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# **Government of Canada: Consultation on Amendment to the Interim Guidance re New Medicines**

**Submitted by: Neighbourhood Pharmacy Association  
of Canada**

**August 21, 2023**

**Submitted to:  
Patented Medicines Prices Review Board**

## **Introduction**

The Neighbourhood Pharmacy Association of Canada (Neighbourhood Pharmacies) represents leading pharmacy organizations across the country, including chain, banner, long-term care, grocery chains, specialty pharmacies, and mass merchandisers with pharmacies. We advance the delivery of care through more than 11,500 pharmacies and their teams, that serve as integral community health hubs in urban, suburban, rural, remote and First Nations neighbourhoods. As the association representing pharmacy operators across the country, we act at a pan-Canadian level to support policy makers with the development of innovative solutions that allow pharmacists to support primary care while advocating for fair and sustainable funding for community pharmacies.

We are pleased to provide the Patented Medicine Prices Review Board (PMPRB) with feedback on the proposed update to the approach for conducting interim price reviews on new medicines, pending the development of new Guidelines.

### ***Impact of PMPRB Policies on Patient Access to Medications and Care***

Canada's pharmacies depend almost entirely on the funding generated through dispensing fees and mark-ups tied to drug prices to support the vast majority of the clinical and patient care services they provide. Pharmacies use these funds to pay their staff (including pharmacists, technicians, assistants and all support positions), acquire and maintain their inventories and operate their facilities (e.g., cover rent, utilities, etc.) in order to deliver care and services. While dispensing fees and allowable mark-up percentages are provincially negotiated, any changes at the federal level on medication pricing policies have profound consequences on pharmacy's ability to sustain the delivery of medications, care, and services.

Before their delay, the impending PMPRB guidelines were anticipated to remove an estimated \$113 million in funding from the pharmacy sector on an annual basis.<sup>1</sup> At the same time, the pharmacy sector is also bracing for hundreds of millions of funding losses resulting from other federal and jurisdictional pharmaceutical price compression and cost-containment policies. These funding losses come at a time in which the pharmacy sector is operating under considerable strain due to increases in labour, warehousing, and fuel costs, combined with record inflation and workforce shortages. Operating costs are rising, critical funding tied to medication pricing is decreasing, and the pharmacy sector has no avenue through which to offset these losses, severely constraining the sector's ability to provide care and service.

**Without our services, Canadians cannot get their medications or access the pharmacy care they need to effectively manage them.**

Our comments are intended to help the PMPRB minimize the negative downstream impacts that patented medicine pricing policy changes will have on Canadians' success to medication and care through their community pharmacies.

### ***Predictability and Consistency***

We were pleased to see the PMPRB's stated objective to provide rights holders with greater predictability. It is critical that both interim and upcoming guidelines be clear and give pharmaceutical rights holders (i.e., patentees) unambiguous direction on what they need to do to be compliant so that they, and by extension, the pharmacy sector, have better predictability for their business planning. Uncertainty in pricing compliance requirements could impact the launch of new medications in Canada and compromise the conditions to attract future

innovations. Delays in access or no access to critical therapies will have significant repercussions to vulnerable Canadians with complex conditions and intricate medication needs, as well as populations in remote, rural, and First Nations communities. Reductions or delays in the availability of community-based innovative medication.

To support predictability and better list price stability over time, **we recommend the PMPRB ensure that any in-market medicines, including those reviewed prior to the final publication of the Guidelines, are excluded from reassessment against the PMPRB11.** As the sector works with interim guidelines, it is important to avoid having to course correct and reprice drugs if the final published guidelines differ significantly from the interim guidelines.

The Interim Guidance proposal does not specify whether the prices of new medicines that are considered “reviewed” are at risk of reassessment over time, with the effect of lowering the price ceiling as prices decline in the basket of reference countries. Provisions that guarantee that PMPRB will not reassess or ‘re-benchmark’ medicines once reviewed, provided the rights holder does not increase its price by more than the consumer price index, would support sustainable patient access to medication and care by providing greater predictability.

### ***Meaningful Stakeholder Consultation***

The preamble to the PMPRB’s Interim Guidance proposal speaks to its intent to relaunch “fulsome” consultations on new Guidelines. The Interim Guidance period provides an opportunity to redevelop the PMPRB’s stakeholder consultation approach on Guideline development to allow a more comprehensive process that encompasses the perspectives of a broader range of stakeholders, includes ample opportunity for consultation, review, and finalization, as well as sufficient time between notification and full implementation. A refreshed process should give due consideration to the full range of downstream impacts on all stakeholders in the supply chain and care delivery pathway, include stakeholder participation in working tables in addition to written submissions, and potentially include a dialogue on principles before draft Guidelines are published.

Neighbourhood Pharmacies has taken every opportunity in the last several years to engage with the Federal Government and the PMPRB on the development of various regulations and guidelines. However, our efforts have been met with little success in terms of meaningful opportunities to contribute to the development of policies that will dramatically impact our sector, as the current mandate of the PMPRB excludes a number of key stakeholders in the medication access ecosystem. **We encourage the Board to engage in meaningful consultation with broader stakeholder inclusion from across the entire patient care pathway.**

## **Conclusion**

We are pleased to have an opportunity to review and comment on Amendment to the Interim Guidance re New Medicines and take this opportunity to reiterate some of our key concerns and recommendations regarding ongoing guideline development. We are in full support of the Board's mandate to protect Canadians from excessive medication pricing, and we welcome the opportunity to work with the PMPRB, the Federal Government, and all the stakeholders with our shared goal in meeting the medication needs of Canadians.

Sincerely,



Sandra Hanna  
CEO

## **Reference**

1. Neighbourhood Pharmacy Association of Canada, Impact Analysis of PMPRB Guidelines on Pharmacy (October 2022)