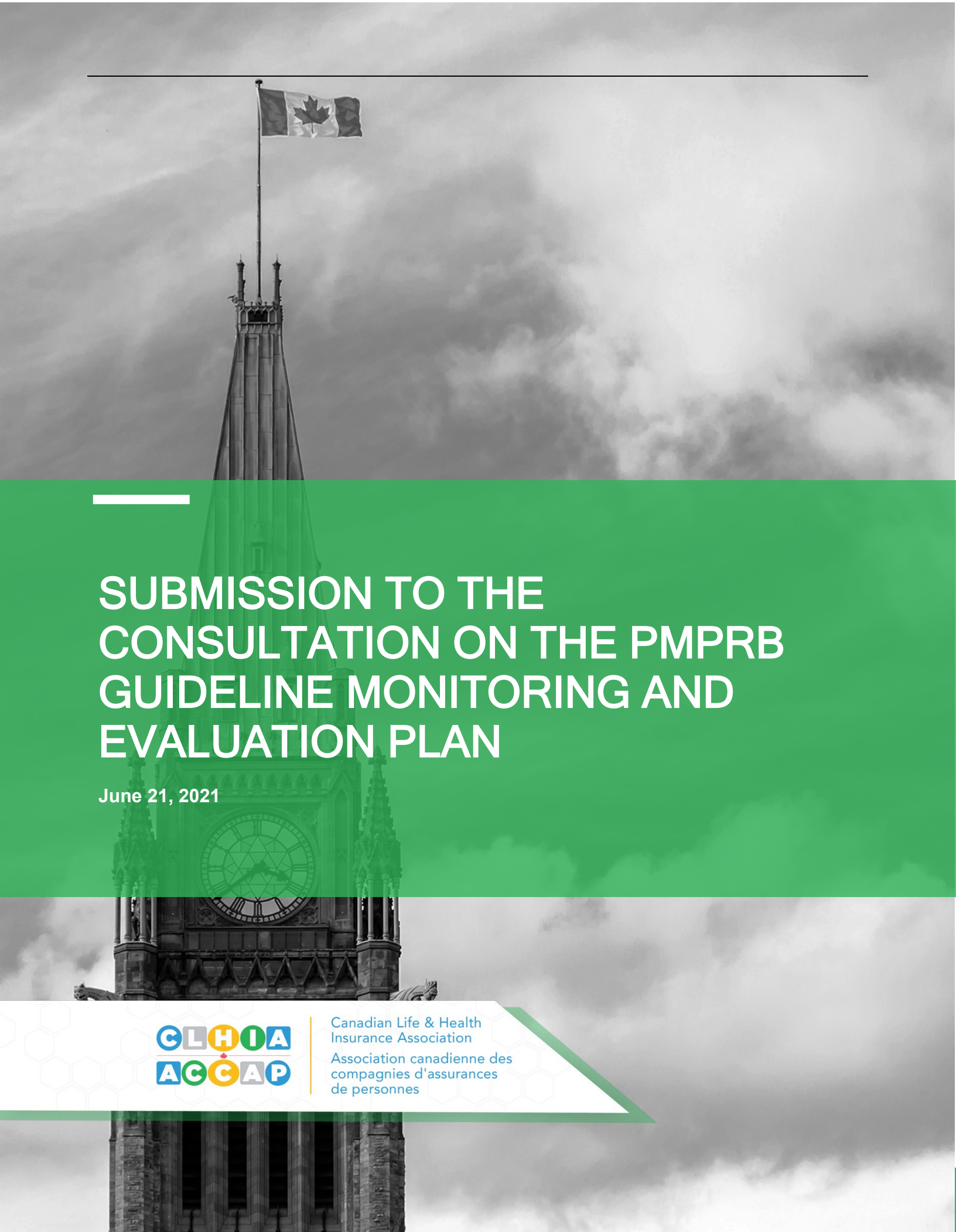

SUBMISSION TO THE CONSULTATION ON THE PMPRB GUIDELINE MONITORING AND EVALUATION PLAN

June 21, 2021

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

OVERVIEW

The Canadian Life and Health Insurance Association (CLHIA) is pleased to provide its comments to the Patented Medicine Prices Review Board (PMPRB) as part of the Consultation on the Guideline Monitoring and Evaluation Plan (GMEP).

The CLHIA is a voluntary association with member companies which account for 99 per cent of Canada's life and health insurance business.

The industry works with over 130,000 large and small employers across all sectors of the economy to provide more than 26 million Canadians with access to a wide range of health supports through extended health care plans, including prescription drugs. In 2019, life and health insurers paid over $38 billion in health benefit claims, including $12.5 billion for prescription drugs.

$8.3 billion in tax contributions

$1.5 billion in corporate income tax

$1.3 billion in payroll and other taxes

$1.6 billion in premium tax

$3.9 billion in retail sales and payroll taxes collected

Investing in Canada

$950 billion in total invested assets

92% held in long-term investments

Protecting **29 million Canadians**

26 million with drug, dental and other health benefits

22 million with life insurance averaging $222,000 per insured

12 million with disability income protection

$103 billion in payments to Canadians

$53 billion in annuities

$38 billion in health and disability claims

$12 billion in life insurance policies

Prescription medicines continue to be a large and growing cost of employers' health benefit plans. While high cost drugs account for only two per cent of claims, these drugs account for over 30 per cent of the cost to drug benefit plans. The cost of new specialized medicines in particular adds 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 are supportive of the proposed PMPRB reforms and believe it's critical that the implementation of these changes not be extended again and come into force on July 1,2021 as planned.

