

# Expanding the early negotiation process (ENP)

Consultation on ENP expansion



Welcome: Understanding the session  
context and objectives

# Agenda

**5 minutes**

## **Introduction**

Overview of the consultation process  
Overview of the pCPA

**Geneviève C. Gagnon**

**25 minutes**

## **Review of the ENP and expansion options**

**Clifford Lo**

**25 minutes**

## **Moderated question period**

**Kelly Cull**

**5 minutes**

## **Closing and next steps**

**Geneviève C. Gagnon**

- Presentation builds on materials available on the pCPA website
- Session recorded for note-taking purposes
- Use Zoom Q&A to submit questions



# Consultation process

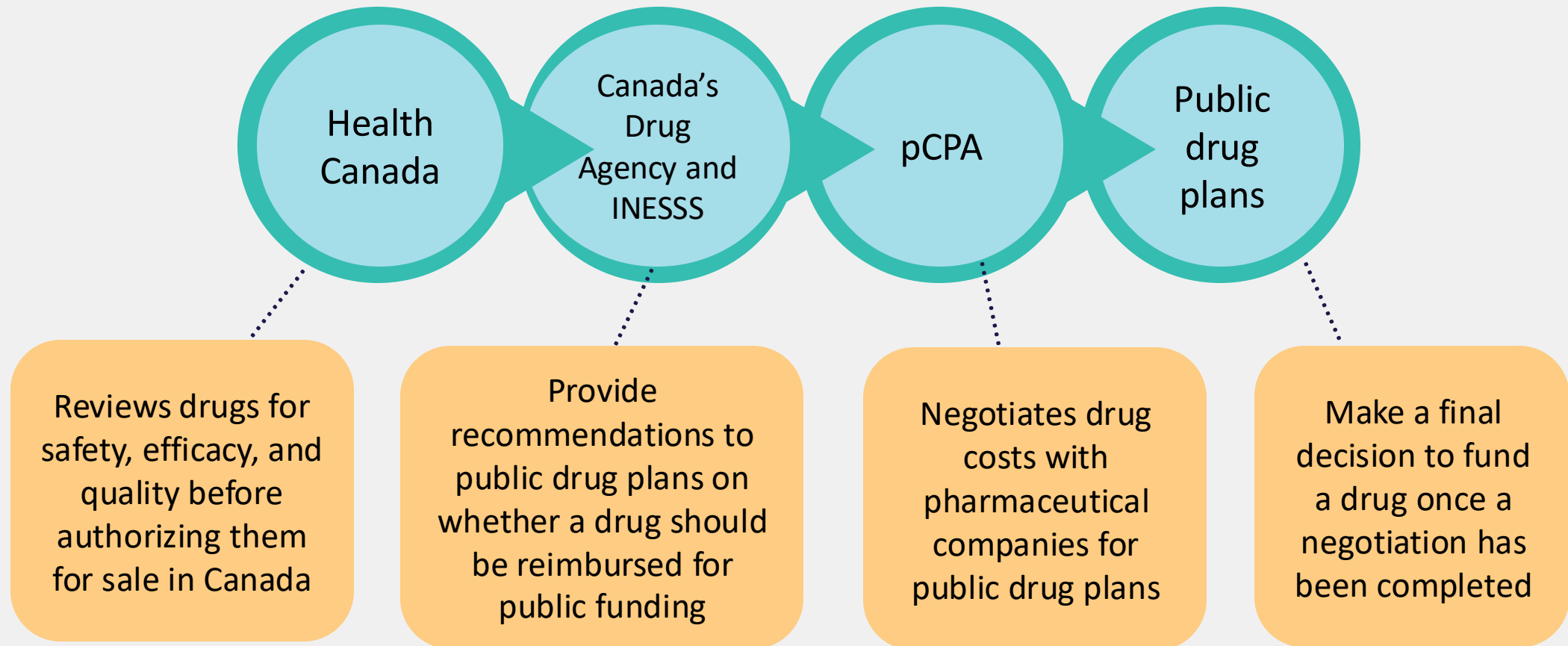
- Virtual consultation sessions:
  - Sessions will be held for clinicians, patient groups, manufacturers, and French-speaking audiences.
- Written consultation
  - Written feedback can be submitted through an online survey, accessible on the pCPA website until September 11.
- “What we heard” report
  - Feedback will be anonymized and summarized for a concise public report.

