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December 20, 2023

The Patented Medicine Prices Review Board (PMPRB)

Sent via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Re: Sun Life's response to the *Scoping paper for the consultations on the Board's Guidelines* (the scoping paper)

I am writing to provide Sun Life's comments on the scoping paper. Sun Life thanks the PMPRB for the opportunity to provide comments on the important matters raised within this consultation.

We play a key role in providing Canadians with access to prescription drugs. Sun Life administers group benefits plans covering ~4.9 million people in Canada, helping them live healthier lives. We are happy to provide our expertise and be a partner to you in responding to this consultation.

Who we are

At Sun Life, our Purpose is clear: to help our Clients achieve lifetime financial security and live healthier lives. Our roots run deep in Canada, where our company began more than 150 years ago. Our business started with the sale of insurance and has expanded to offer wealth and asset management solutions and customized health programs to our Clients.

Today, we have a presence in 11,000 communities across Canada and we are an industry leader, touching the lives of millions of individuals and thousands of companies across the country – and around the world. We are a market leader in the Canadian group benefits market, known for innovation and service excellence, serving millions of Clients nationwide.

Executive summary

Our comments focus on two central themes, in line with our Purpose. These themes are our support for:

- the PMPRB's mandate to protect consumers by ensuring that the prices of patented medicines are not excessive and
- better coordination, sharing of knowledge, and best practices between the private and public sectors regarding prescription drugs.

We have made comments and recommendations throughout this submission that reinforce these themes and would benefit Canadians if realized. Please find our detailed response to select questions the PMPRB poses in the scoping paper. We responded to questions we are best suited to answer.

Theme 1: Efficient Monitoring of Prices without Price Setting

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

Sun Life recommends the PMPRB Guidelines continue to categorize medicines by therapeutic class comparator characteristics. We recognize it can be complicated to identify Domestic Therapeutic Class Comparisons (dTCCs) when new drugs are breakthrough and/or show significant improvement but have not been approved by many jurisdictions at time of review. However, private insurers typically review these drugs before Canadian Agency for Drugs and Technologies in Health (CADTH) and pan-Canadian Pharmaceutical Alliance (pCPA) processes and

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therefore funding decisions are made by insurers. Having access to the dTCC review by the PMPRB would provide us with added information that would help us to make more informed and aligned listing decisions for coverage under private drug plans. This would also benefit Canadians, as the information and inputs in our decision-making processes would be enhanced.

We would also add that 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.

Question 1.4: If international prices are used as the initial triage measure for commencing investigations, what price levels within the PMPRB11 should be used as the triage measure? (e.g., HIP or MIP?)

Sun Life supports ensuring drug prices are not excessive to help group benefit programs to remain financially sustainable, drug coverage to remain affordable, and ultimately support Canadians to live healthier lives. We recommend the PMPRB use the median international price (MIP) as the triage price level. Doing so would provide the PMPRB with greater insight into the price of drugs in Canada relative to others internationally. MIP would also better protect payers should a country become a price outlier as the United States became in the PMPRB7 system.

Theme 2: Transition to PMPRB11 – New versus Existing Medicines

Question 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 price review mechanism for existing medicines (i.e., those that existed as of July 2022), rather than allowing for legacy pricing to remain in place. Doing so is essential to capture market developments for prescription drugs and to protect Canadians from excessive pricing in a consistent and equitable framework.

Over time, existing drugs that have been on the market for a meaningful period may find themselves competing with new drugs for the same indication. These new drugs may offer incremental or exponential benefit and therapeutic improvement. We recommend existing medicines are reviewed within this context, to ensure their prices are not excessive and to reflect current market trends and considerations.

Question 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?

When prices for existing medicines are above the HIP of the PMPRB11, we recommend a review occur as soon as possible after this is identified followed by annual price reassessment. We also recommend the PMPRB consider taking the same course of action for medicines above the MIP of the PMPRB11 where warranted. Doing so would ensure the PMPRB is both responsive to and prevents excessive pricing. Further, this aligns with the PMPRB's mandate to protect consumers. Please refer to our response under question 3.1 for additional details.

Theme 3: Price Reviews during Product Life Cycle

Question 3.1: How often should price reviews be conducted? (1-5 years).

Sun Life recommends annual price reassessment, to prevent excessive pricing for Canadians. Where this is not feasible, the PMPRB should consider prioritizing annual price reassessments for drugs for rare diseases and other high-cost drugs (e.g., drugs with an expected annual cost in excess of $10,000). Other drugs could undergo price reassessment every two to three years.

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Question 3.2: What criteria besides time should be used to trigger a price review?

i. Approval of a significant new indication?

Sun Life believes approval of a new significant indication warrants a price review. This is especially relevant when a significant, incremental number of patients could receive treatment via an existing drug that is approved for a new indication. We recommend prices be reviewed in this case to:

- reflect changes in how the drug will be used,
- reflect the expanded patient population in which the drug may be eligible,
- protect Canadians using this drug for a new purpose, and
- reflect an evolving landscape for the sale and use of a drug.

ii. Significant change to the therapeutic class comparators? Availability of new/stronger evidence related to benefit vis-à-vis therapeutic class comparators?

