Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada

PLEASE STAND BY

THE WEBINAR WILL BEGIN SHORTLY
1:00pm to 2:30pm (EDT)

THANK YOU

Patented Medicine Prices Review Board

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Canada

PMPRB GMEP

Guideline Monitoring & Evaluation Plan

Public Webinar

May 2021

About the Patented Medicine Prices Review Board

- PMPRB is an independent, quasi-judicial body established by Parliament in 1987 under the *Patent Act*. It has a dual mandate:
  - Regulatory: it protects consumers by ensuring that the prices of patented medicines are not excessive;
  - Reporting: it provides information on pricing trends in the pharmaceutical industry.
- The PMPRB regulatory framework reposes on three legal instruments: the Patent Act, the Patented Medicines Regulations and the PMPRB Guidelines
- PMPRB issues non-binding Guidelines are intended to provide transparency and predictability to patentees regarding the price review process.

OUR MISSION

The PMPRB is a respected agency that makes a unique and valued contribution to sustainable spending on pharmaceuticals in Canada by:

- Providing stakeholders with price, cost, and utilization information to help them make timely and knowledgeable pricing, purchasing, and reimbursement decisions; and
- Acting as an effective check on the prices of patented medicines through the responsible and efficient use of its consumer protection powers.

Recent developments

Strengthen and modernize Canada's pricing framework

Regulatory Amendments

- Patented Medicines Regulations amended August 2019, coming into force July 1, 2021
- Canada's response to high priced patented medicines & evolving market
- New countries: PMPRB11
- New factors: pharmacoeconomic value, market size, GDP, GDP/capita

PMPRB Guidelines

- New Guidelines published October 23, 2020 following an extensive consultation process
- Give effect to amended Regulations
- Identify steps typically taken by PMPRB Staff in assessing whether a patented medicine appears to be priced excessively.

Framework implementation

Coming into Force

July 1, 2021

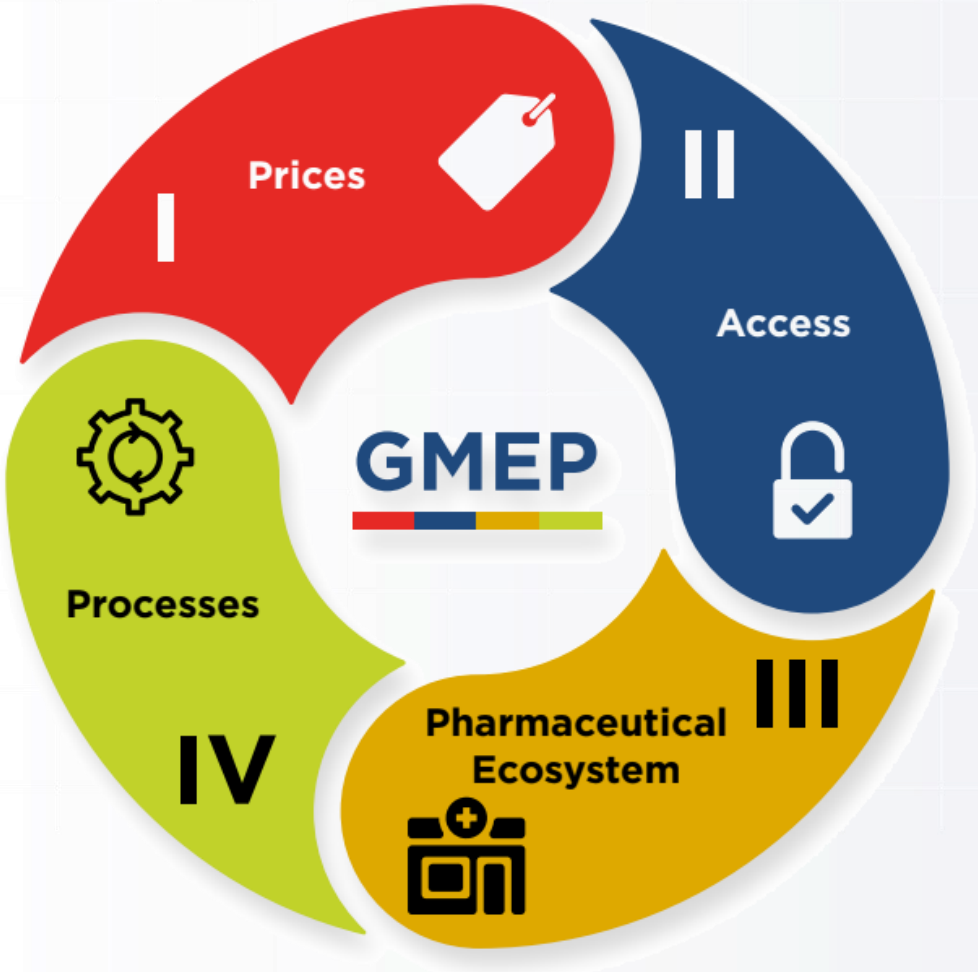
- Patentees must files information as per the new requirements
- Grandfathered and Gap Medicines have two filing periods to comply with the MLP (July 1, 2022)
- New medicines have one filing period to comply with the MLP.
- New factors will be considered only in an investigation or hearing.

GMEP

- Released on May 3
- Analyzes trends in the pharmaceutical market before and after the implementation of the new framework
- Intended to inform the need for any future Guideline adjustments
- Four key areas of analysis
- Stakeholder input being sought

PMPRB11: Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United Kingdom.

Building a Guidelines Monitoring and Evaluation Plan (GMEP)



- Purpose: Analyze trends in the pharmaceutical market before and after the implementation of the new framework to assess whether it is working as intended, and to inform the need for any future adjustments.
- Proposed GMEP is a starting point for discussions, stakeholders are invited to help shape the development of the GMEP
- Four key areas are proposed: I. Prices; II. Access; III. Pharmaceutical ecosystem; IV. PMPRB processes
- For each of these, relevant indicators will be identified and baseline results (benchmarks) will be generated
- Important to recognize complexities and limitations in analyzing these issues
- Starting with 2022, GMEP will monitor and report on trends in support of an evidence-based evaluation.

