



Eli Lilly Canada's Submission to the Consultation by the Patented Medicines Price Review Board on the Draft Guidelines of November 21, 2019

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 (IMC) written submission to the draft PMPRB Guidelines consultation. Lilly's submission serves to provide additional perspective and detail, to complement and reinforce key elements of the IMC submission.

Introduction

This document represents Eli Lilly Canada's (Lilly's) submission to the consultation by the Patented Medicine Prices Review Board (PMPRB) on the draft Guidelines of November 21, 2019. While it is not Lilly's intent to address the Amended Regulations in this submission, we do wish to emphasize in the strongest terms possible that we do not support the use of Economic Factors by the PMPRB to set price ceilings. They are out of step with the intent of *The Patent Act 1987*, from which the PMPRB takes its mandate. Further, they encroach on the jurisdiction of the provinces over the delivery of health care by presuming the authority to determine "willingness to pay" and "affordability". These are serious breaches.

Lilly does acknowledge that the PMPRB is duty bound to operationalize the Regulations – and to do so through the Guidelines. However, it is also important to note that in doing so, the PMPRB Board and staff have significant discretion: these draft Guidelines are their *subjective interpretation*, one that has drawn heavily on a particular (some would say extreme) school of thought out of the University of York in the United Kingdom (UK)¹ whose claim to fame is the creation of the Quality Adjusted Life Year (QALY) and its use as a threshold measure of willingness to pay. The QALY was developed for use by the National Institute of Community and Health Excellence (NICE) in the UK's single payer public system, a significant difference from Canada's two-market structure.

In basing their interpretation on the UK model, Lilly believes that the PMPRB has given insufficient attention to **key principles and values** that define health care in Canada. Other interpretations

¹ Of the health economists engaged with the PMPRB's Technical Working Group, the majority represented this school of thought

would be more suited to key facets of the Canadian context: the public-private insurance system and its federalism. At base, these represent deep-seated principles for Canadians. Canada's long-standing social contract – to provide more help to those who need it by giving less to those who do not² – will be compromised by a blunt cost-effectiveness tool that will drive prices down equally and drastically across both of these markets, while crippling the ability of the pan-Canadian Pricing Alliance (pCPA) to continue to negotiate the substantial discounts it has achieved for public drug plans and their vulnerable recipients – more than \$2.0B annually as of 2018.

The changes to the **ceiling price methodology** proposed by PMPRB will mean private insurers will pay substantially less because of the lower ceiling price, and, because there is less revenue available to transfer from the private market, public payers will pay more than they do now. The drop in the ceiling price shrinks the overall pool of resources available to provide discounts to public payers, though providing these discounts is fully aligned with principles of other federal government programs that provide differential benefit based on need: for example, the Guaranteed Income Supplement to Old Age Security, Canada's Income Tax rates, and the Child Tax Credit. In essence, under the draft Guidelines, the PMPRB is implementing what might be termed **Reverse Robin Hood**: taking from the most vulnerable to give to those who are better off. Moreover, the private insurance market will reap more, with no obligation to pass on financial benefits to its plan recipients. The decision is baffling.

Further, in Canada's federated system, jurisdiction over the delivery of health care, including budgetary affordability and willingness to pay, rests with the provinces and territories: they steer their own ship. On December 2, 2019, Canada's Premiers met as the Council of the Federation. On health care, they were resolute in protecting their jurisdictional sovereignty: "The federation works best when provinces and territories have the autonomy and resources to pursue their economic and social objectives."

Further and of critical importance to patentees, the **methodology** that the PMPRB has chosen to implement the new framework is unacceptably complicated, creating a high level of pricing – and so – market uncertainty that is unparalleled in other like jurisdictions. In line with the IMC submission, we emphasize that the specific methods chosen by the PMPRB to implement the new economic factors are not strictly required by the regulations. There are no other jurisdictions that combine all of the factors and methodologies in the same manner that is proposed for Canada. A recent impact analysis by PDCI, based on the methodology in the draft Guidelines and not the more general measures used by Health Canada in CG1, indicate revenue impacts up to five times greater than estimated by Health Canada – some \$41.8 B over ten years³.

Further, the methodology they have chosen to implement the new framework for the ceiling price is unacceptably complicated, creating pricing – and, so, market – uncertainty that is unparalleled in other like jurisdictions. Moreover, we emphasize that the specific methods chosen by the PMPRB to implement the new economic factors are not strictly required by the regulations.

² Prime Minister Justin Trudeau included this in each exact statement in his mandate letters to his Cabinet. 22/02/2017.

³ PDCI. Impact Analysis of the Draft PMPRB Excessive Price Guidelines. February 12, 2020.

