The Suspension and Reformulation of the PMPRB Guidelines is Urgently Required:

IMC Response to PMPRB 2022 Guidelines Proposals

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Introduction

This submission is made on behalf of Innovative Medicines Canada (IMC) in response to the 2022 Proposed updates to the PMPRB Guidelines (the Draft Guidelines).[1] IMC is the national association of biopharmaceutical and vaccine companies representing the majority of rights holders subject to the PMPRB's jurisdiction. IMC members are working steadfastly with Federal, Provincial and Territorial governments, to address the COVID-19 pandemic and bring a range of innovative therapies and vaccines to Canadians. Guided by a strict Code of Ethical Practices, we work with governments, insurance companies, healthcare professionals and other stakeholders to enhance the wellbeing of Canadians.

The suspension and reformulation of the Guidelines is required

IMC calls on the PMPRB to suspend and fundamentally reconsider its Draft Guidelines and establish a more robust consultation process in 2023. We further call on the Federal Government to intervene to provide more leadership and oversight of the PMPRB file. This is essential because the Draft Guidelines are inconsistent with the government's health and life sciences priorities, including the National Strategy on Drugs for Rare Diseases and the Biomanufacturing and Life Sciences Strategy. A coherent, whole-of-government approach following meaningful stakeholder consultation would be appropriate given that Draft Guidelines constitute the most significant change to PMPRB's framework in many years, would have an impact of up to $27 billion over ten years (see below), and will have a major impact on patient access to new medicines in Canada.

Guidelines inconsistent with an excessive price standard

The Draft Guidelines have not been designed from the perspective of, or with any reference to, the PMPRB's mandate regarding excessive prices and the detection of specific instances of patent abuse. Rather, the Draft Guidelines appear to be designed to regulate pharmaceutical prices downward. This runs counter to recent appellate court decisions that have constrained the role of the PMPRB within its proper constitutional and legislative limits, given that property and civil rights is an area of exclusive provincial jurisdiction.

For example, the draft Guidelines have not apparently taken into consideration rulings which confirm that *Patent Act* section 85 factors are to be applied solely when dealing with negative effects of excessive prices flowing from the patent monopoly.

The Draft Guidelines also propose pricing above the median as an investigation trigger.[2] Effective enforcement of prices at the median of the PMPRB11 or lower in many cases is inconsistent with controlling patent abuse in accordance with section 85 of the Patent Act. The proposed criteria are indicia of "reasonable pricing, price-regulation and consumer protection at large", which are contrary to the limits on the PMPRB's mandate.[3]

No predictability and inappropriate role for PMPRB staff

The Draft Guidelines also purport to reflect a shift away from price tests to a series of investigation triggers that appear arbitrary, are not tied to an excessive price standard, and will increase uncertainty for rights holders. These changes inappropriately empower PMPRB staff to develop product specific pricing policies in an untransparent manner, while preventing rights holders from determining likely compliance requirements in advance of making decisions for a given patented medicine such as whether or not to launch a patented medicine in Canada.

The PMPRB has primarily functioned in the past on the basis of very high rates of voluntary compliance by rights holders.[4] The proposed system will in many cases require companies to meet with PMPRB staff on a product-by-product basis. If the patentee does not accept the PMPRB staff recommendation, it may be subject to Board and eventual Federal Court proceedings. Given the time and resources required to participate in such proceedings, companies will be under duress to accept staff recommendations. Moving away from the previous voluntary compliance system will likely result in a less predictable, more litigious, and administratively onerous system.[5] It is also foreseeable that future access to new medicines for Canadian patients will be significantly delayed for the same reasons.[6]

Downward pricing measures over time contrary to *Patent Act*'s consumer price index provisions

The Draft Guidelines would allow the PMPRB to inappropriately force ceiling prices downward over time through annual price reviews. Such downward pricing measures are inconsistent with the *Patent Act's* consumer price index (CPI) provisions, and previous Guidelines that allowed for CPI adjustments. Provisions to reassess therapeutic comparators are similarly problematic and pose challenges for the launch of new indications.

