Sun Life Assurance Company of Canada
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September 11, 2024

The Patented Medicine Prices Review Board (PMPRB)

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

Re: Sun Life's response to *Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines* (the discussion guide)

I am writing to provide Sun Life's comments on the discussion guide. Sun Life thanks the PMPRB for the opportunity to provide our comments and expertise, and to be a partner to you in responding to the important matters raised within 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.

Executive summary

Our comments focus on the seven topics laid out in the discussion guide, in line with our Purpose. They reflect our support for the PMPRB's mandate to protect consumers by ensuring that the prices of patented medicines are not excessive.

As a provider of group benefits to approximately 6.2 million people on behalf of 25,000 employers, we play a key role in providing Canadians access to prescription drugs. This also positions us uniquely to advise on the experience of employers providing group benefits, and why it is important to prevent excessive pricing of patented medicines.

Keeping benefits plans affordable over the long-term is a key concern and ongoing challenge for employers offering benefits. Drug costs are the largest group benefits plan expense, and many organizations are facing increasing cost challenges. This is compounded by other challenges employers face in the current economic climate, and in meeting the health of their employees. In addition, new high-cost specialty drugs can sometimes test the limits of group benefit plan affordability.

Please find our detailed response to the topics presented in the discussion guide below.

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Topic 1: Price level within the PMPRB11 to be used in the initial and post-initial price review.

We understand the Board is considering the following options:

- **Option 1:** Median International Price (MIP)
- **Option 2:** Highest International Price (HIP)
- **Option 3:** the midpoint between the MIP and the HIP

Sun Life supports ensuring drug prices are not excessive, to help group benefit plans to remain financially sustainable, drug coverage to remain affordable, and ultimately support Canadians to live healthier lives.

We strongly recommend that the PMPRB implement the MIP as the triage price level for initial and post-initial price review.

As noted in the discussion guide, in 2023, more than half of all DINs had Canadian list prices above the midpoint of the MIP and the HIP, with more than thirty percent above the HIP. As such, we feel strongly that the only appropriate option for the International Price Comparison (IPC) triage price level is the MIP.

Despite more drugs being above the MIP, potentially prompting additional in-depth reviews (versus other price levels), implementing the MIP would best allow the PMPRB to fulfill its mandate of ensuring patented drug prices are not excessive. Using the MIP would also better protect Canadians should a country in the PMPRB11 become a price outlier, as the United States did in the PMPRB7.

Topic 2: The length of time Staff should wait, following the implementation of the Guidelines, to determine whether the IPC identification criteria for an Existing medicine is met.

We understand the Board is considering the following options:

- **Option 1:** one year
- **Option 2:** two years
- **Option 3:** three years

Sun Life supports the PMPRB's proposed approach to not distinguish between "New medicines" and "Existing medicines" as part of the price review process. We believe that having a review mechanism for Existing medicines (versus allowing legacy pricing to remain in place) is essential to capturing market developments for prescription drugs and protecting Canadians from excessive prices.

We understand that the PMPRB intends to provide Rights Holders with a period of time, following the implementation of the Guidelines, before a review that can lead to a subsequent, in-depth review is initiated. We recommend that this period be set at one year.

The IPC is known in advance to Rights Holders. The PMPRB has communicated clearly and transparently the IPC identification criteria and triage price level options being contemplated for the final Guidelines. As such, it is our belief that Rights Holders should be able to prepare proactively for Guideline implementation, to facilitate the shortest possible period of adaptation before a price review is initiated.

Expediting the review of Existing medicines, to the greatest extent possible, and ensuring their prices are not excessive is of critical importance to Canadians. This is especially true in the context of delays that have occurred in final Guideline implementation and given that such a significant proportion of Canadian drug list prices currently exceed the HIP of the PMPRB11.

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Topic 3: In-depth review based on Consumer Price Index (CPI) increase criteria.

We understand the Board is considering the following options:

- **Option 1:** if the list price increase is above one-year CPI
- **Option 2:** if the cumulative increase in list price over the last two years is above the combined CPI for the past two years and the increase only took place within the last year (i.e., no increase in price in the first of the two years, followed by an increase in the second year)

We understand that, as per s. 85(1)(d) of the *Patent Act*, the Board is required to consider changes in the CPI. We would agree with the Board that option 1 is predictable and transparent. Although not specifically described in the discussion guide, we are inferring that perhaps option 2 provides a degree of flexibility to Rights Holders to account for the fact that the CPI for a particular year cannot be known in advance. We would be supportive of the option that the Board deems superior as far as ensuring that the CPI criteria triggering in-depth review is robust and enables the PMPRB to best meet its mandate.