## About the pCPA



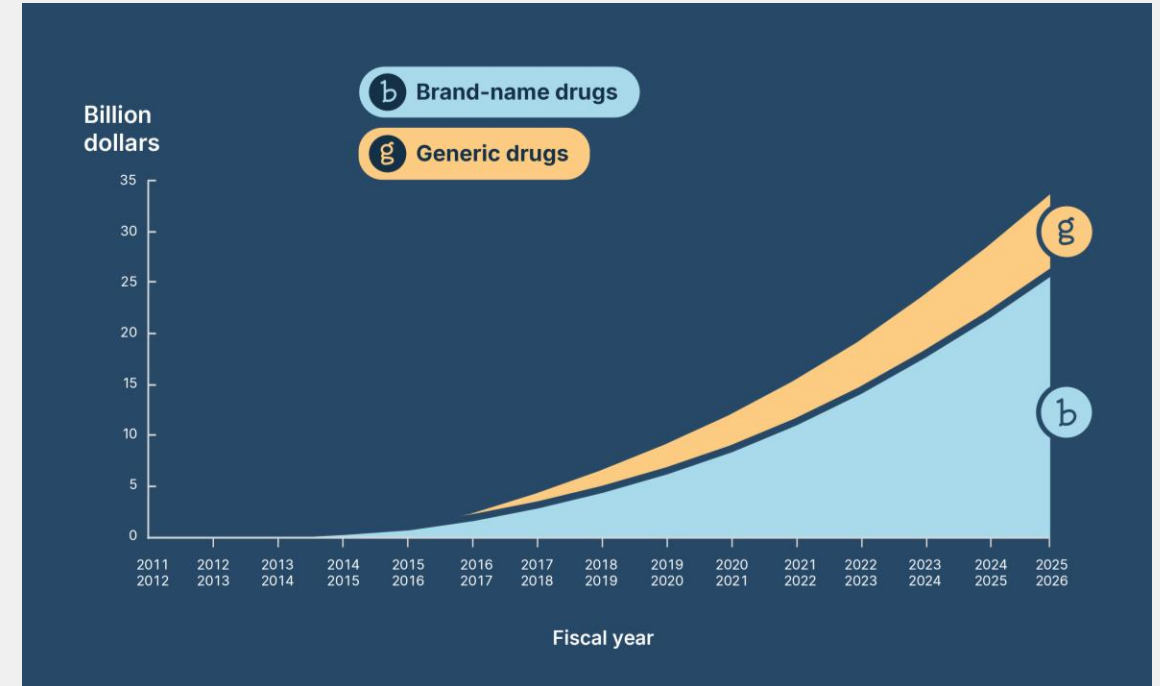
Vision: To support the sustainability of publicly funded health care systems through world-class drug price negotiations.

# Where we fit in the process



# pCPA savings

In 2025–26, pCPA activities saved jurisdictions an estimated:



**\$4.4 billion**

Brand name drugs savings

**\$940 million**

Generic drugs savings

**\$5.4 billion**

Total savings

# pCPA negotiations

In 2025-26:

Negotiations increased by 11% over the previous fiscal year.

The number of agreements reached increased by 15%

In consideration and active negotiation times were both reduced.



