Bristol Myers Squibb™

July 18, 2022

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

Re: BMS response to PMPRB Price Review Approach During the Interim Period Posted on June 30, 2022

Bristol Myers Squibb (BMS) Canada would like to acknowledge the opportunity to provide comments on the proposed "interim period" guidance which we believe is inconsistent with both Patented Medicine Pricing Review Board and Government of Canada commitment to provide manufacturers with appropriate timelines as well as transparent, clear and predictable pricing guidance moving forward.

As a member of Innovative Medicines Canada (IMC), we also wish to acknowledge our support for their recent response.

Specific to the June 30, 2022 request for comments on the proposed interim guidance, we have the following comments:

1. **Patentees need assurance that new launches over the interim period (July 1, 2022 until an undetermined date for publication of new guidelines) will not lead to future fines retroactive to market entry. It is unreasonable for the PMPRB to require companies to repay excess revenues in an interim period where future guidelines are not yet known. The proposed interim period requires clarity and defined parameters.**

   PMPRB has acknowledged that neither the existing, nor the October 2020 Guidelines, address the set of regulations which came into force on July 1, 2022. The PMPRB proposed to adopt a "status quo" approach during the interim period, thus any excess revenue calculation should only begin to accumulate after the final guidelines are in force.

   While the PMPRB stated that they will not conduct a price review until the new guidelines are in place, they have also indicated that they could later open investigations for the interim period. Without approved and defined guidelines to address the July 1, 2022 regulations, patentees are left exposed and vulnerable. Patentees should not be required to repay amounts deemed excessive over the interim period provided they are within a reasonable level.

2. **Patentees require a fair transition period for implementation of new regulations and guidelines. We request that the PMPRB define a reasonable transition as a full two-reporting periods equal to 12 months. This should apply for both the newly introduced interim period and later to the finalization of the guidelines.**

   The June 30th PMPRB proposal does not specify that a 12-month transition period, committed to by PMPRB on April 16, 2021, will exist for compliance to both the interim period and the finalization of the guidelines. Patentees need reassurance that this full 12-month transition period remains in place to allow patentees and other pharmaceutical supply chain stakeholders to adjust their business plans to the new Guidelines.

3. **The 2017 PMPRB guidelines acknowledged and permitted price increases on already approved drugs to enable manufacturers to align to inflation and the Consumer Price Index (CPI). Inflation is one of the regulatory factors in the Patent Act[i] that did not change and must be considered by PMPRB in assessing whether a price is excessive or not. The June 30, 2022 "status quo" proposed by PMPRB is inconsistent with the 2017 guidelines and puts patentees at a significant economic disadvantage as a Canadian business.**

   Canadians and Canadian businesses continue to feel the significant impact of rising prices as consumer inflation rose 7.7 per cent year-over-year from May 2021 to May 2022, which was the largest increase since January 1983.[ii] In addition, the pandemic recovery across all businesses is not unique to the pharmaceutical industry and in some cases, an increase in price may be necessary to continue to manufacture and supply innovative medicines to Canadians. Given that the PMPRB is proposing to adopt a "status quo" approach to carrying out its regulatory mandate, imposing a new requirement, namely "list price does not increase during the Interim Period" is unfair and inconsistent to the "status quo".

BMS Remains Committed to Deliver Innovative Medicines to Canadians

We reiterate our belief that a framework can be implemented that ensures Canadian patients, especially those with rare diseases, can continue to access the medicines they need. Given that neither the 2017 nor 2020 guidelines align to new regulations effective July 1st, it is unclear how the PMPRB will proceed with the implementation of new Guidelines by Jan 1, 2023. Commencing new regulations based only on the sudden imposition of interim guidelines is disingenuous to principles of an open, transparent and predictable process.

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 the innovative patentees to meet your needs while also prioritizing what matters most, our mission to transform the lives of Canadians through lifesaving, innovative medicines.

Sincerely,

Troy André
General Manager
Bristol Myers Squibb Canada Co.

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[i] https://laws-lois.justice.gc.ca/eng/acts/p-4/fulltext.html
[ii] https://www150.statcan.gc.ca/n1/daily-quotidien/220622/dq220622a-eng.htm?indid=3665-1&indgeo=0