GMEP Engagement Plan – 2021

Pre-release of GMEP — January

Intergovernmental Workshop
Engagement with Public Agencies, Federal, Provincial and Territorial governments.

Release of GMEP — May – June

Public Webinar: Broad stakeholder engagement, intended as a more rudimentary overview of GMEP.
Technical Webinar: Engagement with technical experts on specific research questions, metrics and methodologies in GMEP's four key areas of focus.

Release of Benchmark Results — November

Series of Public GMEP Baseline Webinars
The PMPRB will disseminate to all its audiences the baseline results of trends prior to the implementation of the new Guidelines.

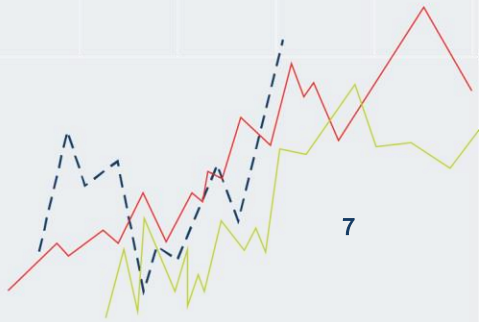
Complexities and Limitations

Trends in the pharmaceutical market are driven by multiple variables, many of which are difficult to quantify.

The greater the number of variables at play, the less certain are the conclusions one can draw about the import of any single one.

Changes in the magnitude of a factor may correlate with an overall trend, but that does not necessarily mean that the factor is causing the trend

To the extent possible, PMPRB intends to monitor and report on trends in support of an evidence-based evaluation.

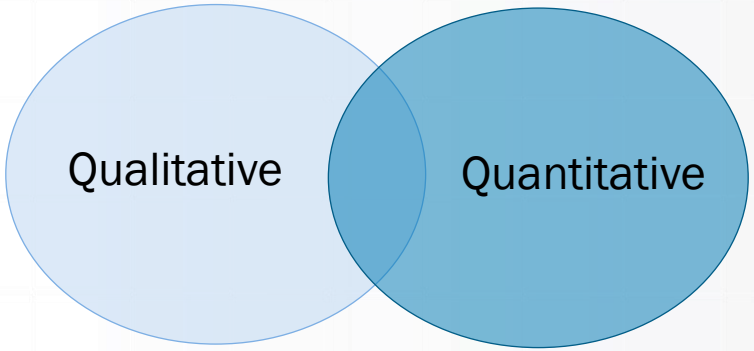


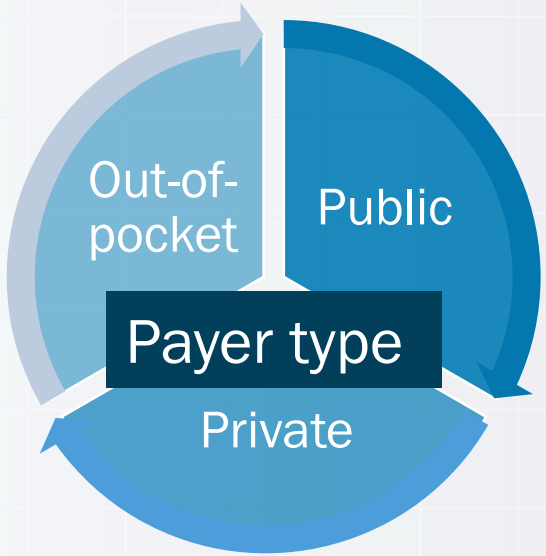
Key features of the Guidelines

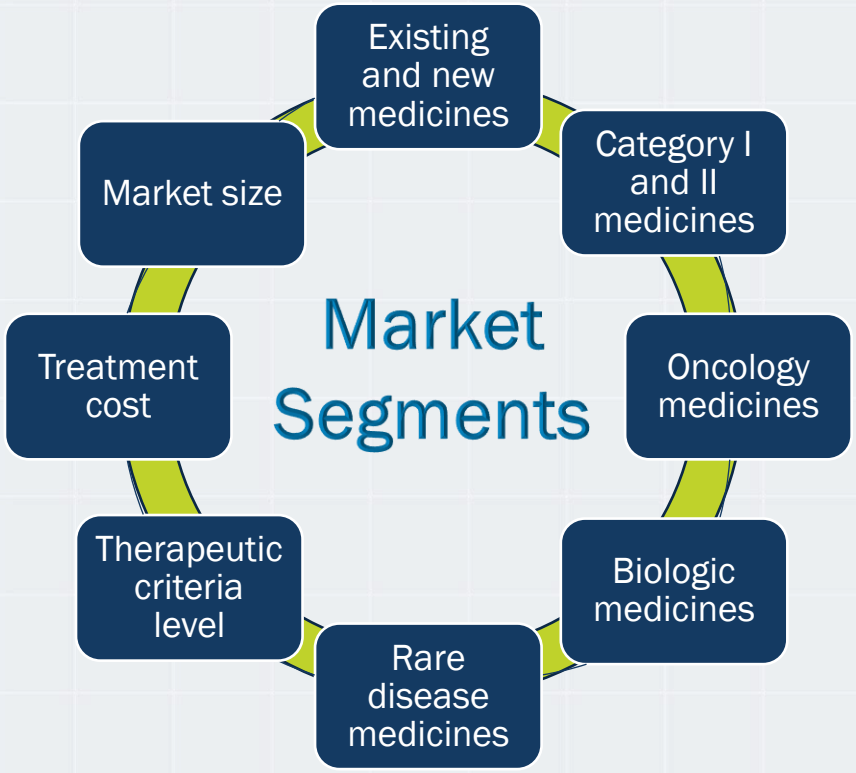
- A risk-based approach to reviewing the prices of new patented medicines:
  - Higher risk new medicines—those that are High Cost or are expected to have a High Market Size—will face greater regulatory scrutiny in Category I.
  - All other new medicines will be classified as Category II. This will be the case even for patented generic medicines and biosimilar medicines that would otherwise meet the Category I criteria.
- Maximum List Price (MLP) ceiling for all medicines
  - For Grandfathered medicines and their line extensions, the MLP is set by the highest price (HIP) in the new group of PMPRB11 countries.
  - For all other patented medicines, the MLP is set by the median price in the PMPRB11 (MIP).
- Maximum Rebated Price (MRP) ceiling for Category I medicines.
  - The MRP is derived by taking into account the new economic factors, namely pharmacoeconomic value, market size, the gross domestic product (GDP) and the GDP per capita in Canada.
  - The PMPRB will only commence an investigation into the price of a new patented medicine if it appears not to comply with the MLP, or if the PMPRB receives a complaint.