# Early negotiation process (ENP)

Current state

# ENP: Current state



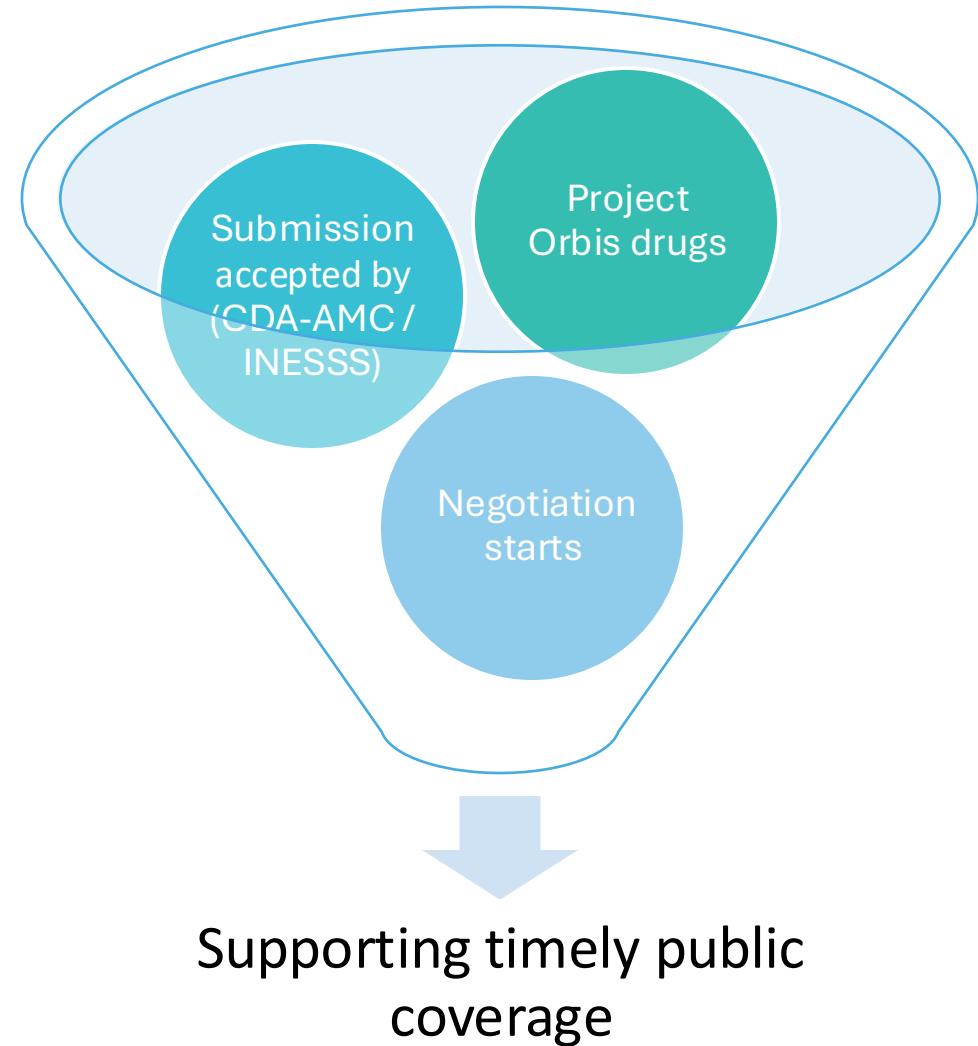
Public consultation informed  
final pathway design



