Innovation today, healthier tomorrows

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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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RE: PMPRB Interim Guidelines Consultation

To whom it may concern:

Since the launch of the draft guidelines in late 2019, Sunovion Pharmaceuticals Canada Inc. ("Sunovion") has expressed to the PMPRB our major concerns with specific examples shared on the impact to Sunovion's current and future patented medicine portfolio. Despite all the feedback provided throughout the consultation process and a comprehensive communication strategy undertaken by Sunovion with numerous policy makers, no amendments to these guidelines were made to reflect the feedback shared by Sunovion.

As the PMPRB moves forward to launch interim guidelines and final guidelines in 2022, Sunovion requests that the PMPRB actively listen to the feedback provided by all patentees. Sunovion has been engaged in the feedback process surrounding the PMPRB proposed interim guidelines consultation as a member of Innovative Medicines Canada ("IMC"). Sunovion strongly agrees with the comments and recommendations submitted by IMC in response to the consultation and would like to provide additional feedback.

Interim Period Guidelines

Sunovion agrees with the status quo approach where existing patented medicine will not trigger an investigation provided that its national average transaction price (N-ATP) remains at or below its most non-excessive average price (NEAP) established under the existing guidelines.

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Sunovion does not agree with the fact that a patentee is not able to take a price increase during the interim period despite the PMPRB publishing and making available to patentees the 2022 and 2023 CPI-Based Price Adjustment Factors for Patented Drug Products. (https://www.canada.ca/en/patented-medicine-prices-review/services/are-you-patentee/cpi-adjustment-factors/2022-cpi-adjustment-factors.html; https://www.canada.ca/en/patented-medicine-prices-review/services/are-you-patentee/cpi-adjustment-factors/2023-cpi-adjustment-factors.html).

Effective July 1, 2022, patentees will now be required to submit on a semi-annual basis the Block 5 form aligned to the PMPRB11. Sunovion does not agree with the PMPRB not providing any guidance in the interim period on how the PMPRB11 will be applied to patented medicines. Furthermore, the PMPRB has not provided any guidance on the price review on any new patented medicines. The lack of clear guidance continues to prevent innovative medicines from being launched in the Canadian market and reaching Canadian patients.

New Guidelines Moving Forward

As the PMPRB moves forward with a revised set of guidelines, Sunovion is seeking a balanced policy to ensure Canadians have access to patented medicines while allowing patentees to achieve the establishment of a fair price point that supports the cost of innovation. The government has, itself, conceded that price does have a negative impact on access by bringing forward a COVID-19 exception to the PMPRB October 2020 guidelines.

As echoed to the PMPRB and other stakeholders, the October 2020 guidelines do not place any value on level of therapeutic improvement offered by any innovative medicine. Furthermore, the guidelines as proposed forced patented medicines to be sold at generic prices in a therapeutic category where there are no branded medicines and, where patented medicines do not exist in the PMPRB11 reference countries.

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 years has made Canada an unfavorable market to incentive 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).

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Sunovion has communicated our specific concerns with the guidelines with respect to our business operations; however, our greatest concern remains with implications on the health and mental well-being of Canadians today and tomorrow. The implementation of these guidelines is casting a negative shadow on the Canadian market and will make Canada an unfavorable environment to introduce innovative medicines. Canadians will not have access to the treatments that are otherwise available in other countries as echoed by many patient stakeholders. Now, more than ever, Canadians need access to innovative medicines and companies need a regulatory environment that fosters innovation.

Sincerely,

SUNOVION PHARMACEUTICALS CANADA INC.

Lisa Mullett
General Manager