Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada

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THE WEBINAR WILL BEGIN SHORTLY

PMPRB Webinar

An Overview of the PMPRB Discussion Guide

August 13, 2024 13:00 to 15:30 EST

About PMPRB, Jurisdiction and Legislation

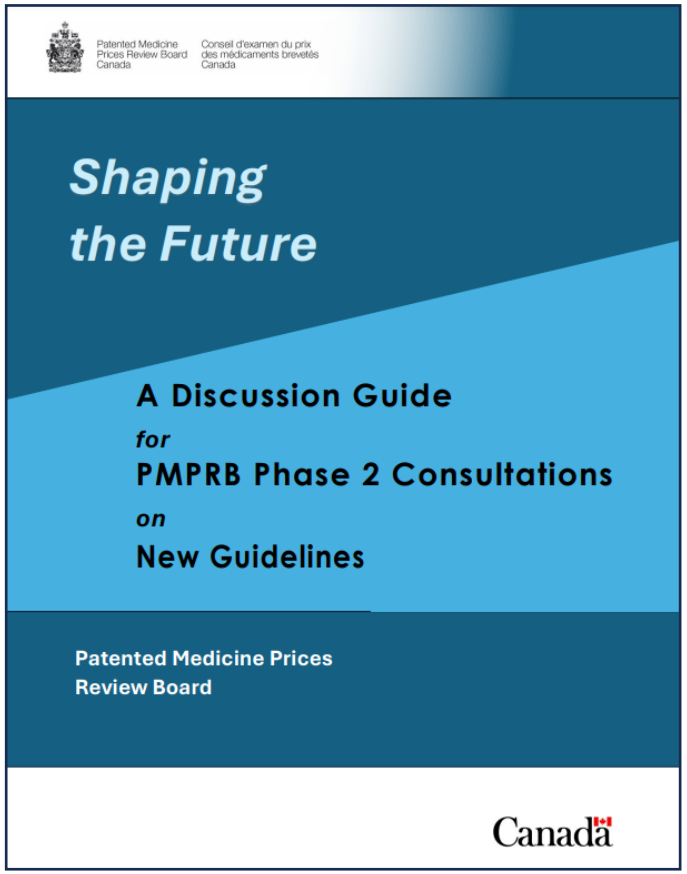
- **The PMPRB is an independent quasi-judicial body** with a dual price monitoring and reporting mandate.
- **Price Review mandate:** to monitor the prices of patented medicines to ensure that they are not excessive.
- **The PMPRB's powers and obligations** are set out in ss. 79-103 of the *Patent Act* and associated regulations.
- **A public pricing hearing** is the only setting in which the PMPRB can conclusively determine whether a price is excessive.
- **Section 85 (1) of the Act** specifies the following factors that the Board shall take into consideration:
  - the prices at which the medicine has been sold in the relevant market;
  - the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
  - the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
  - changes in the Consumer Price Index.

About the PMPRB Guidelines

- **The PMPRB issues non-binding Guidelines** which set out the price review processes performed by PMPRB staff when preparing recommendations on whether the PMPRB should hold a public pricing hearing.
  - The guidelines are not price-setting guidelines;
  - The guidelines set out a hearing candidate identification process;
  - The guidelines do not deem or presume prices excessive or non-excessive;
  - Staff have no authority to decide whether a price is excessive or not.
- **Few Reminders:**
  - The Chairperson is designated under the *Patent Act* as the Chief Executive Officer of the PMPRB. The Chairperson decides to commence hearings and appoints members to act as hearing Panel members.
  - The Board develops and issues Guidelines. Board members are adjudicators in hearings.
  - Only the Board, in a hearing, can make decision as to whether a price is excessive under the Patent Act.
  - Staff, via its Director General, assist the Board to do its work.