Coverage up to 6 months earlier

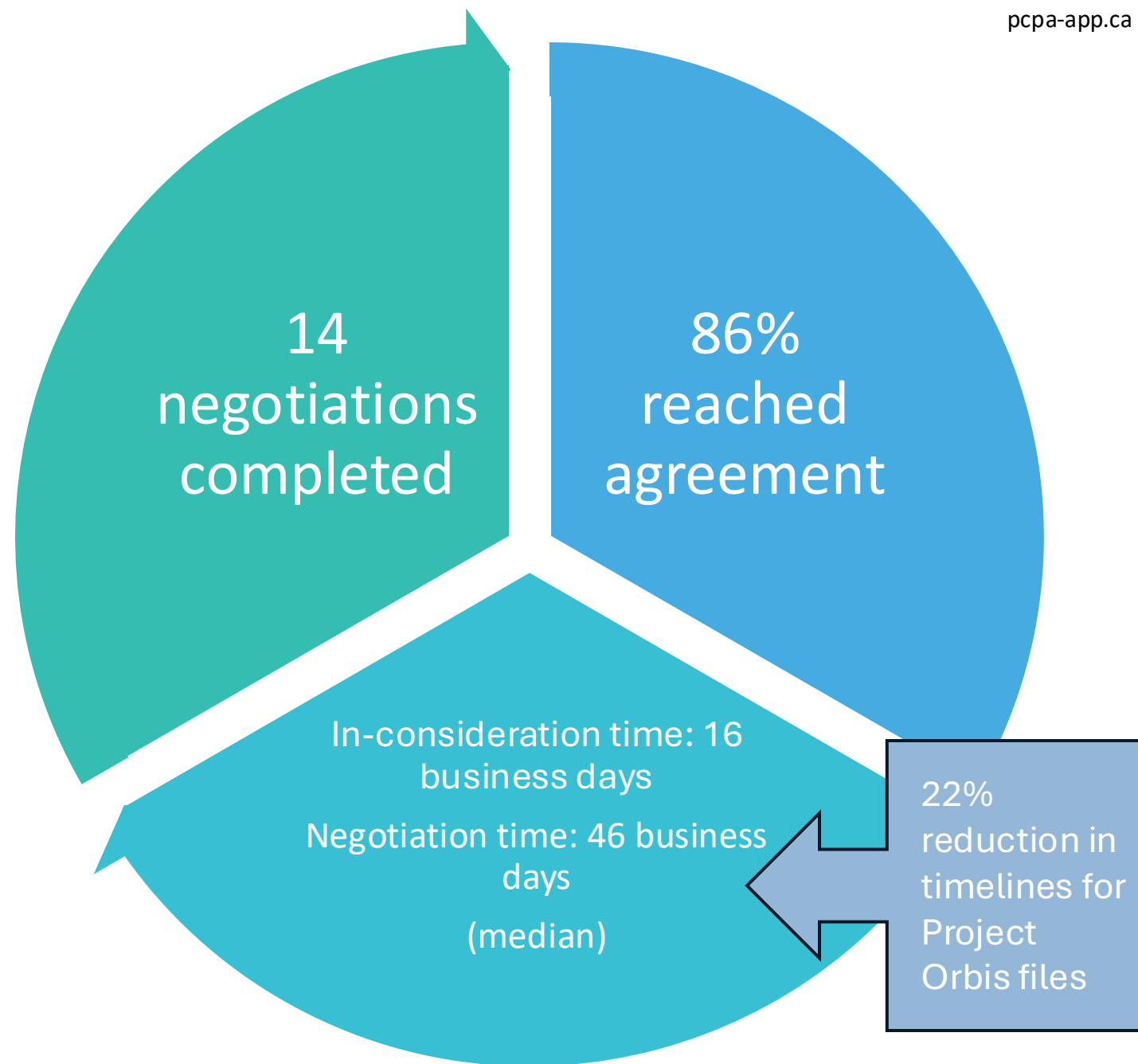


Launched December 2025



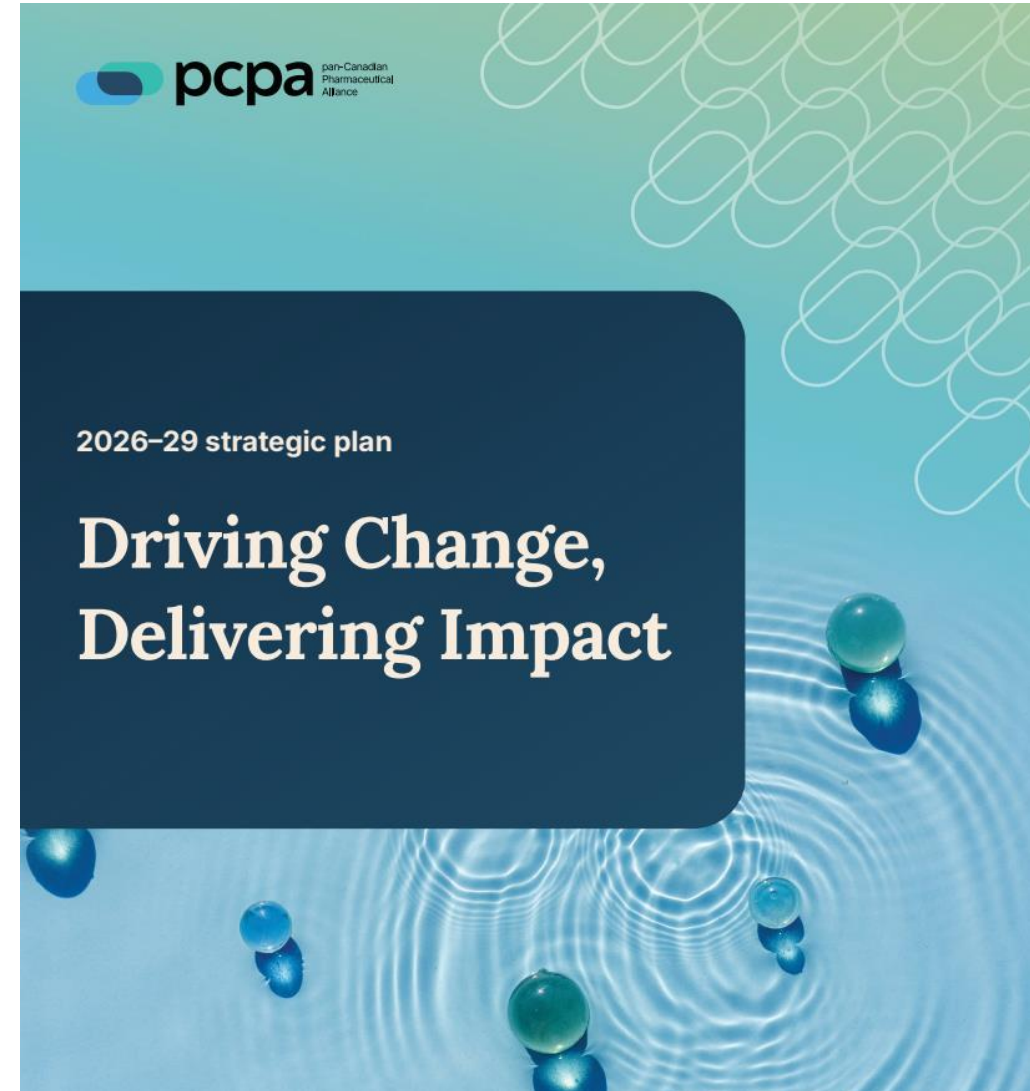
# Progress with Project Orbis files to date

October 1, 2025 – July 31, 2026



ENP: Future state

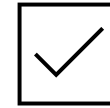
# Why expand?



