Bristol Myers Squibb™

September 11, 2024

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

Subject: BMS Response to PMPRB Discussion Guide (June 2024)

In response to the Patented Medicine Prices Review Board (PMPRB) June 2024 Discussion Guide, Bristol Myers Squibb (BMS) Canada would like to submit the following submission to support a predictable and sustainable non-excessive pricing system where medical innovation is valued to enable the launch of new treatments that can benefit Canadians is paramount.

As a member of Innovative Medicines Canada (IMC), we fully support the IMC response and believe that any policy changes which arise from the Discussion Guide must reflect PMPRB's jurisdiction with respect to excessive pricing due to abuse of patent rights and follow their mandate to provide transparency and predictability to Rights Holders. More specifically, we would like to highlight the following points:

1. **Full Legacy Exemption for Existing Medicines**
   Existing medicines that were launched under the previous regulations should be permitted to retain their prior non-excessive prices, adjusted for applicable inflation. The decision to introduce these medicines to the Canadian market were made with a reasonable expectation that maximum price thresholds would remain in place throughout the life of the patent.

2. **Highest International Price (HIP)**
   The highest international price (HIP) from the PMPRB11 is the only standard consistent with the non-excessive mandate conferred by the courts. The use of a median or newly created 'midpoint' test diverges from the PMPRB's mandate and implies a price control role which are beyond the PMPRB's scope. The new framework should instead focus on addressing excessive pricing based on the highest international price.

3. **Complaint Validation**
   While stakeholder input is important, we are concerned that an approach allowing anyone to complain is too wide. It can lead to a significant influx of unwarranted and unvalidated complaints, potentially overwhelming the PMPRB's capacity, causing unnecessary in-depth reviews, even delaying access of essential treatments to Canadians. To ensure that only legitimate concerns are addressed, we strongly recommend the PMPRB implement a robust complaint validation process prior to triggering in-depth reviews.

4. **Predictability**
   Providing a stable pricing environment over the patent life our medicines is key to maintaining the inflow of new innovative medicines into our country. Therapeutic class comparisons should only include comparators present at the time of launch of a new medicine. The 2024 Discussion Guide is suggesting that later market entries be included in future dTCC tests which could trigger price reductions at any time. This unplanned re-

benching would severely impact our company's ability to continue supplying new medicines to Canadian patients. In addition, the proposed IPC test should not be conducted until three years post implementation of the new Guidelines.

In closing, we ask that the Board acknowledge the valid and serious concerns from its stakeholders before finalizing the new guidelines. We believe that the June 2024 Discussion Guide proposes a framework which lacks predictable pricing rules, known outcomes, and it opens the door to multiple future re-benching.

Sincerely,

Elaine Phillips
General Manager
Bristol Myers Squibb Canada Co.

BMS Canada Response
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PMPRB Topics for Feedback	BMS Canada
1. Price level within the PMPRB[11] to be used in the initial and post-initial price reviews	The Highest International Price (HIP) is the only standard consistent with the PMPRB's legal mandate to ensure prices are not excessive.
2. Length of time Staff should wait to determine whether the IPC identification criterion for an Existing medicine is met (1, 2 or 3 years)	Given the amended Regulations did not change any of the excessive price factors, existing medicines that were compliant and therefore non-excessive with the applicable legislation and Guidelines, including Interim and 2010 Guidelines, should be granted full exemption into the new Guidelines as long as their prices remain below those levels plus applicable CPI. The IPC test should not be conducted until 3 years post implementation of the new Guidelines.

3. In-depth review based on CPI increase criteria	The Patent Act maintains that CPI is a factor in which the Board must consider in determining whether or not the price of a medicine is excessive. It should therefore be allowed in the new guidelines. The 2010 Guidelines acknowledged and permitted price increases up to 1.5 times the prior year CPI or up to 3 years CPI using the lag methodology. This enabled manufacturers to keep pace with inflation. The board offers no rationale for why more restrictive CPI applications than those of the 2010 Guidelines are necessary. **Option 2** is less restrictive and allows Rights Holders who could not take a price increase in one year the possibility to draw level in the following year.
4. Complaints & Eligibility by Individuals or Groups	Provided a robust complaints validation process is put in place by Staff, Option 1, which limits complaints to the Federal Minister of Health or any of their Provincial or Territorial counterparts, makes the most sense.
5. Expanding list of products (e.g. biosimilars, vaccines etc) subject to review following complaint	Given the prices for these medicines are subject to self-regulating mechanisms within the Canadian market, it is unlikely Rights Holders could abuse their patent monopoly and maintain any significant sales volume if priced above market. **Option 2** makes the most sense for these medicines. In fact, the same rationale should hold for novel medicines who have suffered generic intrusion (ie multi-source meds).
6. Use of clinical evidence to contextualize the degree of similarity of comparators identified for the TCC	A thorough understanding of the forthcoming Guidelines from the PMPRB is required before BMS can make any statements about scientific reviews or the future role of HDAP. It is essential we better understand how these Guidelines will impact the scientific review processes and establish comparator weightings in determining whether a medicine's price is excessive. Other considerations for investigations will depend on the Guideline's content and their intricacies and would best be assessed through technical working groups.
7. Future Role of HDAP	