



Submission to the Patented Medicine Prices Review Board on the Proposed Draft Guidelines

Canadian Life and Health Insurance Association
August 2020



The Canadian Life and Health Insurance Association Inc. (CLHIA) appreciates the opportunity to provide comments on PMPRB's consultation on the proposed draft guidelines to support implementation of the amendments made to the *Patented Medicines Regulations* which will come into force January 1, 2021.

OVERVIEW

Canada's life and health insurers work with over 130,000 large and small employers across all sectors of the economy to provide supplementary health benefits including prescription drug coverage to more than 26 million Canadians. Life insurers, employers and union groups spent about \$11.7 billion dollars on prescription drugs in 2018.

Prescription medicines continue to be a large and growing cost of employers' health benefit plans. While high cost drugs account for only 2% of claims, these drugs account for over 30% of the cost to drug benefit plans. The cost of new specialized medicines in particular add increasing pressure to these plans and Canadians now pay some of the highest patented drug costs in the world.

In our view, the proposed changes strike the right balance between reducing the high cost of prescription drugs in Canada, while also continuing to ensure Canadians have access to affordable and necessary medications. The reduction in prescription drug prices resulting from the PMPRB changes is expected to save Canadian employers hundreds of millions of dollars per year. We therefore strongly support these amendments and believe it is crucial that the federal government move ahead with these long-awaited reforms to achieve affordability for consumers.

COMMENTS FOR CONSIDERATION

While the draft guidelines are more technical in nature and primarily intended to provide transparency and predictability for patentees regarding the process, we are appreciative of the opportunity to participate in the consultation. These guidelines significantly impact the sustainability of both private and public drug plans and are of interest to all Canadians. We also appreciate the efforts to provide clarity on the changes made in the most recent draft, and the rationale for concessions made in both the [background document](#) provided by Health Canada and through the webinars provided to all stakeholders. We recognize modifications from the original approach may be the best way to achieve a balanced outcome.

As a key stakeholder in the system, we offer the following comments for consideration:

- We support retaining the Pharmacoeconomic Value measure as part of the PMPRB guidelines. We believe it introduces an element to link clinical value and price and, supports the goal of improving value for Canadians in a way that prioritizes health outcomes.
- We are very supportive of PMPRB's commitment to the Guideline Monitoring and Evaluation Plan (GMEP) to assess the impact of the guidelines on drug prices and access to medicines and ensure they are meeting the intended purpose. This will also help inform any future enhancements or modifications. We understand discussions with interested stakeholders will help to shape the GMEP. As a key stakeholder in the system we would appreciate being engaged in these discussions. We commend PMPRB in their continued spirit of transparency and open communication as we understand the intent is to post GMEP reviews and benchmarks publicly.
- We believe that a key element of the implementation of this new regime is the reporting and enforcement of the MRP. We look forward to continued discussions with the PMPRB in assessing our role in this process and reviewing the implications of the program for our plan members and sponsors.

- In relation to the concession to the PV threshold of \$60,000 QALY, we encourage a process that ensures that the rigour of the review increases relative to the cost of the medication. The efficacy of this threshold, and similar benchmarks within the guidelines, will need to be monitored and assessed regularly going forward as part of the GMEP process.
- We also remain supportive of retaining the PMPRB11 basket of countries which excludes Switzerland and the U.S. to help protect all consumers including cash paying customers from excessive pricing. Switzerland and the U.S. represent high price outliers.

As noted in our February 2020 submission, we continue to recommend the following for consideration over time:

- A key element of the implementation of this new regime is the enforceability of the list price and we recommend that the PMPRB give the matter due careful consideration.
- When determining the maximum non-excessive price for medications, we encourage PMPRB to consider additional factors beyond those that have traditionally been used by public payers. For example, a drug might help someone return to work, support productivity and improve mental health and such factors have traditionally not been given sufficient weight in health technology assessments (HTA). A healthy, productive workforce ultimately benefits our public health system beyond reduction of hospitalizations and we believe these are valid considerations in any HTA assessment methodology.
- We would also encourage a re-evaluation of the approach to how excessive revenues are determined through voluntary compliance undertakings, or orders by the PMPRB, and how they are returned by the patentees. Currently any excess amount is paid to the Receiver General for Canada and returned to provincial and territorial public payers based on a predetermined formula. Employers in Canada can incur significant excessive costs as well and we believe they should also share in any reimbursements. Accordingly, we recommend modifications to legislation to facilitate the PMPRB developing a mechanism to ensure that all stakeholders who were impacted by excessive revenues, including plan sponsors (employers) who provide drug benefits plans for their employees, are reimbursed equitably.

Thank you for the opportunity to provide the industry's thoughts. The time and commitment by both the PMPRB and Health Canada over the last 3 years to engage with all stakeholders on these important changes are appreciated. We recognize that COVID-19 has impacted the timeline of the coming into force of the amended Patented Medicines Regulations. We support the rationale for this extension, however, these reforms are critical to reduce the cost of prescription drugs for our members, employers and their employees; and to Provinces and Territories. While it will be important to understand any impacts if the recent Federal court ruling is upheld, we strongly suggest that the planned implementation of these changes not be extended again and come into force January 1, 2021. Should you have any questions or wish to discuss further, please do not hesitate to contact Karen Voin, Vice President, Group Benefits and Anti-Fraud at kvoin@clhia.ca or 416-359-2020.

Signed by

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