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Doug Clark

Patented Medicine Prices Review Board Box L40

Standard Life Centre

333 Laurier Avenue West, Suite 1400

Ottawa, Ontario K1P 1C1

December 2, 2022

Dear Mr. Clark,

On behalf of the Myeloma Canada community, I am pleased to provide you with a response to the call for public consultation on the '2022 Proposed Updates to the PMPRB Guidelines' released October 1, 2022. Myeloma Canada is fortunate to be supported by patients and caregivers deeply engaged in health policy discussions which have a direct and undeniable impact on their lives—such as those affecting drug access. Alongside members of our dedicated patient community, Myeloma Canada has participated extensively in the various updates, stakeholder education sessions, and webinars held by the PMPRB over the last four years on the proposed modernization of the PMPRB guidelines, to engage with all stages of the guideline and development of an evaluation process, and to ensure the patient voice remains at the forefront of these conversations. Our feedback is guided by the unique experience of Canadians living with multiple myeloma, and seeks to illuminate the challenges our community expects to face under the regulatory framework currently proposed by the PMPRB. As we have provided extensive comments on previous iterations of the proposed guidelines, we will focus our efforts in this submission on the most pressing concerns.

Firstly, by basing the proposed investigation criteria on the list prices of new medicines, which are by default the highest prices charged in the market, we can expect an increasing number of investigations will be triggered, further burdening the new framework, and compounding the delay in Canadians' access to new drugs. We appreciate the PMPRB's desire for consistency and easier comparison, and we recognize that the average annual transaction price can and should be considered during an investigation. Yet, the 'easier' comparison of list prices does *not* inhere

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a *better* or more thorough evaluation of these prices as compared to the PMPRB11. In fact, without initial consideration of average annual transaction price, the triggering of an investigation is actively divorced from the dollar amounts Canadians *actually pay* for these medicines. Thus, the uncertainty-riddled investigation process is initiated, and Canadians' access to new, potentially lifesaving, medicines is already delayed, *without any direct knowledge of these medicines true cost to Canadian patients*.

Assessing the price of new medicines without any reference to their therapeutic benefit flies directly in the face of improving patient outcomes and care. It is irresponsible to legislate and enforce a regulatory disconnect between the price of medicines and their opportunities for improving and saving the lives of Canadian patients. The objective of drug development is to better cure, heal, and care for patients, to *benefit them*—and we fail to understand why introduction of new medicines to the Canadian market would occur without direct and serious consideration of these drugs' benefit to Canadian patients. Without consideration of therapeutic benefit, the PMPRB appears to be so focused on their goal of overall pharmaceutical price reduction, they are forgetting the narrow scope of their mandate—which has been clearly reaffirmed by recent court decisions. In February 2022, the Quebec Court of Appeal in *Merck Canada Inc. et al. v. Canada* stated in effect that the constitutional role of the PMPRB is limited to prevent "excessive" prices derived from the monopoly conferred by a patent. Its role is limited to "excessive" pricing and patent abuse and does not include price control and the regulation of an industry.[1]

We want to reiterate and highlight the point made in the CONNECTed submission and stated in the Quebec Court of Appeal Renders Major Decision on the PMPRB. "The Court also found that reference pricing is a legitimate way to assess excessive pricing. Moreover, the list of comparison countries is not static and can evolve. The Court of Appeal found that the fact that such a substitution of reasonably comparable countries could have the effect of reducing drug prices in Canada is irrelevant to the analysis of the constitutional validity of the measure, since the objective pursued remains that of ensuring price competitiveness in Canada relative to those abroad."[2] "Similarly, the Court has stated the PMPRB's mandate had to be narrowed and does not extend to pure price control; and generally

[1] Merck Canada inc. c. Procureur général du Canada, 2022 QCCA 240 (CanLII), <https://canlii.ca/t/jmjbm>, consulté le 2022-11-20

[2] Quebec Court of Appeal Renders Major Decision on the PMPRB. https://www.fasken.com/en/knowledge/2022/02/decision-on-the-pmprb

expressed agreement with recent precedents that the control of excessive prices must result from the monopoly conferred by a patent." [3]

Canada's lack of a national Rare Disease Strategy presents another complicating factor. Since 2019, the Canadian government has acknowledged the need for a national rare disease strategy, and repeatedly reaffirmed its political and financial commitment to crafting one. Despite this, no national rare disease strategy exists in 2022, and subsequently there is no consideration of rare diseases in the draft guidelines. Drugs for rare diseases, rare conditions, or rare cancers such as myeloma, have often been at the forefront of jurisprudence regarding the application of price control by the PMPRB, and thus legal precedent is being set without sufficient consideration of the unique issues surrounding these drugs' development costs and market value. The guidelines do not inherently recognize drugs for rare diseases, nor do they afford these drugs any special/modified basis of consideration, which will likely compound the difficulty faced by patients of rare diseases in accessing the treatments they need.

PMPRB is also required to provide a reasonable explanation for its decisions. In this regard, we would refer to the case *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)* regarding a decision by PMPRB. In paragraph 25, the Court concluded, "a reviewing court must ultimately be satisfied that the [administrator's] reasoning, 'adds up'."[3] Problematically, the proposed 2022 draft Guidelines do not contain any information about publication of the reasons for the decision by the PMPRB staff to ensure stakeholders are able to identify these reasons and analyze the reasonableness of said decision.

If the proposed guidelines come into force as planned, on January 1, 2023, access to innovative treatments will be curtailed due to the considerable uncertainty contained in the proposed process of investigating potentially price-excessive drugs. We appreciate the desire for a 'shorter', 'simplified', 'less prescriptive' approach to regulating the price of patented medicines, but these simplifications cumulate in creating an environment of extreme ambiguity for companies interested in introducing a new medicine to the Canadian market. The proposed process of investigating a possibly excessively priced medicine has *no timeline or specific criteria of evaluation*, and thus deciding to introduce an expensive new drug to the Canadian market represents a significant open-ended investment for pharmaceutical companies. Similarly, the composition of the PMPRB11 makes it very difficult to foresee a situation in which an investigation is triggered. As important as affordability and lower prices

[3] Alexion Pharmaceuticals Inc v Canada (Attorney General), [2021] FCJ No 812, 2021 FCA 157

of drugs fin Canada, it should not jeopardize access to new lifesaving treatments for Canadians who need them to stay alive.

Given the limitations in the 2022 draft Guidelines, we also find that a scenario analysis is not feasible with the current level of information made available by the PMPRB, including what *Domestic Therapeutic Class Comparison (dTCC) will be used since this analysis has not yet been conducted by PMPRB for new medicines.*

Recommendation 1: PMPRB should postpone implementation of the 2022 draft Guidelines until it has conducted a complete analysis, and inclusion of, all information required to be given by the PMPRB as a quasi-judicial body.

Recommendation 2: Revise PMPRB draft Guidelines to undergo final stakeholder consultation prior to coming into effect.

We are grateful to the PMPRB for opening the 2022 guidelines up to consultation and we appreciate the considerable work you have undertaken to try and ensure Canadians pay a fair price for medications. Ultimately, it is crucial that the proposed changes support and advance the present and future health of Canadians by ensuring that they have *timely* access to effective treatments. We look forward to working with the PMPRB to monitor and evaluate the implementation of the proposed changes to ensure that their goals are met.

Regards,

Martine Elias

Martine Elias
Executive Director, Myeloma Canada
on behalf of the National Myeloma Canada Advocacy Committee