We strongly recommend that where there is a change to therapeutic class comparators, this triggers a price review. We believe the maximum price of drugs should reflect evolutions in the marketplace, including new drugs entering the market.

iii. Departure from identified pricing thresholds?

We recommend that where the price of a drug departs from an identified pricing threshold, a price review should occur. In this situation, a review is essential to reinforce the PMPRB's mandate of preventing excessive pricing and to maintain the price ceilings it sets for drugs. Further, we believe the PMPRB and the public should understand whether price increases are justified and a review is an effective mechanism to achieve this outcome.

Question 3.4: How should the PMPRB treat the allowable Consumer Price Index increase in the context where international list prices are decreasing?

We understand the need for Consumer Price Index (CPI) increases, given the impacts of inflation. As a result, the PMPRB should pay close attention to scenarios where inflation is increasing in international jurisdictions, but drug prices are decreasing. This scenario would suggest a meaningful decrease in the cost of drugs in other jurisdictions that we believe the PMPRB should account for when setting maximum prices for drugs in Canada. Doing so would improve accuracy and better reflect current market conditions when the PMPRB sets a price ceiling for a new drug.

Theme 4: Investigations and Referral to Hearing

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

We recommend the Guidelines set out as much detail as possible to promote transparency and ensure the industry is aware of developments in the market. However, we also recommend a balance between informing the public regarding complaints and the status of investigations, while also protecting the confidentiality of those filing complaints. We recommend the name of organizations or individuals filing a complaint remain confidential.

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

We support the use of voluntary undertakings, provided the remediation actions or measures are reasonable and executed ("enforced").

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Our industry recognizes that the proposed remedies for undertakings and excessive price hearings are designed to return excessive payments received by pharmaceutical companies back to the Receiver General for Canada. Today, the only remedy available to private payers is to take the role of intervenor at a hearing. Experience to date by the insurance industry is such that the industry has not been successful in obtaining a remedy. Yet, the PMPRB establishes maximum ceiling pricing for all Canadians.

We recommend that the PMPRB reconsider this issue. Sun Life believes that monies paid out on drugs under investigation should include those monies paid out on behalf of plan sponsors as well as Canadians paying out of pocket. Leaving the insurance industry out of the remedy process leaves employers and their employees shouldering a higher cost for the period of time the price was deemed to be in excess.

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

Question 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'excellence en santé et services sociaux (INESSS) and pan-Canadian Pharmaceutical Alliance (pCPA) or insurers (public and private)?

Sun Life supports efforts to promote harmonization between jurisdictions to reduce administrative burden. We understand that the PMPRB has no jurisdiction over a drug until there is a sale for the patented drug in Canada. However, there would be potential efficiencies to having the initial review start before notice of compliance (and therefore before a sale). Co-ordinating decisions and timelines with other pan-Canadian organizations could result in more timely listing decisions by all payers (public-private) and ultimately better equity in access to drugs.

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

Question 6.1: What is your experience with innovative medicines and their list prices in Canada?

Private payers provide coverage for innovative medicines, and they are increasingly having to negotiate confidential prices given the focus on high-cost, specialty, and rare disease drugs. A challenge for private payers is that even when they undertake price negotiations, it is unlikely that the final net price will be equitable to public plans. Another concern from a private payer perspective is scenarios where rights holders do not seek public funding and instead private payers assume the full financial burden for certain innovative drugs.

Question 6.3: Canada and the world are facing a generation of new high-priced drugs for the treatment of rare diseases.

i. ***Should the PMPRB view the question of whether the prices of these medicines are "excessive" through a different lens than other types of medicines?***

ii. ***What quality of evidence should the Board consider when conducting its scientific review of these medicines?***

This response addresses both sub-questions above. When assessing rare disease drug prices, we believe that the PMPRB should place greater attention on the clinical benefit of the drug. There are additional challenges in building evidence and often more uncertainty around the long-term efficacy of rare disease drugs. As a result, we recommend that the PMPRB take steps to incorporate the level of uncertainty into their assessment of what constitutes an excessive price. Doing so would provide us with valuable insight into how the PMPRB evaluates the benefit of rare disease drugs when factoring into the price ceiling they receive.

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This could be achieved by tying pricing to the recently introduced CADTH time-limited recommendation pathway and the pCPA Temporary Access Process. After this period, the pricing of the drug should be reassessed based on the new evidence to determine if its price is excessive based on the benefit realized.

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

We applaud the PMPRB for launching this consultation and for engaging with the life and health insurance industry. Given that millions of Canadians receive prescription drug coverage through Sun Life and our industry partners, we recommend the PMPRB continue to include us in consultations and engage proactively with us. We would also support any efforts to set up a platform for ongoing discussion and collaboration.

Conclusion

We thank the PMPRB for this consultation opportunity. We look forward to further opportunities for Sun Life to share our expertise to help Canadians live healthier lives.

Should you have any questions, please do not hesitate to contact us via email.

Sincerely,

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