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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 2022 PMPRB Guidelines Consultation

As part of the PMPRB consultation process on the draft 2022 PMPRB guidelines ("Draft Guidelines"), Sunovion Pharmaceuticals Canada Inc. ("Sunovion") would like to summarize our major concerns with the Draft Guidelines. Sunovion is proposing solutions to ensure not only a predictable pricing system for patented medicines, but also a sustainable operating environment that incentivizes investment in Canada.

Sunovion is an innovative and entrepreneurial health care company. Our head office is located in Mississauga, Ontario. Sunovion plays a major role in contributing to the North American business of Sumitomo Pharma Co., Ltd., a global pharmaceutical company. The historical regulatory and pricing 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.

As communicated previously, the Draft Guidelines will adversely impact the health of Sunovion's financial operations and consequently, will impact the viability of the current investment that Sunovion makes to the Canadian economy, including bringing new a patented medicine to Canadians. There continues to be a disconnect between the Draft Guidelines and Canadian health policies and life science sector strategies[1,2,3]. The Draft Guidelines do not create a viable market for rewarding innovation and encouraging industry to meet the current and anticipated health needs of Canadian patients.

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[1] https://ised-isde.canada.ca/site/biomanufacturing/en/canadas-biomanufacturing-and-life-sciences-strategy

[2] https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/drugs-health-products/best-brains-exchange-meeting-antimicrobial-resistance/best-brains-exchange-meeting-antimicrobial-resistance.pdf

[3] https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/federal-action-plan-antimicrobial-resistance-canada.html

As a member of Innovative Medicines Canada (IMC), Sunovion 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 Draft Guidelines, including the suspension and fundamental reconsideration of the Draft Guidelines aligned to a robust consultation process in 2023. Sunovion 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.

No Recognition of Therapeutic Innovation

Sunovion requests that innovation be recognized and assessed by the PMPRB for patented medicines launched in Canada.

The Draft Guidelines do not place any value on the level of therapeutic improvement offered by any innovative medicine as done in the past. Canada has placed innovation as a stated goal, but the disconnect between these goals and that of the Draft Guidelines risk extinguishing this innovation and negatively impacting Canada's bioscience and pharmaceutical sectors. The PMPRB has not provided any impact assessment of its proposal; however, Sunovion can confirm that the Draft Guidelines will adversely impact the business case to launch innovative medicines in Canada despite the ability to address current and anticipated treatment needs of Canadian patients.

Sunovion requests that innovation be recognized and assessed by the PMPRB for patented medicines launched in Canada.

Domestic Therapeutic Class Referencing at Generic Level Pricing

Sunovion requests that the domestic therapeutic class comparator (dTCC) test should be calculated using prices of comparators that include those of originator medicine (i.e., brand medicine).

The Draft Guidelines actively drive prices down through therapeutic class referencing, in many cases, to a generic level of pricing. In fact, the PMPRB's proposed use of dTCC may mean that future medicines could be deemed to be excessively priced even if their pricing is within international benchmark.

The use of lowest price of the comparable medicine (i.e., generic price) does not allow for fair market value for innovation. As communicated in the past, many patented medicines are launched in therapeutic classes that are dominated by older, genericized medicines. Sunovion asserts that there are enough examples to demonstrate therapeutic classes that are dominated by generics, including infectious disease, psychiatry, and diabetes.

The result of the proposed 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.

Sunovion requests that the dTCC test should be calculated using prices of comparators that include those of originator medicine (i.e., brand medicine).

List Price Aligned to Fluctuating International PMPRB11 List Prices

Sunovion requests that list price of new medicines be set either to the highest list price of the PMPRB11 countries or if not available, to the domestic therapeutic class at a point in time. Sunovion requests that the list price of existing medicines continues to be monitored according to the interim guidelines. Furthermore, patented medicines with no PMPRB11 pricing to be reported should not have an investigation triggered.

The application of the median of the PMPRB11 for "new medicines" appears to be "free floating", thus eliminating any type of pricing predictability. As international prices fluctuate, patented medicines will continuously trigger investigation criteria. The outcome over time will drive price erosion, thus impacting the ability to make available a patented medicine in Canada. To ensure some form of certainty, the price of patented medicines set at the highest of the PMPRB11 should be established at a point in time. Furthermore, patented medicines with no PMPRB11 pricing to be reported should not have an investigation triggered for this reason as proposed by the Draft Guidelines.

Analysis conducted by Sunovion on the proposed price test indicates that the list price of "existing medicines" will be below costs. Patentees, such as Sunovion, cannot provide patented medicines in Canada at a list price that is below costs and as result, will have to withdraw these existing patented medicines from the market. The pricing of Sunovion's existing patented medicines has always been deemed non-excessive under the current PMPRB pricing framework. As result, continuing to establish the list price of existing medicines, based on the interim guidelines, supports the PMPRB mandate to ensure that patented medicines are non-excessive.

Sunovion requests that list price of "new medicines" be set either to the highest list price of the PMPRB11 or if not available, to the domestic therapeutic class at a point in time. Sunovion requests that the list price of "existing medicines" continues to be monitored according to the interim guidelines. Furthermore, patented medicines with no PMPRB11 pricing to be reported should not have an investigation triggered.

In conclusion, the health of Sunovion's financial operations will be adversely impacted by the Draft Guidelines and, the ability to bring new treatments to Canada will be challenged. In this letter, Sunovion cannot outline specific examples of the impact of the Draft Guidelines due to the confidential nature of our business; however, we have communicated the impact to our product portfolio through many

stakeholder meetings. Sunovion requests that the PMPRB engage and collaborate with IMC to generate final guidelines that ensure a predictable, fair, and transparent pricing system for Canada.

The pandemic has provided valuable lessons on the importance of long-term preparedness and the importance of ensuring that effective treatments are available and accessible to all Canadians. The implementation of the Draft Guidelines would adversely impact Canada as a viable market for R&D investment, thus impacting Canada's competitiveness, and patients' access to innovative medicines. Now more than ever, Canadians need access to new, innovative medicines, and companies need a regulatory environment that fosters, encourages, and supports innovation.

Sincerely,

SUNOVION PHARMACEUTICALS CANADA INC.

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Lisa Mullett
General Manager