Discussion Guide

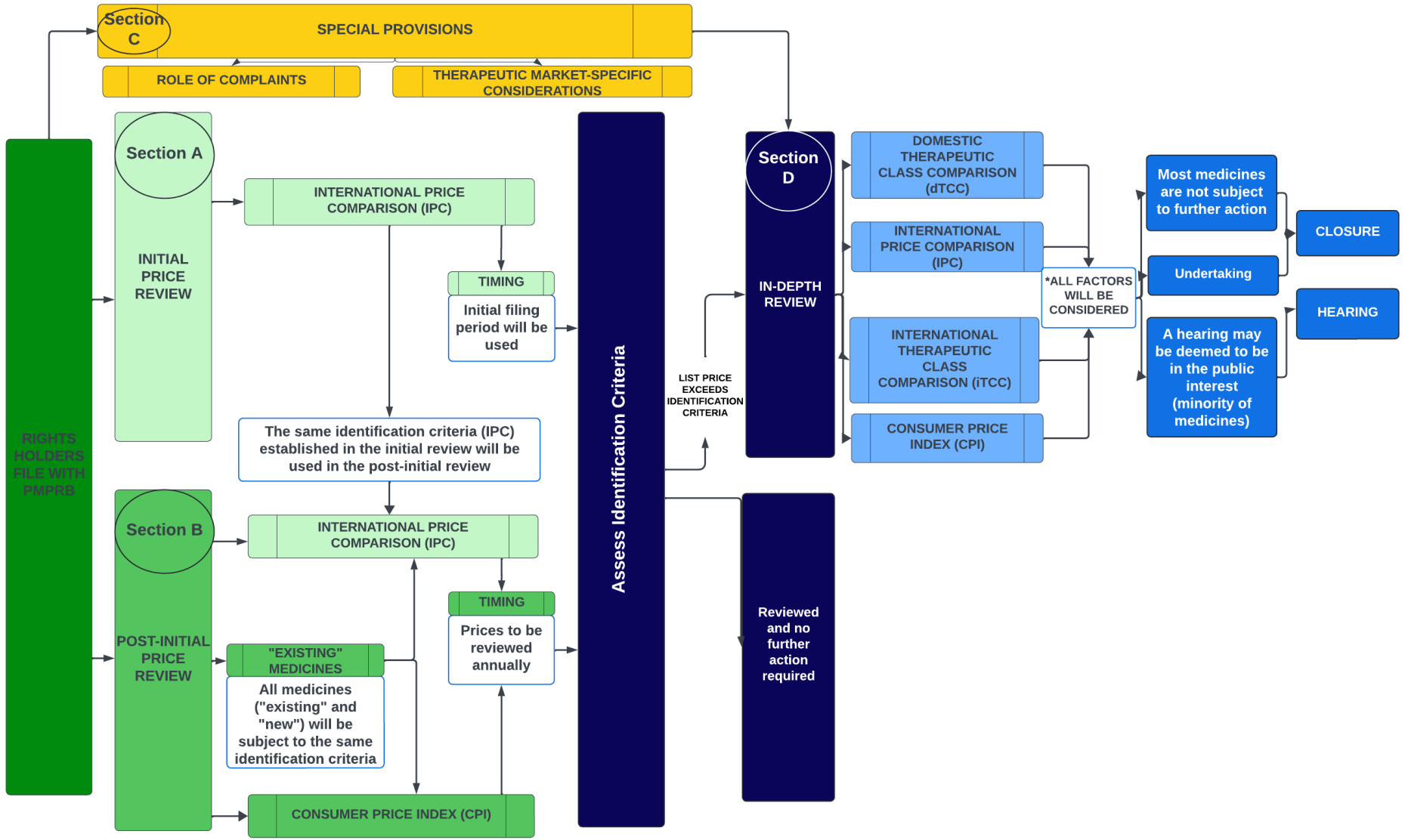
Outline of presentation



1. Overview of the Proposed Framework
2. Topics for Discussion
3. Case Studies
4. Next Steps

1. Overview of the Proposed Framework

Overview of the Proposed Framework

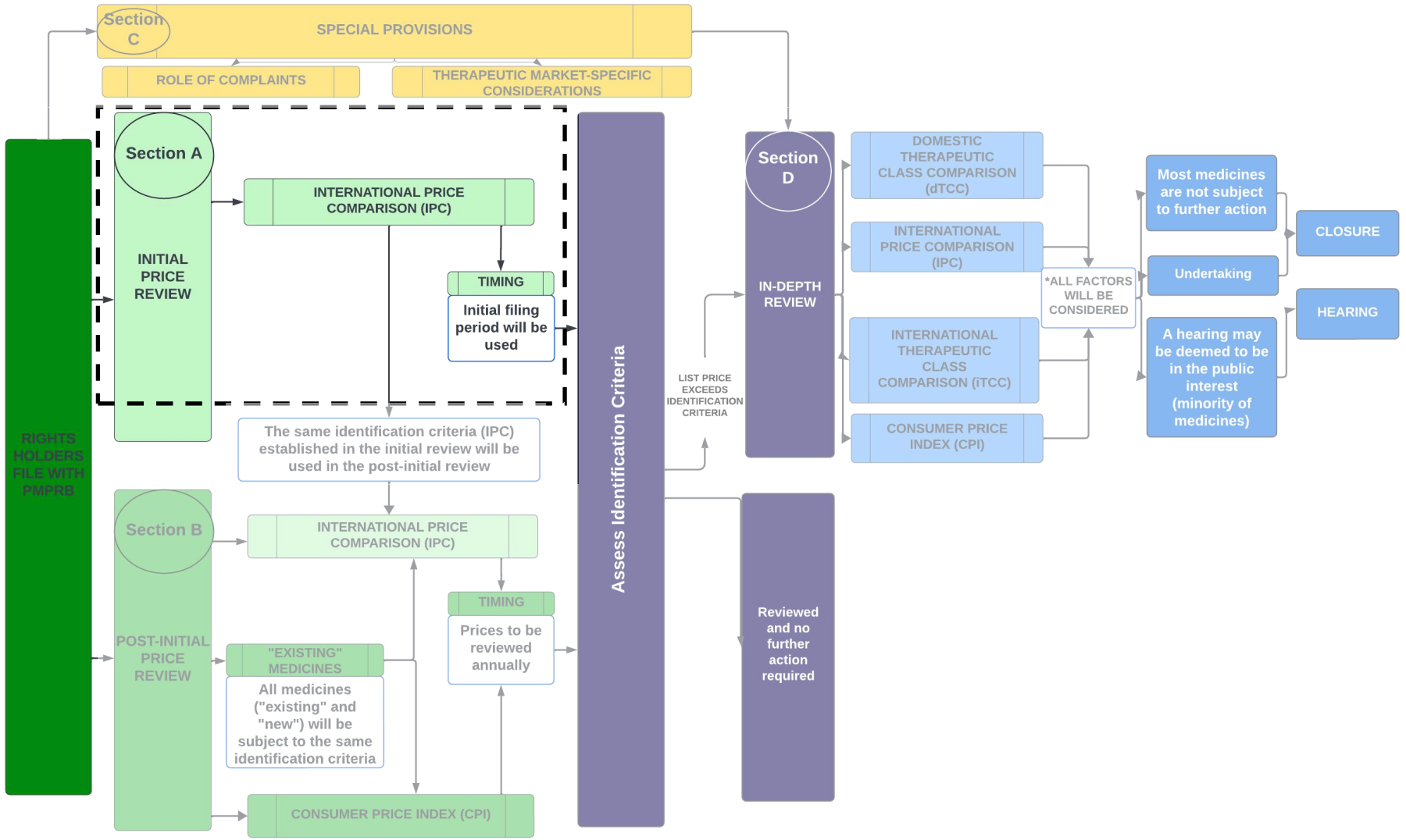


Overview of the Proposed Framework

Section A: Initial Price Review

Refer to Section 5.1 of the Discussion Guide

- Initial review of prices for new patented medicines based on the International Price Comparison (IPC) identification criteria.
- The medicine's first semi-annual filing will be used.

