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February 14, 2020

Mr. Douglas Clark
Executive Director
The Patented Medicine Prices Review Board (PMPRB)
Standard Life Centre, Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario, K1P 1C1
PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Dear Mr. Clark:

CONFIDENTIAL

Subject: PMPRB Draft 2019 Guidelines Consultation

As part of the PMPRB consultation process on the PMPRB draft guidelines 2019 ("guidelines"), Sunovion Pharmaceuticals Canada Inc. ("SPCI") would like to summarize our major concerns with the guidelines and propose solutions to ensure a predictable pricing system for patented medicines and a sustainable operating environment.

SPCI is an innovative and entrepreneurial health care company. Our head office is located in Mississauga, Ontario. SPCI plays a major role in contributing to the North American business of Sumitomo Dainippon Pharma Co., Ltd., a global pharmaceutical company. The historical regulatory environment in Canada has encouraged our company to develop and commercialize innovative medicines in the areas of psychiatry, neurology, cardiology, and infectious disease while supporting the Canadian economy and developing a talented knowledge-based workforce.

SPCI has projected that the guidelines will adversely impact the health of our financial operations. The lack of predictability and pricing stability that will result from the guidelines will impact the viability of the current investment that SPCI makes to the Canadian economy, including bringing new innovative patented medicines to Canadian patients. As a member of Innovative Medicines Canada (IMC), SPCI has been engaged in the feedback process and dialogue surrounding the draft guidelines. We strongly agree with the comments and recommendations submitted by IMC in response to the guidelines. SPCI would also like to identify some specific concerns that directly impact our business. Specifically, SPCI requests that the PMRPB revise the guidelines to

maintain the status quo with regards to the Reasonable Relationship Test (RRT) and Domestic Therapeutic Class Comparator Test (dTCC) and as well, provide a fair and appropriate transition period for patented medicines with DINs issued prior to August 21, 2019. While SPCI would like to provide specific examples of the impact of the guidelines to our product portfolio, we cannot outline our concerns in this letter due to the confidential nature of our business.

Reasonable Relationship Test (RRT)

PMPRB Draft Guidelines 2019 Section XIII B (page 27) states *"The Reasonable Relationship Test may be conducted to determine the Maximum List Price (MLP) or Maximum Rebated Price (MRP) of a new or additional strength of a patented medicine with other existing strengths, where the new or additional strength has the same medicinal ingredient, indication, dosage regimen, and same or comparable dosage form as the existing strength(s). When a new strength of a medicine that is currently sold in Canada is introduced and meets the above requirements of the RR test, the MLP or MRP of the new strength will be set to be equivalent to the price per standard unit of the existing strength(s). This approach will also be applied when multiple strengths of a new medicine are first sold and some strengths are identified specifically as loading, titration, or reduction doses."*

SPCI requests that patented medicines with multiple dosage strengths, that are within the therapeutic dose range as approved in the 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 a result, patentees make available a dose range of strengths, approved by Health Canada, to address this unmet need. The RRT proposed in the guidelines infer that lower dose strengths of the same medicinal ingredient will not be priced at parity to the higher dose strength which implies pricing based on mg per mg dose and not on therapeutic effect. The proposed guidelines fundamentally penalize lower dosage strengths that have been tailored to meet individual patient needs. The status quo for the RRT is needed in order 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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Domestic Therapeutic Class Comparator (dTCC)

PMPRB Draft Guidelines 2019 Section XIII A (page 26) states *"Following the identification of medicines for comparison purposes and of their lowest public price for each medicine, the cost of comparable courses of treatment for each medicine will be calculated. These costs of treatment will be ordered and the median identified. In the event of an even number of medicines used for comparison purposes, the median will be the simple average of the middle two costs of treatment. The median cost of treatment will then be divided by the constituent units of the comparable course of treatment for the medicine under review to establish a per-unit price."*

SPCI requests that the top of the therapeutic class be used for the dTCC price test and not the median. The top of the therapeutic class is the only test consistent with an excessive price standard, especially when this price is compared to the median international price.