Further, we recommend the PMPRB 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 reviewing prices for drugs in Canada.

Topic 4: The individuals/groups permitted to submit a complaint.

We understand the Board is considering the following options:

- **Option 1:** limit complaints to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts
- **Option 2A:** limit complaints to option 1 above plus public payors only; or
- **Option 2B:** limit complaints to option 1 above plus private and public payors
- **Option 3:** limit complaints to everyone except for Rights Holders
- **Option 4:** no limits/restrictions

The proposed price review framework includes reserving therapeutic class comparison (TCC) for in-depth reviews (versus TCC being conducted for all medicines under the previous Guidelines), as well as reduced reporting obligations for certain medicines deemed to be at lower risk of excessive pricing. With this in mind, we share the Board's view of Special Provisions and the role of complaints as being a crucial mechanism to prompt in-depth review in specific situations not captured by Guideline identification criteria.

Per the CLHIA 2023 Fact book, Sun Life, along with the members represented by the Canadian Life and Health Insurance Association, provide 27 million Canadians with access to drugs. In fact, in 2022 Canada's life and health insurers paid $14.3 billion for drugs, accounting for over 35% of prescription drug spending in Canada. As a key stakeholder that provides Canadians with access to prescription drugs, we strongly believe Sun Life and other private payers – individually and through the Canadian Life and Health Insurance Association (CLHIA) – should be permitted to submit a complaint that automatically leads to in-depth review. Additionally, given our role in the market, we may be able to identify price fluctuations in a more timely manner and flag them to the PMPRB through the complaints process. This supports the PMPRB's mandate of preventing excessive drug prices.

As such, our hope is that the final Guidelines will include individual private payers, as well as the CLHIA, as approved complainants.

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Topic 5: Expanding the list of products that would only be subject to an in-depth review following a complaint to include biosimilars and/or vaccines.

We understand the Board is considering the following options:

- **Option 1:** The PMPRB will treat patented biosimilars and/or vaccines the same as other medicines.
- **Option 2:** The PMPRB will only open an in-depth review for biosimilars and/or vaccines when a complaint is received.

While we understand there are reduced reporting obligations for certain medicines deemed to be at lower risk of excessive pricing (i.e., patented over-the-counter (OTC) medicines, certain non-prescription controlled substances, generic and veterinary medicines), we do not believe biosimilars and vaccines should be subject to reduced reporting requirements. We recommend that the PMPRB treat patented biosimilars and vaccines the same as other medicines.

Biosimilars and vaccines represent a more significant risk, as far as excessive pricing, to private group benefit plans than other categories of "lower risk" medicines noted. There is a robust clinical pipeline of innovative drug therapies, including vaccines, poised to potentially enter the Canadian market. Additionally, although biosimilars may enter the Canadian market at list prices below those of originator biologics, biosimilars can still carry high costs, often in the tens of thousands of dollars per person annually.

Biosimilars and vaccines are commonly covered and claimed on private drug plans, whereas OTC and veterinary medicines are typically excluded from coverage. While biosimilar list prices may be lower than corresponding originator biologic products, this does not preclude the possibility that Canadian list prices are excessive relative to the PMRPB11 basket of countries based on the IPC. To this end, and to best meet its mandate of protecting Canadians from excessive drug prices, the PMPRB should review biosimilars and vaccines in the same way as other patented medicines.

Topic 6: Use of clinical evidence to contextualize the degree of similarity of comparators identified for the TCC.

We understand the Board is considering the following options:

- **Option 1:** one level of similarity is identified for the comparators as a whole.
- **Option 2:** each comparator will be assigned a level of similarity.

We share the Board's view, as noted in the discussion guide, that assigning each comparator an individual similarity grade would allow for a more granular and sensitive TCC analysis for a patented medicine under in-depth review. We are supportive of the PMPRB implementing option 2.

Topic 7: Future role of the Human Drug Advisory Panel (HDAP).

We understand the Board is considering the following options:

- **Option 1:** HDAP will be used only on an ad hoc basis when deemed necessary by Staff.
- **Option 2:** No HDAP – the scientific process will be conducted by Staff.

We are supportive of an arrangement that ensures the scientific review process operates independently of the price review process, that scientific analyses are evidence-based and are conducted by individuals with the necessary expertise. We would defer to the Board on which of the options being considered best meets its needs and mandate.

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Conclusion

We thank the PMPRB for this consultation opportunity. We would also like to express our support for the submission being made to the PMPRB by the CLHIA.

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,

Michael Bradie
Vice President, Market Development and Growth