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The Patented Medicine Prices Review Board
Standard Life Centre, Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
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To whom it may concern:

RE: Scoping Paper for the Consultations on the Board's Guidelines November 2023

Sumitomo Pharma Canada, Inc. (formerly Sunovion Pharmaceuticals Canada Inc.) would like to thank you for the opportunity to provide input into the *PMPRB Scoping Paper for the Consultations on the Board's Guidelines* (November 2023). Sumitomo Pharma Canada, Inc. (SMPCA) 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 Canada, Inc. (SMPCA) has provided feedback over the course of all the PMPRB consultations. SMPCA has expressed our major concerns, providing specific business case examples on the negative impact to SMPCA's current and future patented medicine portfolio. Despite the feedback provided throughout these consultations, and a comprehensive communication strategy undertaken by SMPCA 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 scoping paper for the consultations on the Board's Guidelines (November 2023), SMPCA 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. The pandemic has shown the price that all Canadians pay when governments focus on short-term cost savings at the expense of long-term preparedness. The PMPRB has, itself, conceded that price does have a negative impact on access by bringing forward a COVID-19 exception to the PMPRB October 2020 proposed draft guidelines[4].

[1] https://www.canada.ca/en/public-health/services/publications/drugs-health-products/pan-canadian-action-plan-antimicrobial-resistance.html

[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
[4] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines.html

SMPCA'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), SMPCA strongly agrees with the comments and recommendations submitted by IMC in response to the consultation. SMPCA would also like to provide additional feedback to the various themes that will inform the development of the Guidelines.

Elements of 2010 Guidelines[2]

Therapeutic Class Comparator Characteristics - Level of Therapeutic Improvement

The government of Canada has placed medical innovation as a stated goal and made it a priority to ensure that Canadians have access to critical vaccines, therapeutics, and other life-saving medicines[5]. Such an example can be seen with initiatives such as Health Canada's updated Pathogens of Interest list, which outlines pathogens with limited or unavailable treatment options and, therefore, areas requiring the greatest innovation in drug development[6]. To ensure accessibility of these drugs developed to treat these pathogens, Health Canada supports these innovative drugs through a priority review regulatory process[7].

As the PMPRB moves forward in drafting the Guidelines, the PMPRB must implement pricing rules that support innovative medicines. The establishment of a non-excessive price of a patented medicine should be aligned to the level of innovation and therapeutic improvement offered by the patented medicine and, to reflect the cost of bringing this innovation to Canadian patients. The Guidelines should continue to categorize medicines by therapeutic class comparator characteristics such as the Level of Therapeutic Improvement. The level of therapeutic improvement of a patented medicine drug, i.e., whether it is a breakthrough medicine, substantial improvement, moderate improvement or a slight to no improvement, should be valued and aligned to current health policy and life science strategy. The level of therapeutic improvement of a medicine should be evaluated through a scientific review and evidence-based process. The timing of the scientific review process and therapeutic comparator identification should be applied at the time of the first day sale of the patented medicine and be conducted in a timely manner.

Domestic Therapeutic Class

For patented medicines deemed to have a level of therapeutic improvement of slight or no improvement, the domestic Therapeutic Class Comparison (dTCC) should continue to be used as a test to determine the non-excessive price of a patented medicine. Many patented medicines, including those designated priority review by Health Canada, are launched in therapeutic areas dominated by older, genericized medicines, such as diabetes, infectious disease, and psychiatry. As a result, the dTCC should reference prices of all comparators, including those of originator medicine (i.e., brand medicine). Aligning to the top of the comparator class will provide fair market value not only for innovation offered by the patented medicine, including those designated a priority review by Health Canada, but also for addressing an unmet need.

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Relative Relationship Test

SMPCA requests that patented medicines with multiple dosage strengths, that are within the therapeutic dose range as approved in the Health Canada Product Monograph, be flat priced at parity to the highest strength dose of the same medicinal ingredient. It is well recognized that individual patients can demonstrate substantial variability in the response to the same drug treatment. The interindividual patient variability in drug response underlines the need for individualized dose selection. As result, patentees make available a dose range of strengths, approved by Health Canada, to address this unmet need. The relative relationship test as proposed by SMPCA is needed to ensure that additional dosage strengths that are within a therapeutic dose range, as approved by Health Canada, are launched in the Canadian market.

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[5] https://ised-isde.canada.ca/site/biomanufacturing/en/overview-canadas-biomanufacturing-and-life-sciences-strategy
[6] https://www.canada.ca/en/health-canada/programs/consultation-new-addition-pathogens-interest-list/document.html
[7] *https://www.canada.ca/en/health-canada/programs/consultation-proposed-pathogens-interest-list/notice-efforts-combat-antimicrobial-resistance.html*

Highest International Price (PMPRB11)

The review of the price of a patented medicine should be conducted at the point in time of the first day sale of the patented medicine sold in Canada. The use of the level of therapeutic improvement, in addition to the highest international price, would align to previous PMPRB methodologies in determining if the price of patented medicine sold in Canada is non-excessive and whether an investigation should be triggered.

In circumstances where there are no international prices for the patented medicine available at the point in time of the first day sale of the patented medicine, the level of therapeutic improvement would determine the price test to be used in determining the non-excessive price. In circumstances where there are few international prices for the patented medicine at the point in time of the first day sale, the price of a patented medicine sold in Canada can be determined non-excessive with the use of the level of therapeutic improvement, in addition to the highest international price using those available PMPRB11 prices.

SMPCA does not agree with the use of the Median International Price (MIP) as a measure to ensure an expedited review of patented medicine. Analysis conducted by SMPCA on the median PMPRB11 price test indicated that the list price of our current 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, 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.

SPMCA recommends that once the price of a patented medicine sold in Canada is deemed non-excessive, the PMPRB does not need to continue to monitor the price should it remain stable throughout the life of the patent. Furthermore, a price review investigation should only be triggered when the price of the patented medicine is above the maximum allowable price and as result, the PMPRB should not dedicate resources to conduct frequent price reviews.

New Medicines Versus Existing Medicines

SMPCA is aligned to distinguish between Existing and New Medicines in the Guidelines; where Existing Medicines are those patented medicines with Notice of Compliance prior to the implementation date of the Guidelines and New Medicines are those patented medicines with Notice of Compliance at or after the implementation date of the Guidelines. The Existing Medicines should be deemed compliant when its national average transaction price (N-ATP) remains at or below its non-excessive average price (NEAP) based on the compliance year. Currently, the NEAP for 2023 has not been provided to patentees in the most recent PMPRB compliance letter delivered to patentees for the 2022 reporting period. The price of Existing Medicines should not be monitored through PMPRB11 as these prices were deemed non-excessive at first day sale and validated through PMPRB's compliance report.

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). SMPCA'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, SMPCA 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. SMPCA 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, 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