2344 Alfred Nobel, Suite 300
Montreal, Quebec H4S 0A4

February 15, 2021

Re: BMS response to PMPRB consultation: Proposed change to the definition of GAP medicines and the timelines for compliance

In response to the Patented Medicine Prices Review Board (PMPRB) January 15, 2021 Notice and Comment, Bristol Myers Squibb (BMS) Canada would like to submit the following response to the proposed consequential amendments for PMPRB consideration.

As stated during previous consultation opportunities, we remain deeply concerned that the proposed Guideline implementation and associated timelines will significantly limit our ability to live out our mission to help patients in Canada. As a member of Innovative Medicines Canada (IMC), we fully concur with the IMC response and believe that, during a time of continued uncertainty, the new condensed proposal will have a swift, significant and negative impact on industry, and subsequently Canadians and their health.

It is our assertion that a fair and reasonable timeline associated to the definition of Gap medicines and compliance for Grandfathered and Gap Medicines must be implemented in order to ensure industry business continuity, uninterrupted access and uninterrupted supply.

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

1. **Definition of Gap Medicines:** *PMPRB proposing that the definition of Gap medicines under the new Guidelines applies to medicines for which a DIN was assigned on or after August 21, 2019 and that were first sold in Canada prior to July 1, 2021.*

   BMS Canada supports the PMPRB's proposal to extend the date of first sale to the new coming-into-force date of July 1, 2021 only on the basis that the previously established two reporting periods are also shifted to enable an equitable 12-month (two reporting period) timeline. This two-reporting period as set out in the October 2020 Guidelines was operationally feasible. A reduced timeline will place unnecessary and unavoidable administration and compliance pressure on drug manufacturers and health system partners during the most significant human health event in modern history.

   The federal government's decision to delay the implementation was made to allow drug manufacturers and health system partners to remain focused on responding to COVID-19. The significantly condensed timeline, as proposed, will divert the industry's focus and force a rushed implementation, directly in contradiction to the intent of the delay.

2. **Compliance Timelines for Grandfathered and Gap Medicines:** *PMPRB is proposing that compliance with the Maximum List Price (MLP) for Grandfathered and Gap medicines be reduced by 50 percent (reduced from 2 to 1 filing periods).*

   BMS is adamantly opposed to the proposal that the compliance timeline with the Maximum List Price (MLP) for Grandfathered and Gap medicines be reduced by 50 percent. BMS

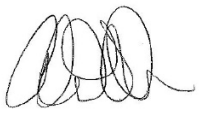
believes the more equitable solution to the coming-into-force date of July 1, 2021 is to maintain the minimum of two reporting periods for compliance with new MLP levels. Alternatively, the PMPRB could apply an additional reporting period (from 2 to 3 periods) with a compliance date of January 1, 2023.

Maintaining a minimum of two reporting periods is a must. A significant investment in time and resources will be required not just by drug manufacturers, but also provincial public payers - who each have unique province-specific requirements, timelines and processes - as well as other parties within the reimbursement and distribution system, such as wholesalers, distributors, and pharmacies. The proposed changes also place a significant administrative burden internally for Patentees, over and above the adjustments needed to existing reporting requirements, such as the additional new reporting of market size forecasts, the additional reporting of five new country prices and reporting of Pharmacoeconomic analysis from CADTH and INESSS.

As the PMPRB embarked on the *2015-2018 Strategic Plan*, there has been an ongoing commitment to a transparent consultation process that would ensure stakeholders have opportunities to comment on activities that may affect them. Given this dedication to effective consultations based on integrity and mutual respect[i], we trust that these valid industry concerns will be appropriately considered, and that everyone involved – not just manufacturers - will be given adequate time to coordinate the essential processes needed to adapt and adhere to the new regulations during a very unstable environment.

As an industry, since the COVID-19 pandemic began, we have risen to the occasion by working closely with federal and provincial government agencies to address challenges experienced by the health-care system. At the same time, we have experienced tremendous pressure and challenges to our business. While we manage through these many complexities, it is our hope that you will allow us to continue to focus on our mission to transform the lives of Canadians through lifesaving, innovative medicines. We truly believe a framework can be implemented that ensures Canadian patients, especially those with rare diseases, can continue to access the medicines they need, but there needs to be a thoughtful understanding and consideration of the impact of these changes as we attempt to successfully navigate these extraordinary times.

Sincerely,



Al Reba
General Manager
Bristol Myers Squibb Canada Co.

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