Differential Pricing: The Tale of Two Markets

To reiterate, under the current system, public payers in Canada are able to achieve heavily discounted patented medicine prices for their most vulnerable citizens. The size of the discounts that are available to public payers is dependent on private insurers paying a higher price: usually the list price. This supports the policy goal of the current government to redress the imbalance between those who have and those who have not. Although the PMPRB describes differential pricing between the public and private markets as *discriminatory pricing*, on the global stage, and in the opinion of the World Health Organization, it is more aptly seen as “*equity pricing*.”⁴

The PMPRB’s characterization of differential pricing between public and private markets as *discriminatory* pricing fails to account for the very different drivers and populations that characterize each one. Public drug plans take on the needs of economically and otherwise vulnerable citizens and do so within fixed annual healthcare budgets. Any savings they obtain from discounts through the pCPA are directed back into public coffers – often to offset budget deficits. In fact, Canada’s public health budgets absorb 70% of all health care costs for all Canadians, including those with private drug plan coverage. The public share of this burden has not declined in more than 40 years.

In contrast with public payers, private payers operate in a highly-competitive, profit-driven marketplace where individual insurers seek an edge over competitors through enhanced product offerings. As the most popular product line offered by private insurers, prescription drugs and other health offerings are often used as a “sweetener” or “loss leader” to gain access to a client base for their other lines of business: life and disability insurance and retirement benefits. For 2017, the most recent data available, the Canadian Health and Life Insurance Association (CHLIA) reported an \$18.8B surplus of premiums over benefits paid across their three lines of business; health accounted for almost half of that surplus⁵.

The implementation of the draft Guidelines, including the Economic Factors will shrink the size of the pool of resources available to manufacturers from which to transfer discounts to the public plans. It appears to be deliberate intent by the PMPRB to quash equity pricing. This decision does not rest with the PMPRB.

The Work of the Institute for Clinical and Economic Review: Affordability and Willingness to Pay:

In commenting on the PMPRB’s application of Economic Factors in setting an Excessive Price, we re-emphasize in the strongest terms that we do not support the use of pharmacoeconomic factors to set prices or ceiling thresholds. At the same time, we feel it important to identify key concerns about the specific manner in which the PMPRB has incorporated them into its framework. In doing so, we draw on the work of Steven D Pearson, Founder and President of the Institute for Clinical and Economic Review (ICER), because he specifically addresses the

⁴ Equity pricing is defined as pricing based on ability to pay. It relates to the policy goal of maximizing health impact by making medicines affordable. Globally it may be used to describe the transfer of wealth between countries of vastly different means. It is a policy of the World Health Organization and the World Bank. Rovira J. Equity pricing as a strategy for improving the affordability of drugs in developing countries”.2003: Washington, DC: World Bank.

⁵ CHLIA. Canadian Life and Health Insurance Facts. 2018 Edition. 2018: Toronto.

implications of different markets and health technology assessment (HTA) systems on determining value and prices.

From his work,^{6,7}we briefly highlight the following:

Citing CADTH's HTA process as an example, Pearson makes a distinction between QALY's established for the purposes of HTA – which are meant to inform a near-to-final price for **negotiations** with public payers – and the much higher range established by the Institute for Clinical and Economic Review to set a ceiling threshold for defining a maximum non-excessive price. As per the ICER framework, QALY thresholds for setting a true ceiling price would be expected to be much higher than those meant to inform price negotiations with payers.

Finally, Pearson has been emphatic regarding the inappropriateness of using the same thresholds, be they affordability or willingness to pay, across payers: “there was no illusion that a single threshold should be applicable across different payers, nor was it ever envisioned as a cap on spending for individual drugs.”⁸ This observation is of key importance to the Canadian system.

The Technical Content of the Draft Guidelines

Though Lilly opposes the very fundamentals of the draft Guidelines, we feel it also important to address concerns regarding the particular rules and procedures proposed within the text

Existing Patented Medicines

Regarding the establishment of a Maximum List Price (MLP) for existing medicines, the draft Guidelines state (p. 15):

The MLP for all grandfathered patented medicines will be set at the lower of (i) the MIP for the PMPRB11 countries for which the patentee has provided information, or (ii) the patented medicine's ceiling under the Guidelines applicable prior to the issuance of these Guidelines. (s. 59)

Patentees will be granted until the subsequent reporting period after the MLP is set to ensure the List Price of the grandfathered patented medicine is lowered to a level that is no higher than the MLP or may be subject to additional review or investigation by Staff. (s. 61)

Patented medicines that received a Drug Information Number (DIN) prior to the publication of the amended *Patented Medicines Regulations* on August 21, 2019, should be grandfathered. Investments associated with regulatory approval, reimbursement, distribution and customer support for these medicines were made prior to the initiation of discussions regarding changes to the PMPRB regulatory framework. At a minimum, existing medicines should be offered a fair and appropriate transition. Lilly's portfolio includes medicines that would undergo list price

⁶Pearson SD. The ICER value framework: integrating cost effectiveness and affordability in the assessment of health care value. *Value in Health*.2018: 258 – 265.

