

August 10, 2023

The Patented Medicine Prices Review Board
Standard Life Centre, Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
K1P 1C1

RE: Consultation on PMPRB Proposed Amendments to Interim Guidance

To whom it may concern:

Since the launch of the draft guidelines in late 2019, Sumitomo Pharma Canada, Inc. [(SMPCA) - (formerly Sunovion Pharmaceuticals Canada Inc.)] has expressed to the PMPRB our major concerns with specific examples shared on the impact to SMPCA's current and future patented medicine portfolio. Despite all the feedback provided throughout the consultation process and a comprehensive communication strategy undertaken by SMPCA with numerous policy makers, no amendments to the draft guidelines and the interim guidance were made to reflect the feedback shared.

As the PMPRB continues to move forward with the interim guidelines and expected final guidelines in 2024 ("guidelines"), SMPCA requests that the PMPRB takes the required steps to actively consult with patentees and stakeholders. As member of Innovative Medicines Canada ("IMC"), SMPCA has been engaged in the feedback process surrounding the PMPRB proposed amendments to the interim guidelines; however, the PMPRB has not taken the action to understand our concerns and the implications to patients' access to new innovative medications. SMPCA strongly agrees with the comments and recommendations submitted by IMC in response to the consultation and would like to provide additional feedback.

Existing Medicines

SMPCA agrees with the status quo approach where existing patented medicine will not trigger an investigation provided that its national average transaction price (N-ATP) remains at or below its most non-excessive average price (NEAP) generated from the PMPRB existing guidelines. SMPCA requests that the PMPRB provide to all patentees the projected NEAP for 2023 which was not provided in the most recent PMPRB compliance letter to patentees for the 2022 reporting period.

SMPCA does not agree with the fact that a patentee is not able to take a price increase during the interim guidance period despite the PMPRB publishing *the 2023 CPI-Based Price Adjustment Factors for Patented Drug Products* (<https://www.canada.ca/en/patented-medicine-prices-review/services/are-you-patentee/cpi-adjustment-factors/2023-cpi-adjustment-factors.html>). The PMPRB should not use a price increase as a *de facto* investigation trigger when "changes in the consumer price index" is specifically referenced in the *Patent Act*. Furthermore, the PMPRB must continue to update its *CPI-Based Price-Adjustment Factors for Patented Drug Products* on an ongoing basis.

New Medicines

Patentees require predictability in pricing when bringing a new patented medicine to the Canadian market. Without visibility on the strategic direction of the new guidelines, patentees are unable to clearly identify the implications to their current and future patented medicines portfolio. The PMPRB has noted that it will re-engage with stakeholders and will consult on the guidelines, which are anticipated to be finalized in 2024. Until there is a fulsome consultation process on the guidelines, the PMPRB should not conduct a price review of any patented medicines using the PMPRB11.

Moving forward, the guidelines should anchor the list price to the highest of the PMPRB11 which is the test most consistent with a non-excessive price standard as per the PMPRB's mandate. The application of the median of the PMPRB11 for patented medicines appears to be "free floating", thus eliminating any type of pricing predictability. The outcome of the median PMPRB11 over time will drive price erosion, thus impacting the ability to make available a patented medicine in Canada.

Analysis conducted by SMPCA on the median PMPRB11 price test indicates that the list price of our patented medicines will be below costs. Patentees, such as SMPCA, cannot provide patented medicines in Canada at a list price that is below costs and as result, will have to withdraw these patented medicines from the market or not launch in Canada, thus affecting patient access to their medicines.

New Guidelines Moving Forward

As the PMPRB moves forward with the guidelines, SMPCA is seeking a balanced policy to ensure Canadians have access to patented medicines while allowing patentees to achieve the establishment of a fair price point that supports the cost of innovation. As echoed to the PMPRB and other stakeholders, the previous proposed draft guidelines and the interim guidance continue to not place any value on level of therapeutic improvement offered by any innovative medicine.

PMPRB has pushed forward with a mandate to modernize its regulatory drug pricing framework in Canada for over five years. The uncertainty in price policy framework over these years has made Canada an unfavorable market to incentivize patentees to bring life-saving therapies to Canadian patients, including those therapies that are aligned to Public Health Agency of Canada's (PHAC) action plan to address Antimicrobial Resistance (AMR). Overall, the current pricing environment is impacting the viability and attractiveness to launch innovative medicines to Canadian patients.

SMPCA has communicated our specific concerns on the implications to our business operations; however, our greatest concern remains with the implications on the health and mental well-being of Canadians today and tomorrow. Should these interim guidelines move forward, Canadians will not have access to the treatments that are otherwise available in other countries as echoed by many patient stakeholders. Now, more than ever, Canadians need access to innovative medicines and companies need a regulatory environment that fosters innovation.

SMPCA asks for the PMPRB to take the required steps to actively consult with patentees and stakeholders. Moving forward, SMPCA requests to be included in any direct consultation with the PMPRB not only to have fulsome engagement, but also to get alignment on a solution to bring innovative medicines to Canadians.

Sincerely,

SUMITOMO PHARMA CANADA, INC.



Lisa Mullett
General Manager