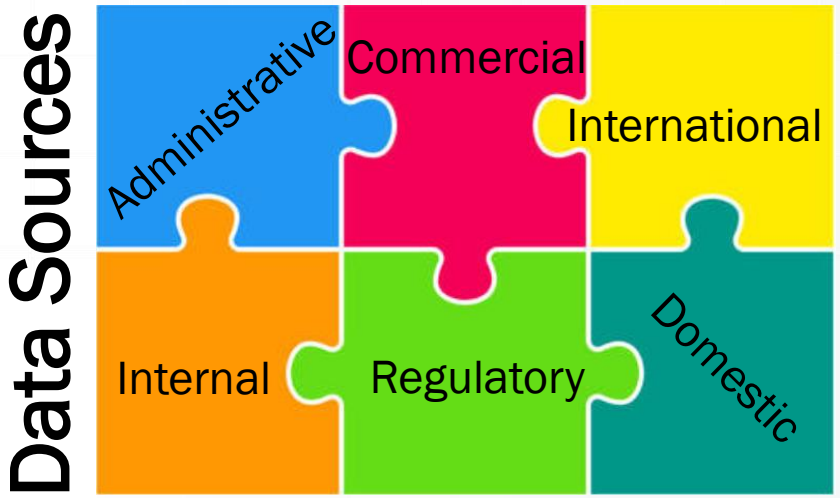
PMPRB11: Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United Kingdom.

