Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada

PMPRB Public Webinar
Draft Guidelines 2022

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Outline

A. About the PMPRB and its path to reform

B. Key features of the Draft Guidelines

C. Next steps

D. Questions and answers

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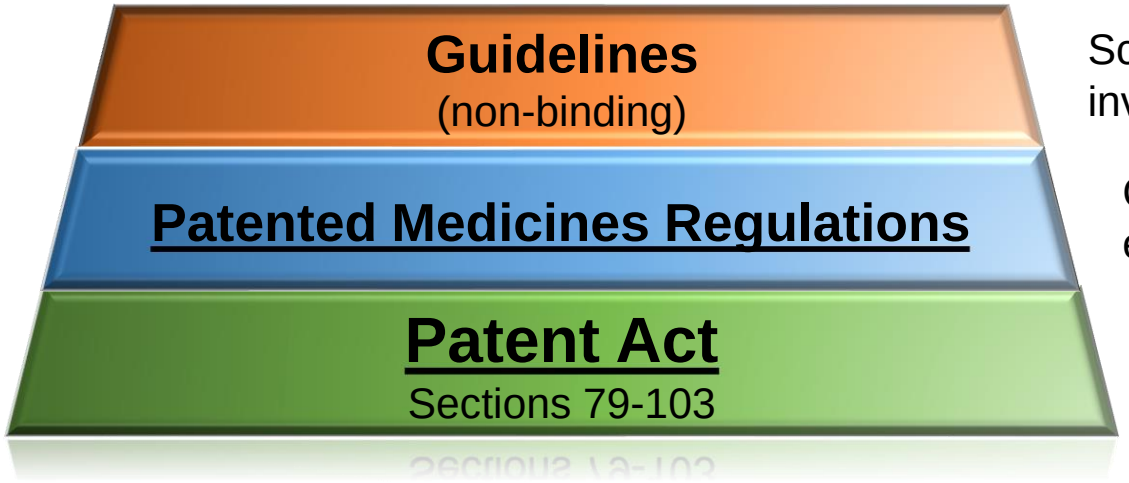
A. About the PMPRB and its path to reform

About the PMPRB

- An independent, quasi-judicial body established by Parliament in 1987 under the Patent Act.
- A consumer protection agency with a dual regulatory and reporting mandate.
- Through its regulatory mandate, it ensures that the prices of patented medicines sold in Canada are not excessive.
- The PMPRB regulatory framework reposes on three legal instruments:



Scientific and price review process, investigation criteria, etc.

Comparator countries and reporting requirements: e.g. prices of medicines, R&D investment.

Excessivity factors, mandate, jurisdiction, structure and powers of the Board.

History of the PMPRB

Prior to 1987

The Canadian Patent Act ("Act") allowed generic drug manufacturers to obtain compulsory licenses to produce generic versions of patented brand name drugs at any time during the patent term.

Bill C-22 and the creation of the PMPRB in 1987

In 1987, Canada enacted a two-fold reform of its medicine patent regime (Bill C-22) that sought to balance competing industrial and social policy objectives:

- Incentivize R&D expenditure through stronger patent protection;
- Mitigate the economic impact of stronger patent protection on the health system.

The intent was to double R&D in Canada (to 10% of revenues) while keeping prices in line with high R&D countries on the assumption we would come to emulate their level of investments.

Elimination of compulsory licensing in 1993

The Act was amended again to eliminate the compulsory licensing regime and provide the PMPRB with additional remedial powers in dealing with cases of excessively priced patented medicines.

Previous Approach of the PMPRB Guidelines

New patented medicines were assessed for level of therapeutic benefit relative to existing therapies and assigned a ceiling price that was based on one, or a combination of the following:

1. The median international price based on the PMPRB7;
2. The highest price in the domestic therapeutic class.

After entering the market, the price of a medicine was able to increase in keeping with the Consumer Price Index (CPI) but never to the point of becoming highest of the PMPRB7.

Where PMPRB Staff was unable to close the investigation, a hearing could be held before a panel of Board Members. If the Board decided a medicine was excessively priced, the patentee could be ordered to reduce its price and/or pay back excess revenues.

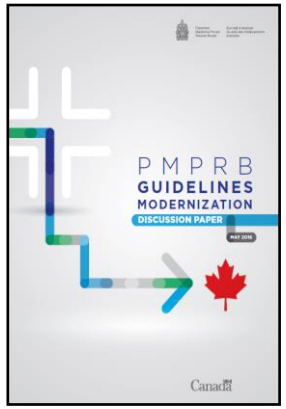
The path to PMPRB reform

The release of the Draft Guidelines is the culmination of an 7-year process, dating back to the release of the PMPRB's Strategic Plan in December 2015, when framework modernization was identified as a key priority.

