.</td>
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<tr>
<td>[- Create artificial marketed medication prices.</td>
<td>[+May improve efficiency and effectiveness.</td>
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<td>[- Disparity between public and private insurers.</td>
<td>[+&quot;Value for money.&quot;</td>
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<td>[+Timely access to new drugs.</td>
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<td>[+Reduce any uncertainty following clinical evaluation.</td>
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<td></td>
<td>[-Risk of removal from list owing to lack of strong clinical evidence.</td>
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<tr>
<td></td>
<td>[-Difficulty in assessing clinical outcomes.</td>
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<td>[-Lack of transparency.</td>
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<td>[+Link the price of a medication to its effectiveness for each patient.</td>
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<td>[+Limit uncertainty concerning the drug’s impact on clinical decisions.</td>
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<td></td>
<td>[-Clearly defined evidence-based parameters for measuring success.</td>
</tr>
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</table>

Source: Product Listing Agreements (PLAs): A New Tool for Reaching Quebec’s Pharmaceutical Policy Objectives? (August 2013) Proprietary and Confidential
pCPA Process

How is decision made to negotiate/not negotiate on a drug? Once a drug is selected to be negotiated, what are the next steps? What happens when an agreement has been made?

The pCPA Process

1. Product consideration
2. Decision & engagement
3. Information exchange
4. Participating jurisdictions discuss initial proposal
5. Parties exchange responses
6. LOI development & completion
7. Jurisdictional PLA implementation & product listing

There are 7 broad steps in the pCPA process
The pCPA Process

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**Step 1**
The pCPA holds weekly teleconferences in which they discuss products with recent CDR or pCODR recommendations.

**Step 2**
- Pre-work completed to determine initial pCPA mandate
- Individual provincial representatives decide if they will participate in product negotiation.
- Lead negotiating jurisdiction is selected as necessary.
- Letter sent to the manufacturer notifying them of decision and expectations.
## The pCPA Process

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### Step 3
First meeting: generally, the manufacturer provides an initial proposal.

### Step 4
Lead jurisdiction discusses proposal with pCPA and provides feedback/response to the manufacturer.
### The pCPA Process

1. **Product consideration**
2. **Decision & engagement**
3. **Information exchange**
4. **Participating jurisdictions discuss initial proposal**
5. **Parties exchange responses**
6. **Letter of Intent (LOI) development and completion**
7. **Jurisdictional PLA implementation & product listing**

#### Step 5
Counter proposals or responses are exchanged until agreement is reached (~6 months on average but can range from weeks to >1 year).

#### Step 6
- LOI contains elements of PLA written on behalf of all participating jurisdictions.
- Signed by a senior delegate of lead jurisdiction and manufacturer.
### The pCPA Process

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**Step 7**
- Listing still dependent on local rules and budget capacity of the individual public plans.
- Benefit status is effective following formal listing procedures for relevant drug benefit formulary/list.

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**pCPA Metrics**

How many products have been negotiated to date? Overall trends ex pre-post pCPA. What has been the impact on the time to list? To date have they achieved their mandate?
Thus far the pCPA has completed 142 joint PLA negotiations.

The median national TTL decreased significantly from 706 days to 502 days since the initiation of the pCPA.

Time to Listing (TTL) from NOC Pre-pCPA vs. pCPA

Source: pCPA/CDR/pCODR Changes and Impact to Market Access in Canada (IMS Brogan 2016)
The RR has not changed significantly since the invention of the pCPA.

**Summary**

- Created in 2010, the pCPA continues to evolve and is still in its infancy.
- Ongoing consultations with interested stakeholders anticipated
  - Biosimilars First Principles
  - Process Guidelines
  - Performance Metrics
- Continuing evolution aligned with participating drug plan direction