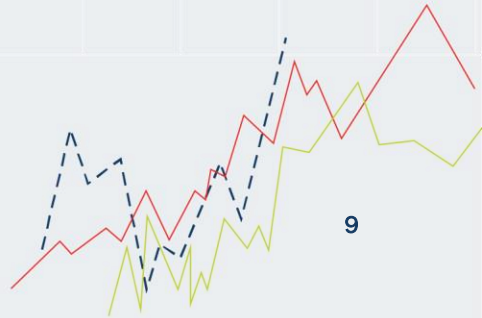
Analytical approaches

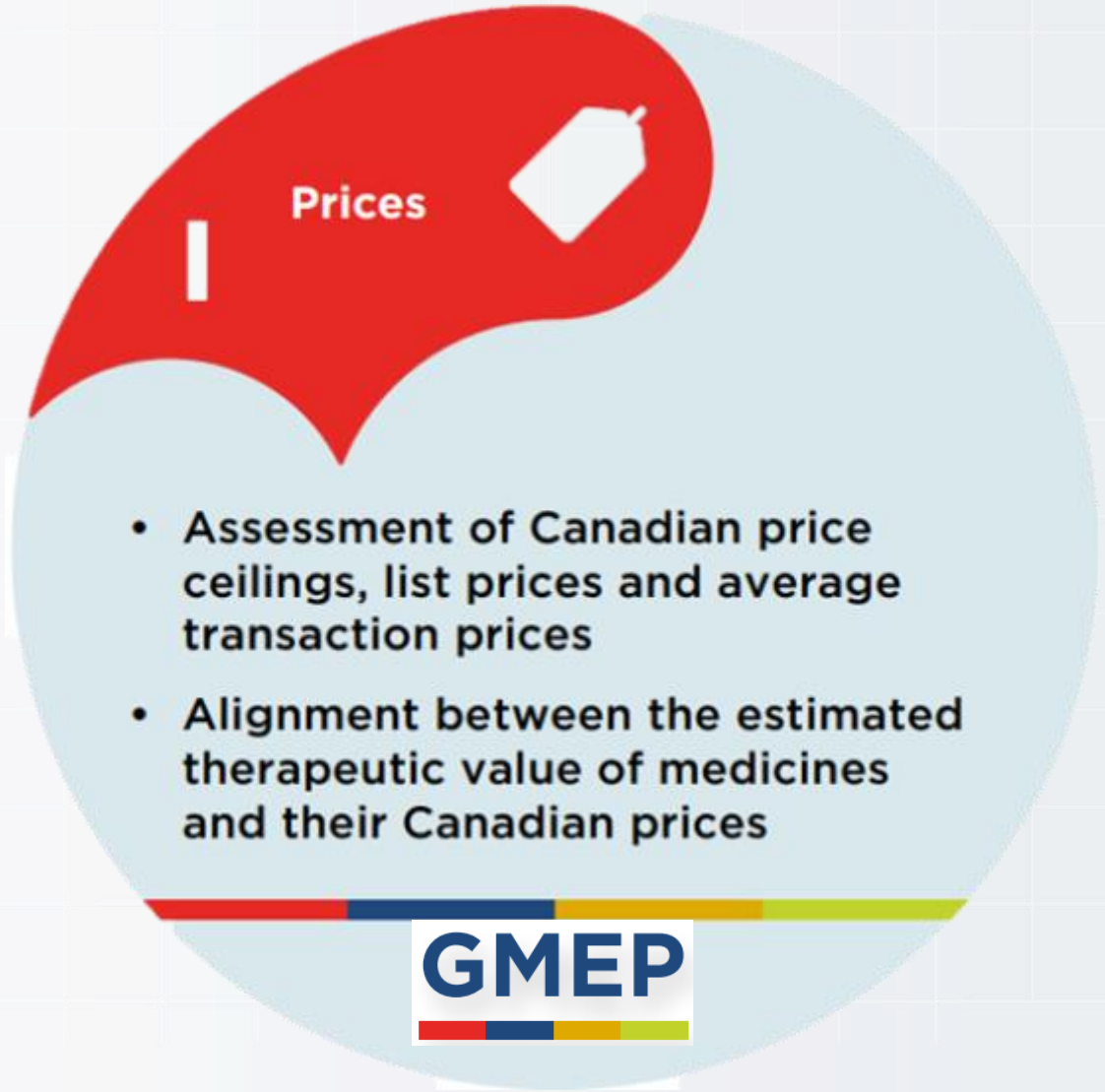








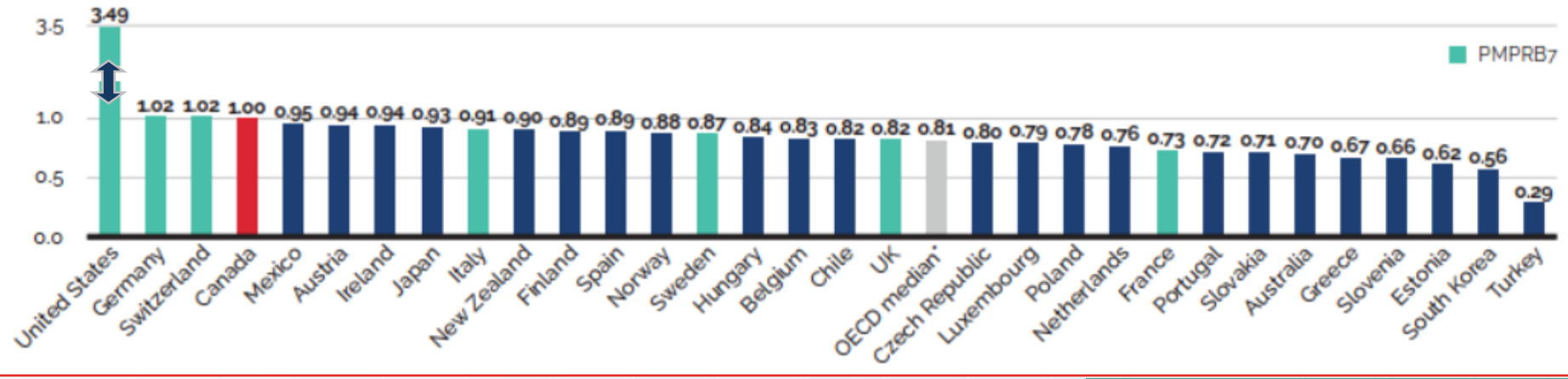



Prices
• Assessment of Canadian price ceilings, list prices and average transaction prices
• Alignment between the estimated therapeutic value of medicines and their Canadian prices
GMEP

Prices

Background

Canadian list prices for patented medicines are fourth highest among the OECD countries and 23% higher than median prices in the OECD.



The impact on list prices is expected to be immediate and directly attributable to the Guidelines changes. The PMPRB expects average list price reductions of:

- 8% for Category I new medicine
- 13% for Category II new medicines
- 5% for existing medicines
  - Existing medicines will continue to account for the majority (59%) of patented medicine sales.

Notwithstanding the reforms, Canada's prices are expected to remain at the higher end of the international scale over the next decade.

Prices

Assessment of Canadian price ceilings, list prices and average transaction prices

The PMPRB intends to monitor and assess the reduction in the list and average transaction prices of existing and new medicines as a result of lower price ceilings post-reforms, compare Canadian prices against international levels and evaluate the impact of price reductions on sales.

Domestic Analysis

- Trends in list and rebated price ceilings, as well as list and average transaction prices
- Gap between the average transaction prices, list prices and price ceilings
- Impact on Canadian patented medicine sales due to the price changes

International Analysis

- Trends in Canada's relative position in terms of patented drug prices
- Comparative analysis of price changes in Canada compared to international norms
- The implications of Foreign-to-Canadian price differentials on Canadian patented drugs sales

Prices

Alignment between the estimated therapeutic value of medicines and their Canadian prices

- The PMPRB intends to monitor and measure whether there is a convergence between the cost-effective price, the new price ceilings and the prevailing prices in Canada.
- The amended Regulations require patentees to provide the PMPRB with cost-utility analyses prepared by publicly funded Canadian organizations for patented medicines with annual treatment costs over 50% of GDP per capita in Canada.
- The inclusion of this factor requires the PMPRB to consider the relationship between the medicine's price and the value it provides to patients within the context of the Canadian health care system.
- For Category I medicines, the Guidelines call for the calculation of a Maximum Rebated Price (MRP) ceiling, which takes into consideration the medicine's pharmacoeconomic value and market size, as per the amended Regulations.

