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

Submission to the

PATENTED MEDICINES PRICING REVIEW BOARD – AMENDMENT TO THE INTERIM GUIDANCE RE: NEW MEDICINES

August 17, 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 draft Interim Guidelines, which define the processes for review of drug pricing for patented drugs approved in Canada. These Interim Guidelines will allow PMPRB to re-start the process of reviewing new patented drugs for maximum price.

OVERVIEW OF SUBMISSION

The insurance industry strongly supports the work of the PMPRB to ensure that prescription drug prices are not excessive. We feel that this work has only become more urgent as inflation has eroded the ability of Canadians to afford necessities, compounding the harm caused by lifesaving treatments that are priced higher than in many comparable countries in the Organization for Economic Co-operation and Development (OECD).

We applaud the introduction of the PMPRB-11 as part of the amendments to the *Patented Medicines Regulations* that came into effect on July 1st 2022. The new list removes outlier countries as comparators and adds new countries with pharmaceutical markets better aligned with Canada's which should provide a more representative pricing sample.

That said, the PMPRB will need to regularly review drug prices over their lifecycles to ensure they do not become excessive over time, particularly in the case of new drugs initially reviewed when they had no comparators. Prompt implementation of the final Guidelines will allow the PMPRB to begin this important work.

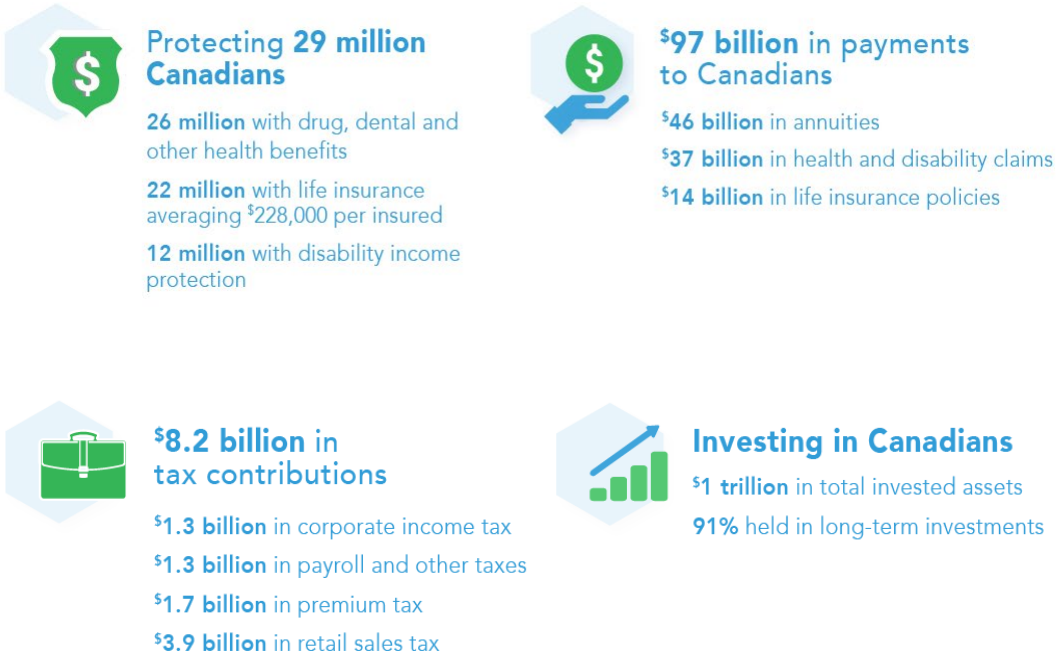
With respect to the Guidelines themselves, we agree that the simplified process of considering a medicine without a MAPP (Maximum Average Potential Price) or NEAP (Non-Excessive Average Price) as of July 1st, 2022, as reviewed if its list price is below the median international price (MIP) for the PMPRB11 countries.

However, our industry does not agree with the proposal that no potential excess revenues will be calculated by staff retrospectively for any new medicines for sales made during the interim period.

Lastly, our industry would request that PMPRB initiate steps to include the insurance industry, as a representative of plan sponsors and members, when considering remedies to excessive pricing.

WHO WE ARE

The CLHIA is a voluntary association whose member companies account for 99 per cent the life and health insurance business in Canada.



Life and health insurers play a key role in providing financial security to Canadians. Additionally, the industry makes a significant 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 significant revenue through taxes to the federal and provincial governments.

Support for affordable prescription medicines

Canadian life and health insurers provide 26 million Canadians with access to a wide range of health services and prescription drugs, including rare disease drugs, through supplementary health plans. In 2021 insurers paid out more than $13.4 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 third highest among OECD countries.

REVIEW OF NEW PATENTED MEDICINES

The interim guidance proposes a simplified process for patented drug pricing review that will allow the current backlog to be cleared and new medicines approved in Canada in future to be reviewed quickly during this interim period. The change to previous guidance is that a medicine without a MAPP or NEAP as of July 1st, 2022, is considered reviewed if its list price is below the median international price (MIP) for the PMPRB11 countries, whereas previously, such drugs would not be reviewed.

This modified approach is supported by our industry to ensure prices for new patended medicines are reviewed, quickly and fairly. It is our expectation that this approach will allow PMPRB resources to be better directed toward higher impact activities such as complex reviews, complaint resolution and ongoing price monitoring.

PATENTED MEDICINES PRICE INCREASES DURING INTERIM PERIOD

It is proposed that list price increases made in 2023 will continue to trigger investigations, consistent with earlier guidance, but that no potential excess revenues will be calculated by staff retrospectively for any new medicines for sales made during the interim period. Our industry does not agree with this approach given that it removes the disincentive to increase prices. As well, the length of the 'interim period' is unknown and could be quite long given the status of the PMPRB board, which we understand to have several open positions. Although we believe the new Guidelines should be implemented promptly to provide Canadians with optimal drug pricing, a long interim period is possible. The PMPRB must continue to deliver on its mandate to protect Canadians from excessive drug prices during this period.

Our position is that, once a price increase has been determined to be excessive, excess revenues should be calculated and imposed retroactively.

RETURN OF EXCESS PATENTED MEDICINES DRUG COSTS TO PRIVATE PAYERS

In the past, remedies for a finding of excessive drug pricing have typically involved reducing the price to a non-excessive level and having the relevant patentholder pay the excessive amount received to the Receiver General for Canada. Yet, this payment to the Receiver General does not make whole those that have actually paid the excessive amounts, being benefit plan sponsors and members. There is currently no mechanism in place for the Receiver General to distribute any amounts awarded to these impacted groups.

Given the foregoing, the CLHIA requests that the PMPRB consider exercising its discretion under paragraph 83(2)(a) of the *Patent Act* (Canada) in the future, and ordering that companies found to have excessively priced a drug to reduce the price to such extent and for such period as results in all payers, the plan member, benefit plan sponsor, insurer and/or industry pool (Quebec Drug Insurance Pooling Corporation, and Canadian Drug Insurance Pooling Corporation) being reimbursed in proportion to the total excess paid.

Appropriate distribution of excess drug costs will help keep drug plans affordable for the thousands of employers and millions of Canadians our industry represents.

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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