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Patented Medicine Prices Review Board
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Boehringer Ingelheim (Canada) Ltd/Ltée

Department: Market Access

August 21, 2023

Re: Patented Medicine Prices Review Board (PMPRB) Draft Guidelines Consultation

Submitted via email

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Dear recipients:

Boehringer Ingelheim (Canada) Ltd. ("BICL") is pleased to provide feedback on the "*PMPRB Proposed Amendment to the Interim Guidance re: New Medicines"* as published by the PMPRB on June 30, 2023, on their website.

BICL would like to remind the PMPRB that guidelines (including the proposed interim and future guidelines) have a significant impact on the pharmaceutical innovation landscape in Canada.

The reality is that the uncertainty associated with the guideline development process over the last few years has resulted in a negative impression of Canada as a country that welcomes, and values innovation and has reduced Canada's attractiveness for new product launches.

With respect to the proposed amendment to the Interim Guidance we have the following feedback for consideration by the PMPRB:

ELEMENT 1. For patented medicines without a MAPP or projected NEAP as of July 1, 2022 ("New Medicines"), the prosed interim guidance states:

> *"Medicines without a MAPP (Maximum Average Potential Price) or NEAP (Non-Excessive Average Price) as of July 1,*

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> *2022, are considered reviewed if their list price is below the median international price for the PMPRB11 countries."*

The recent appellate court decisions held that the PMPRB cannot revise prices below an already non-excessive level in pursuit of optimal or reasonable pricing. As each of the PMPRB11 countries regulate the price of their medicines and have mechanisms in place, the price prevailing in any of the PMPRB11 countries is necessarily a non-excessive price and cannot be considered excessive. Applying a "below the median" price approach to the PMPRB11 suggests price-regulation rather monitoring against abusive pricing practices.

BICL strongly recommends that the interim guidance consider the price of "new medicines" be non-excessive so long as their list price is anywhere within the range of available prices of the basket of PMPRB11 countries.

ELEMENT 2. For patented medicines with a MAPP or projected NEAP as of July 1, 2022, the prosed interim guidance currently states

> "*During the interim period, the price of a patented medicine will not trigger an investigation if:*
> *1) its national average transaction price (N-ATP) remains at or below the NEAP (Non-Excessive Average Price) as projected in the most recent compliance letter from PMPRB staff to the relevant patentee, and;*
> *2) its list price does not increase."*

There continues to be uncertainty and ambiguity in the manufacturer's ability to take price increase in accordance with the Consumer Price Index (CPI). According to section 85(1) of the Patent Act, the PMPRB must take into consideration each of the enumerated factors, including changes in the Consumer Price Index (CPI). A market-wide price freeze without any allowance for inflationary adjustments ignores this required factor. Prohibiting CPI adjustment during a period of high inflation results in a price reduction in "real terms" (i.e., adjusting for purchasing power erosion due to inflation). This leads to the erosion of prices below their MAPP and NEAP, which are intended to be non-excessive price thresholds established

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by the PMPRB. This is directly contrary to the Court of Appeal's ruling that once prices reach a non-excessive level, they cannot be reduced any further under federal patent jurisdiction.

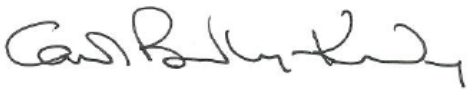
BICL strongly recommends that the PMPRB allow price increases reflecting CPI to a price within the range of available prices of the PMPRB11 countries.

Conclusions

Overall, BICL is concerned that the above elements of the interim guidance do not reflect the guardrails set by recent jurisprudence, including the Quebec Court of Appeal in *Merck Canada c. Canada*, 2022 QCCA 240. BICL urges the PMPRB to take a forward-looking approach which is inclusive and supportive of the innovation within the Canadian business environment.

We thank you for the opportunity to provide feedback on these proposed interim guidelines. We urge the PMPRB to establish interim guidance and new guidelines to demonstrate that Canada is a reasonable, predictable, and stable market for pharmaceutical innovation. BICL would be pleased to be involved in discussions during the development of future guidelines.

Sincerely,



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