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August 29, 2024

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

RE: Discussion Guide for PMPRB Phase 2 Consultation on New Guidelines

To whom it may concern:

Sumitomo Pharma Canada, Inc. (formerly Sunovion Pharmaceuticals Canada, Inc.) would like to thank you for the opportunity to provide input on the D*iscussion Guide for PMPRB Phase 2 Consultation on the New Guidelines* (June 2024). Sumitomo Pharma Canada, Inc. (Sumitomo Pharma) is an innovative and entrepreneurial health care company. Our head office, located in Mississauga, 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 made no changes in approach to reflect the feedback shared, nor have we received any response to our request for consultation on our feedback.

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 to address Antimicrobial Resistance (AMR)[1,2]. 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 moves forward with the Phase 2 consultation, Sumitomo Pharma is seeking a balanced policy to ensure Canadians have access to patented medicines while allowing patentees to achieve the establishment of a fair and predictable price point that supports the cost of innovation.

Sumitomo Pharma's greatest concern remains with implications on the health and mental well-being 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

[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://iris.who.int/bitstream/handle/10665/329404/9789241515481eng.pdf?isAllowed=y&sequence=1

[3] https://www.cca-reports.ca/wp-content/uploads/2023/09/Overcoming-Resistance_digital_FINAL_2.pdf

IMC in response to the Phase 2 consultation. Sumitomo Pharma would also like to provide additional feedback to the various topics as outlined in the Discussion Guide to inform the development of the Guidelines.

Topic 1: Price level within the PMPRB11 to be used in the price review

As communicated previously, Sumitomo Pharma maintains that the PMPRB must adopt the Highest International Price (HIP). With the introduction of the revised scheduled of international reference countries, the Highest International Price (HIP) is consistent with excessive pricing standard. Sumitomo Pharma does not agree with the use of the Median International Price (MIP). Analysis conducted by Sumitomo Pharma on the median PMPRB11 price test indicated that the list price of our current patented medicines will be below costs. Patentees, such as Sumitomo Pharma, cannot provide patented medicines in Canada at a list price that is below costs and as result, would withdraw these patented medicines from the market or not launch in Canada, thus affecting patient access to their medicines. The application of the median of the PMPRB11 for patented medicines would 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.

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. Furthermore, the guidelines should include some reasonable buffers (e.g. +/- 5 to 10% fluctuation against the PMPRB11 benchmark) to ensure changes in exchange rates do not result in unnecessary regulatory burden.

Topic 2: Transitional provisions for Existing Medicines

Sumitomo Pharma recommends a full distinction between New Medicines versus Existing Medicines to be consistent with the previous years' proposals and aligned to patentees business planning assumptions. Sumitomo Pharma recommends full exemption for existing patented medicines as these were deemed compliant and therefore non-excessive with the applicable legislation and Guidelines. Sumitomo Pharma launched its patented medicines under the previous regime and its patented medicines were deemed compliant and therefore, Sumitomo Pharma should not be penalized for the uncertainty introduced by the creation and implementation of new guidelines moving forward.

Topic 3: CPI Methodology

Sumitomo Pharma recommends implementing the HIP and it is therefore unclear of the role that the CPI methodology plays when a price of a patented medicine does not exceed the HIP. Sumitomo Pharma notes that the PMPRB must continue to update its CPI-Based Price-Adjustment Factors for Patented Medicines on an ongoing basis to allow patentees to adjust the ceiling price over time while not exceeding the HIP.

Topic 4: Individuals/groups permitted to submit a complaint

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

Topic 5: In Depth Review Process

As presented in the discussion guide, patentees would not have the insight or the ability to predict the outcome of an in-depth review for a patented medicine. Overall, the discussion guide has not detailed sufficiently the in-depth review to clearly identify the implication on the price of a patented medicine. Furthermore, the in-depth review allows for broad discretion to the PMPRB staff to identify comparator relevance and weighing of Patent Act factors on a case-by-case basis.

Sumitomo Pharma requires predictability in pricing to build a business case to launch a patented medicine in Canada. A lack of clear pricing guidance for the in-depth review creates uncertainty and does not incentivize patentees 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 incentivize patentees 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).

The guidance document notes that the in-depth review will include the use of the domestic therapeutic class comparisons (dTCC). In past guidelines, the dTCC was used to determine the non-excessive price of a patented medicines deemed to have a level of therapeutic improvement of slight or no improvement. The 2024 guidance document proposes to use this price test, irrespective of level of therapeutic innovation that is offered by the patented medicine. Previous proposals for the dTCC test included the inappropriate use of generic medicines unpredictable reassessments of the dTCC over time, 'lower-of' tests, and would have driven prices below a non-excessive pricing standards based on international referencing. Such proposals remain problematic and should be avoided.

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). Sumitomo Pharma's greatest concern with the development of the Guidelines remains with the implications on the health and mental well-being 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. As previously requested, Sumitomo Pharma asks for the PMPRB to take the required steps to actively consult with patentees and to establish working groups to develop fair, transparent, and predictable pricing guidance.

Moving forward, Sumitomo Pharma requests to be included in any direct consultation with the PMPRB on the Guidelines development 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.

Digitally signed by Lisa Mullett
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Lisa Mullett
SVP, General Manager, Canada