Stephen Frank
President and CEO

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E-mail: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Re: PMPRB Consultation on Draft Guidelines

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 July 1, 2020. 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 CLHIA is a voluntary trade association that represents the collective interests of its member life and health insurance companies. The Association's membership accounts for 99 percent of the life and health insurance in force in Canada. In 2018, the life and health insurance industry provided more than 26 million Canadians with private supplementary health insurance coverage and made payments of about $11.7 billion on prescription drugs.

Overall, the life and health insurance industry continues to be very supportive of the recent amendments to the *Patented Medicines Regulations* to strengthen and modernize Canada's pricing framework for patented drugs. We agree, these amendment will allow the PMPRB to better protect Canadian consumers from excessive prices. We understand that the draft Guidelines are primarily intended for patentees and aim to provide transparency and predictability regarding the process, as well as providing an overview of the processes patentees should be aware of regarding their filing obligations. However, as a key stakeholder in the system we offer the following general comments for consideration.

- We are pleased that PMPRB is committed to developing and conducting a public monitoring strategy to continue to assess the impact of the amended Regulations on patients, health care providers, and other stakeholders to facilitate any needed modifications over time.

Canadian Life and Health Insurance Association
79 Wellington St. West, Suite 2300
P.O. Box 99, TD South Tower
Toronto, Ontario M5K 1G8
416-777-2221 www.clhia.ca

Association canadienne des compagnies d'assurances de personnes
79, rue Wellington Ouest, bureau 2300
CP 99, TD South Tower
Toronto (Ontario) M5K 1G8
416-777-2221 www.accap.ca

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- We believe that 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 setting the maximum 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. A healthy, productive workforce ultimately benefits our public health system beyond reduction of hospitalizations and we believe they are valid considerations in any HTA assessment methodology.

- As mentioned in previous submissions, we would 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 any excess amount is paid to the Receiver General for Canada and returned to provincial and territorial public payers based on a pre-determined 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.

We appreciate the lengthy consultation process involving all stakeholders that has provided the opportunity for ongoing feedback as the Guidelines were developed, and for the opportunity to participate in these discussions. We remain supportive of the changes and are available to assist where needed and to respond to any questions.

Yours sincerely,

Stephen Frank