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Innovation today, healthier tomorrows

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

February 11, 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:

As part of the PMPRB consultation, Sunovion Pharmaceuticals Canada Inc. ("SPCI") would like to comment on the change to the definition of Gap medicines and the timeline for compliance with the Maximum List Price (MLP) ceiling for Grandfathered and Gap medicines ("Patented Medicines") as outlined in the Guidelines.

1) **SPCI agrees that the definition of gap medicines should be aligned to the date of the implementation on July 1, 2021.**

2) **SPCI does not agree with the timelines for compliance to be shortened to one reporting period (six months) for Patented Medicines. SPCI demands that the Guidelines continue to be consistent with compliance assessed after two reporting periods for Patented Medicines.**

   - The proposal to amend the Guidelines to only one reporting period (six months) for compliance does not align to the intent of the delay as announced by Health Canada on December 30, 2020, and will put significant strain on SPCI and the industry during a period of extreme uncertainty. Now more than ever, there is a considerable amount of pressure on our industry to direct our efforts on the delivery of patented medicines that Canadians depend for their physical and mental well-being.

   - Following the semi-annual reporting on July 30, 2021, SPCI will receive a PMPRB compliance report approximately mid-September 2021 which will outline the MLP for Patented Medicines. With only one reporting period to adjust the MLP, SPCI would only have approximately three months to implement any price change compared to current guidelines which would provide SPCI with two reporting periods or approximately eight months to adjust the MLP. The

internal process within SPCI and globally to amend pricing changes is a lengthy process that involves many steps and approvals. A three-month timeframe for SPCI to adjust pricing to the MLP for our patented medicines is not feasible.

- This short timeline puts considerable undue pressure on the federal and provincial Ministries of health during a period where their focus has been and should be directed towards COVID related matters. Furthermore, many of the government employees have been seconded to other areas of the government, leaving this area short-staffed and unable to cope with a significant administrative burden involved in amending the public formulary pricing and the associated PLA. The process involved in making amendments to a PLA is a lengthy and resource intensive process. A three-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.

- Section 75 of the Guidelines state that there can be reconsideration of the MLP by the PMPRB Staff if the MLP is set by the NEAP and, the NEAP had been significantly impacted by the reporting of benefits. Patentees will only be able to make this request for reconsideration upon receiving the compliance report mid-September 2021. SPCI questions the ability of the PMPRB to process and respond to all applications for patentees to be compliant by December 31, 2021.

- The PMPRB has noted that the delay in the implementation of the Regulations and Guidelines was to provide the industry with additional time to prepare for the new reporting obligations. SPCI and other patentees do not have access to any of the forms for the new reporting obligations. If the PMPRB intends to give patentees time to prepare for the new reporting obligations, then the Guidelines should continue to provide patentees with a minimum two reporting periods.

3) **As part of the PMPRB consultation, Sunovion Pharmaceuticals Canada Inc. ("SPCI") would like to highlight that the PMPRB has not taken this opportunity to consult on or modify any other sections of the Guidelines, despite the significant feedback provided by both the industry and patient stakeholders.**

- SPCI expressed to the PMPRB our major concerns with the guidelines with specific examples shared on the impact to SPCI patented medicine portfolio. The

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concerns highlighted to the PMPRB continue to not be addressed in the Guidelines. SPCI is concerned that the PMPRB has only taken the opportunity to amend two elements of the Guidelines when there continues to be material issues to be addressed.

SPCI 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 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, encourages and supports innovation.

Sincerely,

SUNOVION PHARMACEUTICALS CANADA INC.

Lisa Mullett
General Manager