Prices

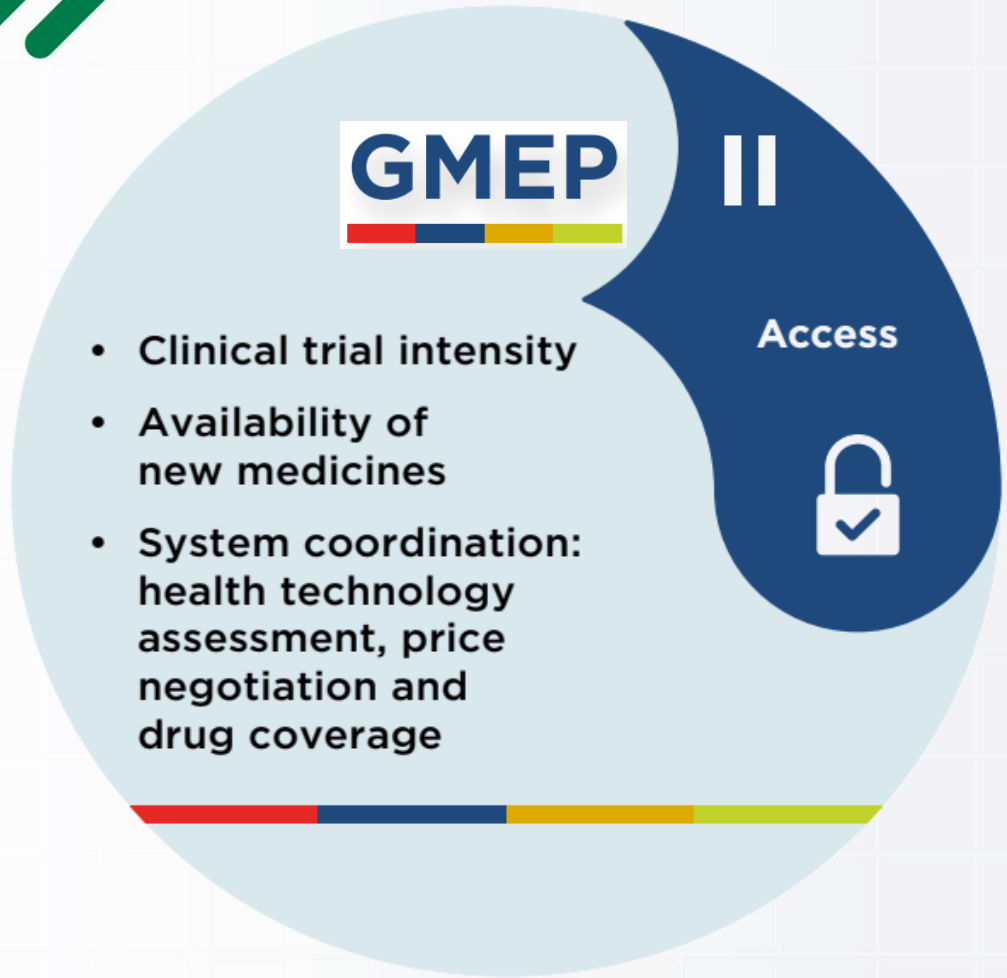
Consultation Questions

LET US KNOW WHAT YOU THINK

In your view, what is the importance of monitoring and evaluating the changes in prices following the Guideline changes?

Which of the proposed objectives around the assessment of price are most important to you?

Are there other aspects of assessment of price that are relevant to you and not already reflected in the PMPRB plan?



- Access to medicines is a multifaceted issue with numerous factors contributing to shifting trends in the availability and affordability of new treatments.
- The PMPRB will monitor and evaluate the continuum of access to medicines for the Canadian consumer.

Access

Background

The high prices of new patented medicines pose a financial barrier to access for Canadians. Medicines costing over $100,000 account for 1/10 of patented medicine sales.

Patentees and some patient groups voiced concerns that the clinical trials and the availability of new medicines may be impacted by the reforms.

The new PMPRB value and affordability factors represent best international practices. High-cost medicines that have small market size will be exempt from these factors.

The number of new meds approved and sold is below most comparator countries despite a sizable number of clinical trials.

The number of clinical trials has been declining in developed countries and COVID-19 has disrupted clinical trial intensity globally.

No early signs that patented medicine price reforms are resulting in fewer clinical trials or less new medicines approved or launched in Canada.

Access

Clinical trial intensity

- The PMPRB proposes to undertake a literature review, and to monitor and evaluate the trends in clinical trial levels in Canada and internationally, to determine if there is any evidence to support claims that pharmaceutical prices in a market and clinical trial intensity are linked.
- The trends in the number of new clinical trials will be analyzed by source of funds, phase of clinical evaluation, and therapeutic area. Results for Canada will be compared with foreign markets and an analysis of trends in single-country versus multinational trials will also be conducted.

Domestic Analysis

- Trends in the number of clinical trials
- Breakdown of clinical trials by phase and source of funds
- Impact of COVID-19 on the number and type of clinical trials

International Analysis

- Trends in Canada's relative position in terms of clinical trials
- Trends in single-country versus multinational trials
- Investigate relation between pharmaceutical prices and clinical trials

Access

Availability of new medicines

The analysis will monitor and evaluate the trends in the availability of new medicines in Canada and compare these to trends in foreign market.

Domestic Analysis

- Trends in the number of new active substances (NAS) approved by Health Canada
- Assessment of NAS approved and then subsequently marketed in Canada
- The time from regulatory approval of NAS to actual sale
- Assessment of NASs not seeking HC approvals, but accessed through Special Access Program (SAP)
- Drug shortages

International Analysis

- Trends in number of medicines launched internationally and coming to the Canadian market
- Trends in the international sequencing of new medicine launches impacting Canada
- Statistical analysis to determine whether there is link between drug prices and availability of drugs

Access

System coordination

This analysis is from a health systems perspective and will look at the number of medicines undergoing health technology assessment (HTA) in Canada, those that undergo price negotiation with the pan-Canadian Pharmaceutical Alliance (pCPA), and the conditions under which they are ultimately reimbursed by public and private payers.

Health Technology Assessment	- The extent to which patentees are submitting their products to the HTA - The circumstances in which medicines are not submitted for HTA review - The degree of alignment between the indication reviewed by CADTH or INESSS and PMPRB - HTA resubmission for new indications or because of developing evidence
Price Negotiation	- Changes in the number or proportion of new medicines that are subject to price negotiations - Changes in the average duration of pCPA negotiations
Reimbursement	- Degree of public reimbursement for new medicines - Changes in the nature and scope of public coverage - Shifts in public plan design (deductible/copayment structures) and eligibility criteria - Trends in private insurance plans: coverage of high-cost medicines, patient copayments and deductibles - Private payer survey related to the impact of the reforms

The PMPRB will also monitor how its own review processes are lining up with the processes for the HTA assessment, price negotiation and reimbursement decisions.

*Canadian Agency For Drugs And Technologies In Health
**Institut national d'excellence en santé et services sociaux.

Access

Consultation Questions

LET US KNOW WHAT YOU THINK

In your view, what is the importance of monitoring and evaluating possible changes in the access to medicines following the Guideline changes?

Which of the proposed objectives around the assessment of access to medicines are most important to you?

Are there other aspects of assessment of the access to medicines that are relevant to you and not already reflected in the PMPRB plan?