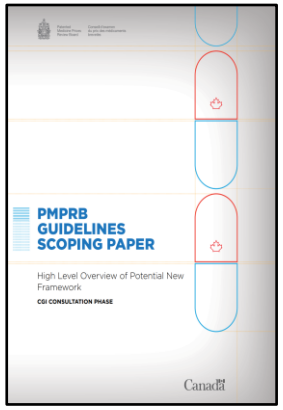
2015 | 2016 | 2017 | 2019 | 2020 | 2022

PMPRB Strategic Plan

PMPRB Discussion Paper on Guideline Reform

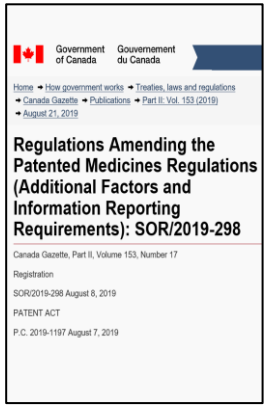


PMPRB Guidelines Scoping Paper



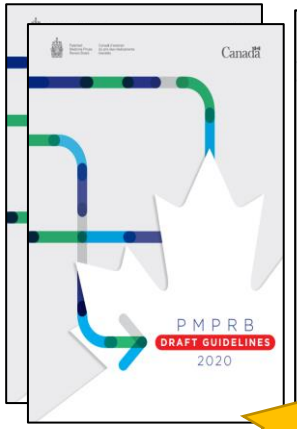
PMPRB Steering Committee Report

Health Canada Canada Gazette II

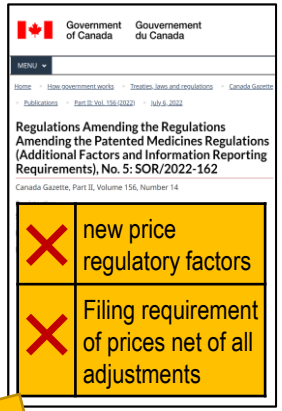


PMPRB November Draft Guidelines

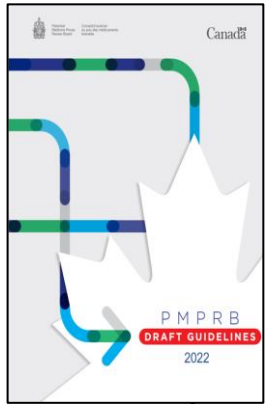
PMPRB June Draft and October Final Guidelines



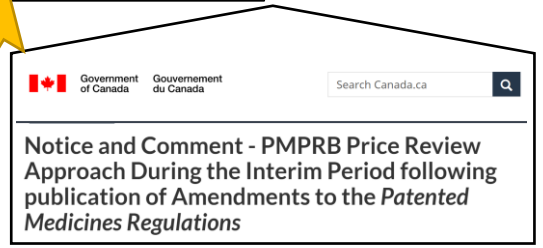
Health Canada Canada Gazette II



PMPRB October Draft Guidelines



The Minister announced that the Government would not proceed with the amendments related to new price regulatory factors and to the requirements on rights holders to file information net of all price adjustments.



Amendments to the Patented Medicines Regulations

Key changes in effect since July 1, 2022

1. **An updated schedule of comparator countries (the new "PMPRB11").**

PMPRB7 (*retained in new basket)			CDN Price Ratio
	✗	United States	3.32
	✗	Switzerland	1.01
	☑	Italy*	0.97
	☑	Germany*	0.96
	☑	Sweden*	0.91
	☑	United Kingdom*	0.87
	☑	France*	0.79

Added countries		CDN Price Ratio
	Spain	0.96
	Japan	0.90
	Belgium	0.88
	Norway	0.88
	Netherlands	0.77
	Australia	0.71

2. **Reduced reporting obligations for patented veterinary, over the-counter and generic medicines** so that the PMPRB can focus its attention and resources on patented medicines at greater risk of excessive pricing.

PMPRB is consulting on New Draft Guidelines

- As neither the existing nor the October 2020 Guidelines address the set of regulations which came into force on July 1, 2022, it is necessary for the Board to consult on a new set of guidelines.
- On October 6, 2022, the PMPRB released new draft Guidelines and an accompanying Backgrounder document.
- A 60-day Notice and Comment consultation period is underway, during which stakeholders and interested members of the public are invited to provide feedback through the PMPRB consultation portal.
- The PMPRB is hosting a series of webinars for industry and the public.
- Requests from individual stakeholders to meet with the PMPRB to discuss the Draft Guidelines will be considered on a case-by-case basis during the consultation period.
- The deadline to submit feedback is December 5, 2022, and it may be submitted through the PMPRB consultation portal.

B. Key features of the new Draft Guidelines

What's different about the Draft Guidelines?

More pragmatic, less prescriptive guidance

Simple

- **Clear link to Act and Regulations**: investigation criteria based strictly on s.85 factors and information filed by rights holders.
- **Focus on publicly verifiable prices**: allows for "apples-to-apples" price comparisons with domestic and international list prices.
- **Concise and streamlined structure**: stripped down of technical jargon and extraneous content.

