Bristol Myers Squibb™

Anie Perrault
Acting Board Chair
Patented Medicine Prices Review Board (PMPRB)
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Ottawa, ON K1P 1C1

March 19, 2025

Bristol Myers Squibb Canada Response to PMPRB Draft Guidelines (December 2024)

Dear Ms. Perrault,

At Bristol Myers Squibb (BMS) Canada, our mission is to discover, develop, and deliver innovative medicines that help patients prevail over serious diseases. We appreciate this opportunity to provide feedback on the December 2024 Draft Guidelines, which have the objective of enhancing transparency, predictability, and procedural fairness in the identification and management of potentially excessive pricing. We believe the PMPRB's draft guidelines currently provide Rights Holders with very little certainty regarding the pricing outcomes of new medicines prior to final Board rulings.
BMS is advocating for more balanced guidelines that integrate the perspectives of Rights Holders to support and ensure the continued inflow of innovation and patient access to the medicines we provide to Canadians. As a member of Innovation Medicines Canada (IMC), we support the position and recommendations contained in the IMC submission, and would like to reinforce our position on the following:

Predictability & Consistency

1. Annual re-benchmarking using an evolving Therapeutic Class Comparison (TCC) creates uncertainty for innovative drug launches and may hinder access to life-saving treatments in Canada. Rights Holders should be allowed to maintain previously deemed non-excessive prices even after market shifts have occurred, to ensure predictability and continued investment. This approach respects the initial market conditions upon which launch decisions were based and avoids penalizing innovation.

2. For new medicines with no international reference prices, the initial review should only be conducted after the earlier of five PMPRB11 reference country prices are available, or three years have passed. If the Canadian price is found to be above the HIP and is deemed excessive, retroactive reimbursement may be required. This approach discourages inflated launch prices while avoiding launch delays due to reference basket limitations.

3. Existing medicines compliant under previous PMPRB guidelines, should maintain their compliant status under the new guidelines. Businesses require regulatory

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predictability for long-term decisions, and retrofitting new rules onto existing products creates uncertainty, as well as discourages future investments in Canada. By grandfathering compliant pricing for existing medicines, the PMPRB maintains the integrity of prior policy frameworks and focuses on regulating new medicines under revised guidelines, thereby reinforcing Canada's reputation as a fair and competitive marketplace. Forcing price reductions, despite previous compliance, devalues past regulatory decisions, creating inconsistency and risking disruptions or delays in treatment options for patients who rely on these medicines.

Managing Reviews, Complaints and Market Factors

1. The proposed guidelines risk creating a repetitive cycle of In-Depth Reviews (IDRs), even for medicines deemed at low risk for excessive pricing. This places a significant and unnecessary regulatory burden on Rights Holders. To avoid unnecessary reviews, we suggest that a minimum three-year moratorium on new IDRs be implemented after a review is closed, provided list prices remain stable.

2. There is concern that complaints from private payers could lead to an increase in unwarranted requests due to competing business interests or strategic positioning. To prevent this, clear criteria, strict evidence requirements, or a review process to filter out meritless submissions should be implemented before any IDR's are triggered. We believe that implementing a robust complaint validation process would be beneficial for the PMPRB in ensuring that only legitimate IDRs will be opened.

3. Consideration should be given to the necessity of tolerance around market factors, like Consumer Price Index (CPI) and Foreign Exchange Rate (FX) fluctuations, as these variables fall outside of Rights Holders' control, and often resolve themselves within two-or three reporting periods. To address this, the PMPRB should implement tolerance margins, such as a 5% FX rate lenience, that would account for transient issues and prevent too many reviews from being triggered by uncontrollable factors.

Furthermore, the recent implementation of US tariffs on Canadian products has increased the cost of medicines entering Canada. As the trade war escalates in the coming months, the risk of Canadian counter-tariffs on US pharmaceutical imports continues to rise. If imposed, Rights Holders will need to pass these uncontrollable increases onto Canadian payers in the form of sudden List Price increases to maintain the inflow of necessary medicines into Canada. It is understood that once the tariffs are removed, list prices would revert to prior levels. **Special accommodations (i.e. Temporary Tariff Adjustment**

Allowances) will be needed to permit Rights Holders to continue importing medicines without triggering IDRs, ensuring Canadians maintain access to life-saving medications during this conflict.

We continue to believe that the PMPRB's guidelines must prioritize timely access to essential medicines for Canadian patients, particularly those with rare diseases. As we look towards the completion of these guidelines, we reiterate our ask that the PMPRB engage in a thorough and collaborative consultation process, including a technical working group with Rights Holders, to facilitate a fair and iterative development of the next guidelines.

We value the chance to offer our perspective and readily anticipate continued discussions, contributing our insights and expertise to a collaborative effort to refine the guidelines. At Bristol Myers Squibb Canada, we are proud to be a part of the Canadian healthcare landscape and are dedicated to working collaboratively to improve the lives of Canadians affected by serious diseases.

Sincerely,

Elaine Phillips
General Manager