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October 20, 2016

Patented Medicine Prices Review Board (PMPRB) (Rethinking the Guidelines)
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

To: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Dear Sir / Madam:

Re: PMPRB Guidelines Modernization: Discussion Paper

We thank you for the opportunity to provide comments in response to the *PMPRB Guidelines Modernization: Discussion Paper* ("the Discussion Paper") released in June 2016. Our comments below supplement the submission filed by the Canadian Life and Health Insurance Association (CLHIA), which we support. We commend the PMPRB for undertaking the current review and modernization of its *Compendium of Policies, Guidelines and Procedures* (the Guidelines), in light of the evolving prescription drug landscape and recognizing the importance of ensuring policy and regulatory frameworks keep pace. This includes efforts to ensure prescription drug prices are set at a level that is sustainable and fair for consumers.

Sun Life Financial is one of Canada's largest financial services organizations, and provides life and health insurance, retirement savings and asset management products and services that help millions of people in Canada and internationally meet their lifetime financial protection needs. We are writing to you in our capacity as:

- One of Canada's largest providers of workplace Group Benefits (GB) plans, offered by 17,500 employers across the country, and which provide prescription drug, dental and eye care, critical illness and other health coverage to 5.3 million Canadians.
- A leading provider of personal (individual) health insurance in Canada, covering prescription drug and other health protection needs of more than 32.5 thousand Canadians.

Last year, we reimbursed on behalf of our clients C\$2.4 billion in prescription drug claims.

In Canada, prescription drug coverage is a mixed public and private responsibility. Through workplace GB and personal health insurance plans, Canadian life and health insurers as private payers help cover pharmaceutical and other health expenses for some 24 million Canadians,

representing nearly a third of total pharmaceutical spending in Canada. Insurers can also play a key preventive role by collaborating with employers to promote "health literacy" and wellness in the workplace, thereby contributing to healthier lifestyles and better long-term health outcomes for Canadians—and thus to a more sustainable health care system.

This Canadian system of pharmaceutical coverage by both public and private payers works relatively well. It provides Canadians with access to the pharmaceuticals and therapies they rely on to treat illnesses and conditions ranging from the relatively benign, to those that are chronic or critical. The development and availability of new innovative pharmaceuticals—those which produce demonstrably improved patient outcomes over existing products, followed by the entry into market of generic equivalents / comparable biosimilars, are an important part of a well-functioning pharmaceutical environment. It helps to keep people healthy, allows them to be productive, and saves lives.

However, it is also essential that the pharmaceutical environment ensure medications remain *affordable*—hence *accessible*—for Canadians, within both the public and private payer components of the pharmaceutical coverage system. Today, Canadians pay some of the highest prescription drug costs among Organisation for Economic Co-operation and Development (OECD) countries.² The rise is particularly acute for certain specialty medications; some drugs for the treatment of genetic enzyme disorders, cancer and auto-immune disorders can cost more than C\$50,000 per patient per year.³ Since the publication of the CLHIA's report in 2013, the trend has continued to amplify, with the emergence of more expensive new pharmaceuticals that cost over C\$100,000 per patient per year.

There is a growing concern that the trend of rising drug prices, combined with aging demographics, could impair the sustainability of public and private pharmaceutical coverage for Canadians going forward, in the absence of appropriate policy and regulatory measures. We therefore agree with the CLHIA that while pharmaceutical innovation is important, prescription drug pricing must also be fair and set at a sustainable level for consumers. Pricing regulation should seek to reduce prices to the extent possible in consumers' interest, while ensuring continued access to needed medications. We also support the industry association's suggestion to adopt a budget impact affordability threshold similar to the method used by the Institute for Clinical and Economic Review in the United States.