Flexible

- **Case-by-case resolution**: investigation criteria concept enables staff and rights holders to address pricing issues in a way that is individualized and not rules-oriented.
- **Unrestricted net pricing**: rights holders free to vary net prices year to year without regard for PMPRB Guidelines.

Modern

- **Risk-based oversight**: waiver for vaccines, biosimilars, patented generics, patented over-the-counter (OTC) medicines, certain non-prescription controlled substances and veterinary medicines.
- **Forward looking emphasis**: greater scrutiny of new medicines over existing.
- **Alignment with recent policy/caselaw**: ongoing emphasis on price parity with new PMPRB11 countries and with limitations of PMPRB's role in balance struck by C-22, C-91.
- **Contemporary approach**: present-day government guidance documents are generally more pragmatic and less prescriptive.

Factors in the Patent Act

85 (1) In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:

(a) the prices at which the medicine has been sold in the relevant market;

(b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;

(c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;

(d) changes in the Consumer Price Index; and

(e) such other factors as may be specified in any regulations made for the purposes of this subsection.

Key Guideline Features

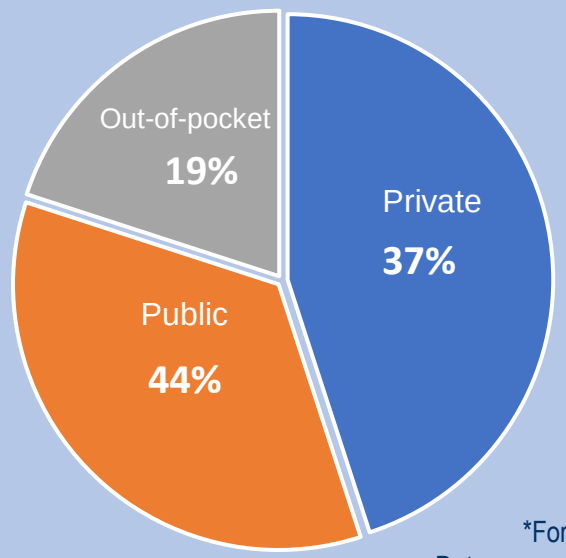
1. List prices of patented medicines
2. New and existing medicines
3. Criteria that may trigger an investigation
4. Special provisions for certain medicines

1. List prices of patented medicines

- The proposed investigation criteria apply to list prices only.
- List prices are by definition the highest prices that rights holders charge in the market, and the most relevant in an investigation into potential excessive pricing.
- The approach allows for a more consistent and robust "apples-to-apples" price comparisons with domestic and international list prices for a medicine and/or its therapeutic comparators.
- Rights holders have a statutory obligation under Section 80 of the Patent Act to file with the PMPRB sales and ex-factory list prices.
- Staff will consider the average transaction price in the context of proposed undertakings by rights holders to offset potential excess revenues.

In Canada, many private plans and out-of-pocket pay the list price, representing almost two thirds of prescription drug spending. This makes the list price central to the PMPRB's mandate.

Prescription drug spending, 2021*



*Forecast
Data source: CIHI

2. Existing and New medicines

Section 32. Existing medicines *are:*

(i) all dosage forms and strengths of medicines for which an NOC was issued prior to July 1, 2022 regardless of whether those dosage forms and strengths have been approved for new indications (without a DIN change) after July 1, 2022,

(ii) new dosage forms and strengths of these medicines to which an NOC was issued on or after July 1, 2022; and

(iii) all dosage forms and strengths of medicines for an authorized sale under the "Special Access Programme" for the Sale of New Drugs for Emergency Treatment under Part C Division 8 of the Food and Drug Regulations that was made prior to July 1, 2022.

New medicines *are all other dosage forms and strengths of medicines that are NOT Existing medicines*

The distinction is solely for administrative purposes, all S.85 factors apply in the context of an investigation or hearing.

