

December 5, 2022

Mélanie Bourassa Forcier
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Patented Medicine Prices Review Board
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Re: Consultation on 2022 Proposed Updates to the PMPRB Guidelines

Dear Ms. Bourassa Forcier,

On behalf of PDCI Market Access (“PDCI”), I thank you for the opportunity to respond to the Consultation on Proposed Updates to the Patented Medicine Prices Review Board (“PMPRB”) Guidelines, which was initiated on October 6, 2022.

PDCI is a Canadian pharmaceutical pricing and market access consultancy with core expertise in pharmaceutical pricing, health technology assessment, 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 proposed updates to the Guidelines, 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. We have assisted pharmaceutical industry manufacturers with advice and guidance based on these analyses and in so doing have often been privy to their business decisions concerning commercialization of medicines in Canada. It is from this vantage point that we share our concerns and observations listed below, and from which we make our key recommendation: **PDCI implores the federal government to pause implementation of final guidelines until appropriate engagement can occur among experienced stakeholders in technical working groups which are empowered to meaningfully shape the final Guidelines.**

Working groups should be challenged to meaningfully assess the anticipated implications of PMPRB’s proposed guidelines (October 2022). The proposed Draft Guidelines represent an enormous departure from both the current guidelines and from earlier proposed Draft Guidelines. Such a significant departure in the proposed Guidelines would fundamentally reshape and redefine the role of the PMPRB. All of this requires that reasonable solution-oriented alternatives be properly assessed and considered to better balance the government’s various – and in this case conflicting – policy goals. Implications must be assessed not only for the near-term objectives to reduce prices of medicines, but also the compounded effects on Canadians’ access to new medicines in the decades to come.

At PDCI we are seriously concerned about the continuing decline in the number of new patented medicines reported to PMPRB. Indeed, in PMPRB’s recently published 2021 Annual Report, the number

of new medicines reported to PMPRB that year was the lowest in PMPRB's history.¹ While fluctuations can be expected from one year to the next, Canada seems out-of-step with similar statistics from the US Food and Drug Administration² and European Medicines Agency³ where numbers of new medicines approved remain more stable, if not increasing.

Additionally, PDCI has recently examined the importance of a country's price regulatory landscape in biopharmaceutical manufacturers' perceptions of a country's attractiveness for new medicine launch and how it affects their launch decisions. In this study, Canada ranked 10th among the 13 other countries PMPRB has or currently considers for international price referencing (the PMPRB11 and PMPRB7 countries) with the price regulatory indicator representing 18% of the Index's weight.⁴ The Index considered the previously effective PMPRB guidelines (last updated in 2017) and Canada ranked ahead of only four countries and tied with four others in providing a price regulatory environment that was not overly attractive, but at least reasonably aligned to some of the other markets. With these proposed updates to PMPRB Guidelines, we expect Canada would fall to last place not just on the pricing indicator but indeed last place on its overall attractiveness ranking as well, given the relatively high weight manufacturers place on the price regulatory environment when making launch decisions.

These proposed updates show PMPRB continues to misunderstand its role amid the federal government's stated objectives for pharmaceutical policy in recent years. In recent stakeholder webinars, PMPRB has explained its need to continue with guideline modernization because it has been working towards it for the last five years. Despite half a decade of evolution in the environment, ground-breaking legal decisions clarifying PMPRB's mandate, and better, more measured policy alternatives being available, PMPRB prevails with its original misconception that investments in innovative therapeutics are price tags to be slashed. Thus, it ignores the interconnection of two critical ecosystems: the need to build a vibrant life sciences sector and the requirement to support a world-class healthcare system. In our view, the sunk costs of the last five years are not a foundation on which sound public policy can be built.

Summary of PDCI's Concerns with 2022 Proposed Updates to PMPRB Guidelines

- **Proposed updates are at odds with federal government priorities and policies** designed to rebuild and grow the domestic biomanufacturing sector, improve access (particularly for innovative rare disease drugs) and ensure security of supply for important medicines.
- **Moving from voluntary compliance to case-by-case reviews sets up a constant and opaque system of moving targets which undermines certainty needed for investment.** Additionally, there are important practical challenges associated with following a moving target of investigation

¹ The Patented Medicine Prices Review Board Annual Report 2021 Accessed December 1, 2022. Available at <https://www.canada.ca/en/patented-medicine-prices-review/services/annual-reports/annual-report-2021.html>

² U.S. Food and Drug Administration Advancing Health through Innovation: New Drug Approvals 2021. Accessed December 1, 2022. Available at: <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2021>

³ European Medicines Agency Human Medicines Highlights 2021 Accessed December 5, 2022. Available at [https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines/medicine-evaluation-figures#annual-medicines-highlights-\(2015-2021\)-section](https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines/medicine-evaluation-figures#annual-medicines-highlights-(2015-2021)-section)

⁴ PDCI Market Access *Biopharmaceutical Ecosystem Index: Where does Canada Rank on its Attractiveness for New Medicine Launch?* June 2022 <https://www.pdci.ca/press-release/>

criteria for any medicine with NOC after July 1, 2022. As international policies and markets change, exchange rates fluctuate, comparators in other countries enter those markets or lose patent protection in those markets, there will be constant need to monitor and evaluate the impact on Canadian pricing to avoid an investigation. Such uncertainty will undermine stability of access to products if the result of an investigation – not unrealistically – is that a medicine becomes commercially unviable in Canada.