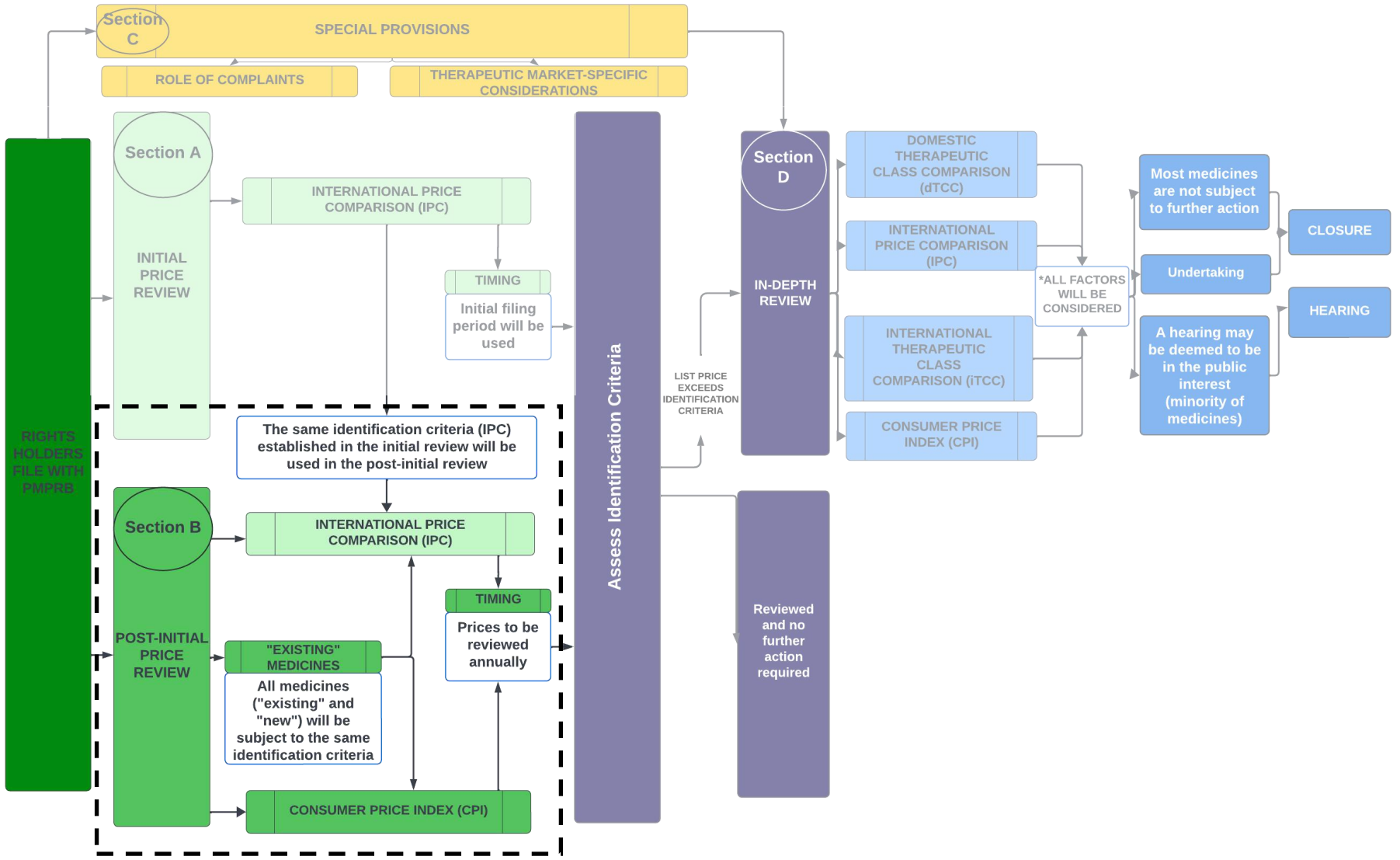


Overview of the Proposed Framework

Section B: Post-Initial Price Review

Refer to Section 5.2 of the Discussion Guide

- Annual post-initial reviews of prices for all patented medicines based on (1) list price vs. the IPC and (2) list price changes vs. changes in the Consumer Price Index (CPI).
- The same IPC identification criteria used during the initial review will be used.
- No distinction between “New medicines” and “Existing Medicine”

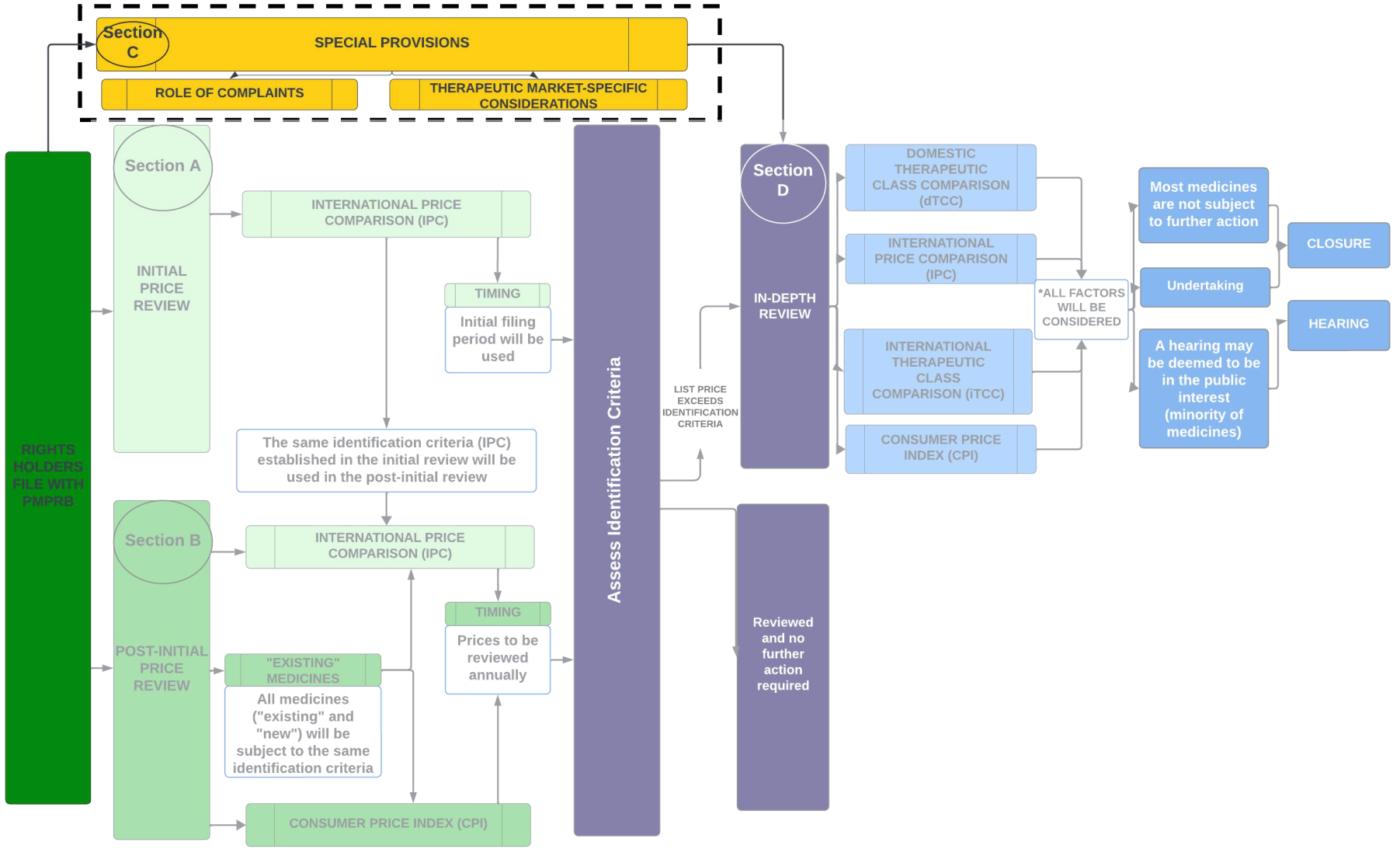


Overview of the Proposed Framework

Section C: Special Provisions

Refer to Section 5.3 of the Discussion Guide

- The receipt of the complaint will lead to an in-depth review.
- For medicines subject to reduced reporting obligations, an in-depth review will only be commenced if a complaint is received.