⁷ ICER. 2020-2023 Value Assessment Framework. Institute for Clinical and Economic Review: Boston, MA. 2020.

⁸ Pearson. op cit. p 265.

reductions in excess of 30% under the provisions of the draft Guidelines. Existing medicines should not be required to lower list prices any earlier than 2022, and the annual reduction in list price should be capped at five percent or less.

In this context, it is important to address the category of medicines receiving a DIN after August 21, 2019, but prior to July 1, 2020 (“gap medicines”). Lilly’s portfolio includes a gap medicine for which Canadian launch planning began in early 2017. This medicine - a treatment for the potentially life-threatening condition of severe hypoglycemia - was invented in Canada, and subsequently acquired by Lilly to advance through development, worldwide market approvals and commercialization. Investments associated with the launch of gap medicines like this one are being made without knowledge of the complete PMPRB framework that will apply. As a result, these medicines should be afforded the same treatment as medicines receiving a DIN prior to August 21, 2019.

There should be no use of non-excessive average price (NEAP) or maximum average potential price (MAPP) pricing and no re-assessment of existing and gap products. Price reductions should not be required in cases where list prices are already lower than the price target identified in July 2020.

Transition provisions should be clearly expressed in final Guidelines for patentees to rely upon for compliance and financial considerations.

New Patented Medicines

Risks to Confidentiality of Commercially Sensitive Net Price Information

In a section regarding the new requirement that patentees report price and revenues net of all price adjustments, the Regulatory Impact Analysis Statement (RIAS) that accompanied the amended *Patented Medicines Regulations* states (p.21):

However, low-priority medicines are anticipated to face lower price ceilings that reflect actual market prices of their competitors. New medicines introduced in a therapeutic class with existing comparator products will be tested against the price of all medicines in that class, net of all discounts.

Lilly notes that the draft Guidelines do not propose the use of net price information to determine price ceilings. PMPRB staff have communicated to industry that this approach was taken due to concerns regarding the potential exposure of patentees’ confidential pricing information. The Guidelines should include an explicit statement that the PMPRB will not use net price information to determine price ceilings for any medicine, owing to confidentiality concerns.

The draft Guidelines propose to regulate the net prices of patented medicines via the Maximum Rebated Price (MRP) concept. With reference to the calculation of the MRP, the draft Guidelines state (p. 14):

- *The Incremental Cost-Effectiveness Ratio (“ICER”) measured in cost per quality-adjusted life years (“QALYs”) for each indication of the patented medicine will be identified from the cost-utility analyses filed by the patentee.*
- *The ICER will be compared against the applicable Pharmacoeconomic Value Threshold (“PVT”) of \$60,000 per QALY.*

- *The price at which the patented medicines's ICER would be equivalent to the PVT will be identified (the "Pharmacoeconomic Price" or "PEP").*

Clearly, the MRP of any patented medicine could be back-calculated on the basis of information readily available in the public domain – namely, the cost-utility analysis, the proposed Pharmacoeconomic Price equation and the Pharmacoeconomic Value Threshold. The draft Guidelines would, therefore, result in unacceptable risk of exposure of the Maximum Rebated Price, which is sensitive commercial information. We are unaware of any regulator worldwide that exposes net price information in this manner.

Inconsistency with Excessive Price Standard

Regarding the calculation of the Maximum List Price (MLP), the draft Guidelines state (p. 12):

The MLP will be set by the lower of the MIP or the median domestic Therapeutic Class Comparison ("dTCC") but is subject to a price floor set by the lowest international price ("LIP") for the PMPRB11 countries for which the patentee has provided information at the end of the interim period.

The median dTCC price test is novel, and did not appear in any early drafts of Guideline concepts released by the PMPRB. In practice, it will drive allowable price ceilings for many medicines down to the Lowest International Price, particularly in therapeutic areas that are highly genericized. The median dTCC test is clearly inconsistent with the PMPRB's mandate to define non-excessive prices.

For a medicine in Lilly's portfolio of investigational compounds, the use of the median dTCC test would have the effect of lowering the allowable price to the Lowest International Price in the PMPRB11 basket. This has triggered a review of the feasibility of launching this medicine in Canada.

Operational Barriers to Implementation of MRP Concept

As noted above, the draft Guidelines propose to regulate the net prices of patented medicines via the Maximum Rebated Price (MRP) concept. The draft Guidelines state (p. 13, s. 48):

In addition to iMLP/MLP, Category I patented medicines are also subject to a "Maximum Rebated Price" ceiling ("MRP"). ... Patentees must ensure that the patented medicine's Net Price in Canada (i.e. its average transaction price or "ATP") is no higher than the MRP, failing which the price may be subject to additional review or investigation by Staff.

