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Private & Confidential
Via Electronic Mail

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Patent Medicines Regulations Consultations
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Via Consultation Response Portal

RE: 2022 Proposed Updated to the PMPRB Guidelines

We would like to thank the Patent Medicine Pricing Review Board (PMPRB, or the Board) for the opportunity to comment on the draft guidelines (the Guidelines). We are concerned by drug pricing trends in Canada and fear for the sustainability of access to the medicines Canadians need. We are therefore pleased with the recent amendments to the *Patented Medicines Regulations* (the Regulations) under the *Patent Act* (Canada) (the Act), as well as the Board's overall approach in the draft Guidelines. It is obvious that the Board has engaged in a thoughtful review of the Guidelines, and that the latest draft represents the culmination of years of effort that will help ensure that all Canadians continue to enjoy access to needed drug treatments.

Operating in every province and territory with over 11,000 employees, Canada Life is a leading insurance, wealth management and benefits provider focused on improving the financial, physical and mental well-being of Canadians. Canada Life serves more than 13 million people across Canada and, in 2021, paid \$8.9 billion in benefits on behalf of plan sponsors and plan members. As a major provider of private drug coverage in Canada, we have had a front-row view of patent medicine pricing trends over many decades. Private drug plans offer vital protection for Canadians and the members and sponsors which pay into these plans, ultimately, bear the brunt of excessive drug prices

We participated in the drafting of the Canadian Life and Health Insurance Association's submission to the current consultation and endorse its content. However, we feel that it is appropriate to submit a response due to the importance of these issues to the well-being of the millions of Canadians we serve.

Lifecycle Approach to Investigations

It's clear that a "one and done" approach to drug pricing has not worked. The role and duty of the PMPRB is ongoing and does not end with the initial determination of a non-excessive price when

a drug first enters the Canadian market. Such an approach encourages manufacturers to seek initial approval of a new medication for a narrow range of indications and smallest possible patient population. A price that is found to be non-excessive in these circumstances may well become excessive as circumstances change (e.g., changes to international pricing).

We also note that the Guidelines have a forward-looking emphasis that places greater scrutiny on new versus existing drugs. This division seems arbitrary, and will prevent Canadians from seeing the full benefit of the changes to the Regulations.

We encourage the PMPRB to develop a process to re-examine existing drugs over time, and to apply the same tests to both new and re-examined drugs (e.g., ensuring that prices in both cases do not exceed the median international price).

Complaints Process

The Guidelines make it clear that any individual or group who believes that the price of a patented medicine is excessive may submit a complaint to the Board. This broad access to the complaints process is appropriate given the large variety of parties that may be negatively impacted by excessive pricing.

We recommend that the Guidelines be updated to indicate the type of information about a complaint that will be made available to the public. In particular, the number of complaints about the price of a patented drug should be reported to the public in a timely manner to better enhance transparency. In our view, greater transparency is almost always beneficial to good public policy.

However, we would recommend that the guidance with respect to complaints on the PMPRB's website be updated to make it clear that organizations will have their identities protected (to the extent possible) as the current guidance references the *Privacy Act*, which may not protect such complainants.

We see the complaints process as a crucial element needed to ensure that new and existing drugs are priced at non-excessive levels. A clear process that protects complainants will encourage stakeholders to identify potential situations of excessive pricing, enhancing the PMPRB's ability to meet its mandate.

Remedies

In Canada, the majority of individuals are covered under private group drug plans, so employers and plan members bear a disproportionate burden, through premiums, fee or co-pays, when drugs are excessively priced. However, despite its broad remedial powers under the Act, the Board's remedies in such cases have not reflected this reality.

In most cases, where the Board has found that a drug has been excessively priced, it has ordered the relevant patentholder to reduce the price to a non-excessive level and pay the excess to the Receiver General for Canada. Yet, this payment to the Receiver General does not assist those that



have actually incurred the excessive cost. There is currently no mechanism in place for the Federal Government to distribute any amounts awarded to those who actually paid the excessive price.

Given the foregoing, we ask that in future cases of excessive pricing, the PMPRB exercise its discretion by ordering the relevant patentholder to reduce the price of the relevant drug to such extent and for such period as results in payers being reimbursed over time in an amount equal to the total excess.

Conclusion

We are very pleased with the spirit of dialogue under which this process has operated. As an insurer serving more than 13 million of our fellow citizens, and an organization with a corporate goal of improving the well-being of Canadians, we feel that we have an important voice in this discussion. We look forward to the continuation of this process and further consultation as the Board determines appropriate.

Sincerely,

A handwritten signature in black ink that reads "Brad Fedorchuk".

Brad Fedorchuk

EVP Group Customer