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Mr. Douglas Clark
Executive Director
The Patented Medicine Prices Review Board
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:

RE: Draft 2020 PMPRB Guidelines Consultation

As part of the PMPRB consultation process on the draft 2020 PMPRB guidelines ("draft guidelines"), Sunovion Pharmaceuticals Canada Inc. ("SPCI") would like to summarize our major concerns with the guidelines once again 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 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 and infectious disease while supporting the Canadian economy and developing a talented knowledge-based workforce.

The PMPRB 2018 Annual Report noted that the sales of patented medicines remained relatively unchanged, decreasing slightly by 0.6% from the previous year. Furthermore, prices of existing patented medicines were stable, while the Consumer Price Index rose by 2.3%. SPCI asserts that the current PMPRB guidelines are relevant as the prices of patented medicines sold in Canada are not excessive as recently reported.

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SPCI has projected that the draft guidelines as proposed do not offer a predictable or stable pricing environment, thus adversely impacting the health of our financial operations. The draft guidelines as proposed will impact the viability of the current investment that SPCI makes to the Canadian economy, including bringing new patented medicine 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 is communicating specifics concerns with respect to our business operations; however, our greatest concern remains with the health and well-being of Canadians today and tomorrow. The implementation of the draft guidelines would make Canada an unfavorable market to introduce new patented medicines and as a result, Canadians will not have access to the treatments that are otherwise available in other countries. Now, more than ever, Canadians need access to new innovative medicines and companies need a regulatory environment that fosters innovation. While SPCI would like to provide specific examples of the impact of the guidelines to our product portfolio, we cannot outline all our concerns in this letter due to the confidential nature of our business and would be pleased to provide this feedback to PMPRB during a confidential meeting.

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

Price Review Process for Grandfathered, Line Extension and Gap Patented Medicines Section V B. 72. (Page 17) states: *"The MLP for Grandfathered and Line Extension medicines is set at the lower of the highest international price ("HIP") for the PMPRB11 countries for which the patentee has provided information; or the patented medicine's ceiling (e.g. the "NEAP") under the Guidelines applicable prior to the issuance of these Guidelines".*

SPCI requests that the Maximum List Price (MLP) of patented medicines with DINS prior to August 21, 2019 ("grandfathered") be set to the highest list price of the patented medicine applicable prior to the issuance of the draft guidelines. Analysis conducted by SPCI on the proposed price test indicates that the proposed MLP will be below costs for certain patented medicines. Patentees, such as SPCI, cannot provide patented

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medicines in Canada at a MLP that is below costs and as result, will have to withdraw these patented medicines from the market. Unfortunately, this will negatively impact the health and well-being of Canadians who have been stabilized on current available patented medicines.

The pricing of SPCI's grandfathered patented medicines has always been deemed non-excessive under the current PMPRB pricing framework. As result, establishing the MLP based on current list price for grandfathered patented medicines will continue to support the mandate of the PMPRB to ensure that patented medicines are non-excessive, especially in light of the 2018 PMPRB annual report findings that patented medications are not excessive in the Canadian marketplace. Furthermore, the continuity of the list price will truly "grandfather" these patented medicines.

Domestic Therapeutic Class Comparator (dTCC)

Domestic Therapeutic Class Comparison (dTCC) and International Therapeutic Class Comparison (iTCC) Appendix A (page 29) states: *"Where there are multiple sellers of a medicine identified as a comparable medicine, the lowest price of the comparable medicine will be identified. The final therapeutic class comparison price is the highest price across all comparable medicines for the MLP and the median for the MRP."*

SPCI requests that the dTCC test should be calculated using prices of comparators that include those of originator medicine (i.e. brand medicine). The dTCC is one factor considered in establishing the iMLP or MLP in the absence of PMPRB11 pricing. Patented medicines, including those designated priority review by Health Canada, will have an iMLP and MLP aligned to generic price as the proposed approach to the dTCC includes lowest price of a comparable medicine where multiple sellers of a medicine are identified. The use of lowest price of the comparable medicine (i.e. generic price) does not allow for fair market value for innovation.

SPCI **strongly disagrees** with the statement from the Backgrounder on the June 2020 Draft Guidelines (Section 1, page 5) that few patented medicines are launched in therapeutic areas dominated by older, genericized medicines. SPCI asserts that there are enough examples to demonstrate therapeutic classes that are dominated by generics, such as diabetes, infectious disease and psychiatry. The result of the proposed

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dTCC using lowest price of comparable medicine 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, resulting in Canadian patients having fewer newer treatment options available to them.

Reasonable Relationship Test (RR Test) and Comparable Dosage Forms

Reasonable Relationship Test Appendix A. Section B. (page 30) states: *"There is no RR test until an MLP is set for the reference strength".*

SPCI requests that this statement be removed as this does not allow patentees to launch multiple strengths of a patented medicine when a patented medicine at introduction has no PMPRB11 prices to report and, whose iMLP is determined by the dTCC. The RR test, as proposed, will not accommodate the practice of level pricing for which a patented medicine with multiple therapeutic doses launched concurrently with no MLP established.

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. 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.

SPCI requests that the statement under the Price Review process Section 41 (page 12) be amended as follows: *If the patentee has not filed international price information for the PMPRB11 countries, the iMLP is set by the top of the domestic Therapeutic Class Comparison ("dTCC")* ***or the Reasonable Relationship ("RR") Test.*** *The dTCC will be calculated based on the highest cost of treatment across the comparator medicines, derived by taking into account the lowest public price of each comparator (see Appendix A for further details).* ***The Reasonable Relationship (RR) test may be conducted to determine the iMLP of a new additional strength of a patented medicine with other existing strengths, where the new additional strength has the same medicinal ingredient, indication, dosage regimen, and same or comparable dosage form as the existing strength(s).***

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Enforcement of Guidelines and Transitional Provisions

Price Review Process for New Patented Medicines Section V A 54. (Page 13) states: *"Guidance on potential sources of ex-factory prices is available through the Help section of the online filing tool". Furthermore, four other sections in the draft guidelines, mention additional information will be provided on the online filing tool.*

SPCI remains unclear on the compliance requirements for reporting. More information is required for patentees to understand how the system will operationalize under the guidelines and the resources required to ensure compliance. SPCI has heavily invested in many resources in order to understand the implication of the PMPRB guidelines to our current product and future product portfolio and as well, to prepare for the new reporting requirements when final guidelines come into force.

Price increases or decreases occur at set dates during the calendar year for patented medicines that are listed on public drug plans. Most jurisdictions have aligned their price policy around the April 1 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. Considering 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. Allowing the continuity of the list price of grandfathered patented medicines, as noted above, will avoid additional administrative burden to the payers.

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 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 in order to

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generate final guidelines that ensure a predictable pricing system for patented medicines and a sustainable operating environment for the innovative pharmaceutical industry in Canada.

As outlined, we are communicating specifics concerns with respect to our business operations; however, our greatest concern remains with implications on the health and well-being of Canadians today and tomorrow. The implementation of the draft guidelines would make Canada an unfavorable market to introduce new patented medicines and as a result, Canadians will not have access to the treatments that are otherwise available in other countries. Now, more than ever, Canadians need access to new, innovative medicines and companies need a regulatory that fosters, encourages and supports innovation.

Sincerely,

SUNOVION PHARMACEUTICALS CANADA INC.

Lisa Mullett
General Manager