

Thomas J. Digby
Chairman of the Board
Patented Medicine Prices Review Board (PMPRB)
333 Laurier Avenue
Suite 1400
Ottawa, ON K1P 1C1

August 21, 2023

**BMS Response to 2023
proposed Amendments to
Interim Guidance re: New
Medicines**

At BMS, our mission is to discover, develop, and deliver innovative medicines that help patients prevail over serious diseases. In a period of unprecedented life sciences innovation, the need for a reasonable, predictable, and stable non-excessive pricing system to help launch new treatments that can benefit Canadians is paramount. As a member of Innovative Medicines Canada (IMC), BMS fully supports the IMC's position to request a collaborative approach to creating a fair and sustainable pricing policy for the industry, governments, stakeholders, and Canadian patients.

The continuing uncertainty caused by the extended reform process is not in the interest of industry, governments, or Canadian patients. Global manufacturers cannot appropriately manage their organizations in Canada without stable and fair guidelines. This is a critical factor in promoting Canada's attractiveness for investment in the Canadian life sciences sector and promoting local research and innovation, clinical trials and patient access to medicines that will improve their lives.

As a member of Innovative Medicines Canada (IMC), we fully concur with the IMC response. In addition, we would like to reiterate that:

- **Fair framework for “reviewed” medicines:** Interim Guidelines need to provide rights holders with predictability and assurance that once a new product is considered “reviewed,” it will not be subject to reassessment or re-benching in future reporting periods OR under new guidelines. There should be a reasonable assurance of stable pricing over the expected commercial life of the product. At a minimum, “reviewed” rulings for new medicines based on a drug price at (or below) the median international price (MIP) should hold as a guarantee of compliance in any new guidelines that are proposed.
- **CPI should NOT trigger investigation:** In accordance with the Regulations [*sect 85 (1) (d)*], the Consumer Price Index (CPI) is one of the factors the Board must consider in determining if a price is potentially excessive. Increases that are aligned with the Canadian CPI should not cause a product to be “under review” or “trigger” an investigation. As previously agreed, the PMPRB should review the 2022 Non-Excessive Average Price (NEAP) benchmark since new guidelines were

not implemented by January 1, 2023, and the interim period needed to be extended into 2023.

- **Meaningful consultation PRIOR to publication:** The PMPRB should proceed in a meaningful, robust consultation which includes a technical working group with rights holders to ensure a fair and iterative development process before circulating their next guidelines. Furthermore, we suggest that the PMPRB not attempt to rework the 2022 Guidelines; instead, entirely new guidelines should be undertaken with input from rights holders.
- **New basket compliance:** Guidelines should align with the original PMPRB defined excessive price standard whereby rights holders are considered compliant with the new basket - and considered as 'reviewed' - as long as their Canadian prices are within the range of available prices in the revised PMPRB schedule of countries.

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,



Elaine Phillips
General Manager
Bristol Myers Squibb Canada Co.