

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

August 4th, 2020

Re: BMS Response to PMPRB 2020 Draft Guidelines

At BMS, we embrace and celebrate our commitment to compassionate science and putting patients and people first. Today, we remain deeply concerned that the proposed Patented Medicine Prices Review Board (PMPRB) 2020 Guidelines, and implementation timeline, will significantly limit our ability to live out our mission to help patients in Canada access scientific breakthroughs. As a member of Innovative Medicines Canada (IMC), we fully agree with the recent IMC response and believe that, during a time of such unprecedented uncertainty, the proposed 2020 Guidelines, if implemented, will have a swift, significant negative impact on Canadians and their health.

In addition to what IMC outlines in terms of operational feasibility, readiness and fairness in the application of the Guidelines, we would also like to emphasize the following areas of concern:

Predictability

To provide a predictable pricing floor, the final Guidelines must provide patentees with clear “bright lines” on anticipated maximum list prices for products in Canada, both pre- and post-launch. To do this effectively, and provide patentees with an expectation of stable pricing over the planning horizon, the PMPRB should focus its approach solely on predictable list price ceilings. This predictability is a key component for industry in estimating market attractiveness, local investment and overall launch feasibility. Using this approach, proactive decisions about local clinical trials, patient access programs and financial assistance initiatives can be made and implemented in support of Canadian patients.

Maximum Rebated Price (MRP)

Bearing in mind the recent Federal Court decision declaring that the compelled disclosure of third-party rebates exceeds the scope of PMPRB’s jurisdiction, all elements of the June 2020 draft guidelines, as they pertain to MRP, are no longer acceptable. The concept has been repeatedly reinforced as central to the proposed Guidelines, and without the third-party payment information, the PMPRB cannot accurately implement the planned approach. The MRP was also based on a complex calculation involving new economic factors – pharmacoeconomic value, market size, and GDP/GDP-per-capita – and therefore can no longer be used in the manner originally contemplated. A complete reset along with a fundamental review of the draft Guidelines is required, with consideration for the use of factors that are within PMPRB’s mandate such as predictable list price ceilings and international price referencing.

Market Size

Implementation of the market size factor is also unacceptable. The draft Guidelines introduce a *de facto* revenue control mechanism through the market size factor, and this approach would compound price reductions. The proposed market size factor implementation measures would move the PMPRB away from its original mandate of determining excessive prices to actively controlling expenditures, which is the responsibility of Canadian provincial and territorial governments.

High-value Medicines

Important measures specific to rare diseases have been removed from the new draft and consequently, the proposed threshold adjustments are now too restrictive for oncology and specialty products. These threshold adjustments cannot be applied as an absolute price setting mechanism due to limited clinical data packages for small patient populations, and this was never the intention. Scientific input is necessary to drive meaningful and sustainable change that supports the unmet medical needs of patients with serious and rare diseases.

Human Drug Advisory Panel (HDAP)

We are concerned that PMPRB staff are not adequately equipped to determine therapeutic value. The HDAP expert committee provides vital scientific expertise in determining levels of therapeutic improvement, appropriate comparators, and/or the relevant indication, often in the investigative stage. HDAP must continue to have a primary and regular role as part of the process, and more specifically, providing pre-sale advisory assistance is of even greater importance during this period of transition. In the absence of these valuable consultations, the health of Canadian patients will be determined by economic factors instead of using evidence-based international best practices.

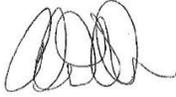
Conclusion

In today's pandemic environment, we do not see how the 2020 Guidelines can be reasonably and effectively implemented by January 2021 and, as stated above, we urge you to consider a reset of the process. In their current state, the proposed Guidelines are complex, difficult to understand and implement, and contain significant information gaps. To ensure a framework that offers operational feasibility, sufficient time to transition to a new way of working, and reasonable transition measures for all in-market products, better guidance and longer timelines must be provided to industry.

Based on our interpretation of the proposed draft, we are also now initiating discussions about the viability of bringing several new products to Canada. If the Guidelines are implemented in their current form, it is almost certain that some of our innovative products may never be available for Canadian patients.

Thank you for the opportunity to provide feedback. We would welcome the opportunity to consult on the Guidelines in more detail, and to provide our input and expertise through technical working groups. We want to continue to transform the lives of Canadians through life-saving, innovative medicines and believe a framework can be implemented that ensures Canadian patients, especially those with rare diseases, can continue to access the medicines they need.

Sincerely,



Al Reba
General Manager
Bristol Myers Squibb Canada Co.