As the dTCC is one factor considered in establishing the Maximum List Price (MLP), patented medicines, including those designated priority review by Health Canada, will have a ceiling price aligned to the generic price due to the median of the therapeutic class. The median of dTCC does not value the therapeutic benefit that patented medicines provide relative to their comparators. The result of the proposed dTCC will position an innovative patented medicine at risk of not being available to Canadian patients, even those designated a priority review by Health Canada. SPCI asserts that this will become a more frequent occurrence.

Patented Medicines with DINs issued prior to August 21, 2019 ("Grandfathered")

Price Review Process for Grandfathered Patented Medicines Section V B. 59. (Page 15) states: *"The MLP for all grandfathered patented medicines will be set at the lower of (i) the Median International Price (MIP) for the PMPRB11 countries for which the patentee has provided information, or (ii) the patented medicine's ceiling under the Guidelines applicable prior to the issuance of these guidelines... Patentees must ensure that the patented medicine's List Price is no higher than the MLP for the period during which it is applicable, failing which the price may be subject to additional review or investigation by the staff."* **Section VB. 61 states:** *"Patentees will be granted until the subsequent reporting period after the MLP is set to ensure that List Price of the grandfathered patented medicine is lowered to a level that is no higher than the MLP or may be subject to additional review or investigation by staff".*

SPCI requests that patented medicines with DINs issued prior to August 21, 2019 should be given an extended transition time to reach the MLP in order to align with long-term strategic planning and financial forecasting. A gradual price erosion in annual increments should be allowed until the median is reached. In addition, a process should be in place for patentees to request exceptions, especially for those patented medicines that are at high-risk of discontinuation from the Canadian market as result of the median of the PMPRB11.

SPCI has been compliant within the current PMPRB pricing framework and our patented medicines have always been deemed non-excessive. Analysis conducted on the proposed median of the PMPRB11 on these patented medicines indicates that it will be difficult for SPCI to continue to make these patented medicines available to Canadian patients.

Enforcement of Guidelines and Transitional Provisions

SPCI is still unclear on the compliance requirements and proposed transition measures based on the currently published information. More information is required for patentees to understand how the system will operationalize under the guidelines.

Price increases or decreases occur at set dates during the calendar year for patented medicines that are listed on public drug plans. For example, the Alberta Price Confirmation Process will be initiated in February of each year; however, the timing of the price change is on April 1 of the calendar year. Most jurisdictions have aligned their price policy around this timeline. As a result, when the MLP is established for all patented medicines, the patentee will only be able to do it at a set time as guided by each jurisdiction's price policy.

In addition, for those patented medicines that have product listing agreements ("PLA"), the patentee and Ministry of Health of each jurisdiction will have to amend the PLA in order to be aligned to the MLP. The process involved in making amendments to a PLA is a lengthy and resource intensive process for both the manufacturer and the jurisdiction. In light of the implementation of the guidelines, jurisdictions must ensure that they will have the resources in place to ensure that patentees are able to establish an MLP in a timely manner in order to be compliant with the PMPRB.

In conclusion, the draft guidelines will impose a significant material adverse impact on the health of SPCI's financial operations. As a small healthcare company in Canada, the

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guidelines create further challenge in bringing new treatments to Canada. While SPCI would like to provide specific examples of the impact of the guidelines to our product portfolio, we cannot outline our concerns in this letter due to the confidential nature of our business.

SPCI would like to ensure that the concerns and solutions that have been communicated are heard during the consultation process and reflected in the final PMPRB guidelines. SPCI requests that the PMPRB work closely with IMC through technical working groups in order to generate final guidelines that ensure a predictable pricing system for patented medicines and a sustainable operating environment for the innovative pharmaceutical industry in Canada. Further, we understand that the PMPRB is striving to reduce prices to improve access to medications. However, the proposed guidelines significantly impair the ability of companies to bring new medications to the Canadian marketplace. This will ultimately reduce access to new medications that could improve patient outcomes and their quality of life.

Sincerely,

SUNOVION PHARMACEUTICALS CANADA INC.

Lisa Mullett
General Manager