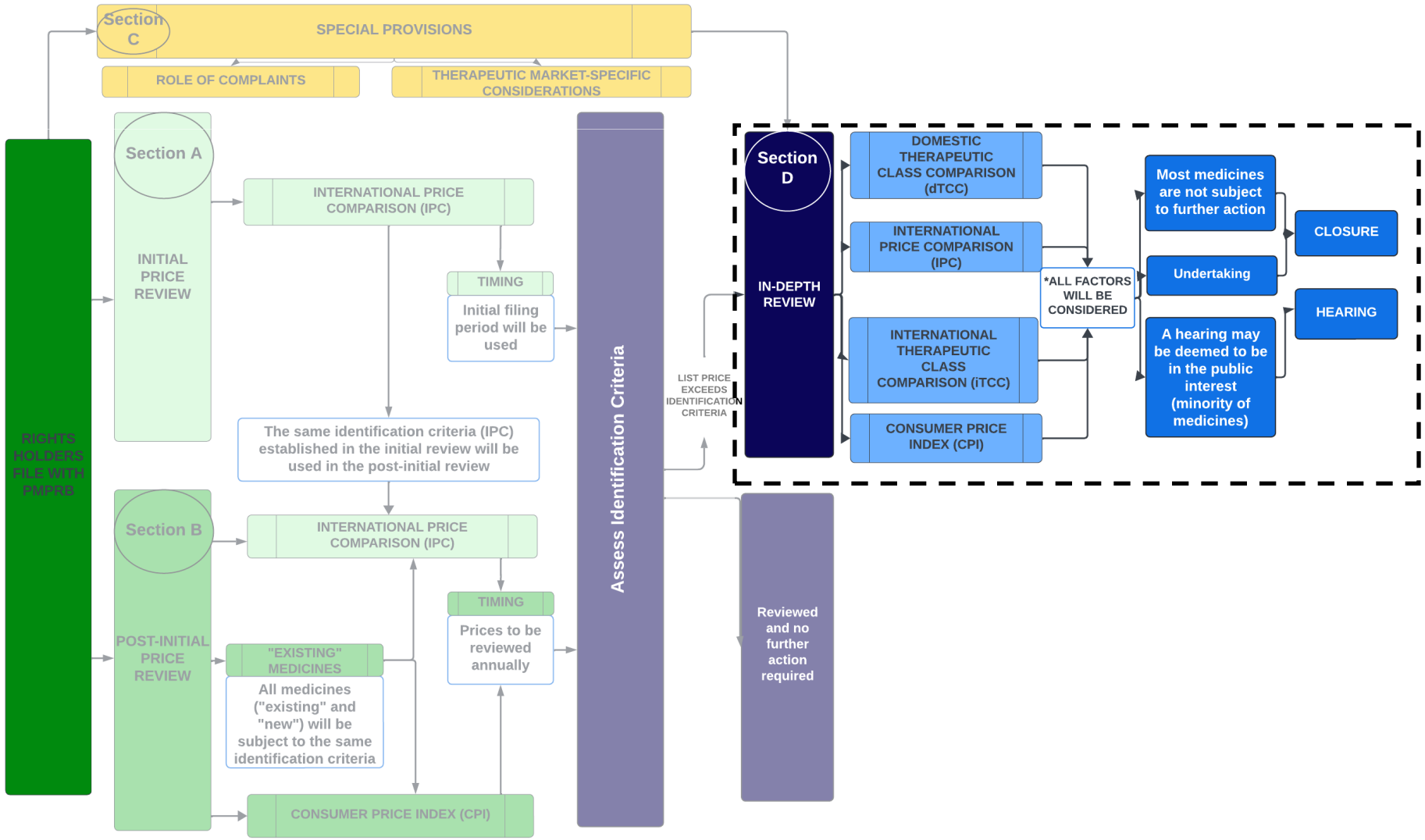


Overview of the Proposed Framework

Section D: In-Depth Review

Refer to Section 5.4 of the Discussion Guide

- Considers all the factors outlined in Section 85(1), including comparing prices to the IPC, changes in CPI, and TCC.
- The balancing of all the price comparisons based on the 85(1) factors will determine whether Staff recommends that the in-depth review be closed or proceed to a Notice of Hearing.



2. Topics for Discussion

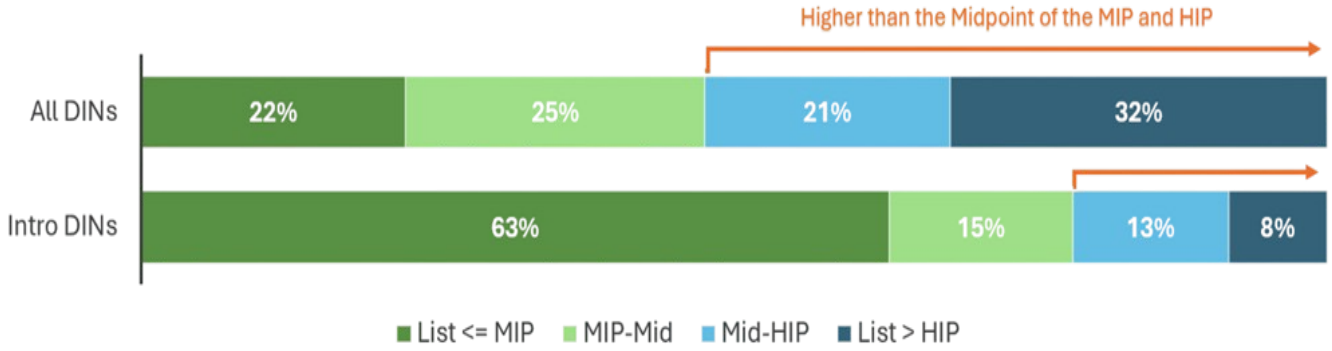
The IPC Identification Criteria

Price level within the PMPRB11

Refer to Section 6.1.1 of the Discussion Guide

- The use of the same International Price Comparison criteria in both the initial and post-initial price reviews.
- The Board aims to achieve a balance between identifying instances of potential excessiveness that would merit a public hearing and managing the Board's resources.

Figure 1. Distribution of Canadian list prices of patented medicines within the PMPRB11



Topic 1: Price level within the PMPRB11 to be used in the initial and post-initial price review

The Board is considering the following options:

- Median International Price (MIP)
- Highest International Price (HIP)
- The midpoint between the MIP and HIP

The IPC Identification Criteria

Transitional provisions for Existing Medicines

Refer to Section 6.1.2 of the Discussion Guide

- PMPRB will not distinguish between “New medicines” or “Existing Medicine”.
- The only difference with Existing medicines is that those above the identification criterion chosen by the Board will be given a period to adapt after the implementation of the Guidelines before a review that can lead to in-depth review is commenced.

Topic 2: The length of time Staff should wait, following the implementation of the Guidelines, to determine whether the IPC identification for an Existing medicine is met

The Board is considering the following options:

- One year
- Two years
- Three years

The CPI Factor

CPI Increase Criteria

Refer to Section 6.1.3 of the Discussion Guide

- As per s. 85(1)(d) of the Act, the Board is required to consider changes in the Consumer Price Index (CPI).
- The CPI factor will be assessed during the annual post-initial price review.
- Staff will compare list price changes of medicines against changes in the CPI to identify medicines that warrant an in-depth review.

Topic 3: In depth review based on CPI increase criteria

The Board is considering the following options:

- if the list price increase is above one-year change in CPI.
- if the cumulative increase in list price over the last two years is above the combined change in CPI for the past two years and the increase only took place within the last year (i.e. no increase in price in the first of the two years, followed by an increase on the second year)

Complaints

An additional pathway to an in-depth review

Refer to Section 6.2.1 of the Discussion Guide

- Complaints will serve as a key mechanism to identify medicines that may warrant an in-depth review.
- Ensures that case-specific situations not captured by PMPRB's price review process can be identified for an in-depth review when needed.

