Lisa Mullett
General Manager
lisa.mullett@sunovion.com

Sunovion Pharmaceuticals Canada Inc.
7025 Langer Drive, Suite 301
Mississauga, ON L5N 0E8

Direct: +1.905.363.3772
Fax: +1.905.363.0162

sunovion.ca

June 21, 2021

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: Patented Medicines Price Review Board ("PMPRB") Guideline Monitoring Evaluation Plan ("GMEP") Consultation

Sunovion Pharmaceuticals Canada Inc. ("Sunovion") expressed to the PMPRB our major concerns with the PMPRB guidelines coming into force July 1, 2021 ("guidelines"), with specific examples shared on the impact to Sunovion's patented medicine portfolio. No amendments to the guidelines have been made to reflect the feedback shared by Sunovion during the consultation process of the guidelines.

As noted on page 6 of the GMEP *"patentees and some patient groups have voiced concern that lower ceiling prices under the new framework may have deleterious effects on clinical trials and the availability of new medicines in Canada".* Sunovion deems that the guidelines will make Canada an unfavorable market to introduce new innovative patented medicines. As a result, Canadians will not have access to treatments that are otherwise available in other countries. Now, more than ever, Canadians need access to medicines and patentees need a regulatory environment that supports innovation.

As a member of Innovative Medicines Canada ("IMC"), Sunovion has been engaged in the feedback process and dialogue surrounding the PMPRB GMEP. Sunovion strongly agrees with the comments and recommendations submitted by IMC in response to the consultation. Sunovion would like to provide additional feedback.

Assessment

The assessment should be conducted by a mutually agreed upon third party body and not the PMPRB itself.

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Targeted Timelines

Any assessment conducted should be committed to targeted timelines that are in line with annual patentee compliance reporting by the PMPRB. The timeliness of the report will ensure that the information is relevant to ensure appropriate action.

Furthermore, data collected should be benchmarked to June 2016 and onward. This benchmark will reflect the changes that has occurred in the environment following the release of the PMPRB Guidelines Modernization – Discussion paper. This document represents one on the first communications to outline the changes being considered for pricing modernization in Canada.

Key Areas of Focus

Prices: Sunovion does not agree with monitoring the average transaction prices for patented medicines and questions the relevance of evaluating this information given the PMRPB's mandate.

Access: Sunovion does not believe that the mandate of the PMPRB is to assess the extent to which the Canadian reimbursement system measures the value of patented medicines, negotiates prices, and funds them for Canadian patients. Currently, all the above-mentioned stakeholders report variations of the information that the PMPRB proposes to collect.

Pharmaceutical Ecosystem: Sunovion agrees with the evaluation of measuring the domestic economic footprint. As noted in previous feedback, the implementation of the guidelines will make Canada less attractive to grow the pharmaceutical ecosystem.

Sunovion recognizes the complexities and limitations in monitoring the relevant trends in the pharmaceutical environment and therefore, questions the extent to which the PMPRB can conduct an evidence-based, unbiased evaluation of the guidelines. Sunovion requests that the PMPRB work closely with IMC in order to generate not only final guidelines that ensure a predictable pricing system for patented medicines and a sustainable operating environment for the innovative pharmaceutical industry in Canada, but also a GMEP that is conducted by an independent body and aligned to the PMPRB's mandate.

Sunovion has communicated our specifics concerns with respect to the implications of the guidelines 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 guidelines will make Canada an unfavorable market to introduce

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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, encourages, and supports innovation.

Sincerely,

SUNOVION PHARMACEUTICALS CANADA INC.

Digitally signed by lmullett
DN: cn=lmullett, email=lisa.mullett@sunovion.com
Date: 2021.06.21 11:03:55 -04'00'

Lisa Mullett
General Manager