Bristol Myers Squibb™

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Patented Medicine Prices Review Board
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BMS response to New Consultation on PMPRB Guidelines (July 15, 2021)

Bristol Myers Squibb (BMS) Canada would like to thank you for providing us with this opportunity to voice our concerns with the most recent proposed changes to the Guidelines.

It is our assertion that these new proposals are inconsistent with both Patented Medicine Prices Review Board and Government of Canada recent commitments to provide manufacturers with both appropriate timelines and clear, uncomplicated rationale for any amendments. In addition, as our industry continues to address the urgent needs of the COVID-19 pandemic, these last-minute changes and compressed timelines for implementation will most certainly divert our focus away from where it needs to be today – supporting the health of all Canadians as we head into another serious wave of the COVID-19 pandemic. As a member of Innovative Medicines Canada (IMC), we also wish to acknowledge our support for their recent response.

Specific to your request for feedback on the proposed changes, we submit the following:

1. **Transition Period for Implementation: The PMRPB propose pricing compliance by July 1, 2022 following a January 1, 2022 implementation.**

   By significantly reducing the transition period, the PMPRB will place unnecessary, incremental administration and compliance pressure on drug manufacturers and health system partners during the most notable human health crisis in modern history. For two previous iterations of the proposed amendments, the PMPRB proposed a twelve-month transition period to bring the prices of existing medicines into compliance and make the necessary adjustments to our business operations. On April 16, 2021, the Board also stated, “In view of the evolving state of the Covid-19 pandemic, the Board has decided to revisit its March 17, 2021, decision regarding the compliance timelines for Grandfathered and Gap medicines. Specifically, the Board has decided that compliance with the Maximum List Price (MLP) for these medicines will be assessed after two filing periods, as was originally provided for in the new Guidelines when they were first published on October 23, 2020.”

   Within these new proposals, there is no rational for the proposed, significantly shortened, transition period. This new timing also contradicts the Government of Canada’s stated rationale for the most recent delay, as mentioned in the Regulatory Impact Analysis Statement that because of, “ongoing efforts related to the pandemic

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response, additional time is required for patentees to prepare for and comply with the changes."

A six-month transition period not only reverses your previous commitments, but will divert attention away from prioritizing pandemic-related issues and will substantially and unnecessarily increase the administrative burden and cost, not just for BMS, but also for the greater health system, including the provincial governments. It is our request that PMPRB maintains two reporting periods from the effective date of the regulatory changes for the purposes of a reasonable transition.

2. **International Price Tests for Grandfathered Medicines and their Line Extensions: The new proposal includes a major change to grandfathered medicines that would have a serious impact to our business in Canada.**

   Moving from the Highest to the Median of international prices is a completely new price test that has never been previously discussed or proposed. The rationale for this change is undefined and various elements remain unclear generating a lack of transparency and providing confusion over potential administration.

   As proposed, the price test will force BMS to apply significant reductions to the prices of our currently marketed medicines. In contrast to the PMPRB's assertion that it will apply to not more than 50% of these in-market products, our initial analysis anticipates an impact on at least 85% of our products which will cause swift and significant financial ramifications for our Canadian business operations. This new proposal is also a deep departure from the previously proposed price tests used by BMS to guide important planning decisions, requiring new and rushed administration implementation at an unacceptable late stage.

   It should also be noted that, since the PMPRB embarked on the reforms in 2016, BMS has continued to invest in Canada. In the last 6 years we've doubled the number of clinical trials we conduct in Canada, with more than 4,000 Canadian patients enrolled in active studies across 43 different therapeutic indications. Each year, we've also continued to launch multiple innovative life-saving products, including a first-in-Canada cell therapy that revolutionizes blood cancer treatment. If implemented, this price test change will have a damaging impact on our current portfolio, and absolutely impair our ability to continue to bring new, much-needed oncology and hematology medicines to patients in Canada. It is our assertion, that the stakeholder impact of this new price test will be profound.

Alignment in the delivery of innovative medicines to Canadians

BMS certainly believes that the PMPRB embarked on the *2015-2018 Strategic Plan* with a commitment to provide a transparent consultation process based on integrity and mutual respect.[i] However, these vacillating proposals provide industry with needless uncertainty in a time of exceptional global uncertainty. The rationale for the proposed

price test is poorly defined, lacks transparency and will have significant impact, not just on our business operations, but for all Canadians. By proposing this change at the last minute, the PMPRB is also being inconsistent with their ongoing commitment to a comprehensive consultation process reflecting stakeholder feedback.

We reassert that a framework can be implemented that ensures Canadian patients, especially those with rare diseases, can continue to access the medicines they need. But, there must be thoughtful understanding, and consideration, of the business impact and timing of these changes as we navigate the COVID-19 pandemic together. We appreciate this opportunity to provide feedback, and it is our sincere hope that you will continue to manage these changes in a way that allows BMS to respectfully meet your needs while also allowing us to prioritize what matters most, our mission to transform the lives of Canadians through lifesaving, innovative medicines.

Sincerely,

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[i] http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1028&lang=en