Topic 4: The individuals/groups permitted to submit a complaint

The Board is considering the following options:

- Limit complaints to the Federal Minister of Health or any of his/her Provincial counterparts
- Limit complaints to option 1 above plus payors only; or
- Limit complaints to option 1 above plus private and public payors
- Limit complaints to everyone except for Rights Holders
- No limits/restrictions

Therapeutic Market Considerations

Expanding the Complaint-only process to prioritize higher-risk cases

Refer to Section 6.2.2 of the Discussion Guide

- For medicines that have reduced reporting requirements under the Regulations, the Board has opted to only open an in-depth review when a complaint is received.
- The Board acknowledges that additional therapeutic categories may also pose a lower risk of excessive pricing.
- The Board is considering expanding the list of medicines eligible for the complaint-only based process to prioritize higher-risk cases.

Topic 5: Expanding the list of products that would only be subject to an in-depth review following a complaint to include biosimilars and/or vaccines

The Board is considering the following options:

- The PMPRB will treat patented biosimilars and/or vaccines the same as other medicines.
- The PMPRB will only open an in-depth review for biosimilars and/or vaccines when a complaint is received.

Therapeutic Class Comparison

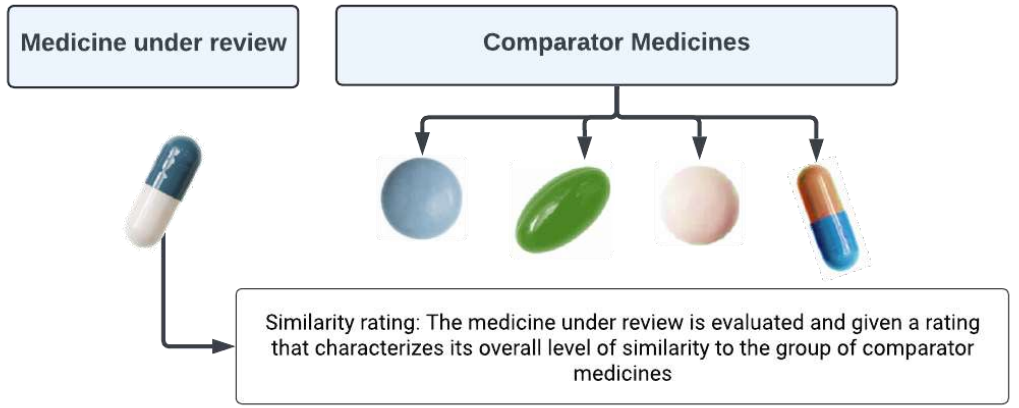
Contextualization of potential TCC

Refer to Section 6.3.1 of the Discussion Guide

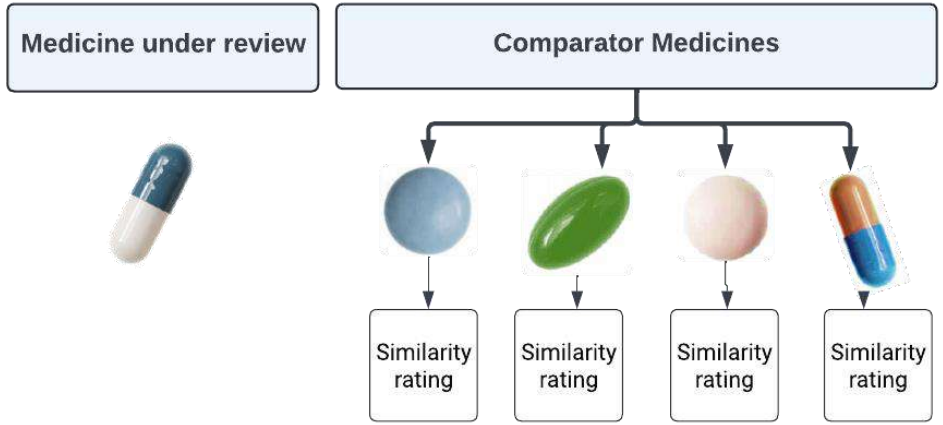
- The Board is proposing a mechanism to evaluate the degree of comparability between medicines identified for the TCC.
- Provides context for PMPRB Staff in considering how to weigh the TCC versus other 85(1) factors.

Topic 6: Use of clinical evidence to contextualize the degree of similarity of comparators identified for the TCC

Option 1: one level of similarity is identified for the comparators as a whole



Option 2: each comparator will be assigned a level of similarity



Scientific Review Process

Human Drug Advisory Panel (HDAP)

Refer to Section 6.3.2 of the Discussion Guide

- HDAP is an advisory body comprised of independent health professionals who are contracted by the PMPRB to assist with scientific evaluations.
- For most cases, PMPRB scientific review Staff have much of the necessary expertise to provide recommendations on comparators and comparable dosage regimens for the purposes of a TCC analysis.
- HDAP members have limited availability and their involvement in all reviews can lead to delays.