NOC – Notice of Compliance

3. Criteria that may trigger an investigation

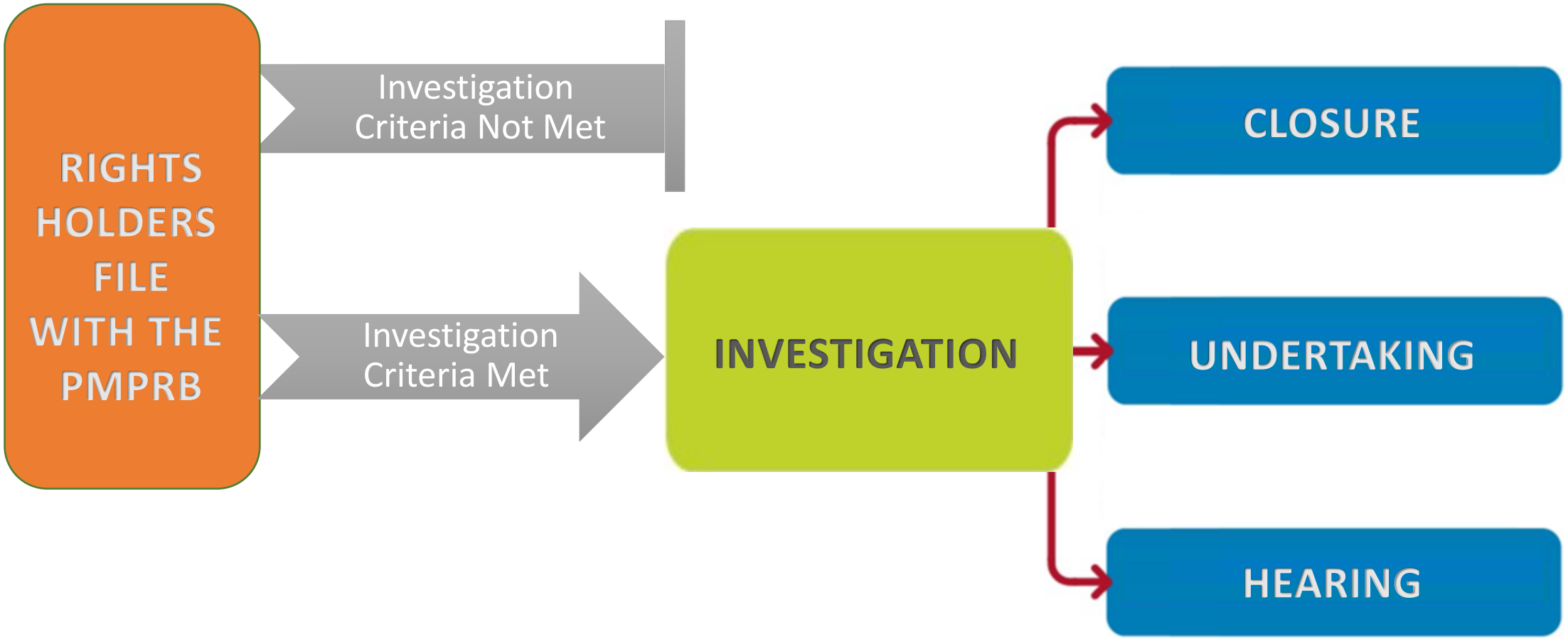
Simple and straightforward criteria anchored in the section 85 factors of the Patent Act

- The draft Guidelines adopt the concept of "investigation criteria" anchored in the section 85 factors of the Patent Act.
- Staff will not presume the price of the medicine to be excessive.
- Staff will close the investigation or recommend to the Chairperson that a hearing be commenced.
- For reasons of administrative efficiency and resource optimization, Staff will work with the rights holder to achieve an outcome that avoids the need for litigation.

Considerations during an investigation:

- The strength of the evidence;
- The degree to which the price of the medicine deviates from the investigation criteria levels;
- The extent to which the facts are aligned with the jurisprudence interpreting the s. 85 factors; and
- Whether the investigation raises new or unique questions that warrant judicial elucidation.

PMPRB process flowchart



3. Criteria that may trigger an investigation

All medicines

Section 33. The following criteria applies to all medicines (i.e., existing medicines and new medicines):

- **A complaint is received in respect of the pricing of the medicine; or**
- **The list price increased by more than the changes in the Consumer Price Index (CPI); or**
- **No international prices were filed by the rights holder.**

Additional criteria

Existing medicines

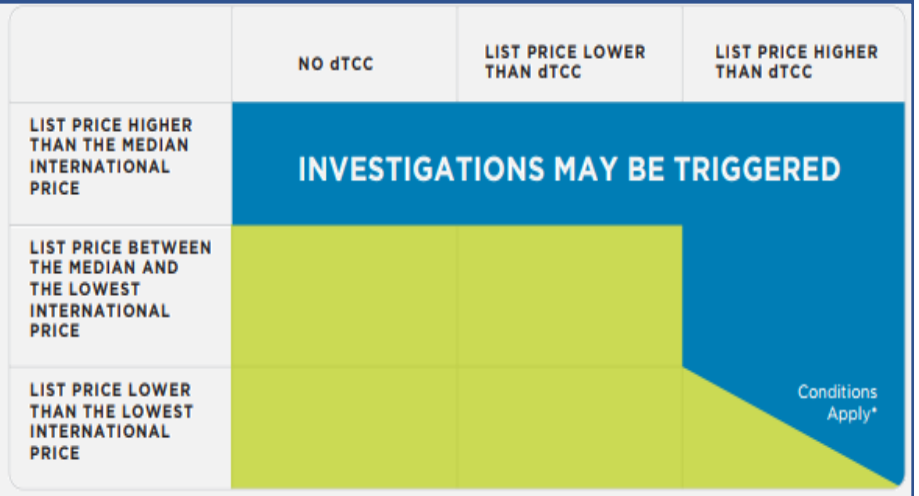
Section 34. The following additional criteria applies to existing medicines:

