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

Submission to the

PATENTED MEDICINES PRICING REVIEW BOARD – SCOPING PAPER FOR THE CONSULTATIONS ON THE BOARD'S GUIDELINES

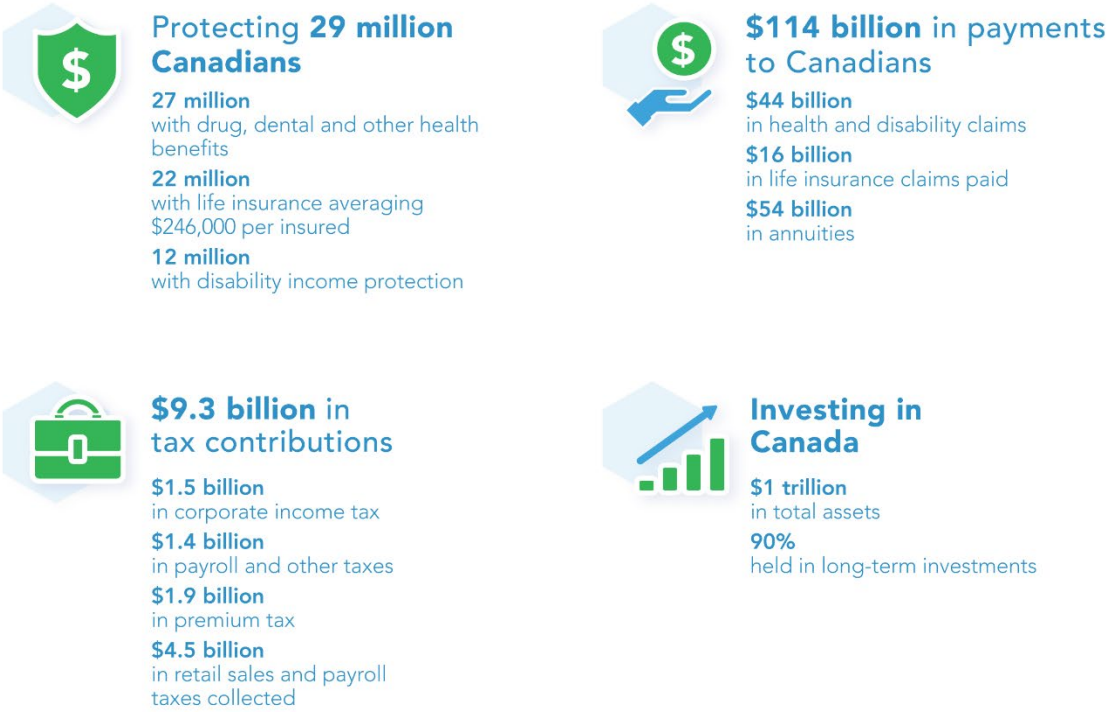
December 20, 2023

OVERVIEW

The Canadian Life and Health Insurance Association (CLHIA) is pleased to provide the views of its members to the Patented Medicines Pricing Review Board (PMPRB) for consideration regarding the Scoping paper for the consultations on the Board's Guidelines, which outline these views to inform the upcoming industry consultation on the development of new guidelines.

WHO WE ARE

The 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 industry provides a wide range of financial security products such as life insurance, annuities, and supplementary health insurance.



Life and health insurers play a key role in providing financial security to Canadians. Additionally, the industry makes a large contribution to the economy, employing over 158,000 Canadians in high value, professional jobs (as employees or independent agents). The industry is also a major investor in domestic assets and contributes meaningful revenue through taxes to the federal and provincial governments.

Support for affordable prescription medicines

Canadian life and health insurers provide 29 million Canadians with access to a wide range of health services and prescription drugs, including rare disease drugs, through supplementary health plans. In 2022 insurers paid out more than $14.3 billion in coverage for prescription drugs in Canada, while in 2020, $650 million was paid for rare disease drugs to 15,000 Canadians. Canadians pay some of the highest prescription drug costs in the world - our drug prices are fourth highest among OECD countries.

Given the number of Canadians covered by private drug plans, we believe that private payers need to be included at the table if we are going to improve access to drugs for all Canadians.

INTRODUCTION

Our industry appreciates this opportunity for consultation. We are supportive of the PMPRB's mandate as we strongly support lower drug prices. Our industry separately negotiates prices for many drugs. Further, we offer plan sponsors several options that can help offset increasing cost pressures on drug plans, without limiting Canadians' access to effective drug therapies.

