Canadian Life & Health Insurance Association
Association canadienne des compagnies d'assurances de personnes

Submission to PMPRB on their SHAPING THE FUTURE: PMPRB PHASE 2 CONSULTATIONS ON NEW GUIDELINES

September 11, 2024

WHO WE ARE

The Canadian Life and Health Insurance Association (CLHIA) is the national trade association for life and health insurers in Canada. Our members account for 99 per cent of Canada's life and health insurance business. The life and health insurance industry is a key contributor to the health and well-being of Canadians and the healthcare system through the provision of supplementary health insurance. The industry also provides financial security to Canadians through a range of financial security products, such as life insurance and annuities.

Protecting **29 million Canadians**

27 million
with drug, dental and other health benefits

22 million
with life insurance averaging $246,000 per insured

12 million
with disability income protection

$114 billion in payments to Canadians

$44 billion
in health and disability claims

$16 billion
in life insurance claims paid

$54 billion
in annuities

$9.3 billion in tax contributions

$1.5 billion
in corporate income tax

$1.4 billion
in payroll and other taxes

$1.9 billion
in premium tax

$4.5 billion
in retail sales and payroll taxes collected

Investing in Canada

$1 trillion
in total assets

90%
held in long-term investments

BACKGROUND

The health insurance industry in Canada manages benefit plans for employers, plan sponsors and individuals and prescription drug reimbursement is a key part of almost all private benefit plans in Canada. We offer employers options that can help offset increasing cost pressures on drug plans and ensure their financial sustainability, while also supporting Canadians' access to effective drug therapies.

Employers are looking for tools to help manage the rising cost of drugs today and for those innovative therapies currently under development. The work of the PMPRB to ensure prices are not excessive, is very important to helping employers continue to fund prescription drugs.

Private payers value the work of the PMPRB and appreciate the opportunity to provide comment into the Phase 2 Consultations.

KEY CONCERNS AND RECOMMENDATIONS

To identify our key industry concerns and comments around the discussion paper, we refer to the topics as listed in A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines (Discussion Guide).

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

We understand that the Board is considering using an international price test (IPC) to determine if further review of a medication's price is warranted with the following three options as a basis for the IPC:

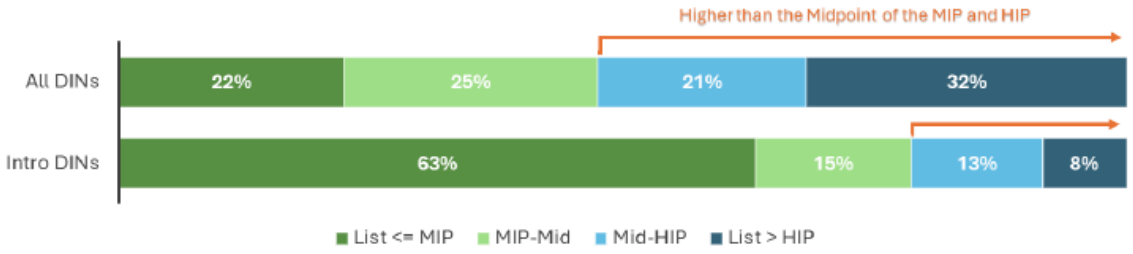
1. Median International Price (MIP)
2. Highest International Price (HIP)
3. The midpoint between the MIP and HIP

CLHIA members feel strongly that Option 1 should be the only option considered by the Board. Given the regulatory mandate of the PMPRB, "to protect and inform Canadians by ensuring that the prices of patented medicines sold in Canada are not excessive", it is essential to choose the MIP in order to meet and fulfil this mandate.

We would further note that one of the reasons that the list of countries used for price comparisons was updated in the *Patent Act* (Canada) was to better align with the median pricing of countries in the Organisation for Economic Co-operation and Development (OECD), and this goal cannot be achieved if HIP is used as a basis for comparison.

We would further note that previous PMPRB guidelines assigned a ceiling price that was based either on the median price of that same drug in the PMPRB7 countries, the highest priced drug in Canada in the same therapeutic class, or some combination of the two. Given this, using HIP (i.e., Option 2) for the IPC test would be a step backwards in our view and would not allow the PMPRB to meet its mandate of monitoring for excessive pricing.

