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Mr. Thomas J. Digby
Chairperson
Patented Medicine Prices Review Board (PMPRB)
Box L40
Standard Life Centre
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Suite 1400
Ottawa, Ontario
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Submitted via the PMPRB Website: Consultation Submission Portal

Re: Eli Lilly Canada's ("Lilly") Response to the Scoping Paper for the Consultations on the Board's Guidelines

Dear Mr. Digby,

On behalf of Eli Lilly Canada, thank you for the opportunity to provide input into the future PMPRB Guidelines. Lilly strongly believes that, through meaningful collaboration with stakeholders focused on the PMPRB's historic principles of fairness, transparency, openness, and predictability, new Guidelines that are consistent with the Board's statutory mandate and that are fair, efficient, and sustainable can be achieved.

The importance of implementing Guidelines that ensure both predictability and fairness in order to foster confidence in the Canadian pharmaceutical market cannot be overstated. A recent analysis (PhRMA, Global Access to New Medicines, April 2023) shows that only 45% of all new innovative medicines were launched in Canada between 2012 and 2021, the lowest rate of launches in the G7. As noted in the submission of Innovative Medicines Canada (IMC), we believe timely access to new innovative medicines for the benefit of Canadians remains a public policy consideration, of which the critical impact of the PMPRB must not be understated. It is of the utmost importance that all stakeholders recognize the impact the PMPRB can have on innovative medicines being launched in the Canadian market.

Effective Guidelines must be derived from the PMPRB's Statutory Mandate

Ensuring the new Guidelines appropriately reflect the statutory mandate of the PMPRB is paramount. The mandate of the PMPRB is to determine whether the prices at which

medicines have been sold by rights holders are excessive due in consideration of the protection afforded to them through the *Patent Act*. This was confirmed by the Federal Court of Appeal in July 2021 in the case of Alexion Pharmaceuticals Inc. v. Canada (Attorney General), where it stated:

> *Over and over again, authorities have stressed that the excessive pricing provisions in the Patent Act are directed at controlling patent abuse, not reasonable pricing, price-regulation or consumer protection at large…*
>
> *…[T]he Patent Act aims at a balance between incentivizing the research and development of patented medicines and their introduction into Canada through the grant of a monopoly and protecting against abuse of that monopoly…*

This sentiment has been echoed by Health Canada in its 2017 consultation document Protecting Canadians from Excessive Drug Prices.

It is Lilly's position that the focus of the new Guidelines should be aligned with the statutory mandate of the PMPRB: the PMPRB Guidelines should focus its attention during its review of patented medicines on those for which the risk of patent abuse through excessive pricing exists.

The PMPRB must define excessive pricing in a fair and transparent manner

With the mandate of the PMPRB clearly defined, it is necessary to create a fair and transparent definition of excessive pricing. Section 85(1) of the *Patent Act* establishes factors that must be considered when making a determination of whether a price is excessive. Given the Federal Court of Appeal decision, arbitrary selection of subsets of any one factor amount to inappropriate price controls, which is inconsistent with the Board's statutory mandate.

A clear example of this is the use of international pricing in Section 85(1). Section 85(1) requires the consideration of the prices at which the medicine has "been sold in countries other than Canada." Lilly submits that no price within the PMPRB11 range would be excessive and that the Highest International Price (HIP) Comparison test would be an appropriate trigger to review for potential excessive pricing within the context of the PMPRB Guidelines, absent a justification by a rights holder to price beyond the HIP based on Section 85(1) factors.

Once a definition of excessive pricing has been established, it will be necessary for the tools used for evaluating the effectiveness of the PMPRB to be reviewed and appropriately revised. For example, the 2022-2023 Departmental Results Report published by the PMPRB uses the percentage of patented drug prices in Canada below the median of the

PMPRB's comparator countries as a key performance metric, with the target being 50%. Targets such as these incentivize the PMPRB to use the median of the PMPRB11 as its defined threshold for excessive pricing; it is important for such incentives to be removed if true progress is to be made on the Guidelines.

Improved Operational Efficiency

The PMPRB's statutory mandate and existing jurisprudence should also define how the PMPRB operates, improving operational efficiency and decreasing administration burden on the PMPRB and rights holders alike.

To align the Guidelines with its mandate, the PMPRB should only actively monitor patented medicines for which patent abuse through excessive pricing is possible. Products that are subject to competition due to the existence of multiple substitutes carry a low risk of excessive pricing. Such medicines include, but are not limited to:

- Patented medicines with generic competition;
- Patented medicines with biosimilar competition; and
- Patented medicines that are subjected to competitive tenders (e.g., vaccines).

By reducing its involvement in the monitoring of all low-risk patented medicines, the PMPRB would greatly improve its efficiency while reducing the administrative burden on both the Board and rights holders alike. A variation of this approach was implemented in the 2017 Guidelines for patented generic medicines. Lilly strongly encourages the PMPRB to consider this general approach when developing its new Guidelines.

Statement of Alignment with Submissions from Innovative Medicines Canada and BIOTECanada

Lilly is aligned with all elements of both the IMC and BIOTECanada written submissions in response to the ***"Scoping Paper for the Consultations on the Board's Guidelines."*** Although we have provided additional perspective and detail in this response to complement and reinforce key elements of the IMC and BIOTECanada submissions, there remain several noteworthy concerns that have been raised in current and past submissions by IMC and BIOTECanada members that still require attention. Some of these concerns are listed below.

- Pursuant to existing jurisprudent, pharmacoeconomic value, market size, gross domestic product (GDP) and GDP per capita should not be used to establish non-excessive price thresholds;

- Failure to exempt (i.e. grandfather) existing medicines amounts to price control, again beyond the statutory mandate of the PMPRB;
- Prices should only be assessed at launch; re-evaluation of the prices of medicines as a price control measure (i.e., rebenching) should not be included in the Guidelines;
- To develop effective Guidelines, the PMPRB must establish Technical Working Groups with rights holders; and
- The PMPRB must provide rights holders with a minimum of two full reporting periods (i.e., 12 months) to adjust to the new Guidelines.

As we look towards a new round of consultations on the PMPRB Guidelines, it is important for the PMPRB to leverage feedback provided by stakeholders and related jurisprudence since the reform was first introduced to ensure new Guidelines are aligned with its statutory mandate.

Next steps

As we look to next steps in this process, it is important for the PMPRB to focus on getting the Guidelines right rather than rushing a new approach forward. This can only be achieved if a collaborative approach is adopted to co-create new Guidelines. We do not recommend that the PMPRB present stakeholders with a new version of the Guidelines before launching working groups as this will limit discussion, forcing stakeholders to react to the PMPRB's proposal rather than help co-create new Guidelines in a manner that adheres to the PMPRB's principles of fairness, transparency, openness, and predictability.

To close, we would like to thank you once again for the opportunity to input into the development of new PMPRB Guidelines.

Best regards,

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