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March 19, 2025

Ms. Anie Perrault
Acting Chairperson
Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
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Dear Ms. Perrault,

Thank you for this opportunity to provide feedback regarding the proposed PMPRB Guidelines. As Eli Lilly Canada Inc. (Lilly), we are committed to bringing innovative medicines to Canadians and we believe that the Guidelines in their current form should not advance without important revisions. By ensuring the Guidelines are anchored on the PMPRB's historic principles of fairness, transparency, openness, and predictability, the new Guidelines will ensure that the PMPRB effectively addresses its mandate today and in the years to come.

Provide clear guidance to rights holders regarding excessive pricing

The PMPRB Guidelines must be written in a manner that provides clarity and transparency for both Board Staff and rights holders. The absence of any guidance to aid rights holders in assessing their prices creates uncertainty and hinders the ability of rights holders to provide Canadians with patented medicines at non-excessive prices in an effective manner. This undermines commercial confidence in the Canadian market and the resultant uncertainty has the potential to impact the introduction of new innovative medicines for Canadian patients.

As was the case with the previous PMPRB Guidelines, the new Guidelines should provide a clear, initial determination of whether a price is excessive, thereby allowing rights holders to sell their medicines with confidence. If the proposed guidelines are adopted in their current form, they will create an environment for rights holders that lacks clear rules and departs from the PMPRB's historic principles of fairness, transparency and predictability.

In particular, the new draft Guidelines propose performing an Initial Review using the highest international price (HIP) as long as one PMPRB11 list price is filed. Comparing list

prices against only one country introduces uncertainty as that one country may be an outlier within the PMPRB11 for a variety of reasons, including regulatory and economic, that are completely extraneous to whether a rights holder is abusing its patent in Canada.

Under the previous PMPRB Guidelines, the launch price of a patented medicine would only be firmly established once the product had been launched in 5 reference countries or after the product has been on the Canadian market for 3 years. The PMPRB should incorporate this approach in its new Guidelines whenever an assessment of the HIP is performed.

Similar to the Initial Review, only one test should be performed to determine whether an In-Depth Review is required at the Annual Review stage. That test should be to compare the price change of a patented medicine against changes in the Consumer Price Index (CPI) – nothing more. This approach is recommended as it provides Board Staff with a clear, one-test method for determining whether a medicine's price warrants further examination. Use of this test (i.e. CPI) also provides rights holders with the predictability needed to manage their medicines' prices efficiently and effectively.

Ensure the PMPRB reviews prices without becoming a general price control body

It is important to ensure the PMPRB does not overstep its mandate by acting as a general price control entity. The Federal Court of Appeal's decision in *Alexion Pharmaceuticals v. Canada (Attorney General)*, 2021 FCA 157 and the Québec Cour of Appeal's decision in *Merck Canada et al. v. Canada (Attorney General)*, 2022 QCCA 240 both clearly indicated that general price control is not part of the PMPRB's mandate; instead, it is to prevent excessive pricing flowing from patent abuse.[1] The thresholds defined in the PMPRB Guidelines, at all review stages, must reflect the limitations of the PMPRB's mandate; they must not have the effect of lowering prices in pursuit of optimal or reasonable pricing.

It is Lilly's position that only the use of maximum prices, such as the HIP or the highest priced comparator, should be considered when assessing whether a price is excessive. This is because use of a price point below the highest price introduces subjectivity and, as a result, a form of general price control. As the Quebec Court of Appeal confirmed in *Merck Canada et al. v. Canada (Attorney General)*, an excessive price is one that "without justification, exceeds the price of other medicines in the same therapeutic class or that otherwise exceeds the price for the same medicine in countries reasonably comparable to Canada."[2] Necessarily, this means comparing Canadian prices to the highest priced comparators. It also means that a price could still be considered non-excessive, even if it surpasses the highest priced comparators, if there is reasonable justification for such price. One such example is tariffs which may be imposed by local or foreign governments and which can impact the Canadian price. There are countless other possible justifications. While it is not possible to enumerate a list of reasonable justifications, the Guidelines should properly reflect that Board staff ought to consider same in their decision to refer a matter to a hearing.