Inappropriate use of therapeutic class comparisons

The Draft Guidelines include proposals for therapeutic referencing based on a domestic Therapeutic Class Comparison (dTCC) to lower prices below the PMPRB11 median. These proposals remove any recognition of innovation or differentiation based on therapeutic improvement and would result in new innovative medicines being inappropriately compared to older technologies including potentially generic drugs, whose prices are set and managed by other, non-PMPRB related mechanisms.[7] Nothing in the *Patent Act* requires the PMPRB to apply therapeutic referencing in this manner proposed. The launch of new indications for existing products could also be negatively impacted through unnecessary and unpredictable reassessments of the dTCC over time.

Differentiation between types of innovative medicines

The Draft Guidelines propose radically different treatment for existing medicines (i.e., those with an NOC issued prior to July 1, 2022) and new medicines (i.e., all other medicines). The former category will generally be assessed using the highest international price. PMPRB's Backgrounder document released with the Draft Guidelines notes that this is an administrative differentiation, as opposed to one required by the *Patent Act* or the *Patented Medicines Regulations*. It is further explained that this represents a policy choice, and that "[T]he Board is of the view that the misalignment of Canadian and international prices is best addressed by applying more probing investigation criteria to new medicines on a go forward basis."

The higher regulatory threshold and differential treatment of all new medicines, as defined solely by approval before or after July 1, 2022, and without any other applicable considerations or factors, is both arbitrary and concerning. The Draft Guidelines also contain price-test like provisions in relation to the lowest international price that are inappropriate for an excessive price ceiling regulator.[8]

No impact assessment despite foreseeable negative consequences

PMPRB has not provided an impact assessment of its proposals and has stated to industry stakeholders that an assessment will not be conducted prior to Guidelines implementation. Instead, the PMPRB proposes to assess the impact of the changes after implementation through a Guideline Monitoring and Evaluation Plan (GMEP).[9] This is inconsistent with modern and transparent regulatory processes, and genuinely concerning given that the new Guidelines, once finalized, will likely be in place for many years to come.

In light of the absence of a PMPRB impact assessment prior to implementation, IMC has commissioned a third-party analysis. The analysis suggests that many new patented medicines would be automatically subject to PMPRB staff investigations, despite being within the range of international pricing norms.

- Approximately 25% of products have no international comparators at launch in Canada (e.g., other than the U.S. which is no longer part of the PMPRB's reference schedule), and will therefore be automatically subject to PMPRB staff investigations.

- More than 30% of products have likely therapeutic class comparators lower than the median, calling into question what the allowable price for those products might be.

- More than 11% of patented medicines would have prices impacted by generic comparators. This figure is projected to increase over time as current innovations go off patent but remain therapeutic comparators for new medicines.

- The Draft Guidelines do not provide guidance on what price tests might apply to products under investigation. As such, the estimated range of their impact is from $21 - $27 billion over ten years, which exceeds previous estimates of impacts based on changes to the *Patented Medicines Regulations.* Corresponding product launch and investment impacts are also foreseeable given the absence of overall regulatory predictability.

Better availability of innovative medicines for Canadian patients and the path forward

Reference is sometimes made to PMPRB's consumer protection role, notwithstanding recent cases that clarify that its mandate should be focussed on excessive pricing. But we must never lose sight of the fact that consumers are also patients who need better access to innovative medicines. Canadian patients are already disadvantaged by having demonstrably limited access to new innovative medicines in comparison with patients in other developed nations. Less than one in five (18%) new medicines are reimbursed by Canadian public drug plans.[10] The lack of access to new medicines should be deeply concerning for all Canadians, since it is:

- The lowest availability percentage among G7 nations;
- Significantly lower than the OECD average; and
- Lower than any of the PMPRB11 comparator nations.

The inappropriate and unclear measures set out in the Draft Guidelines will only exacerbate this issue, given the degree of uncertainty inherent in the new system.

The substantial gap in policy and intent between Canada and peer nations is at the core of industry and stakeholder concerns, and emphasizes why the federal government needs to take a whole of government approach to this complex issue. The future consequences for Canadian patient health outcomes must be appropriately considered and addressed.

The proposed Draft Guidelines undermine the Federal Government's efforts to transition after years of PMPRB policy challenges and, if implemented, will result in more controversy and legal issues. While

there have been past discussions with stakeholders on previous Guidelines proposals, the previously proposed changes were completely different from the present draft Guidelines, and are therefore not a substitute for full and appropriate consultation on the present October 2022 proposals.