## ENP: Principles and conditions



Time-bound



Simultaneous submissions to both CDA-AMC and INESSS



Good faith negotiations



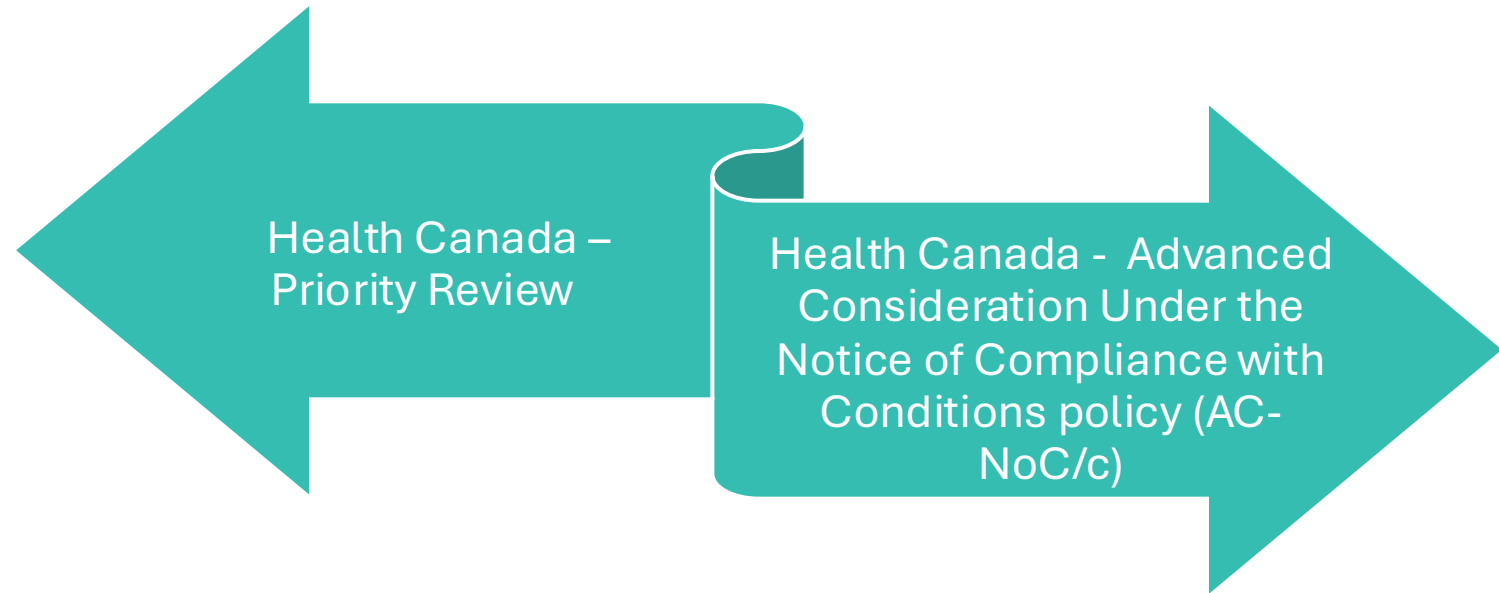
Guided by evidence

# ENP negotiation timelines

| Phase         | Associated deliverable                        | Target completion time                                           |
|---------------|-----------------------------------------------|------------------------------------------------------------------|
| Initiation    | Letter of acknowledgement                     | ≤ 10 business days of CDA-AMC or INESSS acceptance of submission |
| Consideration | Letter of engagement or no negotiation letter | ≤ 25 business days from CDA-AMC draft review report              |
| Negotiation   | Proposals/counterproposals                    | ≤ 90 business days from LOE                                      |
| Completion    | Letter of intent/close letter                 | ≤ 90 business days from LOE                                      |

# Expansion pathway options

Two regulatory routes to support timely coverage



# Option A: Health Canada Priority Review

Health Canada Priority Review applies to a New Drug Submission (NDS) or Supplemental New Drug Submission (S/NDS) “for a serious, life-threatening or severely debilitating disease or condition for which there is substantial evidence of clinical effectiveness that the drug provides:

- effective treatment, prevention or diagnosis of a disease or condition for which no drug is presently marketed in Canada; or
- a significant increase in efficacy and/or significant decrease in risk such that the overall benefit/risk profile is improved over existing therapies, preventatives or diagnostic agents for a disease or condition that is not adequately managed by a drug marketed in Canada.”

