

PMPRB Price Review Approach During the Interim Period following publication of Amendments to the *Patented Medicines Regulations* July 2022

1. Introduction

The Canadian Forum for Rare Disease Innovators (RAREi) appreciates the opportunity to comment on the Patented Medicine Prices Review Board's (PMPRB's or the Board's) proposed approach to price reviews of patented medicines during the period between the coming into force of the new *Patented Medicines Regulations* and the final publication of a corresponding set of new PMPRB guidelines.

RAREi members appreciate the PMPRB's focus on pragmatism and feasibility regarding its regulatory mandate during the interim phase, and we hope that this approach carries forward in consultations later this year on a new set of guidelines. As well, we trust that any ongoing investigations into potential excessive price issues can be dealt with efficiently, so that all patentees, the regulator, and other stakeholders can focus efforts on developing guidelines that provide certainty, predictability and a pricing environment that encourages research and access to rare disease medicines in Canada.

As we have said in previous submissions, the PMPRB changes have created a period of unprecedented uncertainty throughout the past seven years. We are hopeful that the final changes to the regulations, as part of the broader federal government approaches and key court decisions on the PMPRB's mandate, inform any approach taken by the PMPRB going forward. Specifically:

- a. **Biomufacturing and Life Sciences Strategy (BLSS):** Improving Canada's price regulations for patented medicines is particularly important as Canadians and our health systems are battered by the effects of the global pandemic. The pandemic highlighted gaps in Canada's health and innovation ecosystem that had developed over time. To address the pandemic and health care challenges of the future, the government launched its new life sciences strategy last July, including a commitment to pursue 'world class regulation' for the sector.
- b. **Pan-Canadian Rare Disease Drug Strategy:** The federal government also made a substantial multi-year commitment to invest in improving patient access to orphan medicines in its Budget 2019 pledge to spend \$1 billion between 2022-23 and 2023-24, and \$500 million per year thereafter, on a new national rare disease treatment strategy. As RAREi, has stated in past commentaries to the Board, the previously proposed price review regime reforms imposed severe and negative effects on patients, especially those suffering from rare disorders, by putting Canada at a competitive disadvantage in terms of medication launches and clinical research. Almost all other developed jurisdictions, notably the EU and the United States, provide numerous intellectual property incentives including market exclusivity for orphan medicines. Canada provides no additional IP incentives for rare diseases and does not even provide orphan drug designations and enhanced pathways for reimbursement and access. The PMPRB's ongoing focus on rare diseases as an area it determines is at particular risk for excessive pricing is at odds with the strategies of other jurisdictions that provide specific incentives for developing and commercializing medicines for small patient populations.

- c. **Court decisions:** Several legal decisions have clarified the mandate of the PMPRB. Collectively, the courts confirmed that the proper role of the PMPRB is to guard against abuse of patent rights through excessive pricing practice. They stressed that the Board does not have a broader consumer protection mandate and the federal government does not have the authority to determine “reasonable” pricing, which is generally the role of payers and specifically the provinces when considering our health systems. Prices are already negotiated through the pan-Canadian Pharmaceutical Alliance, and nearly all major private insurance organizations have negotiation teams as well.

In this context, RAREi has specific comments on the proposed interim approach.

2. Response to the proposed changes

RAREi supports the concept of a “status quo” approach, with the following considerations to help PMPRB move forward in the interim period.

- a. **Take a true “status quo” approach and only apply new rules on a go-forward basis:** RAREi recommends that the Board apply the new basket of comparator countries prospectively only. That would mean that prices of medicines marketed before July 1, 2022 which were compliant with the previous guidelines and regulatory regime would not be subject to the new regime. Imposing new rules of existing medicines would lead to significant operational challenges and could result in supply disruptions.
- b. **CPI increases should continue to be allowed:** Given the inclusion of the consumer price index as a factor in the *Patent Act*, the PMPRB’s longstanding practice has been to allow price increases based on a three-year rolling average of changes in the consumer price index (CPI). No rationale has been provided in the consultation document to support the proposed “freeze” to the established non-excessive average price (NEAP) for medicines. The lack of access to CPI increases is very problematic when patentees like all stakeholders in the Canadian economy are challenged by a period of very high inflation.
- c. **Commit to avoiding excessive pricing investigations and board hearings on patented medicines sales for medicines that do not have a NEAP:** While the Board has committed to avoid undertaking pricing investigations during the interim phase, it has not waived the capacity to penalize patentees for potential findings of inadvertent excessive pricing during that time frame. That potential continues the uncertainty that patentees face when trying to assess what might be an acceptable launch price in the Canadian market that has persisted since the regulations were altered in August 2019. The only regulatory guidance on what might be considered excessive in the interim period is found in case law, in past board orders and judicial reviews. This provides some general guidance for how patentees should price medicines in the interim period, and in the absence of a *prima facie* case of price excessiveness as a function of patent abuse, the PMPRB should avoid investigations and excessive price determinations that would retroactively apply final guidelines. Providing clarity on this point would be helpful in the interim guidelines in order to address a period of uncertainty and risk for medicines that have had a first sale in 2022 but do not have a NEAP and for medicines that are set to launch in Canada before final guidelines are in place. Under the current proposal, too many patentees are flying blind and operating at risk of being found non-compliant with rules that have yet to be established. The uncertainty created when patentees are unsure about what price point might be considered excessive in the development or early-launch phase of marketing results in Canadian launches being delayed or abandoned altogether.

d. **Ensure the PMPRB's guidelines and regulatory approaches are informed by research and case studies:**

There are several recent bodies of research that RAREi wants to bring forward in the context of these consultations that we believe should inform the PMPRB's approach.

