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Patented Medicine Prices Review Board
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December 5th, 2022

**BMS Response to PMPRB
2022 Guidelines Proposals**

At BMS, our mission is to discover, develop, and deliver innovative medicines that help patients prevail over serious diseases. However, BMS remains deeply concerned that the proposed Patented Medicine Prices Review Board (PMPRB) Guidelines (the Proposed Guidelines) and their implementation timeline, will significantly limit BMS's ability to deliver on this mission and bring scientific breakthroughs to patients in Canada.

BMS believes that the Proposed Guidelines will not only stifle innovation in Canada, but more importantly, impair access to novel medicines for Canadians living with serious diseases.

As a member of Innovative Medicines Canada (IMC), BMS agrees with IMC's submission and believes that the Proposed Guidelines, if implemented, will have a significant and negative impact on patient care and the Canadian biopharmaceutical industry. BMS agrees that the PMPRB must suspend implementation of the Proposed Guidelines so that they may be reformulated following a meaningful and robust consultation process with the right stakeholders that is also consistent with the federal government's health and life sciences priorities including the National Strategy on Drugs for Rare Diseases and the Biomanufacturing and Life Sciences Strategy.

- Given the fundamental importance of the Guidelines to Canadians, the process should allow for adequate time to review and incorporate stakeholder feedback received during the consultation phase closes on December 5, 2022. The proposed go-live date of January 1, 2023 does not allow for a good faith consideration of stakeholder input and no time for more in-depth member meetings or extended dialogue.
- More fundamentally, it seems premature to proceed with implementing guidelines that originate from Regulations which are currently subject to judicial review before the Federal Court of Appeal.

Any future version of the Guidelines also needs to address:

1. The Guidelines should recognize the value of innovation, which is a fundamental objective of the *Patent Act*. The Proposed Guidelines will undermine the

“patent bargain” by unduly impacting a patentee’s ability to recoup the time, effort and risk associated with bringing innovation to the market.

- The Proposed Guidelines abandon the PMPRB’s past practice of recognizing innovation through defined tiers of therapeutic improvement. BMS believes such a practice is grounded in defensible and predictable public policy and should be restored to the Proposed Guidelines.

2. The Proposed Guidelines should align with an excessive price standard.

- In the Proposed Guidelines, the median price investigational trigger does not reflect a focus on excessive pricing, but rather appears to be designed to regulate prices and to drive pharmaceutical pricing downward. This is inconsistent with the PMPRB’s mandate to guard against patent abuse in the form of excessive pricing, a mandate that has been confirmed by the Federal Court of Appeal.
- Furthermore, the proposal for therapeutic referencing based on a domestic Therapeutic Class Comparison (dTCC) discourages innovation as it forces patentees to set the price of their medicines in reference to older drugs, including generic and biosimilar products, which have their own price control mechanisms and are not subject to regulation by the PMPRB. Nothing in the Patent Act requires the PMPRB to apply therapeutic referencing in this manner proposed. By doing so, the PMPRB has improperly limited the patentee’s right to be rewarded for innovation which will disincentivize the timely launch of new medicines in Canada.

Finally, we believe the Proposed Guidelines are too open-ended and they remove any certainty and predictability in pricing new medicines. Global manufacturers cannot appropriately manage their organizations in Canada without stable and fair guidelines. As a result, Canada’s attractiveness for investment in the Canadian life sciences sector will be impacted, resulting in reduced local research and innovation, along with less clinical trials, patient access programs and financial assistance initiatives.

As currently drafted, the Proposed Guidelines undermine the federal government’s clearly articulated aim to promote the health and life sciences sector as an important priority for our country.

We reiterate our belief that any guidelines implemented by the PMPRB must ensure that Canadian patients, especially those with rare diseases, have timely access to the medicines they need. We appreciate this opportunity to provide feedback, and we would welcome further dialogue to provide input and expertise as part of a constructive

process to reformulate the Guidelines. It is our sincere hope that prioritizing meaningful consultation on this critical issue for industry, stakeholders and Canadian patients will benefit what matters to us most, Canadians, and our mission to transform their lives through lifesaving, innovative medicines.

Sincerely,

A handwritten signature in black ink, appearing to read 'T. André', with a long horizontal stroke extending to the left.

Troy André
General Manager
Bristol Myers Squibb Canada Co.