August 31, 2021

Eli Lilly Canada's Submission to the Patented Medicine Prices Review Board RE: On the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions

This document represents Eli Lilly Canada Inc.'s (Lilly's) response to the Patented Medicine Prices Review Board's (PMPRB's) invitation for comment on the most recent proposed amendments to the Guidelines, namely the revised price tests for Grandfathered medicines and their Line Extensions and the shortened timeline of one six-month filing period for Grandfathered and Gap medicines to come into compliance by July 2022.

Disclaimer

Lilly understands that the PMPRB intends to update its Guidelines within the framework of the amendments to the *Patented Medicines Regulations*, which are not yet in force. While Lilly is committed to constructive engagement with the PMPRB on its draft Guidelines, Lilly's participation in this consultation is not intended and should not be interpreted as supporting the amendments to the Regulations, which we submit exceed the authority under the *Patent Act*.

Statement of Alignment with Innovative Medicines Canada Submission

Lilly is aligned with all elements of the Innovative Medicines Canada's (IMC's) written submission to the PMPRB's Notice and Comment. Lilly's submission serves to provide additional perspective and detail to complement and reinforce key elements of the IMC submission.

Proposed changes to price tests lack a clear rationale and contradict previous statements made by the PMPRB

The PMPRB proposes a significant change in how ceiling prices for Grandfathered medicines and Line Extensions are determined without clear rationale for doing so, re-benching these medicines at the lower of their current ceiling prices and the current median of the PMPRB7. This contrasts with the PMPRB's conclusion after the February 2020 consultation[1], when the Board decided to apply the highest international price (HIP) test to Grandfathered medicines in recognition of the impact of the new schedule of comparator countries. Since then, subsequent consultations have been conducted in February 2021 and these changes were not proposed then. This deviation is disconnected from the Board's previous statements and warrants a clear explanation.

1. For example, on April 2, 2020, the PMPRB Chair issued a statement that "[t]he PMPRB will be making significant changes to the draft Guidelines in response to the feedback it has received." This resulted in the highest of the PMPRB11 schedule used as part of the final Guidelines. PMPRB, June 19, 2020, Backgrounder on June 2020 Draft Guidelines: Explanation of Changes from November 2019 Draft Guidelines, page 7, https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/2020/PMPRB-Backgrounder2020-en.pdf

Moreover, the PMRPB confirmed to IMC that it intends to proceed with this significant change even if the new amended Regulations do not come into force on January 1, 2022. This disregard of the consultation process and enabling statute is unprecedented and seems punitive, particularly in light of recent regulatory implementation delays due to the ongoing COVID-19 pandemic and with no clear rationale provided.

Proposed changes to price tests are not grounded in an excessive pricing standard, which is what the PMPRB's jurisdiction is limited to

The PMPRB was established to ensure that the prices of patented medicines sold in Canada would not be "excessive". This is clearly reinforced in the recent Federal Court of Appeal's decision in *Alexion Pharmaceuticals Inc. v Canada (Attorney General)*[2] which held "*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*".

The impact of these proposed changes on existing medicines is puzzling and unwarranted. By arbitrarily revoking prior commitments, it appears that the PMPRB is inappropriately setting prices rather than exercising its statutory mandate. These proposed changes are unexpected, unreasonable, and are not grounded in the PMPRB's jurisdiction of regulating excessive pricing.

Moreover, these changes are based on flawed premises including the mischaracterization that Canada is paying higher prices for prescription drugs than other countries. This could not be further from the truth. In fact, a recent CHPI study showed that median Canadian prices have been lower than median foreign prices for the last 13 years, as much as by 14% in 2019[3]. Even by the PMPRB's own analysis of its proposed changes, the impact on Grandfathered medicines and Line Extensions is nearly double that of the final October 2020 Guidelines. In analyzing the impact of the currently proposed changes, Lilly's portfolio of medicines will require price reductions which significantly exceed the impact previously hypothesized by the PMPRB. As Lilly's investments associated with regulatory approval, reimbursement, distribution, and customer support were made prior to these prior changes, these factors will likely have to be reconsidered in order to balance the impact associated with these proposed Guideline changes.

