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Dr. Mitch Levine
Patented Medicine Prices Review Board
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Re: Response to PMPRB Draft Guidelines Consultation

Dear Dr. Levine,

On behalf of PDCI Market Access Inc. ("PDCI"), I would like to thank you for the opportunity to provide written comments as part of the Patented Medicine Prices Review Board (PMPRB) Draft Guidelines Consultation process.

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.

Since 2015, when discussions about potential PMPRB price reforms began, PDCI has conducted ongoing iterative analyses to assess the impact of the proposed changes. Those findings indicate the proposed changes as outlined in the June 2020 Draft Guidelines will make many patented medicines commercially unviable in the Canadian market.

PDCI has witnessed first-hand the unintended consequences the proposed reforms have already had, and will continue to have, on industry's decisions to bring innovative medicines to the Canadian market. Some of the changes reflected in the June 2020 draft Guidelines may be more in step with the realities of the pharmaceutical market in Canada, but they are still, ultimately, arbitrary. The overall impact of the proposed Guidelines is an onerous financial penalty on patentees, and a degree of uncertainty that impedes business planning and effective decision making. Such penalties and uncertainties have led, and will lead, patentees to question whether they can commercialize products in Canada.

There are many significant issues with the current draft Guidelines, the most significant of which is that they are built around the central notion of regulating the net price paid by third-party payers. Yet the

PMPRB does not have (nor has it ever had) access to the third-party rebates required to calculate rebated prices which are fundamental to the policy.[1]

Given that the draft guidelines for the maximum rebated price are premised on the patentees reporting third-party rebates, the current draft Guidelines are not fit for purpose and must be completely re-worked to eliminate the concept of a maximum rebated price.

Apart from the Federal Court decision, as a policy matter, regulation of pharmaceutical prices net of third-party rebates duplicates and interferes with the jurisdiction and role of the pan-Canadian Pharmaceutical Alliance (pCPA), the provinces and private insurers. While the PMPRB has expressed its intent to move Canada's pharmaceutical pricing system towards uniform net prices for both public and private payers, this is well beyond the scope of PMPRB's mandate. Furthermore, private payers are dominated by large, multi-billion-dollar corporations with the resources and ability to engage pharmaceutical manufacturers, on a business to business basis, in price negotiations without Federal Government intervention.

PDCI recommends that development of the next set of Guidelines incorporate all relevant stakeholder feedback received to date but rely primarily on bilateral Working Groups comprising pharmaceutical patentees and PMPRB Board members and staff. This collaborative approach to Guideline development will ensure the new Guidelines are practical and workable for both patentees and Board Staff.

The following are several major issues we have identified with the current draft Guidelines:

- **Uncertainty**

  The purpose of the PMPRB Guidelines is to provide patentees with certainty regarding the maximum allowable prices for medicines. The current draft does not provide certainty, or the promised "bright-line" price tests.

  In fact, there are a multitude of lingering information gaps and questions related to the application and implications of the Guidelines. Under the current PMPRB regime, many of the gaps in the current Guidelines are clarified through the Patentees' Guide to Reporting. PMPRB Staff have stated they will not update the Patentee' Guide to Reporting, but will instead provide guidance in the form of a "Help" function to support the online PMPRB filing tool still in development and expected to be available within a few weeks of the publication of final Guidelines. Board Staff have also declined to provide guidance on specific technical questions, stating that these important details will be clarified during workshops to be held following the issuance of the final Guidelines.

  It is unacceptable that critical questions associated with the change in Guidelines remain unanswered with less than six months to their implementation. Without access to these details it is impossible for

[1] The July 2020 Federal Court decision (IMC et al v AG) confirmed the earlier 2009 (Pfizer et al v AG) Federal Court decision denying PMPRB access to 3rd party rebates

patentees to reliably assess price expectations for near to mid-term product launches. Additionally, details related to filing obligations and technical implementation should be subject to consultation.

Finally, we note that unlike the publicly available Patentees' Guide to Reporting, the current online filing tool is available only to patentees with log-in credentials for online filing. Furthermore, it appears that the Patentees' Guide will be replaced by an online help function associate with PMPRB's online filing tool. PMPPRB must ensure this help function is publicly available to all patentees and other non-patentee stakeholders.

- **Unprecedented Powers for Board Staff**

The current draft of the Guidelines confers extraordinary powers on Board Staff, well beyond what is templated by the Patent Act. The current draft Guidelines give Board Staff absolute discretion over price tests in the context of any Investigations, which can be commenced without any evidence of excessive pricing. The Guidelines state that any complaint received by the Board, will result in an Investigation, even if the complaint is groundless. The mere existence of a complaint allows the Board Staff to apply any price test and any thresholds it so chooses. The Patent Act requires the Board to consult on its Guidelines, these provisions are an unacceptable end-run around the Act and the PMPRB-stated objectives that the Guidelines are "intended to provide transparency and predictability to patentees..."

These extraordinary powers, plus the reduced role of the Human Drug Advisory Panel (HDAP) in the independent scientific review of all new medicines, contribute to patentees' uncertainty. These proposed changes also introduce a potential bias, since Board Staff are not a disinterested third party, and the fundamental separation of scientific assessment and price test inherent in the current PMPRB framework is eliminated.

- **Application of New Price Factors**

While we fundamentally object to the notion of using pharmacoeconomic value and market size to regulate prices in the Canadian market, PDCI recognizes that the Amended Regulations require the PMPRB Guidelines to provide a mechanism to implement these new price factors. However, we assert that there are alternative approaches to the application of these new factors that would satisfy the Amended Regulations in a less injurious manner, specifically restricting their use to the context of a hearing before the Board.

Beyond our disagreement with the new price factors, there are multiple issues that make their implementation in the manner proposed in the July 2020 draft Guidelines completely impractical and not feasible. It is unclear whether the relevant comparators and assumptions for the HTA PE analysis and PMPRB analysis would be aligned. Relevant comparators and indications will likely differ between CADTH and PMRPB. CADTH reviews take the perspective of the public payer, and pharmacoeconomic model assumptions in the CADTH base case are purposely biased towards minimizing public payer risk.

The PMPRB's mandate is to ensure prices for patented medicines in Canada are not excessive, and this requires a broad societal perspective and risk tolerance. Simply put, Canadian HTA approaches to pharmacoeconomic assessment are not fit for the PMPRB's purposes.

The proposed application of the market size factor is well beyond PMPRB's mandate to ensure Canadians do not pay excessive prices for medicines. The proposed Adjusted Maximum Rebated Price (MRP[A]) is a revenue control measure rather than a price regulation approach and should be stricken from the Guidelines.

PDCI is hopeful that the PMPRB will consider these concerns and recommendations seriously and collaborate with patentees through focused technical working groups to make the changes necessary to prioritize access to innovative medicines in Canada.

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

Regards,

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