



Neighbourhood
Pharmacy
Association of Canada

Association canadienne
des pharmacies
de quartier

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Patented Medicine Prices Preview Board
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Standard Life Centre
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Ottawa, ON K1P 1C1
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RE: Submission in response to open consultation on 2022 Proposed updates to the Patented Medicine Prices Review Board Guidelines

The Neighbourhood Pharmacy Association of Canada (Neighbourhood Pharmacies) advocates for pharmacies' role in caring for Canadians. We represent leading pharmacy organizations, including chain, banner, long-term care, grocery chains, specialty pharmacies and distributors, and mass merchandisers with pharmacies. Across Canada, we advance the delivery of care through close to 11,500 community pharmacies and their teams, serving as integral community health hubs in urban, suburban, rural, remote and First Nations neighbourhoods.

The pharmacy sector, including community pharmacies and pharmacy distributors, provides essential medication access for Canadians. Our sector has demonstrated its 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, medications cannot get to Canadians.

Neighbourhood Pharmacies has taken every opportunity in the last several years to engage with the Federal Government and the Patented Medicine Prices Review Board (PMPRB) on the development of the patented medicines Regulations and Guidelines. Because our sector's business model is intrinsically linked to the list price of medications, any changes to medication pricing policies will have profound consequences on pharmacy's ability to sustain the delivery of medications, care, and services upon which Canadians rely. **We are deeply concerned that the most recent iteration of proposed Guidelines will add significant burden and uncertainty to the sector to navigate the operational and financial impacts, and more importantly, will have a severe impact on patient access to medications and care:**

1) The current draft Guidelines pose significant risks to Canadians' timely access to critical medications, pharmacy services and care.

The current Guidelines present dramatic changes and unpredictability in how pharmaceutical manufacturers will determine appropriate prices for their patented medications. This uncertainty 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 medications will put additional pressures on an increasingly burdened healthcare system.

Canada's pharmacies depend almost entirely on the funding generated through dispensing fees and markups tied to drug prices to support the care and services they provide to Canadians. This includes maintaining robust inventories to ensure timely access to medications, providing clinical and patient care services such as assessments, counselling and monitoring, in addition to operating costs including ensuring pharmacies are staffed appropriately to provide care and services to Canadians. The pharmacy sector is bracing for an estimated annual impact of \$113 million in reduced funding as a result of the proposed Guidelines, with little predictability on future impacts due to uncertainty regarding investigation triggers.¹ In addition, in the absence of clarity on how the sector will be reimbursed for inventories on their shelves (through washout periods agreed upon with public and private payors), we may see pharmacies carrying reduced inventories, which may further delay access to medicines for Canadians.

These impacts come when the pharmacy sector has already absorbed millions of dollars of cost cuts from governments and other policy changes to drive down the cost of drugs over the last several years. They also come at a time in which the sector is operating under considerable strain due to increases in labour, warehousing, and fuel costs, combined with record inflation and workforce shortages. Pharmacy cannot pass on these increased operating costs to the public (as has been seen in most other sectors) due to strictly regulated provincial public and private drug plan policies.

2) The Guideline consultation and implementation process is insufficient for meaningful stakeholder assessment and engagement:

- a) *The timing of the consultation window is too short.* The timeframe between the close of the consultation window in December and the expected implementation of the Guidelines in January is insufficient to allow meaningful evaluation of feedback, subsequent modifications to the Guidelines or any assessment of additional changes. There is no opportunity to engage in substantial dialogue with the stakeholders whose operations will be directly and indirectly affected. Or, even if the Guidelines are implemented as currently written, planning for the implementation of such fundamental changes is a massive undertaking and requires far more lead time for all stakeholders.
- b) *There has been no impact assessment of the draft Guidelines on stakeholders.* While the PMPRB estimated the impact of previous Guidelines on brand manufacturers, there has yet to be any impact assessment carried out on the most recent iteration on any stakeholders including generic manufacturers, pharmacy distributors or pharmacies or Canadians themselves. Given the clear and fundamental downstream impact pricing changes will have on all the points in the supply chain, it is imperative that these impacts be evaluated, understood and communicated with all involved, prior to their implementation.
- c) *The intended outcomes of the Guidelines are outside of the PMPRB's mandate.* We understand the PMPRB's intent with the Guidelines is to prevent instances of excessive patented medicine pricing. However, we interpret these revised Guidelines as intending

to, generally, reduce the price of patented medicines, which is under the exclusive purview of jurisdictional governments.

- d) *The intended outcomes of the Guidelines are inconsistent with the objectives of other government policies.* Canada has placed considerable importance on ensuring and increasing domestic access to innovative medications, through initiatives like the Rare Diseases Strategy or the Biomanufacturing and Life Sciences Strategy. The outcomes of Guidelines will work in opposition to these particular policy strategies. Such mixed signals provided by the Federal Government in different policy areas generate additional uncertainty for stakeholders.

Based on these concerns, we have the following two key recommendations:

- 1. The Guideline development, consultation and implementation process be paused and re-evaluated.** The ongoing consultation and subsequent implementation of the regulatory framework should be redeveloped 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 include opportunities to consider the full range of downstream impacts on all stakeholders in the supply chain and care delivery pathway.
- 2. An Impact Analysis of the new Guidelines on all stakeholders in the supply chain and care delivery pathway be developed.** The results of this new analysis must be considered before further revision and subsequent implementation of the new Guidelines, so they do not negatively impact medication access and patient care across the country.

Conclusion

We are pleased to have an opportunity to review and comment on the draft PMPRB Guidelines and we are in full support of the Board's mandate to protect Canadians from excessive medication pricing. However, we remain deeply concerned that the implementation of the current Guidelines poses significant risks to Canadians' access to medication, pharmacy services and care. Canadians rely heavily upon the services delivered by the pharmacy sector to ensure timely and consistent access to their medications, as well as trusted, reliable counsel and care to ensure the best possible outcomes from the medicines they are prescribed.

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, RPh
Chief Executive Officer

References

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