As an industry, we are very supportive of PMPRB's commitment to the GMEP to assess the impact of the guidelines and analyze trends in the pharmaceutical market before and after the implementation of the new framework to assess whether it is working as intended (sustainable costs, access to new therapies, and a robust Canadian pharmaceutical industry) and to inform the need for any future adjustments.

We understand that in each of the four areas, in consultation with its stakeholders, PMPRB will identify relevant benchmarks. As part of developing benchmarks, consideration of a clear and transparent definition of what constitutes success will be important. For example, what improved access looks like and how will it be measured. We would also recommend clarity on how results will be communicated and in what timeframe. As an important stakeholder, life and health insurers need to be part of these discussions.

The following reflect the specific questions included in the consultation on the four key areas noted and the industry's response:

1. PRICES

In your view, what is the importance of monitoring and evaluating the changes in prices following the Guideline changes?

- The Guidelines significantly impact the sustainability of both private and public drug plans and are of interest to all Canadians
- A key element of the implementation of this new regime is the enforceability of the list price and we recommend that there be private payer representation at the table while the GMEP is being developed
- We remain very supportive of retaining the PMPRB11 basket of countries which excludes Switzerland and the U.S.—which represent high price outliers—to help protect all consumers from excessive drug pricing.

Are there other aspects of assessment of price that are relevant to you and not already reflected in the PMPRB plan?

- We continue to encourage 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 amounts deemed to be excessive are 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 costs as well as a result of excessive drug prices and we believe they should also share in any reimbursements. Another approach, in lieu of a legislative change would be remediation through lowered go-forward prices until the stakeholders (public and private plans) have been reimbursed. Our understanding is that PMPRB has some discretion under paragraph 83(2)(a) of the Act to compel manufacturers to reduce drug prices to an amount that would, over time, pay back the amount of the excess. Accordingly, we recommend these proposed changes be considered as the GMEP process is developed 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.

2. ACCESS

In your view, what is the importance of monitoring and evaluating possible changes in the access to medicines following the Guideline changes?

- Please refer to response in Question #1

Which of the proposed objectives around the assessment of access to medicines are most important to you?

- Since access is about more than availability, we encourage monitoring to identify any links between the drug price (affordability) and availability of drugs in Canada and if there is impact, adjust as needed
- We also recommend that, in benchmarking access, the PMPRB avoid over-emphasizing the number of clinical trials undertaken in Canada

Are there other aspects of assessment of the access to medicines that are relevant to you and not already reflected in the PMPRB plan?

- We would encourage analysis to identify driving factors for any variances to understand which other jurisdictions are the most applicable for benchmarks and why
- It would be helpful to have a quantitative way of measuring or validating if there is truly reduced access based on manufacturer input, that they may implement fewer clinical trials and product launches in Canada, and if such reduced access is solely based on the anticipated price reform. There should also be definitions or metrics in place to define what signifies poor access vs acceptable levels of access.

3. PHARMACEUTICAL ECOSYSTEM

In your view, what is the importance of monitoring and evaluating the changes in the pharmaceutical ecosystem following the Guideline changes?

- Throughout the multi-year consultation, a number of stakeholders have raised concerns that the changes will impact the attractiveness of manufacturers making new drugs available in the Canadian marketplace
- Concerns have also been raised on the R & D investments within Canada
- To date, R & D investment has lagged behind the 10 per cent target as demonstrated in both PMPRB's 2017 annual report, as well as a recent report by Statistics Canada
- Given the significant differences in the reports, establishing an initial benchmark and monitoring this through a transparent and agreed upon approach through GMEP will be important to ensure a common understanding on any impacts to R & D investments in Canada as we move forward
- In terms of drug spending, as noted in #1 (prices) it will be important to monitor if the anticipated savings from the changes are realized and reduce overall drug spending by public and private plans to assist with sustainability over time

Are there other aspects of assessment of the pharmaceutical ecosystem that are relevant to you and not already reflected in the PMPRB plan?

- As per the access section above, it will be important to monitor the pharmaceutical ecosystem to understand any impact directly related to the reforms as several pharmaceutical manufacturers have provided feedback that they may reduce their investment in Canada through fewer clinical trials and product launches, based on their forecasted deteriorating return on investment due to pricing reform
- We would also encourage having objective criteria in place to understand if and why changes are occurring. For example, if the analysis indicates there are less clinical trials or launches occurring in Canada following the July 1 implementation, it will be important to understand why as other factors beyond the reforms could be playing a role.

4. PROCESSES

The PMPRB will assess the administrative burden of the reforms on patentees and PMPRB staff, patentee compliance with the filing requirements and ceilings, enforcement activities, the scientific review, the application of the price tests as well as the number of engagement activities the PMPRB is undertaking to assist patentees in understanding the Guidelines and their application.

Comments:

- We encourage PMPRB to proactively and continually reach out to patentees and other stakeholders following the implementation of GMEP to assess the administrative impact of the application of the new guideline
- Prescription medicines continue to be a large and growing cost of employers' health benefit plans. While high cost drugs account for only two per cent of claims, these drugs account for over 30 per cent of the cost to drug benefit plans. The cost of new specialized medicines in particular adds increasing pressure to these plans and Canadians now pay some of the highest patented drug costs in the world. Anticipated savings from the reforms will help to alleviate some of these sustainability concerns
- We encourage some form of measurement through the GMEP process to assess if payers are achieving the anticipated savings and would recommend that PMPRB work closely with both public and private payers in establishing the benchmarks to achieve this.

CONCLUSION

The life and health insurance industry would like to thank you for the opportunity to give input on the planned PMPRB's GMEP process. We encourage PMPRB to continue to include private payers in ongoing discussions on GMEP development and we remain available to respond to any questions. Please don't hesitate to contact Karen Voin, Vice-President, Group Benefits and Anti-Fraud at kvoin@clhia.ca 416-359-2020.

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