- i. **Impact of price regulations on launch decisions:** First, there is growing body of evidence showing that price limitations are a disincentive to launch new medicines and to invest in research and development. A recent Canadian academic review of the impact that relative medication prices have on new product launches suggested that higher prices in a given jurisdiction increases the relative number of launches. The researchers used statistical modelling to assess the relative effect of price and market size on the timing of product launches in different jurisdictions. The modeling exercise indicated that that a 25% decrease in list prices in given country would lead to a 6-10% and 4.5-6% decrease in the number of new medicines launched during a 1- and 7-8-year period, respectively.¹
- ii. **Impact of uncertainty and Canada's declining access to globally launched medicines:** That evidence was given practical application by an IQVIA review of new medication launch trends indicating that Canada has not kept up with comparable jurisdictions since the federal government announced its pharmaceutical price review reforms in 2017. Between 2017 and 2021, the number of new active substance launches in Canada declined each year and lagged the number launched globally, (particularly in the United States). Fewer than 60% of the products introduced in the US since 2017 had launched in Canada by the end of 2021. In the five years prior to 2017, Canada launched more than 80% of the products marketed in the US. In addition, Canadian launches occurred after a median delay following the first global launch of 2.1 years since 2012, ranking it ninth out of the top-23 launch countries. Previously Canada ranked either fourth or fifth globally. As Life Sciences Ontario (LSO) president Dr. Jason Field, commented in response, "as we had feared, it's a natural reaction that companies would delay launching new treatments in the uncertain environment we have had for the past four years. We need a stable environment that welcomes innovation in order for patients to benefit promptly from new treatments."²
- iii. **Case studies to help inform best regulatory practices:** Taking a case study approach to understand how regulatory signals are considered by patentees will help ensure the PMPRB can develop guidelines that work well in the real world. RAREi contributed to efforts to take a case study approach for how rare disease medicine prices are regulated working with Dr. Nigel Rawson and a team of researchers on case studies at several points throughout the regulatory proposals since 2017.³ Throughout the regulations' evolution, studies published in 2020⁴ and most recently in July 2022⁵ demonstrate that the regulatory environment proposed by the PMPRB has caused significant uncertainty resulting in either delays in launches of rare disease medicines in Canada or simply no launch at all. We recommend the PMPRB adopt and incorporate case studies to help inform how the updated regulations and interim

¹ Grootendorst P & Spicer O, *The effect of patented drug price on the share of new medicines across OECD countries*, Health Policy, Volume 126, Issue 8, August 2022, pp. 795-801: <https://www.sciencedirect.com/science/article/pii/S0168851022001154>.

² Life Sciences Ontario Webinar, *New Medicine Launches: Canada in a Global Context*, June 22, 2022: https://lifesciencesontario.ca/wp-content/uploads/2022/05/EN_LSO_Global-Launch-Benchmarking_Webinar-June22-20_Final.pdf.

³ <https://www.canadianhealthpolicy.com/product/new-patented-medicine-regulations-in-canada-case-study-of-a-manufacturer-s-decision-making-2/>.

⁴ <https://www.canadianhealthpolicy.com/product/new-patented-medicine-regulations-in-canada-updated-case-study-en-fr-2/>.

⁵ <https://www.canadianhealthpolicy.com/product/effect-of-amended-patented-medicine-regulations-on-industry-decisions-to-launch-new-drugs-in-canada/>.

and final guidelines can be understood and navigated by patentees operating in a competitive global context. This is especially important for rare disease innovators in the context of the new basket of comparator countries. Often, the United States is the only comparison available for a given rare disease medicine. This raises real questions about how innovators will be able to determine compliant launch price before launching in Canada.

3. Questions and Concepts for Consideration

Given the issues above, the proposed price regulation approach during the interim phase raises a number of questions on which we would appreciate clarification:

- a. What is the rationale for not allowing inflationary increases for existing medicines, especially in the context of a high-inflation environment that affects the cost of doing business in Canada and globally?
- b. How will price reviews of medicines that do not have a NEAP (i.e., products launched in the first half of 2022 or during the interim phase) be handled?
- c. What certainty can the PMPRB provide to patentees about the risks associated with potential future findings of excess revenues because of a price review related to products launched during the interim phase?
- d. How does the Board propose to address the value of free and compassionate goods in the context of its price review activities?
- e. How much time will patentees be afforded to ensure compliance with the new guidelines?

4. Concluding remarks

RAREi hopes that its feedback will be helpful in assisting the Board determine a way forward that will achieve its mandate to ensure that patentees are not abusing the market exclusivity rights accorded to them by patents, but in a thoughtful and considerate way that does not discourage innovators from launching products in Canada and investing here.

The proposed adoption of a pragmatic way forward during the interim phase offers some hope for a renewed relationship between the PMPRB and the patentees. In addition, RAREi members were encouraged by the promise of “certainty and predictability” outlined in the context of the regulatory impact analysis statement that accompanied the published regulations in late June 2022.

As you know, the federal pharmaceutical price review reforms have been a major challenge for patentees here in Canada and at the global level for several years now. RAREi’s hope is that all this new approach will set the stage for a constructive dialogue between the Board and patentees, both in the context of discussions regarding specific products as well as the upcoming guidelines consultations.