July 18, 2022

Patented Medicine Prices Review Board (PMPRB)
333 Laurier Avenue West, Suite 1400 Ottawa, Ontario K1P 1C1

PMPRB Price Review Approach During the Interim Period following publication of Amendments to the Patented Medicines Regulations

To whom it may concern,

On behalf of PDCI Market Access ("PDCI"), thank you for the opportunity to provide written feedback on the PMPRB's *Price Review Approach During the Interim Period following publication of Amendments to the Patented Medicines Regulations*.

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.

Since its inception, PDCI has supported patentees in complying with PMPRB's guidelines, ensuring prices of patented medicine are non-excessive, resolving pricing investigations, and completing semi-annual requirements. With these recent changes to the guidelines and regulations, it is imperative there is clarity during the Interim Period to ensure that patentees remain compliant.

In response to the most recent Notice and Comment, we offer the following comments related to each element of the proposed Interim Guidance:

1) **Existing medicines will not trigger an investigation provided its N-ATP remains at or below its most recent NEAP**

PDCI interprets this provision to imply that all prior Guidelines and Practices (with the exception of the reference country basket and related price ceilings) are carrying over to the Interim Period. If this is not the case, then a number of concerns must be raised. Specifically:

- Will excess revenues in the interim period be based on N-ATPs and NEAPs over 2 reporting periods, in line with prior Guidelines?

- Will the usual remedies to investigations, such as Simple and Regular DIP, be available in the Interim Period?
- Will there be confirmation that the new basket of reference countries will not be used to set price ceilings during the interim period?

Patentees seeking to remain in compliance with the Interim Guidance require additional clarity on this provision.

2) Existing medicines will not trigger an investigation provided its list price does not increase during the Interim Period

This provision is completely novel and has not appeared in any prior proposal from PMPRB. As such, it raises the following concerns:

- Patentees may have already implemented list price increases since the preceding Form 2 documents were submitted to PMPRB. At a minimum, patentees must have assurance that increases that occurred between January 1st and June 30th, 2022, will not trigger an investigation.
- "Changes in the Consumer Price Index" is one of the enumerated factors in Section 85 of the Patent Act and should be used in the determination of excessive pricing. This provision of the Interim Guidance in effect precludes the use of prior CPI-adjustment methodology. This is of major concern, particularly in this current period of high inflation.
- The enforcement of a List Price freeze is in opposition to the stated 'status quo' approach of the Interim Guidance. PMPRB did not set List Prices ceilings for existing medicines under the previous Regulations and Guidelines.

Accordingly, this provision should be removed from final versions of the Interim Guidance. Increases to List Prices should not automatically be treated as excessive, consistent with both 2010 and 2020 Guidelines, the Regulations, and the Patent Act.

3) The PMPRB will not conduct a price review of any new patented medicines or open any investigations in respect of them until the new guidelines come into effect.

This provision provides no guidance for the pricing of New Medicines and continues the uncertainty that Patentees have faced since the Patented Medicines Regulations were first amended in 2019.

- Patentees must be assured that good faith efforts at setting non-excessive pricing will not face a retroactive application of the New Guidelines.
- PMPRB should clarify whether products first sold between Jan 1st – June 30th, 2022 will receive a price review. These medicines must have an opportunity to be reviewed under the previous Regulations and Guidelines, including the use of US and Swiss prices in setting Median and Highest International Prices.

- Patentees launching New Medicines have prepared scientific submissions to HDAP for the Fall meeting dates. Without guidance from PMPRB, these submissions cannot meaningfully contribute to the scientific review process. Patentees must be provided another opportunity to submit a Scientific Submission in time for the upcoming HDAP meetings, regardless of previously stated deadlines.

At a minimum, PMPRB should provide guarantees that New Medicines first sold in the Interim Period will benefit from Grandfathering provisions and will not start accruing excess revenues until New Guidelines are implemented. Otherwise, this provision will greatly discourage New Medicine launches until New Guidelines are finalized.

This submission focuses on the narrow scope of the Notice and Comment. However, PDCI maintains the view that there are other major issues beyond the scope of the Interim Guidance that will require addressing. We look forward to addressing these issues and further collaborating during the consultation process for the New Guidelines this coming Fall.

Regards,

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