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August 21, 2023

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

Notice and Comment - Amendment to the Interim Guidance re: New Medicines

To whom it may concern,

On behalf of PDCI Market Access ("PDCI"), we want to thank you for the opportunity to provide feedback on the proposed Amendment to the Interim Guidance regarding New Medicines.

PDCI is a leading pharmaceutical pricing and reimbursement consultancy owned by McKesson Canada Corporation. Since 1996, PDCI has provided patentees in both Canada and globally with advice and expertise in pharmaceutical pricing, health technology assessment (HTA), clinical and pharmacoeconomic evaluations and modelling. Since the start of the reforms in 2017, PDCI has supported patentees with navigating the complexities of each version of the proposed guidelines to ensure innovative and life changing therapies continue to launch for Canadian patients.

In response to the recent Notice and Comment, we are commenting on the following elements:

1) **Patented medicines with a MAPP or projected NEAP as of July 1, 2022 – CPI Allowable Increases**

The proposed amendments to the Interim Guidance do not include needed updates regarding older 'existing' medicines with prior price reviews. As per Section 85 of the Patent Act, "Changes in the Consumer Price Index" is one of the enumerated factors and should be used in the determination of excessive pricing. This proposal would use 2022 price ceilings for control 2023 prices and launch investigations into any list price increases. This is of major concern, particularly in this current period of high inflation and uncertainty with the guidelines.

This issue was raised during the previous Notice and Comment period regarding the 2022 Interim Guidance. Once again, the current proposal has come long after price increase deadlines set by Provincial Drug Programs. Patentees have, once again, been put in a position where usual and customary list price increases to list prices, already accepted by payers, will be retroactively deemed to have been inappropriate.

Accordingly, this provision should be amended in final versions of the 2023 Interim Guidance. Likewise-increases to List Prices should not automatically be treated as excessive, consistent with both 2010 and 2020 Guidelines, the Regulations, and the Patent Act. Average Transaction Prices should be compared against a CPI-Adjusted 2023 N-NEAP.

2) For patented medicines without a MAPP or projected NEAP as of July 1, 2022 ("New Medicines")

The proposed amendments to the Interim Guidance would have a "New Medicine" be considered "reviewed" by the PMPRB if its list price "is below the median international price for the PMPRB11 countries".

The reason prompting this amendment was to give "greater predictability" to patentees of new medicines. We believe that much greater detail is required to provide patentees this needed predictability. Most importantly, the PMRPB should provide greater clarity into what 'considered as reviewed' means; if it is equivalent to 'non-excessive'; and how their treatment will differ from the products that remain 'under review'.

If this proposal functions to 'grandparent' newer medicines, patentees should be provided assurance that a 'reviewed' price today would not face a review in the future based on a different standard. If the price test is international price referencing, it should remain that post-New Guidelines. In order to meet the stated goal of "greater predictability" for patentees, any Median International Price standard should not be a 'floating' median but based on an initial benchmark, similar to the prior PMPRB Guidelines. Floating medians, reflective of changes in pricing, product availability, and exchange rates across 11 countries and 6 currencies, often see significant fluctuations period to period and so cannot be used to provide 'greater predictability' to patentees.

The Median International Price as a basis for a price standard in this interim period is itself problematic. Many patentees have had to launch their products at risk in this interim period. These patentees have made good faith efforts to set list prices within the expected range of PMPRB11 prices despite being provided minimal guidance from the PMPRB on methods of price referencing in these new countries.

It would therefore be much more appropriate to use the Highest International Price to determine non-excessive pricing for all products launched or sold during this interim period. The price of any product, "new" or "existing", should be considered 'reviewed' and found 'non-excessive' so long as it remains at or below the Highest International Price. The framework established in the upcoming New Guidelines should therefore only apply to those products launched after implementation of the New Guidelines.

We look forward to further collaborating in the consultation process when new Draft Guidelines are published in this coming Fall.

Regards,

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