The impact of rising drug costs would ultimately be borne by Canadian consumers, through both the public and private payer components of pharmaceutical coverage:

 Public payer coverage (under various provincial plans) is ultimately funded by Canadian taxpayers. While public payers have some discretion over formularies and volume-based price negotiations with pharmaceutical suppliers (through confidential Product Listing Agreements), such arrangements can disadvantage private plans and out-of-pocket payers by keeping prices outside the public plans high—thereby resulting in inequitable drug access for Canadians.

¹ Canadian Life and Health Insurance Facts, 2016 Edition (Canadian Life and Health Insurance Association)

² Health at a Glance 2015 (Organisation for Economic Co-operation and Development)

³ Ensuring the Affordability, Accessibility and Sustainability of Prescription Drugs in Canada (2013, Canadian Life and Health Insurance Association)

• Private payer coverage includes both employer-sponsored GB and personal health insurance plans, and individual out-of-pocket expenses. Through risk-pooling, the professional financial / risk management of insurance providers, and employers' sponsorship of often generous GB plans, millions of Canadians benefit from affordable and relatively comprehensive prescription pharmaceutical coverage. Increasing drug prices risk making it unaffordable for some employers to sponsor such plans, notably smaller employers whose resources are more limited, and there would be pressure for premiums to grow to maintain personal plan coverage as well. The result could be Canadians paying more out-of-pocket for their medications.

We therefore submit that ensuring prescription drug prices are set at a level that is consistently sustainable and fair for consumers through both public and private payer coverage, should be an essential objective of good pharmaceutical policy and regulation. Also, such an objective should not (and need not) contradict the other important objective of ensuring innovative medications continue to be developed and remain available for Canadians' needs, as the experience of other OECD countries suggests.

While the current PMPRB review is focused on potential changes to the Guidelines, we join the CLHIA in urging the PMPRB to move swiftly to a broader review of both its legislative and regulatory frameworks so that even more fundamental reforms can be contemplated. Notably, the life and health insurance industry association's view is that the mandate of the PMPRB requires revision, so that therapeutic drug class pricing is not just set as "not excessive", but rather strives for prices that are as low as possible for Canadian consumers based on prevailing market forces. Such an approach would better align with the overall consumer protection goal of the PMPRB.⁴

Also, we do not believe that pharmaceutical pricing policy should aim or seek to attract / increase investment in pharmaceutical research and development in Canada. As your Discussion Paper rightly observes, there is little evidence that pharmaceutical pricing policy is either effective or appropriate as a means to draw such investment. Head office location, clinical trials infrastructure and scientific clusters are more relevant factors in determining where pharmaceutical investment takes place.

Finally, we join the CLHIA in underscoring that international price referencing should only be one factor to consider in setting patented pharmaceutical pricing, and that the basket of comparator countries used should also be modified so that it is more representative of the OECD as a whole. The current basket is not an adequate basis of comparison or guidance for setting patented drug prices in Canada. For example, the United States within the current basket is generally an outlier on pricing, and prices in OECD countries outside the basket (e.g. Australia, Austria, Spain, Finland, the Netherlands and New Zealand) are significantly lower than Canadian prices, as the Discussion Paper observes. Until that basket can be reviewed, Canada's prices should strive to reach the lower levels achieved among the OECD comparator countries used.

To conclude, we welcome the current and timely review of the PMPRB Guidelines, and join the CLHIA in advocating for an early and broader review of the agency's mandate, to ensure patented medication remains available—but also affordable and accessible—for Canadians through both

 ⁴ Ensuring the Affordability, Accessibility and Sustainability of Prescription Drugs in Canada (2013, Canadian Life and Health Insurance Association)
 ⁵ PMPRB Guidelines Modernization: Discussion Paper (June 2016, Patented Medicine Prices Review Board)

their public and private payer coverage going forward. This is critical to ensure all Canadians can continue to live healthy and productive lives. We look forward to continued consultation during the Guidelines review process, and to sharing our experience and expertise with your Board where they may be helpful, through subsequent discussions.

Sincerely,

Brigitte Parent Senior Vice President

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