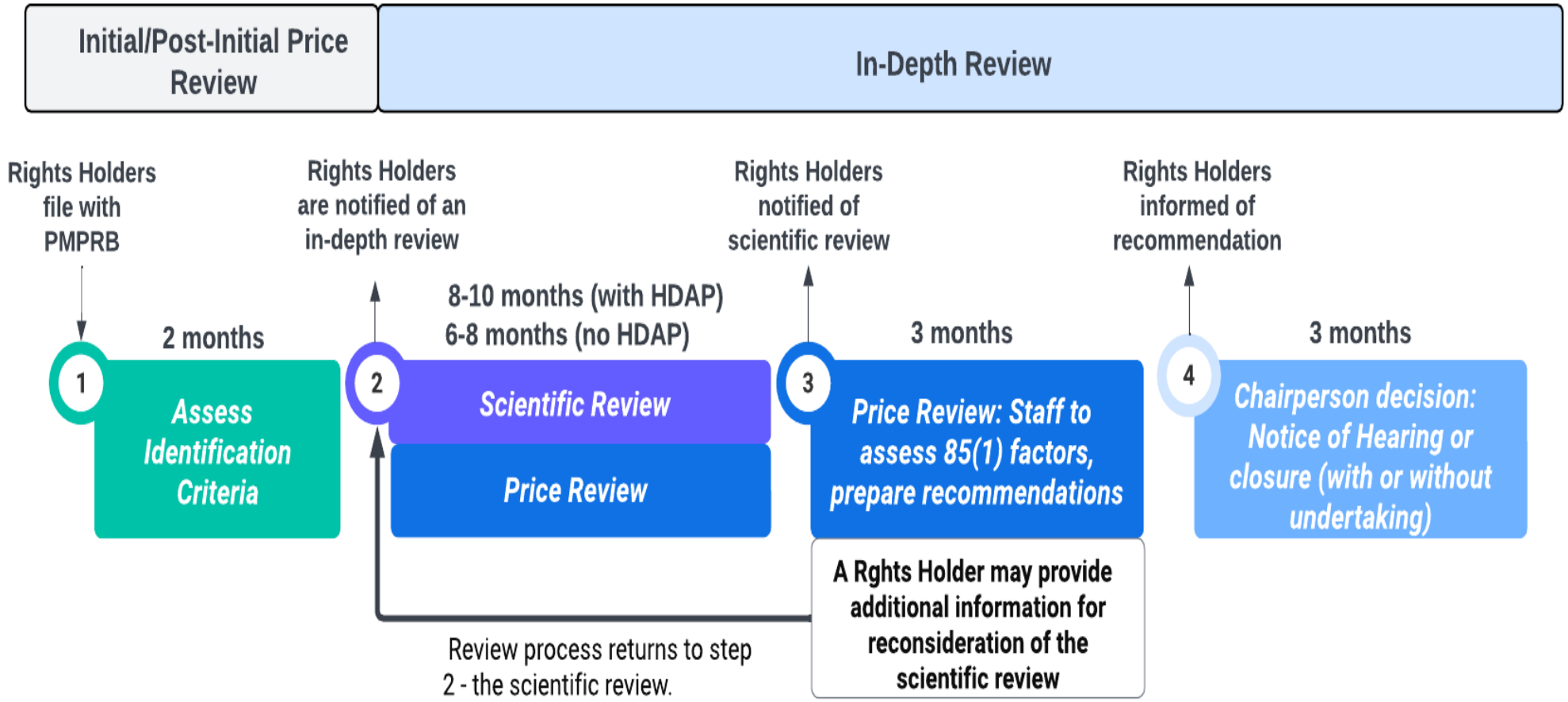
Topic 7: Future role of HDAP

The Board is considering the following options:

- HDAP will be used only on an ad hoc basis when deemed necessary by Staff.
- No HDAP – the scientific process will be conducted by Staff.

Transparency and Ongoing Communication with Rights Holders

- The following process timelines and notification steps are being considered:



3. Case Studies

Part 1: No In-Depth Review

- **Case Study 1:** List price below IPC
- **Case Study 2:** List price increase within CPI and list price below IPC

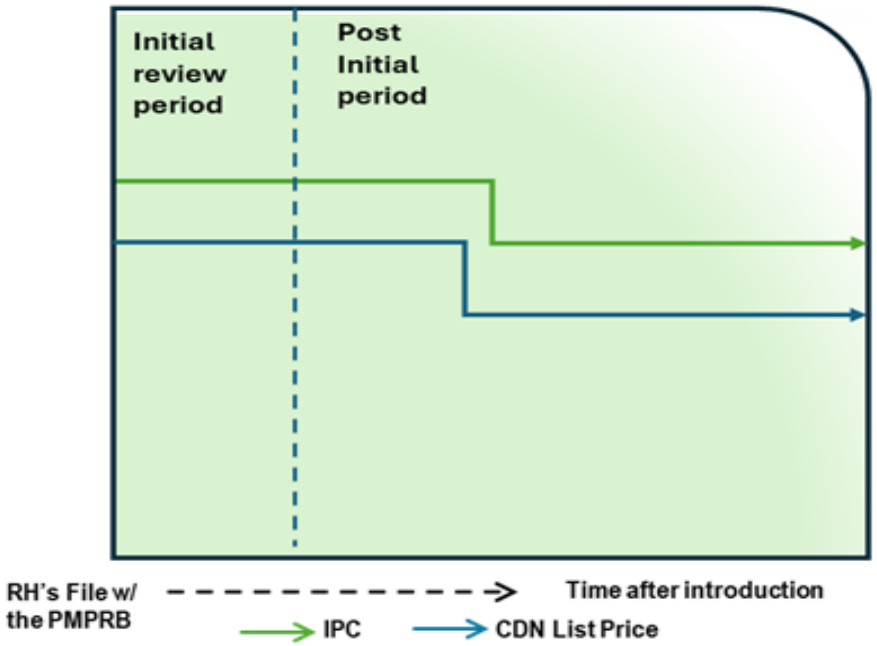
Part 2: In-Depth Review

- **Case Study 3:** List price above IPC, without TCC
- **Case Study 4:** List price above IPC, with TCC below IPC
- **Case Study 5:** List price above IPC, with TCC above IPC
- **Case Study 6:** List price increase above CPI, with TCC
- **Case Study 7:** Complaint, with TCC

Part 1:No In-Depth Review

List price below IPC

Case Study 1: List price below IPC



Potential recommendation: N/A – medicine not subject to in-depth review.

Issues/Facts:

- During the initial review, the Canadian list price is less than the IPC
- The IPC trends downward with time, but the Canadian list price also decreases.
- With no list price increases occurring, changes in CPI are not a consideration.
- No complaint is received regarding this medicine.

Analysis:

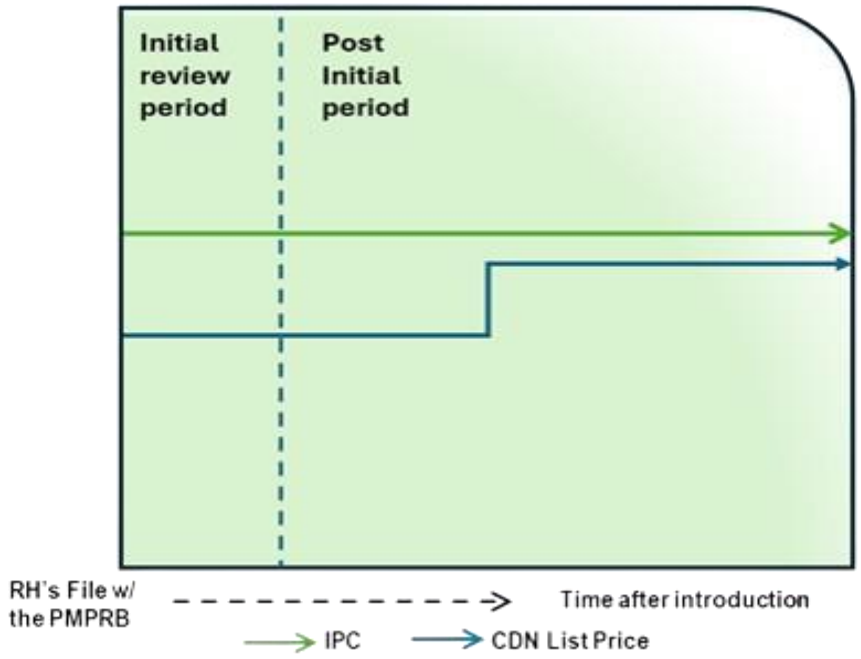
- No additional analysis is required, as the medicine does not trigger an in-depth review.

Note: These examples are not intended to bind the Staff or the Board in any in-depth review or hearing and the analytical approach may be departed from based on the facts available during the review. All recommendations from the Staff and decisions from the Chairperson/Board will depend on the particular circumstances of the matter in question.

