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December 5, 2022

Dr. Mélanie Bourassa Forcier
Acting Chairperson
Patented Medicine Prices Review Board
Box L40, Standard Life Centre
1400–333 Laurier Avenue West
Ottawa, ON K1P 1C1

Via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

RE: PMPRB Draft Guidelines Consultation 2022

Dear Dr. Bourassa Forcier:

Eli Lilly Canada Inc. (**Lilly**) appreciates the opportunity to provide feedback on the PMPRB Draft Guidelines 2022. Given our concerns, we are pleased to provide input on a number of fronts.

We look forward to participating in the next steps of the consultation, which we trust will include integrated industry and PMPRB technical working groups that are given sufficient time and scope to come up with practicable and fair solutions.

Yours sincerely,

Jill Daley
General Counsel and VP, Corporate Affairs
Eli Lilly Canada

Cc: Doug Clark, Executive Director, PMPRB

Eli Lilly Canada's Submission to the
Patented Medicine Prices Review Board on the Draft Guidelines 2022

Statement of Alignment with Innovative Medicines Canada Submission

Eli Lilly Canada Inc. (**Lilly**) is aligned with all elements of the Innovative Medicines Canada (**IMC**) written submission to the draft Patented Medicine Prices Review Board (**PMPRB**) Guidelines consultation. Lilly's submission serves to provide additional perspective and detail, to complement and reinforce key elements of the IMC submission.

Disclaimer

Lilly understands that the PMPRB intends to update its Guidelines within the framework of the recent amendments to the *Patented Medicines Regulations*. While Lilly is committed to constructive engagement with the PMPRB on the draft Guidelines, Lilly's response to this consultation is not intended and should not be interpreted as supporting the amendments to the *Regulations* or current Guidelines proposals. Lilly continues to have significant concerns about the practicality and legality of the amended *Regulations*, which are the subject of an ongoing proceeding before the Federal Court of Appeal (File No. A-215-20). Lilly reserves the right to oppose any aspect of the amended *Regulations* or Guidelines that exceed the jurisdiction of the Board.

Introduction

This document is Lilly's submission to the PMPRB on the proposed PMPRB Draft Guidelines 2022 (**2022 Draft**).

The 2022 Draft represents a significant departure from the price review process envisioned by the Board's October 2020 Guidelines, as well as the previous Compendium of Policies, Guidelines and Procedures (**Compendium**). Lilly recognizes that this departure attempts to address changes to the *Patented Medicines Regulations* (***Regulations***). However, Lilly is deeply concerned that fundamental issues regarding the scope of the Board's mandate remain unaddressed while new issues are raised by increasing focus on Board staff discretion.

By increasing staff discretion while eliminating predictable approach to considering price, the Board has produced a document that is "not intended to be read as pricing guidelines." On its face, the 2022 Draft provides little information about how rights holders should approach complying with their obligations under the *Patent Act*. As a result, the 2022 Draft fails to fulfil its most important function and increases the complexity and unpredictability of launching new medicines in Canada—particularly the most innovative ones. While Lilly understands the PMPRB's goal is to "protect consumers from excessively priced patented medicines", that goal should not be achieved by making it impractical and unsustainable to sell those medicines in Canada at all.

Despite Lilly's concerns with the 2022 Draft, Lilly remains willing to work with the PMPRB and the federal government on a reasonable alternative to the approach taken in the 2022 Draft. Below, we have explained Lilly's perspective on some of the key issues that we believe must be addressed in a new guidelines package.

Unpredictability Creates Disincentives for Rights Holders

The PMPRB's guidelines have long allowed rights holders to predict the allowable ceiling prices of their medicines, within a reasonable margin of error, using objectively verifiable information. In the vast majority of cases, rights holders have been willing to operate within the Board's guidelines. Even where rights holders exceeded the guidelines, the number of cases resolved through a voluntary compliance undertaking based on the guidelines vastly outnumbers the small number of cases that were taken to a hearing.

The regulatory framework in the 2022 Draft challenges predictability and voluntary compliance in several ways. Most notably, the 2022 Draft allows for significant latitude on the part of PMPRB staff at every stage up to a formal Board hearing. This latitude comes at the expense of rights holders' ability to predict with any meaningful precision what level of pricing may be considered "excessive", whether by staff or by the Board. The 2022 Draft also lacks transparency around the policy and statutory interpretations, made by the PMPRB staff and the Board, which underpin the guidelines.

Together, these features of the 2022 Draft fuel the potential for significant differences of opinion between the Board and staff about the appropriate definition of "excessive" in a given case. Even with the clearer guidance provided by the previous Compendium, staff have recently demonstrated a willingness to advance definitions of "excessive" price that have not been accepted by the Courts. In *Horizon*, all of staff's proposed tests were rejected by the Board. Staff's posture creates a profound disincentive for rights holders to negotiate.

The potential for unanticipated, arbitrary price reductions will also interfere with rights holders' ability to prepare revenue forecasts associated with new medicines within a reasonable margin of error. Reasonably accurate forecasts are critical for Lilly to secure budget, to ensure sustainability of supply and make the substantial investments required for new medicine launch in Canada (e.g., regulatory approval, reimbursement, distribution, and market support).

Further, is is proposed meetings with PMPRB staff will no longer be held on a "without prejudice" basis and the assurance regarding the protections set out in the *Patent Act* are lukewarm. The 2022 Draft also state that the Access to Information Act may apply to discussions between patentees and PMPRB Staff. The point of all of this is that the draft Guidelines do not encourage good faith discussions with patentees to resolve matters before proceeding to a hearing and the reasons for these new settlement-avoiding mechanisms ought to be explained or eliminated.