Implementation of the MRP concept is not feasible in the Canadian drug funding system.

Provincial/federal/territorial government-funded drug plans will only consider reimbursement of a medicine following a positive recommendation by a Health Technology Assessment (HTA) agency, and a price negotiation through the pan Canadian Pharmaceutical Alliance (pCPA - a buying coalition of government-funded drug plans). In Lilly's recent experience, it takes upwards of two years to achieve reimbursement on government-funded drug plans following the issuance of a DIN by Health Canada. Moreover, reimbursement may never be achieved, if the HTA agency does not recommend funding or if a pCPA negotiation closes unsuccessfully. Months or years may elapse before rebates to government-funded plans are paid, and where formulary listing are not achieved, rebates are never paid.

Among private drug plans, not all negotiate Product Listing Agreements, as they have other mechanisms available to control drug plan costs for their clients that are less burdensome and costly from an administrative perspective. Among those that do negotiate such agreements, not all are able to furnish manufacturers the information required to develop Product Listing Agreement proposals. Point-of-sale systems used by private payers to capture price discounts cannot guarantee complete confidentiality of sensitive pricing information.

Challenges to Predictability and Voluntary Compliance

Under the current PMPRB regime, allowable ceiling prices can be predicted by patentees, within a reasonable margin of error. The price tests used to establish non-excessive price ceilings are based on objectively verifiable information - namely, the prices of the patentee's own medicine in other markets and the price of comparable medicines in Canada. This predictability has underpinned a system of voluntary compliance by patentees, which has been functioning well for three decades. Excessive pricing investigations and hearings are exceptional.

Predictability has also meant that revenue forecasts associated with new medicines can be prepared within a reasonable margin of error. This has allowed Lilly to secure budget and make the investments required for new medicine launch in Canada (regulatory approval, reimbursement, distribution and market support).

The regulatory framework in the draft Guidelines challenges predictability and voluntary compliance in several ways, notably:

- *Pharmacoeconomic Price (PEP) concept:* Pharmacoeconomic studies are, by definition, built on multiple assumptions. The uncertainty associated with the results is typically expressed as a range of values, which in Lilly's experience, can be very broad. For Category I medicines subject to the PEP, patentees would not be in a position to predict, within a reasonable margin of error, an allowable ceiling price at launch.
- *Market Size Adjustment Concept:* As demonstrated in the case studies appended to the IMC Guideline consultation submission, the application of the Market Size Adjustment results in an allowable price ceiling that is a moving target. In practice, patentees would be forced to rely on PMPRB staff to notify them of an allowable ceiling.
- *Reassessment Triggers:* The draft Guidelines introduce multiple triggers for the reassessment of an allowable ceiling price, most notably the approval of a new indication (use) for a medicine, or sales exceeding the Market Size Threshold of \$25 million (p. 16, s. 63).
- *Staff Discretion:* The draft Guidelines allow for significant latitude on the part of PMPRB staff, notably in the conduct of the dTCC and International Therapeutic Class Comparison (iTCC) tests. For these tests, it is proposed that PMPRB staff make judgment calls at several steps in the process (p. 25-27).

Guidelines Consultation Process

The draft Guidelines were conceived in the absence of meaningful engagement with the regulated stakeholder, namely patentees. As a result, the proposed price regulation framework is fundamentally flawed, and presents significant operational barriers.

The case studies appended to the IMC Guidelines submission highlight some perverse – and presumably unintended – consequences. The draft Guidelines could result in a generic medicine having a higher price than would be allowable for an innovative medicine in the same therapeutic area. A breakthrough medicine could be forced to the Lowest International Price. And, medicines that achieve better health outcomes at a lower cost versus the standard of care (i.e. medicines assessed as dominant in a pharmacoeconomic analysis) would be penalized for displacing inferior and more costly technologies already in the market.

It should also be noted that patentees have been asked to comment on an incomplete package. The draft Guidelines suffer from omissions, and they contain concepts the application of which could be interpreted in materially different ways. Moreover, the draft Guidelines were not accompanied by a Guide to Reporting.

There is no requirement to implement a new regulatory package by July 1, 2020, and sufficient time must be taken to get the regulatory package right for Canadians. Patented medicines are an integral component of our healthcare system. A new regulatory framework governing price ceilings for patented medicines should not be implemented until it is complete and coherent, and stakeholders can be assured that it respects a reasonable set of core principles: predictability, fairness, and transparency; operational feasibility and efficiency; full grandfathering or 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.

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