Part 1:No In-Depth Review

List price increase within CPI and list price below IPC

Case Study 2: List price increase within CPI and list price below IPC



Potential recommendation: N/A – medicine not subject to in-depth review.

Issues/Facts:

- During the initial review, the Canadian list price is less than the IPC.
- The IPC is constant over time, but the Canadian list price increases.
- The list price increase is less than CPI.
- No complaint is received regarding this medicine.

Analysis:

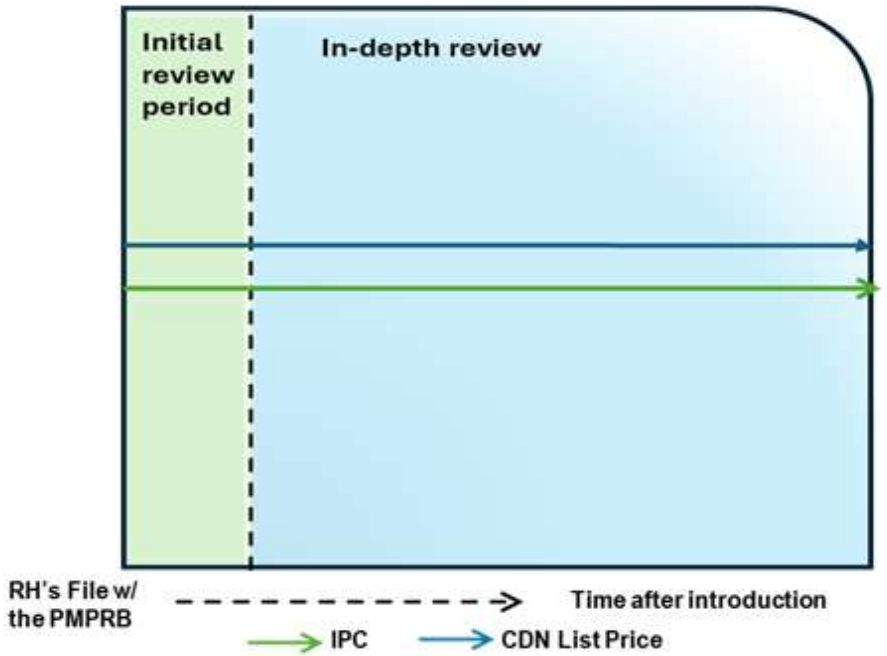
- No additional analysis is required, as the medicine does not trigger an in-depth review.

Note: These examples are not intended to bind the Staff or the Board in any in-depth review or hearing and the analytical approach may be departed from based on the facts available during the review. All recommendations from the Staff and decisions from the Chairperson/Board will depend on the particular circumstances of the matter in question.

Part 2:In-Depth Review

List price above IPC, without TCC

Case Study 3: List price above IPC, without TCC



Potential recommendation: This case could result in a recommendation for closure or Notice of Hearing, depending upon how the Canadian list price is positioned relative to the more comprehensive analysis of the international market.

Issue/Facts:

- During the initial review, the Canadian list price is greater than the IPC. This results in an in-depth review.

Analysis:

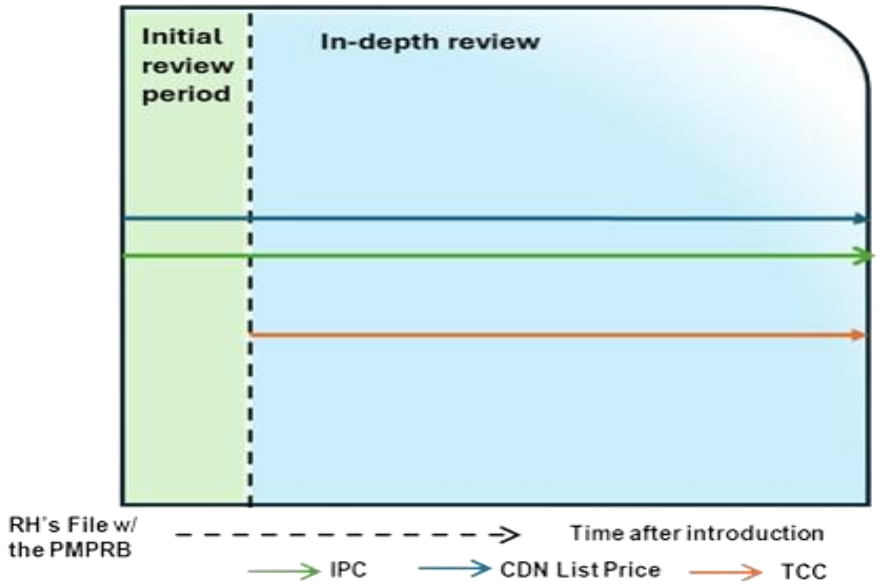
- There are no therapeutic comparators and a TCC analysis cannot be conducted.
- The Canadian list price continues to be greater than the IPC.
- No list price increases are taken by the Rights Holder.
- The only 85(1) factor available for consideration is the IPC.
- PMPRB Staff may consider:
  - the difference between the Canadian list price and the IPC
  - the number of countries with a reported price for the medicine
  - the range in prices across the PMPRB11.

Note: These examples are not intended to bind the Staff or the Board in any in-depth review or hearing and the analytical approach may be departed from based on the facts available during the review. All recommendations from the Staff and decisions from the Chairperson/Board will depend on the particular circumstances of the matter in question.

Part 2:In-Depth Review

List price above IPC, with TCC below IPC

Case Study 4: List price above IPC, with TCC below IPC



Potential recommendation: The case-specific context within those factors would need to be supportive of the price of the medicine for PMPRB Staff to recommend closure of this in-depth review. More likely, this case would result in the recommendation for a Notice of Hearing.

Issue/Facts:

- During the initial review, the Canadian list price is greater than the IPC. This results in an in-depth review.

Analysis:

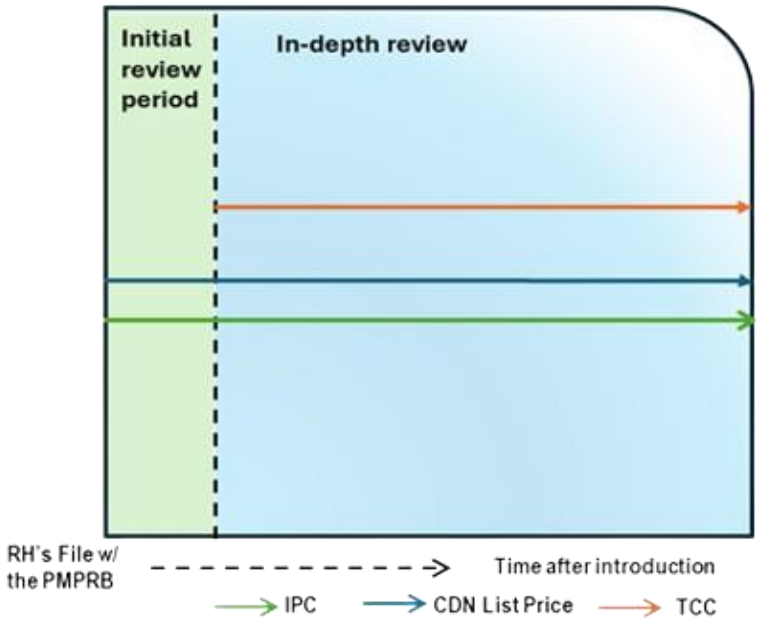
- The list price of the medicine is greater than the result of the TCC analysis.
- No list price increase has been taken by the Rights Holder.
- The Canadian list price is above both the IPC and TCC.
- PMPRB Staff may consider:
  - the strength of the TCC
  - the difference between the Canadian list price and the IPC
  - the number of countries with a reported price for the medicine
  - the range in prices across the PMPRB11.