- **The list price of any dosage form or strength of the medicine exceeds the highest international price for the PMPRB11 based on pricing information provided by the rights holder.**

New medicines

Section 35. The following additional criteria applies to new medicines in the specific circumstances described:

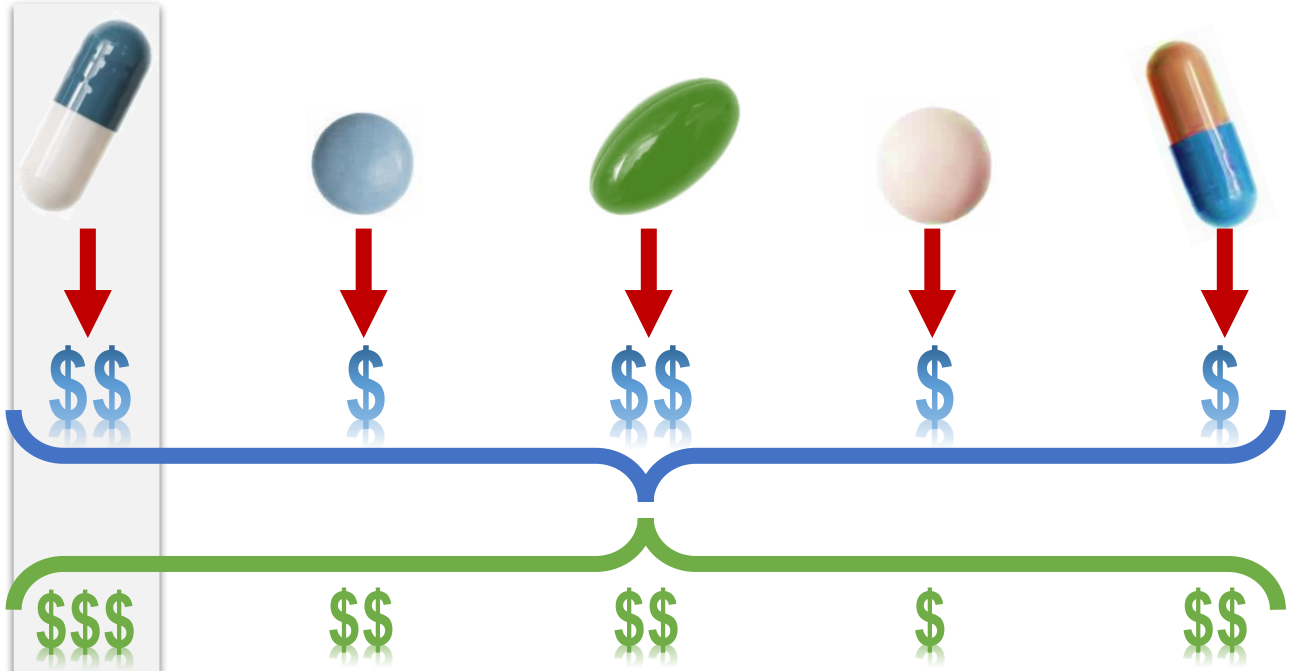
- **The list price exceeds the median international price for the PMPRB11; or**
- **The list price falls between the median and the lowest international price for the PMPRB11, but exceeds the top of the domestic therapeutic class comparator prices ("dTCC"); or**
- **The list price exceeds the midpoint between the top of the dTCC and lowest international price for the PMPRB11, and the top of the dTCC is more than 50% lower than the lowest international price.**



* The dTCC is more than 50% lower than the lowest international price, and the list price exceeds the midpoint between the dTCC and lowest international price.

dTCC – domestic Therapeutic Class Comparison

The domestic Therapeutic Class Comparison (dTCC)



