Sumitomo Pharma

Sumitomo Pharma Canada, Inc.
7025 Langer Drive, Suite 301
Mississauga, Ontario, L5N 0E8
Cell: +1.416.697.5536
Email: lisa.mullett@ca.sumitomo-pharma.com

March 12, 2025

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

To whom it may concern:

RE: Consultation on Draft Guidelines for PMPRB Staff

Sumitomo Pharma Canada, Inc. would like to thank you for the opportunity to provide input on the *Draft Guidelines for PMPRB Staff,* December 2024 ("Draft Guidelines"). Sumitomo Pharma Canada, Inc. (Sumitomo Pharma) is an innovative and entrepreneurial health care company. Our head office, located in Mississauga, Ontario plays a major role in contributing to the North American business of Sumitomo Pharma Co., Ltd., a global pharmaceutical company. Our company develops and commercializes innovative medicines in the areas of psychiatry, neurology, urology, women's health, infectious disease, and oncology while supporting the Canadian economy and developing a talented knowledge-based workforce.

New Guidelines Moving Forward

Sumitomo Pharma has provided feedback over the course of all the PMPRB consultations. Sumitomo Pharma has expressed our major concerns, providing specific business case examples on the negative impact to Sumitomo Pharma's current and future patented medicine portfolio. Despite the feedback provided throughout these consultations, and a comprehensive communication strategy undertaken by Sumitomo Pharma with numerous policy makers, the PMPRB has made no changes in approach to reflect the feedback shared.

The 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 past 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 (2023-2027) to address Antimicrobial Resistance (AMR)[1,2]. To grow an innovative ecosystem in Canada, rights holders require a combination of regulatory and economic incentives to bring new antimicrobials to Canadian patients to address AMR[2]. Overall, the state of the current pricing environment has impacted the viability and attractiveness to launch these innovative medicines to Canadian patients[3].

As the PMPRB consults on the Draft Guidelines, Sumitomo Pharma would like to emphasize the need for Guidelines that offer rights holders predictability in establishing a fair price point for patented medicines in Canada that supports the cost of innovation. A lack of understanding and consideration to the need of rights holders in establishing a predictable price for patented medicines will impact the viability of Canadian patients having access to patented medicines.

Sumitomo Pharma's greatest concern remains with implications on the health and mental wellbeing of Canadians today and tomorrow. Now, more than ever, Canadians need access to innovative medicines and manufacturers need a regulatory environment that fosters innovation. As a member of Innovative Medicines Canada (IMC), Sumitomo Pharma strongly agrees with the comments and recommendations submitted by IMC and in addition, we would also like to provide additional feedback on the Draft Guidelines.

---

[1] https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/drugs-health-products/pan-canadian-action-plan-antimicrobial-resistance/pan-canadian-action-plan-antimicrobial-resistance.pdf
[2] https://www.oag-bvg.gc.ca/internet/English/parl_oag_202310_06_e_44339.html
[3] https://www.cca-reports.ca/wp-content/uploads/2023/09/Overcoming-Resistance_digital_FINAL_2.pdf

Patented Medicine Launch and Life-Cycle Management in Canada

Rights holders price their patented medicines considering many factors, including cost of goods, to build a business case to launch a new medicine in Canada. Rights holders cannot price their patented medicines in Canada as they see fit at any time. Patented medicines in Canada have established cost of goods to which rights holders have limited flexibility in maneuvering and therefore, Rights Holders require a level of predictability to establish a fair price that supports innovation and commercial viability.

The approach presented in the Draft Guidelines does not allow rights holders to determine an allowable price at the time of launch and as well, predict any arbitrary price reductions in the life cycle management of a patented medicines due to re-benchmarking resulting from annual price reviews.

Existing Patented Medicines

Sumitomo Pharma requests that the existing medicines be exempt from the Draft Guidelines as Sumitomo Pharma's patented medicines have been compliant and therefore, non-excessive under the previous and interim guidelines. The Draft Guidelines are a departure from its historical practice and therefore, Sumitomo Pharma disagrees in evaluating the existing medicines with the same lens as new medicines under the Draft Guidelines.

Sumitomo Pharma recommends that the PMPRB leverage the CPI factor to transition existing patented medicines to the new Guidelines.

Annual reviews

Sumitomo Pharma disagrees with annual reviews of patented medicines based on HIP threshold prices as this could trigger an in-depth review leading to arbitrary price reductions due to re-benchmarking.