Note: These examples are not intended to bind the Staff or the Board in any in-depth review or hearing and the analytical approach may be departed from based on the facts available during the review. All recommendations from the Staff and decisions from the Chairperson/Board will depend on the particular circumstances of the matter in question.

Part 2:In-Depth Review

List price above IPC, with TCC above IPC

Case Study 5: List price above IPC, with TCC above IPC



Potential recommendation: The case-specific context within those factors would need to be considered. If TCC has a high degree of comparability, Staff will likely recommendation a closure of the in-depth review. If the TCC has a low degree of comparability, Staff will likely recommend a Notice of Hearing.

Issue/Facts:

- During the initial review, the Canadian list price is greater than the IPC. This results in an in-depth review.

Analysis:

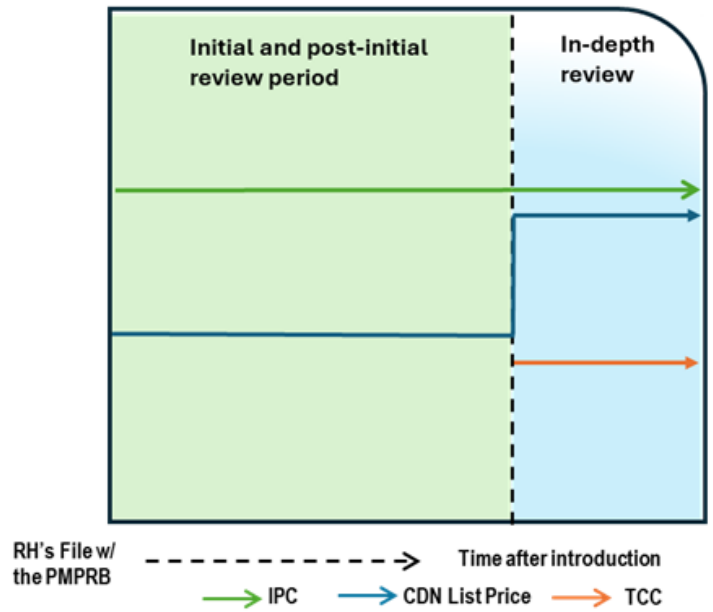
- The result of the TCC analysis of the medicine is greater than the list price.
- No list price increase has been taken by the Right Holder.
- PMPRB Staff may consider:
  - the strength of the TCC
  - the difference between the Canadian list price and the IPC
  - the number of countries with a reported price for the medicine
  - the range in prices across the PMPRB11.

Note: These examples are not intended to bind the Staff or the Board in any in-depth review or hearing and the analytical approach may be departed from based on the facts available during the review. All recommendations from the Staff and decisions from the Chairperson/Board will depend on the particular circumstances of the matter in question.

Part 2:In-Depth Review

List price increase above CPI, with TCC

Case Study 6: List price increase above CPI, with TCC



Potential recommendation:

- The case-specific context within these factors would need to be considered.
- Where the TCC consists of high degree comparable medicines, PMPRB Staff may make a recommendation for a Notice of Hearing.

Issue/Facts:

- After a period of time on the market, the List Price increases greater than CPI.

Analysis:

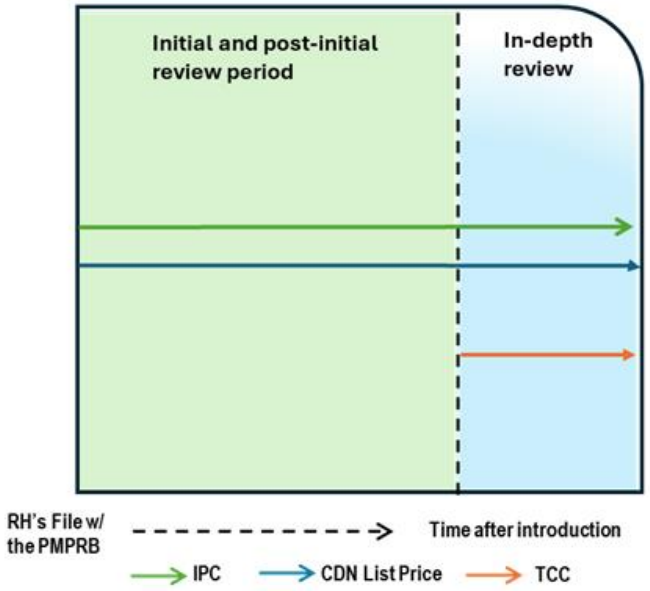
- The list price of the medicine is greater than the result of the TCC analysis.
- The Canadian list price is below the IPC.
- PMPRB Staff may consider:
  - the extent of the price increase
  - the strength of the TCC
  - the difference between the Canadian list price and the IPC
  - the number of countries with a reported price for the medicine, and
  - the range in prices across the PMPRB11.

Note: These examples are not intended to bind the Staff or the Board in any in-depth review or hearing and the analytical approach may be departed from based on the facts available during the review. All recommendations from the Staff and decisions from the Chairperson/Board will depend on the particular circumstances of the matter in question.

Part 2:In-Depth Review

Complaint, with TCC

Case Study 7: Complaint, with TCC



Potential recommendation: In a situation where the IPC has considerably more weight than the TCC given the context, Staff may recommend that the in-depth review be closed. If the reverse is the case, Staff may recommend that a notice of hearing be issued.

Issue/Facts:

- Over time on the market, the Canadian List Price and the IPC remain unchanged.
- A complaint is received. This will result in an in-depth review.

Analysis:

- The list price of the medicine is greater than the result of the TCC analysis.
- Staff must take the TCC into account and weigh it against the IPC and the fact that the Canadian List Price has not changed.
- Staff's recommendation will depend heavily on the TCC context and price differential magnitude.

Note: These examples are not intended to bind the Staff or the Board in any in-depth review or hearing and the analytical approach may be departed from based on the facts available during the review. All recommendations from the Staff and decisions from the Chairperson/Board will depend on the particular circumstances of the matter in question.

4. Next Steps

Next Steps

- Status of pre-2022 Guidelines and 2022/2023 Interim Guidance.
- Questions we received about process details.
- All stakeholders are invited to review the Discussion Guide and submit written feedback via our web portal by September 11, 2024.
- The Board will consider the feedback while it drafts new Guidelines. The new Guidelines will then be published for further consultation.