



**Neighbourhood
Pharmacy**
Association of Canada

Association canadienne
**des pharmacies
de quartier**

Office of the Chief Executive Officer

365 Bloor Street East, Suite 2003
Toronto, ON M4W 3L4
T : 416.226.9100
F : 416.226.9185
info@neighbourhoodpharmacies.ca
neighbourhoodpharmacies.ca

August 31, 2021

Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

RE: Notice and Comment on the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions

The Neighbourhood Pharmacy Association of Canada (Neighbourhood Pharmacy) makes this submission on behalf of the community pharmacy sector - 11,000 pharmacies across Canada, who are concerned that the most recently proposed amendments to the PMPRB Guidelines released on July 15, 2021, conflict with the intent of the most recent coming-into-force delay. Pharmacies are essential players in Canada's health system. We have demonstrated our unwavering commitment to Canadians and health systems throughout the pandemic as critical partners in the timely delivery of products and services – in mitigating supply chain challenges; and in helping Canadians to access vaccines conveniently in virtually every community across the country. Without our services, medicines cannot get to Canadians. The recently proposed changes will add undue burden on pharmacists and pharmacy teams as they navigate the financial impact of these changes on pharmacy operations and, most importantly, will have a severe impact on patient care.

Neighbourhood Pharmacies and our partners in the pharmaceutical distribution system have been raising these concerns with the Patented Medicine Prices Review Board (PMPRB) for years now, yet the impact of the latest proposals appear to be more significant than any that have come before. Price compressions can have a significant impact throughout the supply chain. While the PMPRB estimated the impact on brand manufacturers, we are concerned that it has not yet considered the impact on other stakeholders including generic manufacturers, pharmacy distributors or pharmacies.

While reducing brand pricing will result in immediate savings, it will also have the unintended consequence on the financial viability of future generic launches and critical pharmacy services, which deliver tremendous savings to the broader healthcare system. Canadians rely heavily upon the services delivered by pharmacies to ensure timely and consistent access to medicines, as well as trusted and reliable counsel on the safety and effectiveness of their medicines. These services are critical to ensure that patients receive the best possible

outcomes from the medicines they are prescribed. Without our services, medicines cannot get to Canadians.

Newly proposed changes to price tests for grandfathered medicines and their line extensions mark a reversal of previous Guidelines without the benefit of a clear rationale for doing so or an assessment of the resulting impact. Further, this policy change is in no way related to the delay of the coming-into-force date. As a result of these guidelines, we foresee downstream consequences to pharmaceutical supply chain sectors, namely distributors and pharmacies. The negative impacts of these consequences will be seen not only in business outcomes for pharmaceutical businesses, but also in patient services and quality of care.

To date pharmacies have been bracing for losses of at least \$79 million annually; an estimation that was especially difficult to calculate given the uncertainty caused by the complicated drug pricing models, processes and tests provided under the new Guidelines. This calculation was based on an estimated 5 per cent price reduction in the Maximum List Price (MLP) for grandfathered medicines.

Our updated analysis suggests that the PMPRB's latest policy reversal on price tests will result in more than double our initial estimated impact – an estimation that was still very difficult to make for reasons noted above, and can result in an up to \$221 million annual impact to the pharmacy and distribution sectors alone.

Neighbourhood Pharmacies' feedback has been anchored by concerns about the impact such dramatic price decreases will have on the level of care accessible to patients who depend on the services provided by pharmacies. Funding for these services is based on a percentage of the drug price and thus will also be reduced as a direct result of price reductions the medications provided for by the Guidelines. Patients with the most complex conditions, who are prescribed the most complex medicines, often requiring special handling, complex administration and clinic services will be the most severely impacted. It is critical that the economic impact of the most recent regulatory reforms on drug distribution and front-line delivery network be considered.

Despite our best efforts to provide constructive feedback on the consequential impact of pricing reforms on the drug distribution and front-line delivery network and the patients we support, the latest iteration of pricing models exacerbates our concerns instead of providing clarity or predictability.

This comment opportunity is born from the government's acknowledgement that industry still needs additional time to prepare for new requirements while it continues to bear the load of the challenges associated with pandemic recovery and, in the case of pharmacy, working hard to support vaccination efforts and provide care for Canadians. While the government has elected to extend the coming-into-force date of the Regulations, PMPRB has indicated that no change to the compliance period will follow.

Not only does the decision to not amend the date for assessing compliance at cross purposes with the intent behind the amended coming-into-force date, but it is also at odds with the PMPRB's own decision in April to revisit this very issue.

Planning for the implementation of such fundamental changes to the pharmaceutical reimbursement and distribution model is a massive undertaking and requires far more lead time for all stakeholders, not only to assess and evaluate the economic impact of such changes, but also to establish processes to implement any necessary changes. Implementation will necessitate coordination between manufacturers, payers, distributors, and community pharmacies. More work is required to attain better clarity on impacted medicines and their broad economic implications to be equipped to manage new prices, minimize any potential supply chain disruptions, and determine whether a new framework for patient service funding is required to ensure patient support services continue to maintain the specialized care needed by patients with complex conditions. We believe that it would be prudent for the government to pause the ongoing consultation and subsequent implementation of the regulatory framework until such a time that assurances can be provided to stakeholders on the full downstream impact of the change.

It is equally important that a clear process be established for manufacturers to appropriately communicate new prices to the market and address the current lack of floor-stock protection at the distributor and pharmacy levels in order to prevent supply interruptions and unnecessary shortages as the compliance date approaches.

Neighbourhood Pharmacies continues to be of the view that the PMPRB must revert to the twelve-month timeline for compliance transition as a minimum benchmark for reasonableness to allow sufficient time for manufacturers, provinces, and pharmacy to ensure they are able to maintain the specialized care needed by patients with complex conditions.

We appreciate the ability to provide ongoing feedback on the PMPRB Guidelines and are available to discuss further as required.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Hanna', with a small dot at the end.

Sandra Hanna, RPh.
Chief Executive Officer