



August 21, 2023

Mr. Guillaume Couillard
Acting Executive Director
Patented Medicine Prices Review Board
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Eli Lilly Canada Inc.

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

Dear Mr. Couillard,

Eli Lilly Canada Inc. (Lilly) appreciates this opportunity to provide its feedback on the proposed *Amendment to the Interim Guidance regarding New Medicines* (“Amended Interim Guidance”). During this period of uncertainty, where new PMPRB Guidelines have yet to be proposed, properly consulted upon and implemented, the importance of providing greater predictability to support us as we look to bring new, innovative medicines to Canadian patients cannot be overstated, especially as an uncertain pricing regime creates considerable commercial uncertainty around the Canadian market.

Lilly believes that the Amended Interim Guidance and eventual new Guidelines must:

- Reflect the mandate of the PMPRB as defined by the *Patent Act*, specifically the prevention of patent abuse and not generalized price control / consumer protection
- Permit rights holders to make CPI-based price adjustments for both new and existing medicines, as per the *Patent Act*
- Establish a fair, predictable and stable system that is clear in its definition and enforcement of maximum non-excessive prices to help strengthen the Canadian biotechnology ecosystem and avoid delaying Canadian patients’ timely access to innovative medicines
- Evaluate Canadian prices against all prices from the basket of comparator countries and not just those at or below the median
- Be developed using a principled, collaborative approach that is informed by technical experts (*e.g.*, rights holders).

Additionally, Lilly fully supports the positions of Innovative Medicines Canada (IMC) and BIOTECanada, both with respect to the proposed amendments to the Interim Guidance and with respect to the eventual development and implementation of new PMPRB Guidelines.

With specific reference to the Amended Interim Guidance, it remains unclear how frequently assessments will be conducted and how the goal of providing rights holders with “early guidance and greater predictability to certain New Medicines” will be achieved. As a member of the industry, we stand ready to collaborate with the PMPRB to achieve this overarching

objective and would appreciate the opportunity to engage with PMPRB on this point to bolster commercial confidence by gaining greater clarity.

Thank you for considering Lilly's submission. We look forward to continued engagement with the Board and its Staff with both the Interim Guidance and future PMPRB Guidelines.

Best regards,

Gamze Kuzucu Gürses
Vice President of Pricing and Market Access
Eli Lilly Canada Inc.