Most private payers have developed internal (or use external consultants) capabilities to conduct drug reviews to inform recommendations to plan sponsors regarding the listing of prescription drugs new to market on private plans. Review is based upon a similar package of information submitted to Canadian Agency for Drugs and Technologies in Health (CADTH) and provincial payers for consideration.

In many cases, a Product Listing Agreement (PLA) may be put in place. Information on price regulation by PMPRB may be reviewed and used at times of PLA re-negotiation and throughout the life of the patented drug. This is an area where timing could be addressed to the benefit of privately insured Canadians.

RESPONSE BY THEME

Theme 1: Efficient Monitoring of Prices without Price Setting

Q 1.2: Should new Guidelines continue to categorize medicines by therapeutic class comparator characteristics such as the Level of Therapeutic Improvement?

Our members support the continuation of this factor as key to their evaluation. We recognize that it can be complicated to identify Domestic Therapeutic Class Comparisons (dTCCs) when new drugs are breakthrough and/or show significant improvement but haven't been approved by many countries at time of review. However, the identification of relevant clinical comparators is a critical step in determining that a drug's price is not excessive versus its comparators.

This categorization addresses the notion of excessive pricing not only from the perspective of the international market, but also from the perspective of the local market and other therapeutic options that already exist, which are essential elements.

In terms of timing, these drugs are typically reviewed by private insurers before CADTH and pan Canadian Pharmaceutical Alliance (pCPA) processes and therefore funding decisions are made first by insurers. Having access to the dTCC review by the PMPRB would be helpful with decision making.

Q 1.4 : If international prices are used as the first triage measure for the initiation of an investigation, what price levels within the CEPMB11 should be used (e.g. HIP or MIP)? Note: 'Highest International Price' and 'Median International Price'.

Our view is that MIP protects payers from pricing extremes and they are therefore subject to fewer fluctuations following commercialization. Also, MIP ensures a level of price competition that will benefit Canadians more than a HIP method would create.

MIP is also consistent with the previous PMPRB7 methodology and protects payers should a country become a price outlier as the United States became in the PMPRB7 system.

Q 1.5 : How should the PMPRB conduct an initial review and monitor the prices of patented medicines that have little or no international prices?

Question Q1.2 asks about Therapeutic Level of Improvement. This measure can be used to conduct an initial review. Alternatively, the PMPRB may develop specific guidelines for certain classes of medicines that address an urgent need or demonstrate a significant advantage over alternatives available on the Canadian market.

If international pricing does not exist but there are domestic comparators, then the domestic comparators should be able to be used for review purposes. In the event of no domestic comparators, international comparators could be considered.

In the event a drug comes to market with no international prices and no direct therapeutic comparators, PMPRB could identify diseases with similar incidence and prevalence rates and look at the pricing of those therapies.
These processes could suffice for a brief period of time until international pricing becomes available.

Theme 2: Transition to PMPRB11 – New versus Existing Medicines

Q 2.1: Should the Guidelines distinguish between medicines that existed as of July 2022 (existing medicines) and medicines introduced afterwards (new medicines)?

We strongly recommend that the PMPRB adopt a PMPRB11-based price review mechanism for existing medicines (e.g., those that existed as of July 2022), rather than allowing for legacy pricing to remain in place. We believe doing so is essential to capture market developments for prescription drugs and would protect consumers from excessive pricing.

In addition, the list price of existing medicines may affect the excessive pricing of new medicines (e.g. within the same therapeutic class), so we believe that the PMPRB11 should apply to new medicines as well as through the mechanism of hearings on existing medicines.

Q 2.2 : What approach should the Board take with respect to existing medicines with prices above the HIP of the PMPRB11? Should the Board review these prices, and if so, how soon?

Our industry is of the opinion that the PMPRB should look at medicines that are priced above the PMPRB's HIP to ensure that Canadians do not pay an excessive price for the purchase of their patented medicines.

Theme 3: Price Reviews during Product Life Cycle

The scoping document shows Canada has a positive price index, meaning that prices tend to increase over time. While this may be the result of the allowed yearly CPI increase or other legacy pricing indicators, our industry is concerned that this may also be the result of other factors such as marketing, misinformed prescribing practices and other similar practices. We would recommend that this needs to be investigated, possibly by multiple Canadian organizations including Canadian Drug Agency (CDA), and addressed.

Q3.2 : What criteria besides time should be used to trigger a price review?

Criteria that the PMPRB should consider as relevant are:

- Approval of a significant new indication, resulting in a significant increase in market size for the drug;
- Significant change to the therapeutic class comparators, such as

- the availability of new/stronger evidence related to benefit vis-à-vis therapeutic class comparators;
- the departure from identified pricing thresholds.