Investigation Criteria Signal Focus on Price Reductions

The choice of investigation criteria in the 2022 Draft reinforces the perception that the Board and its staff have maintained their desire for deep price reductions. This is reflected by the same focus on the median of the PMPRB11 (**MIP**) as an upper benchmark for Canadian prices, that have characterized its other recent attempts at Guidelines reform.

As you are aware, the MIP was one of the bases on which Lilly, together with IMC and other members, challenged the Board's October 2022 Guidelines (File No. T-1419-20). In the October 2020 Guidelines, the MIP was expressed as a price ceiling that rights holders "must" comply with. Both the choice of price ceilings and the fact that they were binding on rights holders were problematic under the *Patent Act*.

In the 2022 Draft, the Board has chosen to retain the MIP as a threshold but now suggests that it is no longer a price ceiling. Reframing this price test as an "investigation criterion" has failed to address the fundamental issue concerning use of the MIP. While the new regime may purport to be non-binding, the only criteria it provides are unrelated to the Board's limited mandate to review excessive pricing that rises to the level of patent abuse.

The Board has also chosen to deploy the dTCC in a one-sided manner that can only ever result in a lower trigger for investigation that the MIP. The dTCC is calculated in a way that allows for an investigation to be triggered by exceeding generic prices, even for highly innovative new medicines, without any regard for the level of therapeutic improvement that may be offered by the new medicine.

The uncertainty created by the regime enacted via the 2022 Draft is so significant that the only way to avoid an open-ended investigation by staff is to price below the MIP/dTCC – which appears to be the Board's intention.

Rights holders face an unreasonable choice: either (i) accept these arbitrarily low criteria as ceilings in order to obtain relative certainty or (ii) accept the persistent, annual risk that the Board or its Staff will treat anything that exceeds these criteria as "excessive". Rights holders who cannot accept either option will choose not to bring new medicines to the Canadian market, to the detriment of all Canadians.

The jurisprudence, including the *Alexion* and *Merck* Court of Appeal decisions, makes it clear that the Board's statutory mandate is limited to "excessive" pricing that rises to the level of patent abuse. This limit is necessary to comply with the constitutional division of powers. The Board must ensure that its guidelines reflect the proper scope of its powers.

Automatic Investigation is a Disincentive to Early Launch

Any rights holder that launches a new medicine in Canada without adhering to PMPRB11 pricing is subject to an automatic investigation under the 2022 Draft. For these medicines, rights holders do not even have the option of pricing below the investigation criteria to provide a measure of certainty about whether their launch price will be acceptable. This is a significant disincentive to launch in Canada until after PMPRB11 prices are available.

This disincentive is magnified by the composition of the PMPRB11, which excludes the United States. The United States is an important launch jurisdiction; Canada often benefits from its close geography and integration with the United States to obtain relatively early launch of medicines. As a result of the automatic investigation policy under the Draft Guidelines, rights holders are unlikely to afford Canada that advantage in the future if it would mean launching here earlier than in the PMPRB11 jurisdictions.

Consistency for Existing Medicines

The 2022 Draft fails to provide a reasonable level of certainty with respect to existing patented medicines that are already priced in line with the Board's existing guidelines. Pricing and investment decisions for these medicines were made on the basis that ceilings under the existing guidelines reflected the Board's interpretation of the criteria in the *Patent Act* and generally would not be considered excessive.

The criteria in the *Patent Act* have not changed: as noted in the Board's Backgrounder to the 2022 Draft, "from a legal standpoint, all patented medicines are subject to the same section 85 factors". There is no reason that the prices of existing medicines, which are already compliant with the *Act*, to be arbitrarily lowered as a result of the 2022 Draft nor should they be re-evaluated by the Board or its Staff.

Nonetheless, the 2022 Draft proposes a new approach to prices for existing medicines. Lilly acknowledges that 2022 Draft provides a measure of security for these medicines by using the highest international price in the PMPRB11 as a benchmark. However and per the 2022 Draft, some existing medicines may still require price reductions in order to avoid investigation and any existing medicine without PMPRB11 prices will be investigated automatically. Even if none of these criteria are triggered, an investigation may still be triggered by a complaint.

Given the many ways that an investigation could be triggered, the Board's statements in the Backgrounder are of significant concern. The Board has positioned its approach to existing medicines as a "policy choice by the Board and a concession to rights holders", while maintaining that it perceives a "misalignment of Canadian and international prices"—in other words, a misalignment involving the prices of existing medicines that already comply with the Board's existing guidelines. These statements suggest that once an investigation is commenced, rights holders will be required to accept price reductions that would not have been enforced under the previous guidelines.

Technical Working Groups with Rights Holders are Required

The 2022 Draft was conceived without any engagement in technical working groups with rights holders. As well, the Board and its staff have refused to share impact assessments or meaningful case studies to demonstrate how the 2022 Draft will be operationalized. However, the impact analysis addressed in the IMC Guidelines submission suggests that there may be serious negative consequences for rights holders and Canadians.

As a result of this lack of engagement, rights holders do not have a full understanding of how PMPRB intends to apply a framework that is, on its face, fundamentally flawed.

In order to address these concerns and work toward a guidelines package that will achieve the best result for Canadians, the Board should return to the drawing board and adopt a thorough, methodical approach to new guidelines with the input of rights holders. New guidelines must respect the core principles of predictability and fairness; operational feasibility and efficiency; full exemption or other appropriate transition for in-market medicines; and access to new medicines in a timeframe comparable to what Canadians currently enjoy.

Lilly would welcome an opportunity to engage with PMPRB through technical working groups to generate a Guidelines package that is aligned with these core principles.