The figure below reproduced from Section 6.1.1 of the Discussion Guide, shows the distribution of Canadian list prices of patented medicines within the PMPRB11, where more than half (53%) are higher than midpoint of the MIP and HIP, demonstrating the need to choose MIP as the basis for conducting price reviews and to fulfill the PMPRB's mandate.



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

You have asked what transition period should be provided before the new PMPRB guidelines will apply to existing patented medicines (i.e., one year, two years or three years). It is unfortunate that the implementation of the new Guidelines has been delayed several years.

The long road to reform has caused real harm to Canadians who have not been able to benefit from the new list of comparator countries that came into effect in 2022 and who may have incurred excessive costs on many patented drugs. The private insurance industry would recommend that a one year transition period be implemented to allow Canadians to start benefiting from lower prices more quickly.

Topic 3: In-depth review based on CPI increase criteria

We understand that the Board is considering the following two options regarding how it analyzes changes in the Consumer Price Index (CPI) in the context of whether an in-depth analysis of a patented drug product will be conducted:

1. Where the list price increase is above one-year change in CPI.

2. Where 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 in the second year)

We would recommend Option 1 as it is the easiest to implement, is more predictable and transparent.

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

Our understanding is that the Board is considering the following options:

1. Limit complaints to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts
2. Limit complaints to Item 1 and public payors
3. Limit complaints to Item 2 and public and private payors

4. Allow anyone, other than rights holders, to make a complaint
5. No limits/restrictions

Our industry has an important role as a participant in funding prescription drugs through employer benefit plans. In 2022, 27 million Canadians had private prescription drug plans and insurers paid out over $14.3 billion in drug benefits.

Given this, we would hope that both individual insurers and the industry association, the CLHIA, be permitted to submit complaints (i.e., options 4 and 5).

Further, our understanding is that there have been few complaints made under previous and current guidelines, so there is little data on complaints, including types and resolutions. In our view, it would be prudent to have an open complaints process, to enable the PMPRB to gather and review complaints-related data. This would allow the PMPRB to consider implementing further changes to the complaints process, if and as required.

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

We understand that the following options are under consideration:
1. The PMPRB will treat patented biosimilars and/or vaccines the same as other patented medicines

2. The PMPRB will only open an in-depth review for biosimilars and/or vaccines when a complaint is received.

Our recommendation is that any medicines falling under the *Patent Act* (Canada) should be treated the same from a price review standpoint, and therefore support option one as best protecting Canadians from excessive drug prices. Biosimilars and vaccines can both represent a risk of excessive pricing, similar to other medicines, and should not be treated differently.

Excessive pricing of vaccines may represent different risks to private plans in that vaccines are normally included as a public plan cost, although we have seen change to this over the last number of years, as fewer vaccines obtain provincial reimbursement status.

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

The following options are under consideration:

1. One level of similarity is identified for the comparators as a whole
2. Each comparator will be assigned a level of similarity

Option two as presented in the Discussion Guide, provides staff with a more granular level of similarity in conducting the Therapeutic Class Comparison, by assigning a level of similarity for each comparator, rather than for the comparators as a whole. We would agree that more detailed information should offer a better result during any price review.

Topic 7: Future role of Human Drug Advisory Panel (HDAP)

We understand that the Board is considering the following options:

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

We would support the undertaking of a scientific review by Staff in most cases. They have the necessary expertise and can provide a quicker assessment. However, there may be merit in keeping HDAP for those cases where additional expertise may be necessary.

CONCLUSION

Thank you for the opportunity to comment on these proposed changes. The time and commitment by the PMPRB over the last several years to engage with all stakeholders is appreciated. These reforms are critical to reduce the cost of prescription drugs for employers and their employees, and for provinces and territories.

We appreciate the PMPRB consulting stakeholders on these changes
Should you have any questions, you may contact Joan Weir, VP Group Benefits at jweir@clhia.ca.

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