Identify comparator medicines

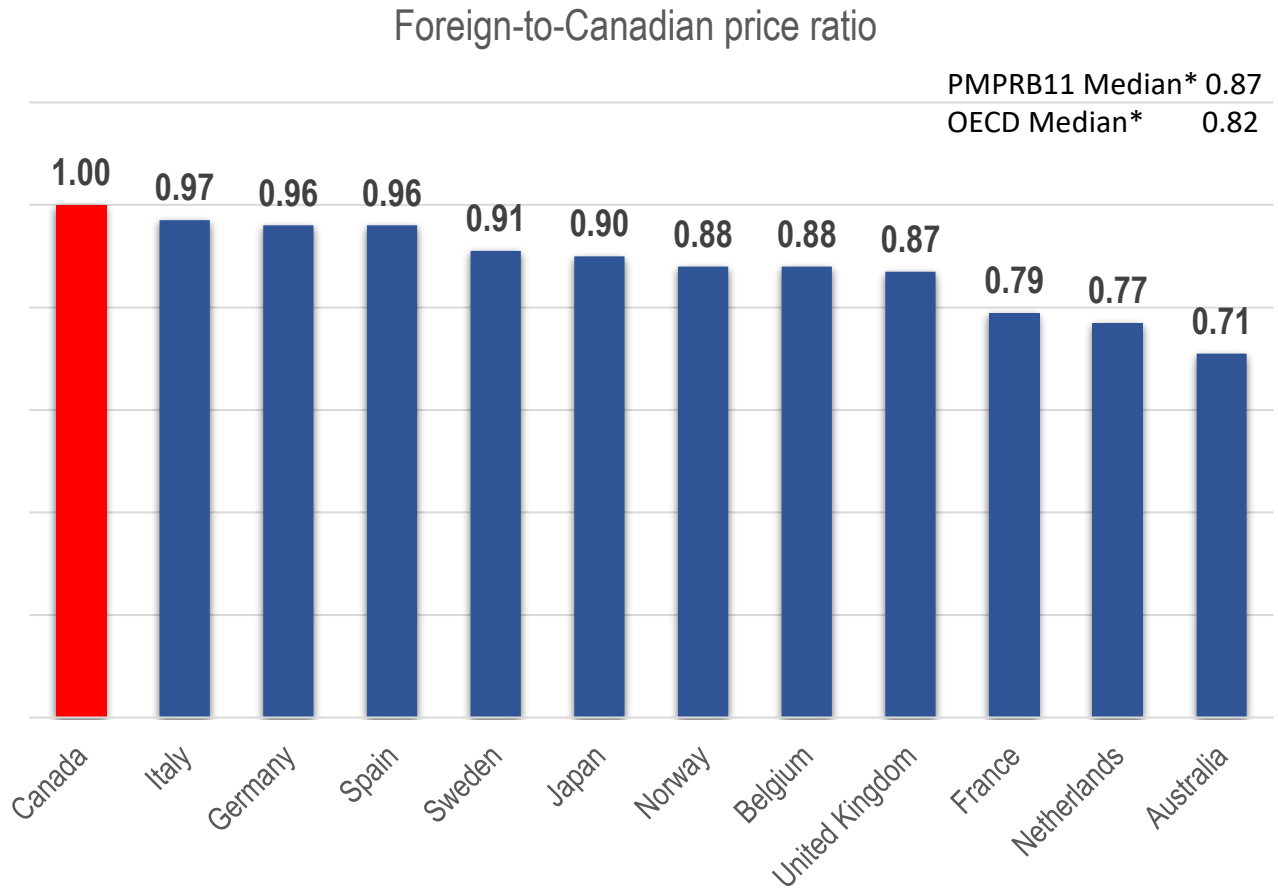
Identify the lowest price for each comparator medicines

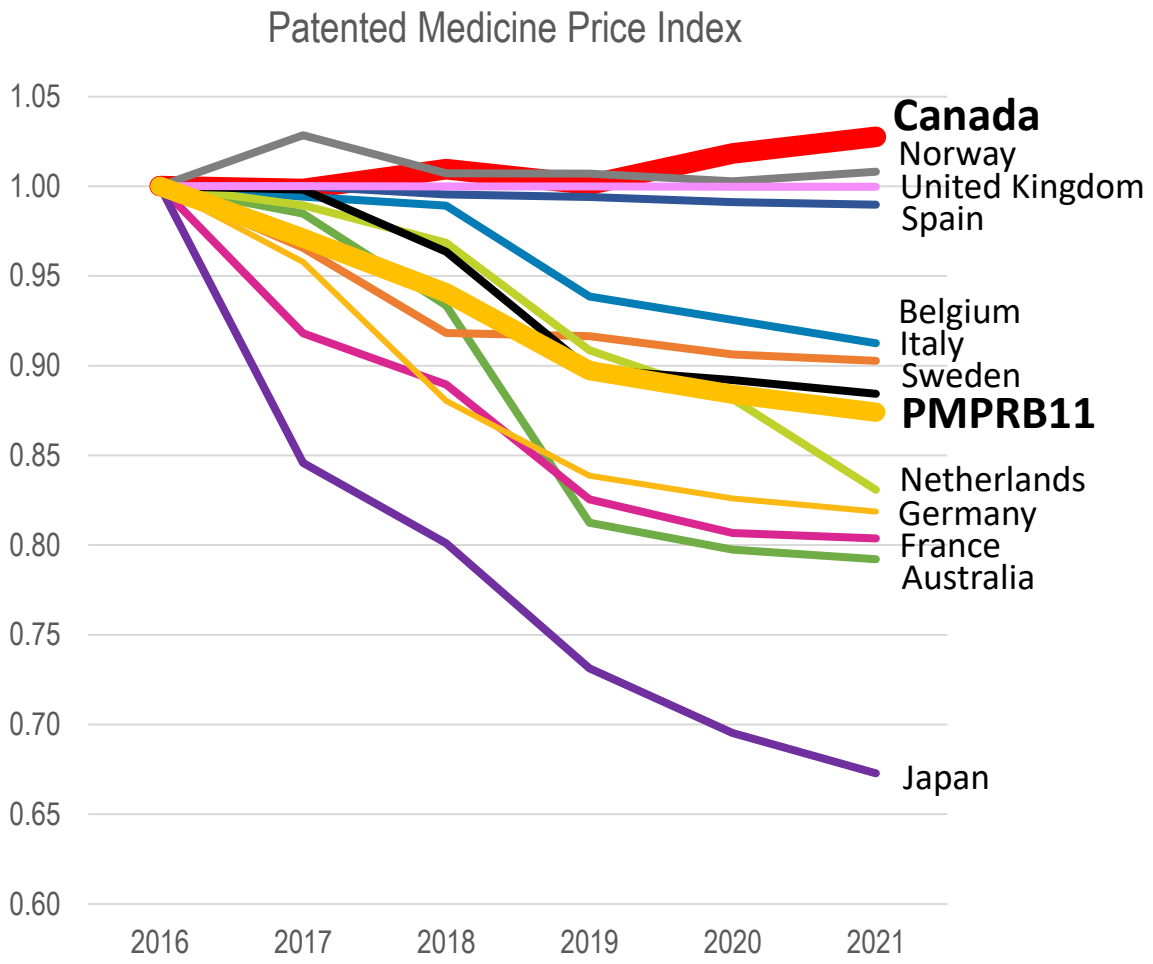
Convert the prices into the cost of treatment for comparable courses