Given the significant fundamental concerns of rights holders and other stakeholders, the PMPRB cannot move forward in a few short weeks while also meeting its consultation obligations. As has been committed to in the past but not delivered, a public policy hearing of the PMPRB Board is needed for rights holders and the general public to hear directly from, and engage with, the Board on its rationale for the proposed Guidelines approach.

We hope that the proposed reset of the Draft Guidelines process will allow all parties and stakeholders to engage in a collaborative, first-principles discussion on a more viable Guidelines for the future. While the development of alternatives may be possible, more time is needed for meaningful consultation and dialogue. Thank you for your consideration of our submission, and we look forward to continuing discussions on this critical issue for industry, stakeholders, and Canadian patients.

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[1] IMC understands that the PMPRB intends to apply Guidelines following amendments to the Regulations which came into force July 1, 2022. While IMC is committed to constructive engagement with the PMPRB on the Guidelines, IMC's engagement is not intended and 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, the Guidelines, or the August 2022 interim guideline approach. IMC reserves the right to oppose any aspect of the amended Regulations or Guidelines that exceed the jurisdiction of the Board. There are a number of Guidelines-related issues that had been identified in previous IMC submissions that have not yet been addressed and which require future consultation (please see IMC's February 2020, August 2020, February 2021, August 2021 and July 2022 submissions).

[2] The Board previously rejected adopting a similar policy that would have limited prices of most new patented medicines to the lower of the median international price test and the therapeutic class comparison test. The Board concluded that the proposed Guideline would, on average, push prices below the median international price in a manner inconsistent with the PMPRB's mandate as a ceiling price regulator of "excessive" price. See PMPRB Bulletin 9 (October 1992) and Bulletin 12 (September 1993).

[3] As set out by the Federal Court of Appeal in the case of *Alexion Pharmaceuticals* 2021.

[4] The PMPRB reviews the prices of over 1,000 new and existing medicines in each year. On average, over 90% of patented medicines reviewed annually between 2003 and 2021 were priced consistent with the Guidelines. This increases when accounting for voluntary compliance undertakings (VCUs). Ultimately, fewer than 1% of patented medicines have ever been the subject of a hearing before the Board for contravening the Guidelines.

The Board has only ever found that the price under review was not "excessive" once, following a hearing that took over a decade to conclude. See PMPRB Annual Reports for 2003–2021, available online: https://www.canada.ca/en/patented-medicine-prices-review/services/annual-reports.html. See the PMPRB's Decisions and Orders, available online: http://www.pmprb-cepmb.gc.ca/en/hearings/decisions-and-orders.

[5] The necessity under the Guidelines for rights holders to launch 'at risk' of future price adjustments and repayment of revenues conflicts with business predictability and standard accounting practices for publicly traded companies.

[6] To bring a product to market, companies must marshal significant human and financial resources, starting two or more years in advance of a product launch. If companies do not know what an allowable price will be, and the only way to avoid an investigation/hearing is to price at an arbitrary level that is below the innovative value of a product, this uncertainty poses a significant barrier within the launch decision-making process.

[7] In Canada, generic prices are often 75% to 90% lower than the original brand price. See the pan-Canadian Tiered Pricing Framework (TPF), online: https://www.pcpacanada.ca/generic-drug-framework; NPDUIS, Generics 360: Generic Drugs in Canada, 2018 available online: http://www.pmprb-cepmb.gc.ca/CMFiles/NPDUIS/Generics360-2018-en.pdf.

[8] Draft Guidelines state: "The list price exceeds the midpoint between the top of the [domestic therapeutic class comparison] dTCC and lowest international price for the PMPRB11, and the top of the dTCC is more than 50% lower than the lowest international price."; "Conditions Apply: The dTCC is more than 50% lower than the lowest international price, and the list price exceeds the midpoint between the dTCC and lowest international price."

[9] As noted in IMC's June 2021 GMEP submission, any future Guidelines assessment should be conducted separately from the PMPRB.

[10] A medicine is considered publicly reimbursed in Canada if 50 percent or more of the population lives in a province where it is publicly reimbursed.