See our response to Q. 2.1. Our industry believes that all of the criteria listed above should trigger a new price review. Additionally, while the Consumer Price Index (CPI) provides a marker that can assist in judging the excessive price of a medicine, it must be considered as one of all factors that can be used to establish the maximum price and should not be a single element in a review of the price of a drug in its life cycle. The PMPRB11 could be used as a preferred indicator in the life cycle of a drug. Other factors, including the CPI, would be useful in the absence of international prices, or in complementarity.

There should be an approach to review prices on existing medicines (pre-July 2022) vs. simply permitting "legacy" price to remain in place. For example, when a drug has been on the market for a long period of time, and new drugs come to market for the same indication, potentially offering incremental (or exponential) added benefit/therapeutic improvement, the "reasonable" price for that older (existing) drug therapy should be reviewed/re-visited in this context.

Additionally, where there is an approval for a significant new indication, the number of patients that could receive treatment may increase significantly and that possibility should trigger a price review.

Theme 4: Investigations and Referral to Hearing

Q 4.2: How much detail should the Guidelines set out regarding what happens once an investigation is opened?

We recommend the Guidelines share as much detail as possible. Certain information may be made public and reportable (e.g.: that a complaint has been received regarding the list price of an identified drug, status updates on investigation), but other information kept confidential (e,g,: name of individual or organization filing a complaint).

Transparency in the guidelines is indeed a positive element for the Canadian market, so that all stakeholders can navigate the landscape and to ensure a favourable Canadian context for the arrival of innovative new patented medicines, while also having an effective cost control that is less burdensome/less resource intensive. Our industry suggests that complaints be vetted through the established complaints review and determined to be substantive prior to being made public.

Q 4.3: Should the PMPRB continue to use Undertakings as an investigation closure mechanism?

Private insurers believe that drugs under investigation should include both monies paid out on behalf of public plans, plan sponsors as well as Canadians paying out of pocket, the entirety of the Canadian payment landscape By limiting penalties to public plan payments only, the manufacturer is not fully penalized for their pricing actions in this dual marketplace.

In fact, the current system leaves no recourse for approximately half of the aggrieved market (i.e. private payers and the uninsured). Any monies recovered on behalf of half of the aggrieved market go to public coffers instead of those who were actually harmed by the excessive pricing.

Theme 5: Relations to pan-Canadian Health Partners, Insurers (Private and Public); and Alignment with Broader Government Initiatives

Q 5.1: What efficiencies could be gained by co-ordinating decisions and timelines of the PMPRB with those of the Canadian Agency for Drugs and Technologies in Health (CADTH),

Institut national d'escellence en santé et services sociaux (INESSS) and pan-Canadian Pharmaceutical Alliance (pCPA) or insurers (pubic and private)?

The CLHIA supports efforts to promote harmonization between jurisdictions to reduce redundancy and administrative burden, as well as shorten the timeline to listing.

Q 5.2: How can the PMPRB optimize its presence within the Canadian bio/pharmaceutical ecosystem to support a whole of government approach to issues relating to patented medicines?

Co-ordinating decisions and timelines with other pan-Canadian organizations could result in more timely listing decisions by all payers (public and private), better equity in access to drugs, better mechanisms for listing that take into account the collection of real-world evidence for continued funding, and better use of resources for negotiating prices for all.

Theme 6: Engaging with Patients, Health Practitioners, Pharmacy, and other Stakeholders

Q 6.4: How can the PMPRB better engage with you?

Given that millions of Canadians receive prescription drug coverage through our industry, we applaud and continue to recommend the PMPRB include us in consultations and engage proactively with us. We would also support efforts to establish a platform for ongoing discussion and collaboration.

CLOSING REMARKS

Drug shortages are having an impact on delivery of private drug plans and may need to be considered within the overall PMPRB plans. Both the drug, alternates available in Canada, alternates available elsewhere (e.g.: Glucagon in the treatment of diabetes) as well as price and therapeutic value should be considered when evaluating alternates.

Excessively-priced drugs are a risk to the sustainability of all drug plans in Canada. For this reason and others we recommend that the work of the PMPRB, coordinated with other government agencies, should be aligned with private payers in order to obtain the best prices on patented drugs for Canadians.

This would mean specifically including private insurers within the purview of all pan-Canadian organizations that have some responsibility in determining price and entry to Canada.

CONCLUSION

We would like to take this opportunity to thank you for your consideration of the views of the Canadian life and health insurance industry. Should you have questions regarding any of our comments, you may contact Joan Weir, Vice-President, Group Benefits at jweir@clhia.ca.

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