dTCC

Identify the most expensive cost of treatment and divide this by the constituent units of the medicine to establish a per-unit price.

Proposed Investigation Criteria in line with policy intent





Data source: MIDAS® database, 2021, IQVIA (all rights reserved)

* Calculated at the medicine level for medicines with prices available in at least three foreign markets.

** Calculated at the medicine level for medicines with prices available in at least two foreign markets.

Data source: MIDAS® database, IQVIA (all rights reserved)

4. Special provisions for certain medicines

Section 36. For Biosimilars, medicines for veterinary use, over the counter (OTC) medicines, and vaccines, an investigation may be opened only when a complaint is received.

Section 37. For Generic medicines, an investigation may only be opened when a complaint is received, and:

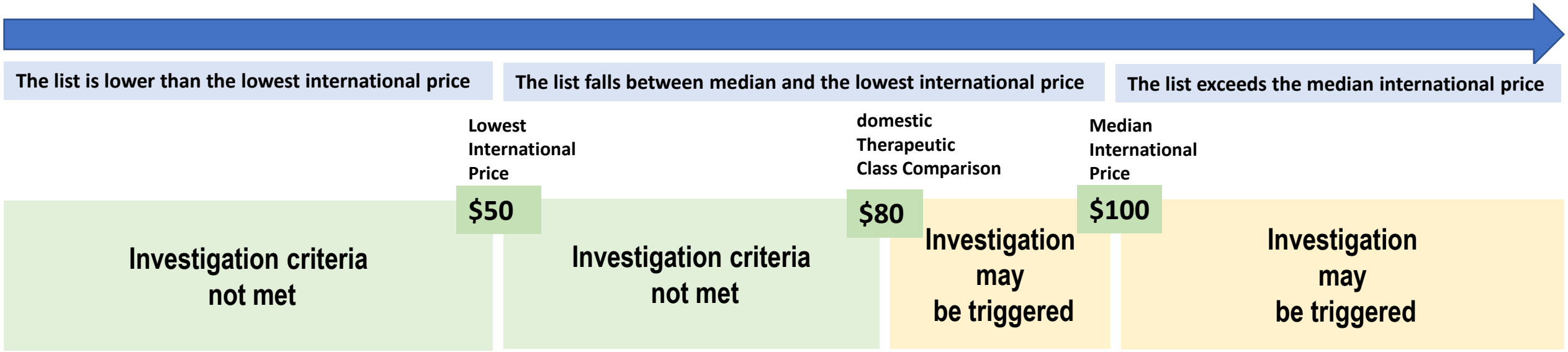
- ***The rights holder of the medicine is the only company in Canada which is selling a generic version of the medicine in Canada; and***
- ***The medicine is not the subject of a pricing agreement with the pCPA to which it is compliant. The onus of proving to Staff that a medicine is subject to, and compliant with, a pricing agreement with pCPA will rest with the rights holder.***

The provisions are solely for administrative purposes, all S.85 factors apply in the context of an investigation or hearing.