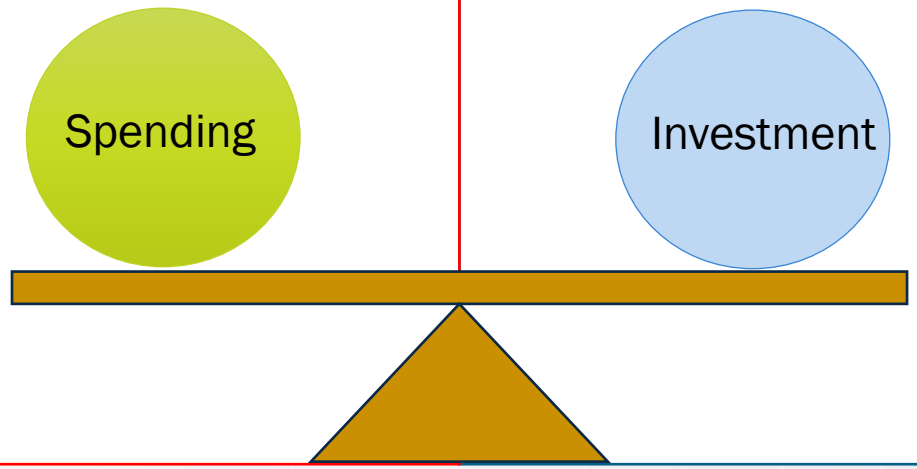
GMEP

- Drug spending
- Research and development
- Economic footprint

Pharmaceutical Ecosystem

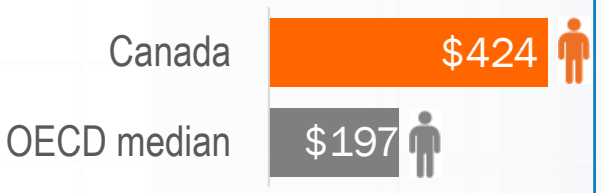
Background

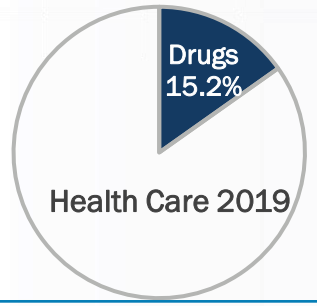
PMPRB reforms driven in large part by concerns from public and private payers with the sustainability of the health care system in Canada.



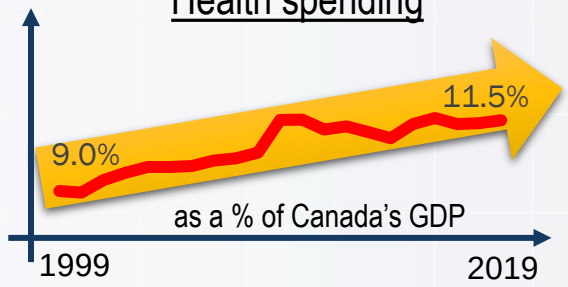
Patentees expressed concerns around Canada's attractiveness in terms of for research and development (R&D) investment and its effects on the industry's domestic economic footprint

Drug spending





Health spending



2019

11.5% of GDP

$7,064

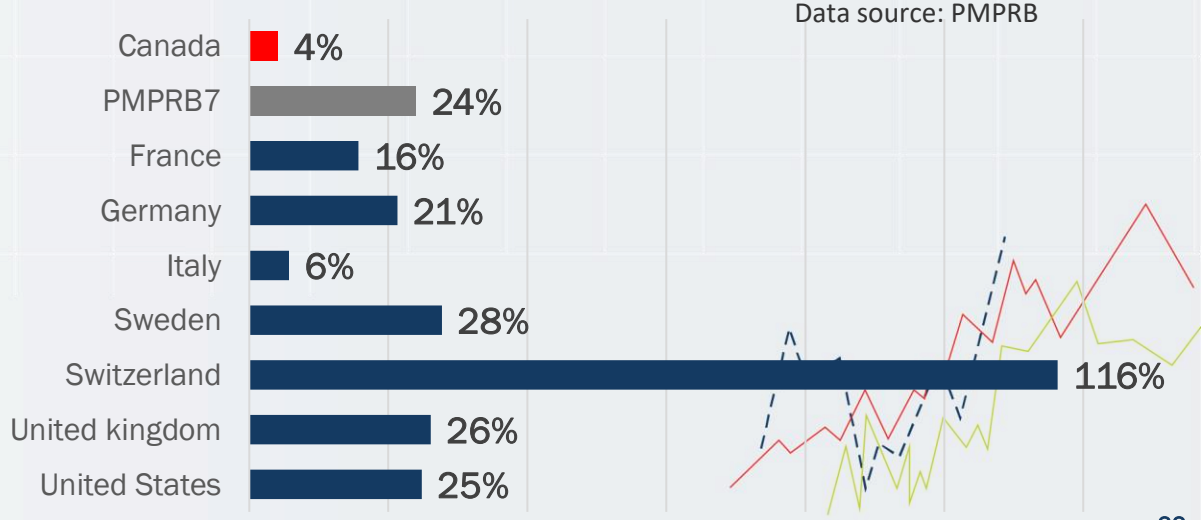
OECD average

8.8% of GDP

$5,514

R&D-to-Sales Ratios, Canada and the PMPRB7, 2017

Data source: PMPRB



Pharmaceutical Ecosystem

Drug spending

The PMPRB will monitor and evaluate any changes in the sales of patented medicines, its drivers, and associated shifts in the proportions of total spending accounted for by individuals, public plans and private insurers. The spending on these medicines will also be evaluated in relation to macroeconomic measures of overall health expenditures and GDP.

Domestic Analysis

- Trends in the patented drug spending at national, provincial and payer level
- Cost drivers
- Trends in patented drug spending relative to other markets, healthcare spending and the GDP

International Analysis

- Patented drug spending per capita and cost drivers
- Patented drug spending relative to other markets, healthcare spending and the GDP

Pharmaceutical Ecosystem

Research and development Economic footprint

Research and development

The PMPRB will monitor and assess domestic and international trends in pharmaceutical R&D expenditures.

Domestic Analysis

- Trends in R&D expenditures by patentees
- R&D-to-sales for patented medicine
- Analysis of the types of R&D investments, including investments beyond the SR&ED definition
- Trends in patentee versus public funding of R&D

International Analysis

- Results from the domestic analysis will be compared with international norms
- Determinants of R&D investments
- Evidence of a relationship between R&D investments and pricing

Economic footprint

The PMPRB will look at patentee investments in Canada, including sector performance, economic output, direct and indirect employment, profitability and returns, as well as how these compare with other sectors of the economy domestically and globally.