Sumitomo Pharma requests that the PMPRB monitors compliance with an initial review of the price of new patented medicine using the HIP threshold, followed by annual reviews using the CPI-adjusted price benchmark established at introduction for new medicines.

Highest International Price

Sumitomo Pharma maintains that moving forward, the new 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.

Shifts in the PMPRB11 pharmaceutical landscape, including foreign exchange rates, can impact the price of patented medicine to which Canadian Rights Holders cannot control. Sumitomo Pharma requests that the new Guidelines include some reasonable buffers (e.g. +/- 5 to 10% fluctuation against the PMPRB11 benchmark) to ensure changes in foreign exchange rates do not result in an in-depth review being triggered, generating unnecessary regulatory burden. This proposed approach would be aligned to the PMPRB's goal to ensure administrative efficiency and resource prioritization.

In Depth Review Process

The Draft Guidelines outlined that PMPRB staff will conduct an annual review of the list price of patented medicines, applying the International Price Comparison, to identify those patented medicines that will be subject to an in-depth review.

The in-depth review allows the PMPRB staff broad discretion when selecting the comparators and identifying their level of comparability to the patented medicine, when conducting a Therapeutic Class Comparison. The relevance of comparators and the weighing of the Patent Act factors is proposed to be done on a case-by-case basis and therefore, does not allow for a consistent approach to each patented medicine. Rights holders would not have the insight or the ability to predict the outcome of an in-depth review for a patented medicine due the ambiguity of the Draft Guidelines and the subjectivity of the PMPRB staff decisions.

A lack of clear pricing guidance and predictable outcome for the in-depth review creates ambiguity and does not incentivize rights holders to make available a patented medicine in Canada. This argument is evident over the past years where the uncertainty in price policy framework have made Canada an unfavorable market to bring life-saving therapies to Canadian patients, including those therapies that are aligned to the Public Health Agency of Canada's (PHAC) action plan to address Antimicrobial Resistance (AMR)[1,2,3].

Sumitomo Pharma requests that the PMPRB actively consult with rights holders and establish working groups to develop fair, transparent, and predictable pricing guidance for patented medicines in Canada.

Transitional provisions for Existing Medicines

Sumitomo Pharma requests a three-year period to transition exiting patented medicine as this would align to the timeline required by the Canadian supply chain to adjust to the impacts of the Draft Guidelines.

Stakeholders Permitted to Submit a Complaint

The Draft Guidelines outline that a complaint will lead to an automatic in-depth review which is completely inappropriate as this would lead to unnecessary review burden to both the PMRPB and rights holders. Sumitom Pharma requests that an alternative complaint resolution mechanism be established to ensure the validity of a complaint prior to the launch of an in-depth review.

Overall, the eligibility of complaint should be narrow, and the process should be transparent to not only the PMPRB, but also the rights holders. We do not agree that for profit commercial insurance companies and their associates should be given the opportunity to launch a complaint as this introduces a conflict of interest.

Sumitomo Pharma requests that the eligibility for complaints should be restricted to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts.

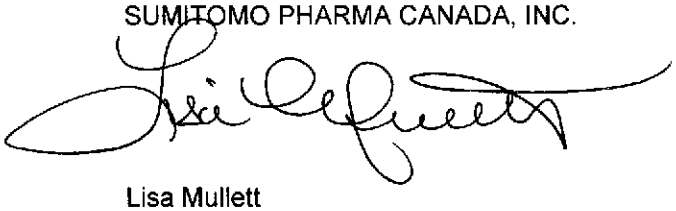
In Summary

The uncertainty in price policy framework over the past 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)[1,2,3]. Sumitomo Pharma's greatest concern with the development of the Guidelines remains with the implications on the health and mental wellbeing of Canadians today and tomorrow. Now, more than ever, Canadians need access to innovative medicines and companies need a regulatory environment that fosters innovation.

As the PMPRB moves forward with the Guidelines, Sumitomo Pharma is seeking a balanced policy not only to ensure Canadians have access to patented medicines, but also to allow patentees to achieve the establishment of a fair price point that supports the cost of innovation, thus making Canada an attractive life science ecosystem.

Sincerely,

SUMITOMO PHARMA CANADA, INC.



Lisa Mullett
Senior Vice President, General Manager, Canada