Illustrative example – New medicines

Circumstances that may trigger an investigation

There is a drug product available in all PMPRB11 countries. The lowest price is **$50** per tablet, and the median price is **$100** per tablet. Other similar drugs in Canada **cost at most $80** for the equivalent regimen **(the dTCC)**. What Canadian price would trigger an investigation?



dTCC – domestic Therapeutic Class Comparison

C. Next steps

Next Steps

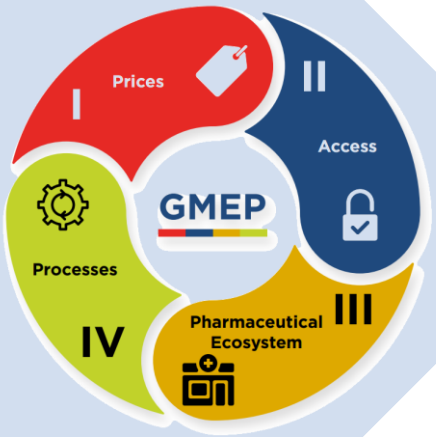
Consultation

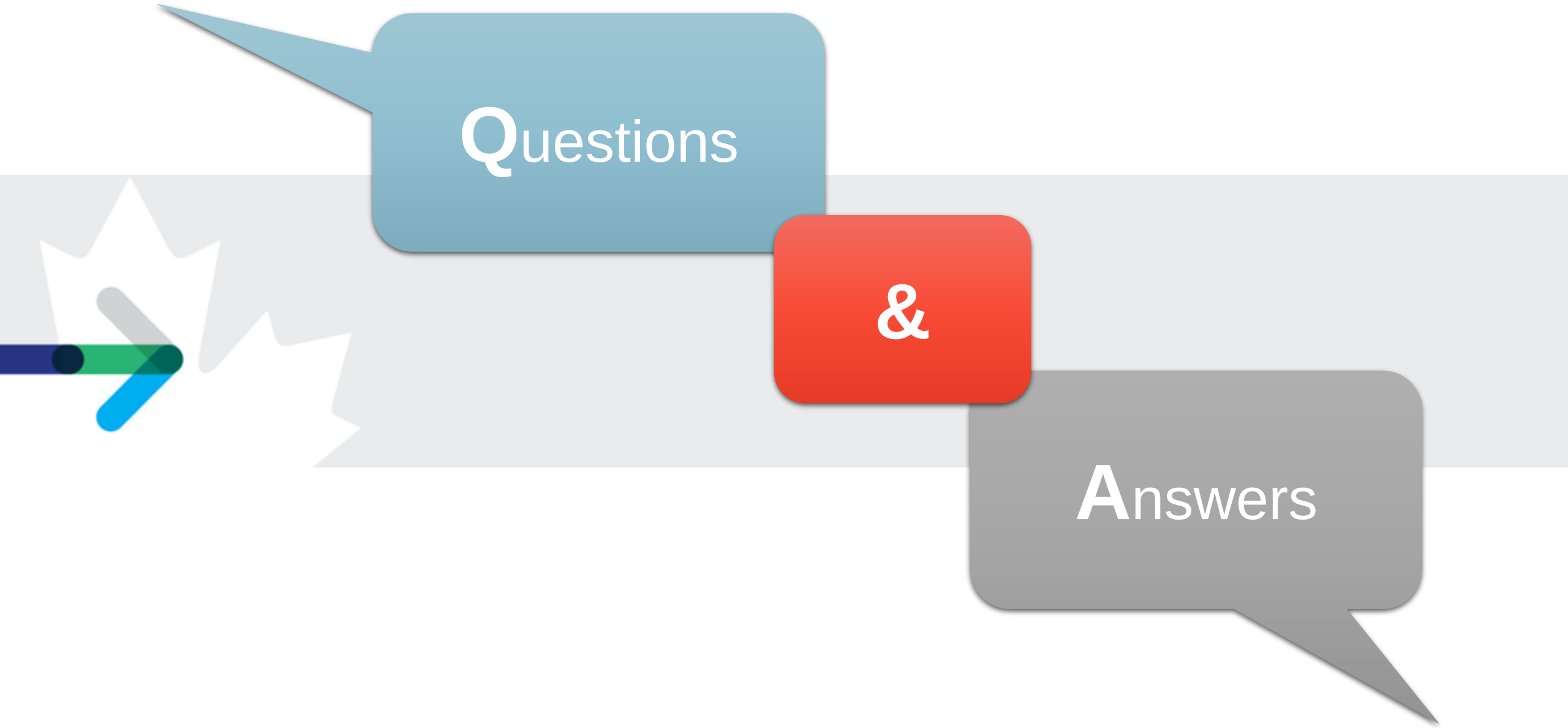
Stakeholders are encouraged to submit their feedback by December 5th to the PMPRB consultation portal.

Final Guidelines

The Board intends to have a final set of guidelines in place by the end of 2022.

GMEP




Questions
&
Answers

THANK YOU