PDCI | MARKET ACCESS

February 15, 2021

Doug Clark, Executive Director
Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West Suite 1400
Ottawa, Ontario K1P 1C1
PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Re: Response to PMPRB Notice and Comment on the change to the definition of Gap medicines and the timeline for compliance.

Dear Mr. Clark,

On behalf of PDCI Market Access ("PDCI"), thank you for the opportunity to provide written comments as part of the above noted Notice and Comment.

PDCI is a pharmaceutical pricing and reimbursement consultancy owned by McKesson Canada Corporation. PDCI has 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 the Canadian pricing and market access landscape with the goal of achieving timely access to the market.

In response to the proposed amendments to the January 1, 2021 Guidelines, we offer the follow comments and recommendations:

Extension of the period defining Gap Medicines.

Extension of the Gap period to on or after August 21, 2019 and prior to July 1, 2021 is necessary and appropriate to align the Guidelines with the new coming into force date of the Amendments to the Amended Patented Medicines Regulations. However, additional changes to Gap medicines should also be implemented.

- The definition of Gap medicines in the new Guidelines is inconsistent with how PMPRB asserts jurisdiction over patented medicines sold in Canada. With the proposed change, we assume the new Guidelines would require that Gap medicines must be both assigned a DIN on or after August 21, 2019 and be sold in Canada prior to July 1, 2021. However, PMPRB will assert jurisdiction over the sales of any patented medicine sold during the proposed Gap period, regardless of whether Health Canada has assigned the product a DIN. It would be more consistent and appropriate if the definition of Gap medicines under the new Guidelines were amended as follows:

  > "Gap medicines are those patented medicines first sold in Canada on or after August 21, 2019 and before July 1, 2021."

- Consideration should also be given to applying the Highest International Price (HIP) to Gap medicines with sales prior to the most recent CG II publication of amendments to the Patented Medicines Regulations (PMR), January 21, 2021. The original Guidelines defined Gap medicines as those sold in the period between the original CG II publication of the Amended Patented Medicines Regulations (August 19, 2019) and the original planned implementation date of the amended PMR and Guidelines (July 1, 2020). The proposed change would be in keeping with the original intent of defining a Gap period with a price test distinct from Grandfathered medicines.

Change to the timeline for compliance.

- The proposed six-month timeline for compliance with the Maximum List Price (MLP) is insufficient for manufacturers to gain internal approvals and execute list price changes.
- Given PMPRB's 45-day post Form 2 filing timeline for notifying manufacturers of the MLPs of their products, the timeline is closer to four months than six months. Manufacturer internal approval processes and local implementation steps cannot be accomplished in such a short amount of time, making compliance simply impossible for most manufacturers.
- PMPRB will be accepting manufacturer submissions for justification of higher MLPs based on uncharacteristically low Average Transaction Price (ATP), due to benefits. It is unclear how many such submissions Board Staff will receive or how long it will take to review and resolve them. However, it is clear this process will only extend the timeline for confirming MLPs, making compliance by December 31, 2021 even less feasible.
- The most appropriate timeline for all stakeholders, including PMPRB Staff is 18 months, consistent with the original 2019 draft of the PMPRB Guidelines. This first draft of the Guidelines acknowledged the need for more than six months lead time, and the impracticality of a 12-month deadline, requiring PMPRB to assess mid-year compliance. Health Canada and PMPRB have stated the latest delay in the coming into force date of the Regulations and new Guidelines was to account for the continuing challenges of the COVID-19 pandemic for all stakeholders. The COVID-19 pandemic is far from over and is still causing challenges for manufacturers and other stakeholders. An 18-month transition period would require list price changes by January 1, 2023, providing both adequate transition time for all stakeholders, and reduced complexity for PMRPB Staff compared to a mid-year deadline for price changes.

This submission focuses on the narrow scope of the Notice and Comment. However, PDCI maintains the view that there are other major issues beyond compliance timelines with the October 2020 Guidelines. The issues are presented fully in our previous submissions to the PMPRB Consultation, and can be broadly categorized as:

- Uncertainty in maximum allowable prices,
- Uncertainty regarding interpretation and implementation of the proposed Guidelines,
- New and extraordinary powers for Board Staff, well beyond what is templated by the Patent Act, and,

- Lack of meaningful consultation and constructive cooperation with patentees on the Guidelines and issues with their implementation.

Please do not hesitate to contact me should you have additional questions concerning the information enclosed.

Regards,

Kaitlyn Proulx

Kaitlyn Proulx
Managing Director
PDCI Market Access,
a division of McKesson Canada Corporation
Kaitlyn.Proulx@pdci.ca
613-742-8225 ext. 33