# Option B: Health Canada Advance Notice of Compliance with Conditions Consideration (AC-NOC/c)

Health Canada's Advance Consideration under the Notice of Compliance with Conditions (AC-NOC/c policy applies to:

- "New Drug Submissions (NDS) and Supplemental New Drug Submissions (S/NDS) for a serious, life-threatening or severely debilitating disease or condition for which there is promising evidence of clinical effectiveness based on the available data that the drug has the potential to provide:
  - effective treatment, prevention, or diagnosis of a disease or condition for which no drug is presently marketed in Canada; or
  - a significant increase in efficacy and/or significant decrease in risk such that the overall benefit/risk profile is improved over existing therapies, preventatives or diagnostic agents for a disease or condition that is not adequately managed by a drug marketed in Canada.
- Abbreviated new drug submissions and supplement to an abbreviated new drug submissions in instances where the Canadian reference product still holds the NOC/c status."

# pCPA experience with the proposed pathways



## Priority Review (n = 53 files\*)

- Oncology: 55%
- Non-oncology: 45%

Examples of drugs previously negotiated:

- Apretude for HIV prevention
- Edaravone for amyotrophic lateral sclerosis
- Entresto for heart failure
- Hemgenix for hemophilia B
- Sohonos for fibrodysplasia ossificans progressiva
- Trikafta for cystic fibrosis

## AC-NOC/c (n = 16 files\*)

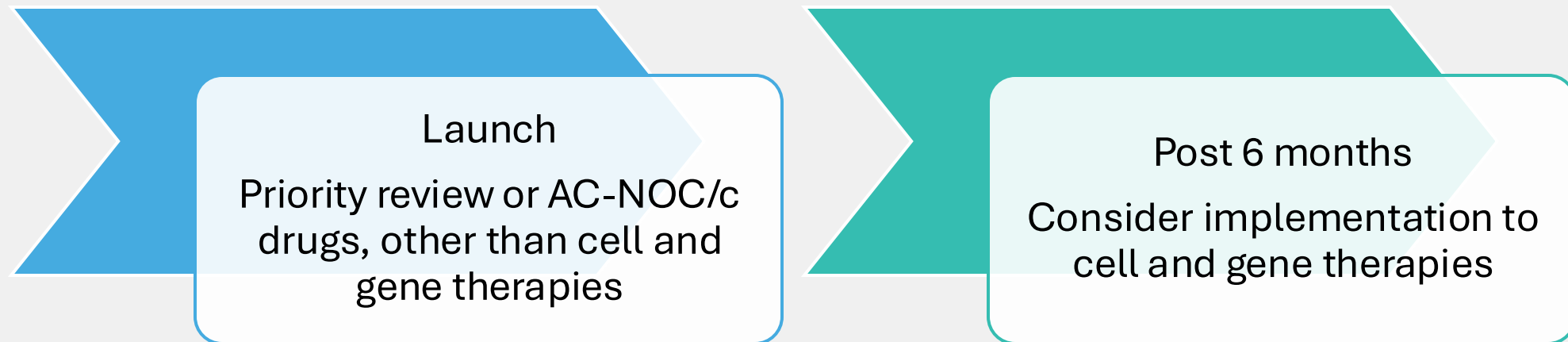
- Oncology: 87%
- Non-oncology: 13%

Example of drugs previously negotiated:

- Balversa for locally advanced or metastatic urothelial carcinoma
- Remdesivir for COVID-19
- Rozlytrek for unresectable locally advanced or metastatic extracranial solid tumours
- Vitrakvi for solid tumours

\* Negotiated between January 1, 2023 and July 31, 2026

# Implementation proposal



# Evaluation



# Moderated question period

## Closing and next steps



- Thank you!
- Written survey open until Friday, September 11
- A concise “what we heard” report will be available at [www.pcpa-app.ca](http://www.pcpa-app.ca)
- Participant survey

Thank you!

[pcpa-app.ca](http://pcpa-app.ca)

[info@pcpa-app.ca](mailto:info@pcpa-app.ca)

