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Eli Lilly Canada's Submission to the Patented Medicine Prices Review Board Notice and Comment - PMPRB Price Review Approach During the Interim Period following publication of Amendments to the *Patented Medicines Regulations*

This document comprises Eli Lilly Canada (Lilly's) submission on the above noted manner.

Lilly commends Board Staff for recommending a "status quo" approach to the interim period between the coming into force of the new Patented Medicines Regulations and the implementation of new Guidelines based on those Regulations. Further, we encourage the Board to establish a goal and principles consistent with its mandate under the Patent Act as well as recent relevant jurisprudence to inform development of the new draft Guidelines.

Lilly appreciates that the Board wishes to expedite implementation of new guidelines, however, it seems ambitious to have new guidelines in place by January 1, 2023. We urge the Board to engage in a thorough and thoughtful consultation on the new guidelines, even if that means extending the interim period beyond December 31, 2022. It is also crucial than manufacturers be provided with at least a 12-month transition period for compliance following implementation of the new guidelines.

We offer the following proposed expansion and clarification of the draft interim approach to provide manufacturers with additional pricing certainty during the interim period.

1. The wording in the Notice and Comment seems to imply a moratorium on price increases, which is not consistent with the status quo, or with the s.85 pricing factors in the Patent Act. Clarifying the wording of the interim rule for existing medicines as follows will resolve this issue, and provide price increase guidance beyond the end of 2022, if required:

   "an existing patented medicine will not trigger an investigation provided… its national 2022 average transaction price (N-ATP) remains at or below its…projected 2022 NEAP from the 2021 PMPRB compliance report, and the within the limits of the CPI-Based Price-Adjustment Factors for Patented Drug Products in subsequent years of the interim period."

2. The interim period definition should be change to "the period between the coming into force of the new *Patented Medicines Regulations* and the final **implementation** of a corresponding set of guidelines", rather than the final **publication** of the guidelines.

3. No price review of any "new" patented medicines during the interim period must be clarified to define "new" medicines as those with first sale on or after July 1, 2022. Existing medicines (i.e., those with first sale on or before June 30th, 2022) which have not yet received an introductory price review must be reviewed as expeditiously as possible and receive an introductory benchmark price based on the terms of the 2017 PMPRB Guidelines. The interim price review process should explicitly acknowledge the ongoing need for these price reviews of existing medicines, and provide a mechanism for submission of PMPRB 7 prices for the affected medicines.

4. Manufacturers require some price certainty for new medicines introduced during the interim period. To provide this, the interim price measures should state that no excess revenues will accrue for new medicines during the interim period, and any investigations of those new medicines under the new guidelines must be limited to sales occurring after the implementation of the new guidelines.

Thank you for considering Lilly's submission. We look forward to engaging with the Board and Board Staff during the upcoming Guidelines Consultation.

Regards,

Thiago Deksnys

Thiago Deksnys
Vice President, Pricing and Market Access

Disclaimer: While Lilly is committed to constructive engagement with the PMPRB on the Guidelines, said engagement should not be interpreted as supporting the amendments to the Regulations, which remain, as of the date of this submission, under review by the Federal Court of Appeal in Court File No. A-215-20. Further, the Lilly period 221 Form 2 filing will include Block 5 price data for the PMRPB 11 countries as listed in the Amended Patented Medicines Regulations which came into force on July 1, 2022. However, submission of those pricing data is without prejudice to Lilly's support of the Federal Court of Appeal review of the amendments to the Regulations.