Pharmaceutical Ecosystem

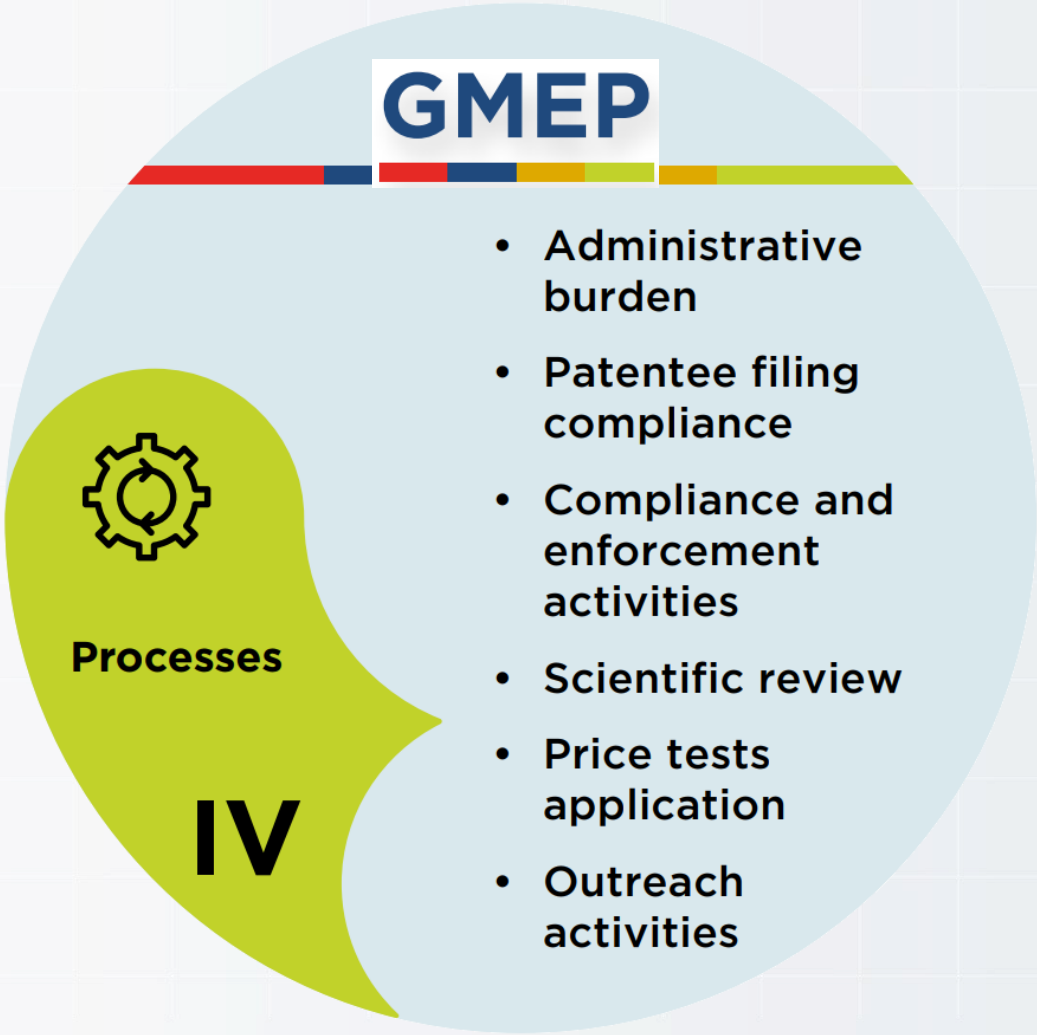
Consultation Questions

LET US KNOW WHAT YOU THINK

In your view, what is the importance of monitoring and evaluating the changes in the pharmaceutical ecosystem following the Guideline changes?

Which of the proposed objectives around the assessment of the pharmaceutical ecosystem are most important to you?

Are there other aspects of assessment of the pharmaceutical ecosystem that are relevant to you and not already reflected in the PMPRB plan?


GMEP
Processes
IV
• Administrative burden
• Patentee filing compliance
• Compliance and enforcement activities
• Scientific review
• Price tests application
• Outreach activities

IV Processes

Administrative burden
Changes in the resources patentees allocate to complying with the new filing requirements will be evaluated, including changes in the volume of information required to be reported by the patentees and the associated time and cost of doing so.

Patentee filing compliance
Patentee adherence with the filing requirements will be monitored.