2. Alexion Pharmaceuticals Inc v. Attorney General of Canada, 2021 FCA 157.
3. Patented Medicines Expenditure in Canada 1990-2019. Canadian Health Policy Institute. Jun 2021. *Canadian Health Policy*

Shortening the transition period undermines the rationale underlying previous decisions by the Board and Health Canada and poses significant challenges for patentees and public stakeholder

Patentees will experience practical challenges in complying with the new Guidelines in such a short period of time. First, until the PMPRB provides the MLP in early 2022, patentees are developing an independent estimate of the MLP based on their own interpretation of the Guidelines. Significant discrepancies between the MLP and the estimated MLP may arise due to different interpretation of the PMPRB Guidelines, evident by continual discussions about the application of the NEAP and new price sources. These differences will inevitably lead to unintended non-compliance, which may trigger an investigation and result in more post-hoc administrative work for both the PMPRB and manufacturers. As such, PMPRB's representations that Staff will simply "work things out" with patentees during this shortened transition is untenable for patentees attempting to navigate an already complex business environment during the pandemic.

Similar challenges will cause significant administrative burden and disruption to public payers and a broader set of stakeholders along the supply chain. This work falls most heavily on them when human resources are depleted by COVID-19. At the annual western meeting of the Canadian Association for Healthcare Reimbursement (CAHR), held on February 9th, 2021, the three Executive Directors of western provincial drug plans were unequivocal that COVID-19 continues to "keep them up at night", citing current drug shortages, vaccines, and secondment of staff to other areas as significant issues.

These hardships have not relented and are unlikely to end soon. Just a few weeks ago, Dr. Theresa Tam stated that Canada is in the midst of the fourth wave of the pandemic, driven by the delta variant[4]. These stakeholders are the ones Health Canada was concerned about and saw the need for in implementing a delay in the coming into force of the PMPRB Regulations. An extension for patentees to 12 months is prudent and will provide much-needed reprieve to public stakeholders as well.

Price uncertainty will lead to delayed access to medicines and loss of investment in Canada's life sciences sector

Lilly believes it is reasonable to expect predictability in the consultation and implementation of the Guidelines. This has not been the case. For instance, the proposed shortening of the transition period contradicts previous decisions made by the Health Canada and the Board in delaying the amended Regulations and retaining the 12-month transition in support of efforts in fighting the COVID-19 pandemic. Reducing the transition period to six months is counterproductive to this objective and will increase administrative burden and cost for stakeholders. This level of inconsistency gives the impression that the PMPRB is not carefully considering the industry's concerns regarding the implementation of these Guidelines, despite their substantial change from the current regime.

4. D'Andrea. Fourth wave of COVID-19 now underway in Canada, Dr. Theresa Tam says. Global News. August 13, 2021.

Regulatory regimes are best when they are stable and predictable, especially as the pharmaceutical industry isn't one that can often pivot quickly. Bringing innovative medicines to Canada and its citizens requires significant time and investment as evident by the Federal Government's recent spending in the life sciences sector and partnership with industry to build vaccine manufacturing facilities in Canada[5]. These collaborations should be celebrated as it speaks to mutual desire for a robust life sciences ecosystem in Canada. An uncertain pricing environment runs contrary to this and will drive global companies away in favour of more predictable jurisdictions or at the very least, deprioritize Canada in the introduction of new medicines. The gravity of the disruptive changes in these Guidelines are such that they are a constant negative factor in global strategy discussions around the feasibility of launching new medicines in Canada. The irony of this is that the PMPRB claims the purpose of this regulatory reform is to ensure patients have access to important medicines.

Summary

In conclusion, Lilly recommends that the PMPRB abandon its proposed changes to the price tests for Grandfathered medicines and their Line Extensions. Not only are these proposed changes arbitrary, but they also lack a fundamental basis in the PMPRB's mandate of policing excessive pricing. Lilly also maintains that the compliance period should revert to a more reasonable duration of two six-month filing periods to align with the federal government's goal of allowing all parties to focus on tackling the COVID-19 pandemic together.

More broadly, abrupt changes to price tests and operational timelines indicate that the Canadian pricing environment is unpredictable and unwilling to listen to its key stakeholders. These signals will inevitably give substantial reason for pause when pharmaceutical companies are considering investments in Canada or discourage future introduction of medicines in Canada. In alignment with IMC's submission, Lilly calls upon the Federal government to urgently intervene to prevent further deterioration of the pharmaceutical market in Canada, which can only harm its stated objectives of "strengthening Canada's biomanufacturing and life sciences sector, improving economic growth, and ensuring pandemic readiness for years to come".

Regards,

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5. Innovation, Science and Economic Development Canada (ISED) July 2021 *Biomanufacturing and Life Sciences Strategy*