- **Additionally leaving vague what “may” trigger an investigation leaves massive power within the discretion of PMPRB staff.** Vague guidance is ineffective guidance which fails to provide rights holders with the certainty needed to bring new medicines to Canada, particularly given its current relative attractiveness ranking in PDCI’s Biopharmaceutical Ecosystem Index and both the cost and opportunity cost of commercializing new medicines in Canada over other countries. Furthermore, while the Guidelines enable rights holders to understand the criteria that may trigger an investigation, they will not know the outcome of the investigation until committing to launch in the Canadian market. The outcome may not be known perhaps for some time while the investigation is ongoing, and all the while, sales of the medicine must be made not knowing whether substantial revenues will need to be repaid, if it is eventually deemed to be priced excessively. Indeed, an investigation may establish a price which makes continued commercialization impossible, and the manufacturer would be forced to discontinue Canadian commercialization.
- **Establishing investigation criteria using “lower of” two methods is excessive to achieve substantial reductions in drug prices.** Recent amendments to the Patented Medicine Regulations have updated the basket of countries PMPRB consults for the purpose of international price referencing. This change, applied to both new and existing medicines, would substantially reduce drug prices and achieve massive savings for drug insurers in Canada. According to recent PDCI analyses, changing the basket of countries alone reduces price ceilings of new medicines by 16% on average. Choosing to regulate prices according to the median of the lower-priced basket of reference countries implies prices in half the international reference countries would be excessive. Furthermore, regulating to the “lower of” the median international price of the basket and prices of domestic comparators represents an unnecessary – indeed excessive – double dip to achieve PMPRB’s objective to cut prices. Here PMPRB is wielding a sledgehammer to crack a nut.
- **Eliminating recognition for therapeutic improvement will undermine access to innovative medicines.** Placing an arbitrary ceiling at the international midpoint does not allow any mechanism to consider that prices from the mid- to highest-priced international reference country may not be excessive by international and domestic standards. However, the proposed guidelines only allow potential for such considerations within the context of an investigation. Eliminating the mechanism to recognize higher value for a new medicine over the existing alternative therapy that may be used to treat the same condition effectively means Canadians are much less likely to achieve access to medicines which improve on an existing option or standard of care – irrespective of how archaic that standard of care may be or unmet needs in efficacy or safety the new medicine may meaningfully fulfill. Furthermore, the Guidelines do not make clear how PMPRB Board Staff (and not its independent, expert Human Drug Advisory Panel (HDAP) which formerly held this responsibility) intend to make determinations about appropriate comparators. From recent PMPRB investigations and hearings, it appears products used off-label,

without robust (i.e., Phase 3 randomized controlled trial) evidence, long genericized products, products used for a different therapeutic intent, treatment goal or line of therapy, or potentially even not commercially available in Canada, could be included in the basket of comparators PMPRB staff considers appropriate.

- **Reduced HDAP role will compromise quality, transparency consistency and independence of scientific review.** Diminishing the role of HDAP from a formal component of PMPRB's mandate to an ad hoc body that contributes context only at the request of PMPRB staff will compromise the quality, transparency, consistency, and independence of the scientific review from pricing considerations and PMPRB staff motives to drive down patented medicine prices.
- **PMPRB says it may investigate cases where there are no international prices but does not further disclose how it would assess excessive pricing in these scenarios.** According to PDCI analyses this may apply to 4% of existing medicines (e.g., those which are only sold in US and Canada). PDCI also estimates that 25% of recent medicines had no PMPRB11 prices at introduction. These products would have triggered an investigation. This incentivizes rights holders to wait until prices become available in other markets in order to better assess the investigation and compliance risks in Canada. The PMPRB must have criteria or benchmarks (e.g., related to annual price/patient, budget impact or some other information) it intends to apply to assess excessive pricing in these scenarios. Such criteria were previously decided to be *ultra vires* the *Patent Act* and PMPRB's mandate) and would be "constitutionally suspect" if included in guidelines according to a recent court decision⁵. If these guidelines were to be put into force, and PMPRB to apply their unstated criteria for investigation, each investigation and hearing would be challenged on the basis of being outside the mandate of PMPRB. Taking the time to implement thoughtful and precise guidelines that align PMPRB's mandate with the jurisprudence will save government and stakeholders substantial efforts and time.
- **Numerous other logistic and operational clarifications are needed** to fully assess the implications of the guidelines and prepare rights holders to successfully commercialize new medicines in Canada while respecting the mandate and authority of PMPRB.

As previously stated, PDCI is uniquely positioned to appreciate both the policy and practical implications of these proposed updates to PMPRB Guidelines. For the reasons stated above, we see the only next appropriate action to be **pausing implementation of final guidelines until appropriate engagement can occur among experienced stakeholders in technical working groups which are empowered to meaningfully shape the final Guidelines.** The compounded effects of using "lower of" median international prices and domestic comparators (dTCC) for new medicines combined with vast uncertainty about PMPRB's actual, unstated approaches for determining excessive (or inappropriately "reasonable") pricing have and will continue to result in manufacturers delaying or abandoning launch of new medicines in Canada. Working groups must document such implications to build real understanding among government to ensure decisions are made thoughtfully and with true understanding of what is at stake when it comes to the future health of Canadians.

Regards,

⁵Alexion Pharmaceuticals Inc. v. Canada (Attorney General) - 2017 FCA 241

A handwritten signature in black ink, appearing to read 'D Lawrence', with a long horizontal flourish extending to the right.

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