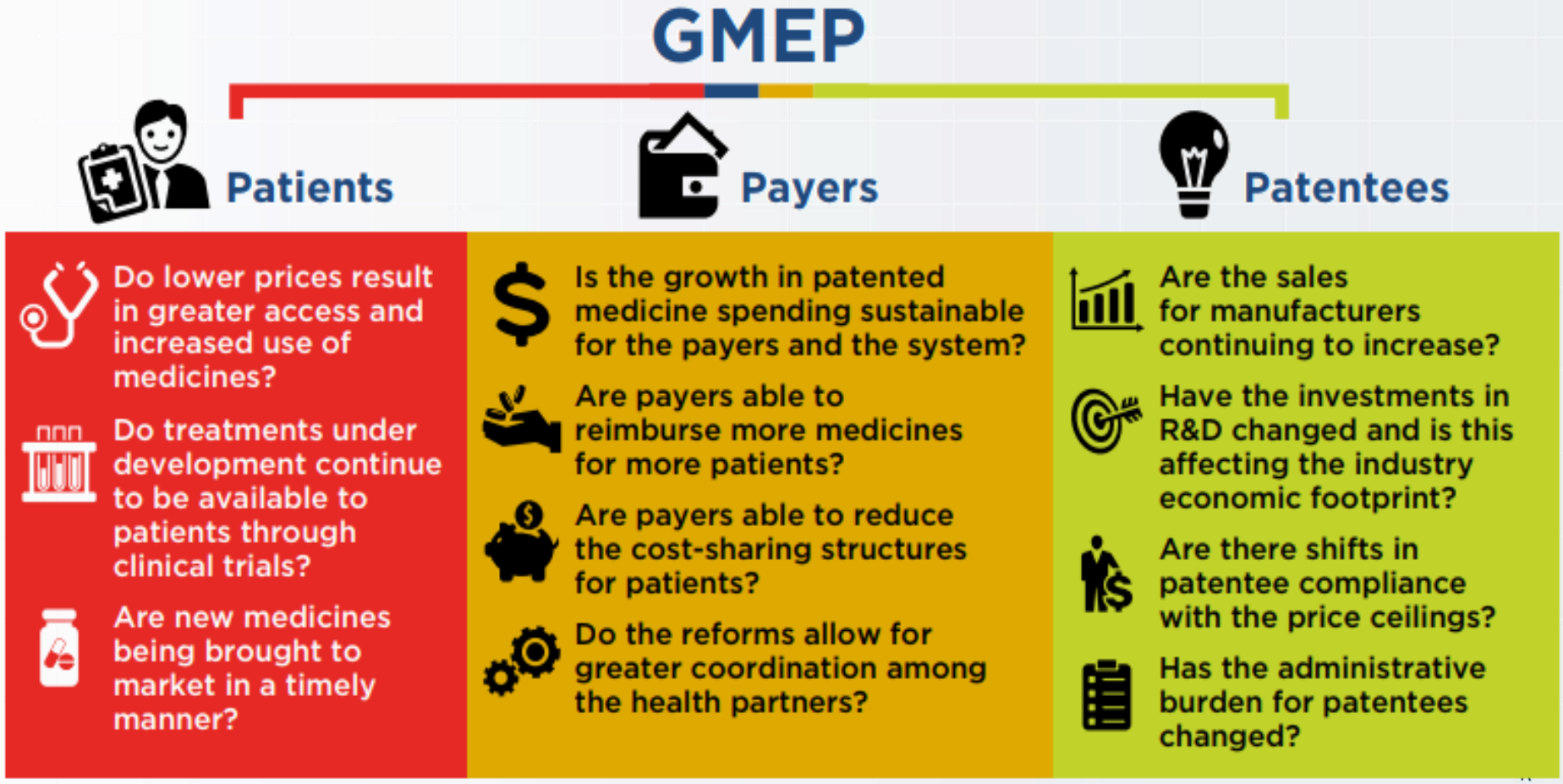
Compliance and enforcement activities
The PMPRB will report on general compliance and enforcement activities and identify any notable changes following the implementation of the regulatory amendments, including the total number of investigations, the number of voluntary compliance undertakings (VCUs) and related payments, notices of hearings and matters before the courts.

Scientific review
The analysis will assess how considerations to the pharmacoeconomic value, treatment cost, therapeutic criteria level and the set of comparators impact PMPRB processes.

Price tests application
The PMPRB will evaluate the operational requirements of applying the new MLP and MRP price tests and their impact on the price assessment process for various categories of patented medicines (e.g., Grandfathered, Line Extensions, Gap and New Medicines (MLP and MRP)). This includes monitoring why and how often new patented medicines are screened into Category I.

Outreach activities
The PMPRB will track the number and frequency of its outreach efforts to help patentees and other stakeholders understand the application and impact of the new Guidelines.

Next Steps: Engaging with Canadians in the development of the GMEP



HOW TO GET INVOLVED

The PMPRB invites stakeholders to comment on this proposed GMEP by **June 21, 2021** by sending feedback through the PMPRB **website**.

For further details on how you can participate in the engagement sessions and provide your feedback, see the PMPRB's website and Twitter account.

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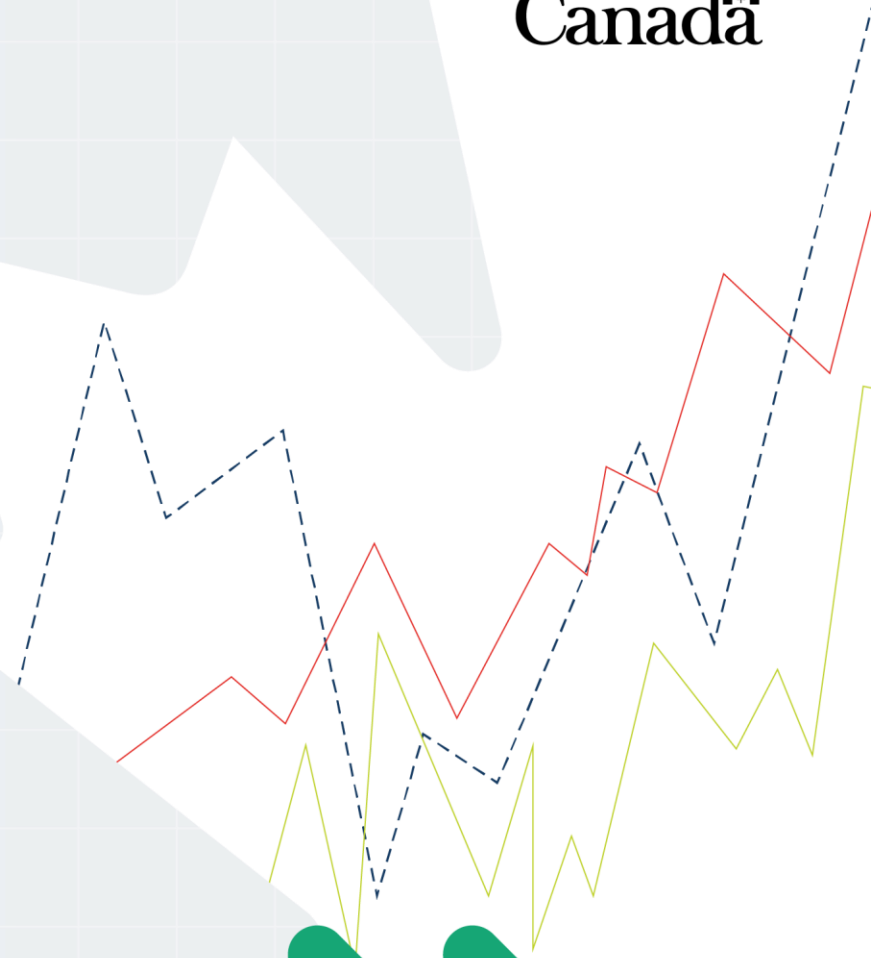
Questions & Answers



Thank you