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[1] *Alexion Pharmaceuticals v. Canada (Attorney General)*, 2021 FCA 157 at paras 55-60; *Merck Canada et al. v. Canada (Attorney General)*, 2022 QCCA 240 at paras 49, 216, 244 (see also paras 143-146, 153, 156, 163, 179, 204, 228, 235).

[2] *Merck Canada et al. v. Canada (Attorney General)*, 2022 QCCA 240 at para 49.

To avoid venturing into the realm of general price control, products that have undergone an Initial Review that has deemed their price to be within the acceptable (i.e. non-excessive) thresholds set by the PMPRB should not be forced to lower their prices over time through the Annual Review process. In particular, it is inappropriate to monitor the HIP as part of Annual Reviews as it allows the PMPRB to act as a general price control body by indirectly introducing in Canada general price control tools from the PMPRB11 countries. Indeed, the HIP may evolve over time due to foreign economic, market, and regulatory conditions. Changing market and political conditions that occur abroad are not reflective of whether a price is excessive as a function of patent abuse in Canada. Instead of using this approach, Annual Reviews for these medicines should be limited to comparing price increases to changes in the Consumer Price Index (CPI), as mentioned previously.

Prices deemed non-excessive, either under the previous Guidelines or future Guidelines, should not be deemed excessive at a later date

Similarly, the Guidelines should not retroactively affect medicines that were launched under previous Guidelines and deemed compliant. These medicines were launched with the understanding that they would be reviewed based on the rules that were in effect when they were launched. Changing the approach for these medicines is not only unfair but also undermines the predictability that is crucial for our industry. These medicines should be monitored in the same manner we have proposed for new medicines: as medicines with compliant prices, they should be evaluated using the Annual Review approach (i.e., evaluate price changes relative to CPI only, and no other factor).

In addition, based on recent status reports sent to rights holders for the 2024 reporting period, Lilly is concerned that the PMPRB appears to be taking the position that the provisions of the new Guidelines will apply retroactively to sales made during the interim period. Any form of retroactive application of the new Guidelines to sales made prior to their adoption and coming into force raises serious questions of fundamental justice and procedural fairness. Indeed, rights holders could not be expected to comply with Guidelines (and the thresholds established therein) that were not yet published.

The PMPRB should reevaluate its proposed use of comparators based on 'Levels of Similarity'

The proposed implementation of the 'Levels of Similarity' analysis should be reevaluated. The *Patent Act* contemplates the use of Section 85(1) factors for the general evaluation of patented medicine prices. Although comparators are to be considered, the introduction of a 'Level of Similarity' assessment may compromise or overly complicate the price review of patented medicines. Any price that falls within the range generated by relevant comparators should be considered non-excessive and, as such, should not be escalated to a Hearing. It is important to include all comparators across all indications for a given medicine, as this is in line with the *Patent Act*. This should be performed only while considering the maximum dose for each medicine, as was the case under the previous Guidelines and only by focusing on the highest priced comparators to avoid the creation of a general price control measure. We strongly recommend the formation of a working group to determine how best to incorporate comparator assessments into the Guidelines.

This collaborative approach will help bridge the gap between the concerns of the PMPRB and our industry.

In conclusion, we urge the PMPRB to reconsider the proposed Guidelines in their current form and to address the concerns outlined above. We believe that working groups are essential to support the alignment of all parties and to foster a regulatory environment that promotes the availability of innovative medicines for Canadians.

Thank you for considering our submission. Our organization remains aligned with our industry associations, Innovative Medicines Canada and BIOTECanada, in this matter. Please do not hesitate to contact us or these associations if there are any questions or if further clarification is needed.

Sincerely,

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