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Dr. Mitch Levine
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**Re: Response to PMPRB Notice and Comment**

Dear Dr. Levine,

On behalf of PDCI Market Access ("PDCI"), I would like to thank you for the opportunity to respond to the Notice and Comment issued by the Patented Medicine Prices Review Board ("PMPRB") on July 15th, 2021.

PDCI is a Canadian pharmaceutical pricing and reimbursement consultancy with core expertise in pharmaceutical pricing, health technology assessment (HTA), clinical and pharmacoeconomic evaluations and modelling. Since 1996, PDCI has provided its advice and expertise to Canadian and global pharmaceutical manufacturers to help navigate the complexities of Canadian pricing and market access landscape with the goal of achieving timely access to the market. In December 2020, PDCI was acquired by McKesson Canada.

We are uniquely qualified to comment on the changes proposed in the Notice and Comment, as we have conducted multiple iterative analyses of the expected impact of changes to the Patented Medicine Regulations and the PMPRB Guidelines since discussions of price reforms began in 2015.

The current Notice and Comment includes two non-contentious proposals; namely, revising the definition of Gap medicines to harmonize with the new coming into force data of the amended Regulations and the new Guidelines, and generalizing the language related to the basket of international reference countries.

The proposal to amend the International Price Test for Grandfathered Medicines and Their Line Extensions, however, is inappropriate at this late date in the consultation process and in the context of the most recent delay in the implementation of the changes to the PMRPB framework, intended to give "industry… additional time to prepare for and comply with the changes introduced in the amendments."

The proposal to change the calculations method for maximum list prices (MLPs) of grandfathered medicines appears arbitrary and has not been subject to consultation with any stakeholders. Our analysis estimates this change will more than double the impact on the prices of these existing medicines, from approximately $1.2 billion annually, to $ 2.4 billion, annually. Additionally, almost twice as many DINs will be subject to price reductions, and neither manufacturers nor the other stakeholders in the life sciences ecosystem are prepared for this significant incremental financial impact.

The Notice and Comment states that the proposals tabled "are believed to be an appropriate response to the most recent six-month extension in the coming-into-force date of the Regulations." This comment seems at odds with introducing a seemingly arbitrary new price test. It is not consistent with the Board's intention to mandate MLP compliance within one PMPRB reporting period. This issue of the compliance timeline for Grandfathered and Gap medicines was the subject of a Notice and Comment earlier this year. The Board refers to the decision from this Notice and Comment In the Frequently Asked Questions accompanying the Notice and Comment, stating: "The operative date for assessing compliance for Grandfathered, Line Extension and Gap medicines with the MLP will remain July 1, 2022, as stated in the PMPRB's announcement on April 16, 2021. A full reading of that announcement includes the following: "the Board has decided that compliance with the Maximum List Price (MLP) for these medicines will be assessed after two filing periods, as was originally provided for in the new Guidelines when they were first published on October 23, 2020". While the initial Board decision on March 17, 2021, was to impose a one-period compliance period, this decision was revised only one month later when the Board announced it had revisited its decision, citing the "evolving state of the Covid-19 pandemic" as the reason for their change of heart. Four months later, still amid the Covid-19 pandemic, it is difficult to understand why this limited reading of the Boards decision would be applied.

The proposed change to the International Price Test (IPC) for grandfathered and gap medicines in the July 15th, 2021, Notice and Comment is not an appropriate response to the most recent delay in the coming into force of those Guidelines, and indeed, is not appropriate at this late stage in a years-long consultation process. This proposed amendment to the 2020 PMPRB Guidelines should not be implemented. In addition, to avoid any future confusion, the October 2020 Guidelines should be amended to reflect a two-period compliance period for Grandfathered and Gap medicines, consistent with the Board's ultimate decision following the winter 2021 Notice and Comment on this subject.

Regards,

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