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Innovation today, healthier tomorrows

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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

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

Re: *Notice and Comment – On the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions* (July 15, 2021)

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 the guidelines that are coming-into-force on January 1, 2022 ("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 throughout the consultation process of the guidelines.

Sunovion affirms that the guidelines will make Canada an unfavorable market to introduce new innovative patented medicines. As a result, Canadians will not have access to innovative treatments that are otherwise available in other countries. Now, more than ever, Canadians need access to medicines and patentees need a predictable 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 proposed amendments. Sunovion strongly agrees with the comments and recommendations submitted by IMC in response to the consultation. Sunovion would like to provide additional feedback.

1) **SPCI agrees that the definition of gap medicines should be aligned to the new coming-into-force date of January 1, 2022.**

2) **SPCI does not agree with the proposed changes to the international price test for grandfathered patented medicines and their line extensions.**

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- Patented medicines sold prior to August 21, 2019 are not being grandfathered. Sunovion questions why the PMPRB has decided to amend the price test to the lower of the Median International Price of the PMPRB7 ("MIP") for the schedule countries or the Non-Excessive Average Price ("NEAP"). In reviewing all stakeholder feedback provided to the PMPRB, there is no evidence of consensus on the implementation of the MIP price test for grandfathered patented medicines and lines extensions. The prices of Sunovion's grandfathered patented medicines have been consistently deemed non-excessive and are now being further penalized by the introduction of the MIP price test. Sunovion demands that the Highest International Price ("HIP") test be implemented.

3) **Sunovion does not agree with the timelines for compliance for grandfathered patented medicines and line extensions to be July 1, 2022. The compliance period referenced in the guidelines is two reporting periods. Sunovion requests that the PMPRB continue to be consistent with compliance assessed after two reporting periods for grandfathered patented medicines and line extensions as noted in the guidelines.**

- The PMPRB announcement of April 16, 2021 stated the following: ***"Upon further review however, the Board has decided that compliance with the MLP for these medicines will be assessed after two filing periods, as was originally provided for in the new Guidelines. Accordingly, upon coming into force of the amended Patented Medicines Regulations on July 1, 2021, the operative date for assessing compliance with the MLP will be July 1, 2022".*** The compliance date of July 1, 2022 represents two reporting periods from July 1, 2021. The PMPRB cannot randomly select a compliance date that is not aligned to the guidelines and it's the coming-into-force date on January 1, 2022. The pricing compliance date should be consistent with January 1, 2023.

- The PMPRB has stated that a compliance report outlining the MLP for grandfathered patented medicines and line extensions will be provided to patentees in October 2021. Thereafter, Sunovion will have less than 3 months to implement any price change. The internal process within Sunovion and globally to amend pricing changes is a lengthy process that involves many steps and approvals. A 3-month timeframe for Sunovion to adjust pricing to the MLP for our patented medicines is not feasible nor reasonable. Now more than ever during this enduring pandemic, there is considerable amount of pressure on our industry to focus efforts on the delivery of patented medicines that Canadians depend for their physical and mental well-being.

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- Most jurisdictions have aligned their price change policy to April 1st. As a result, when the MLP is established for patented medicines, the patentee will only be able to do it in April or a specific date as guided by each jurisdictions' price policy. Furthermore, patentees and the Ministry of Health of each jurisdiction will have to amend a product listing agreement (PLA) of a patented medicine to align with the MLP. The process involved in making amendments to a PLA is a lengthy and resource intensive process. A 3-month period to implement a price change to the MLP is not realistic due to the administrative burden that this process will impose to the drug plans. Jurisdictions do not have the resources in place to ensure that the MLP for all patented medicines can be established in a timely manner.

4) **As part of the PMPRB consultation, Sunovion would like to highlight that the PMPRB has not taken this opportunity to consult on any other sections of the Guidelines.**

- Sunovion expressed to the PMPRB our major concerns with the guidelines with specific examples shared on the impact to Sunovion patented medicine portfolio. The concerns highlighted to the PMPRB continue to not be addressed. Sunovion is concerned that the PMPRB has only taken the opportunity to amend three elements of the guidelines when there continues to be material issues to be addressed.

Sunovion is communicating specifics concerns 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