BAUSCH Health
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September 11, 2024

Patented Medicine Prices Review Board
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Re: PMPRB Discussion Guide for Phase 2 Consultations on New Guidelines

This letter is written in response to the PMPRB Discussion Guide for Phase 2 Consultations on New Guidelines. By way of this letter, Bausch Health, Canada Inc. (Bausch) would like to provide feedback on some of the topics for discussion to assist in the drafting of New Guidelines.

1. **Topic 1: Price level within the PMPRB11 to be used in the initial and post-initial price review.**

In July 2022, the PMPRB implemented a new set of regulations which changes the basket of PMPRB reference countries from the previous PMPRB7 to the PMPRB11. This basket has removed higher priced reference countries, while adding lower prices countries. As such, the implementation of this new basket will result in lower international price comparisons regardless of the price level chosen.

The mandate of the PMPRB is to ensure prices of patented medicines in Canada are not excessive. As such, Bausch suggests that the highest international price is the appropriate benchmark. Other tests, such as the median international price or the midpoint as the IPC would be overstepping the PMPRB mandate.

2. **Topic 2: The length of time Staff should wait, following the implementation of the Guidelines, to determine whether the IPC identification for an Existing medicine is met.**

The implementation of the New Guidelines will operationalize the PMPRB11 basket of reference countries. According to the Discussion Guide, 32% of all patented medicines had Canadian list prices higher than the highest international price in 2023. Given the large number of medicines that will require a price reduction, there will be a significant impact on Rights Holders. Bausch recommends that 3 years be adopted as the length of time Staff should wait, following the implementation of the Guidelines, to determine whether the IPC identification for an Existing medicine is met. This will allow Right's Holders the appropriate time to prepare all business functions for the changes.

3. **Topic 2: Re-benchmarking existing medicines**

Predictability is a key factor to promote a stable pharmaceutical environment and ensuring Canadians access to medicines. Through the proposed framework, an in-depth review can be triggered for any medicine. This would result in existing medicines being re-benchmarked, including those that previously were assessed as compliant at first sale. Given that the mandate is not to price control, but rather to ensure prices are not excessive, re-benchmarking would be inappropriate. These existing drugs were

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deemed compliant at introduction and therefore should have a full exemption from further re-benchmarking.

4. Other topics

While Bausch appreciates the opportunity to provide feedback on elements of the proposed framework, further information of the In-Depth review must be communicated before Bausch can provide comments on other factors such as the level of similarity, weighting of the factors, and the role of the HDAP.

As a final note, predictability and transparency should be the guiding principles in the development of the New Guidelines, while adhering to the mandate of the PMPRB which is to ensure prices are not excessive. Bausch thanks the PMPRB for considering our input and we look forward to the development of New Guidelines which will provide the clarity and certainty that enable access to innovative medicines in Canada.

Sincerely,

Martin Barbeau
Vice-President, Market Access & Government Affairs
Bausch Health, Canada Inc.