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Patented Medicine Prices Review Board: Submission Regarding Questions and Themes Raised in the "Scoping Paper for the Consultations on the Board's Guidelines"

Submitted by: Neighbourhood Pharmacy Association of Canada

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Submitted to:
Patented Medicine 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 12,000 pharmacies and their teams, that serve as integral community health hubs in urban, suburban, rural, remote and First Nations neighbourhoods.[1] 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 insights relating to some of the themes raised in the Board's recent Scoping Paper, to inform the development of new PMPRB Guidelines. Our comments will expand on remarks presented at the PMPRB roundtable on December 5, 2023, and address three themes:

- Theme 2: Transition to PMPRB11 – New vs Existing Medicines
- Theme 5: Relation to pan-Canadian Health Partners, Insurers (Private and Public); and Alignment with Broader Government Initiatives.
- Theme 6: Engaging with Patients, Health Practitioners, Pharmacy and Other Stakeholders

Theme 2: Transition to PMPRB11 – New vs Existing Medicines

Funding to support the delivery of pharmacy services and pharmacy operations – medication access and care – is largely determined by a medication's list price. Canada's pharmacies depend almost entirely on the funding generated through dispensing fees and mark-ups tied to list prices to support 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., 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 that affect a medication's list price have profound consequences on pharmacy's ability to sustain the delivery of medications, care, and services. **It is imperative that the Board develop an understanding of how pharmacy is funded, and what effects pricing reforms (without reinvestments by governments to offset their impacts) have on the pharmacy sector and therefore patients' access to medication.** Canadians will derive minimal benefit from affordable medications if they cannot access them, nor medication-associated care and services, at their community pharmacies.

The previous PMPRB guidelines were anticipated to remove an estimated $113 million in markup funding (based on list price) from the pharmacy sector.[2] While it is difficult to predict what the impact of the new guidelines will be, the changes come at a time when there are several other cost pressures faced by pharmacy related to national and pan-Canadian policy changes, resulting in cumulative pressures that are eroding pharmacy business models. For example, the latest pan Canadian Pharmaceutical Alliance (pCPA) generic pricing framework will remove an estimated $23.4 million from sector in the next five years.[3] Evolving biosimilars transition policies will continue to erode available pharmacy funding by approximately $68

million a year.[4] Should national pharmacare take the form of a single payor system rather than a fill the gap model, pharmacies could lose another $ 1 billion.[5] As governments impose pandemic recovery economic plans, many are looking to save healthcare costs from the drug budgets that fund pharmacy.

At the same time, ongoing external stressors such as increases in labour costs, workforce shortages, and continued inflationary pressures on supplies are expected to continue. As available funding diminishes and operating costs continue to rise, pharmacies' ability to provide care and services without passing costs on to Canadians will be severely constrained. Without these services, Canadians cannot get their medications or access the pharmacy care they need to effectively manage them.

To effectively support pharmacy operations that provide sustainable patient access to medication in such a constrained environment, it is essential that new PMPRB guidelines foster predictable drug pricing by providing pharmaceutical rights holders with unambiguous direction on what they need to do to be compliant, **In particular, any new guidelines should have provisions that guarantee that 'in market medications" (existing or reviewed before the publication of the final guidelines) will not be subject to reassessment against the PMPRB11 basket of comparator companies.** 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. Such a reassessment would affect pharmacies, who do their fiscal planning based on expected inventory costs and sales, and as a result may be forced to reduce inventory levels if there is uncertainty or risk that in-market medication prices might be reduced. This could potentially lead to delays or reduced access for Canadians.

Theme 5: Relation to pan-Canadian Health Partners, Insurers (Private and Public); and Alignment with Broader Government Initiative and Theme 6: Engaging with Patients, Health Practitioners, Pharmacy and Other Stakeholders

In all prior submissions to, and engagements with, the Board, we have emphasized the importance of broad consultation of all the stakeholders in the medication access pathway, including developers, manufacturers, distributors, clinicians, pharmacies and patients. We applaud the Board for recognizing the need for more meaningful consultation with a broader range of stakeholders as an important theme for consideration in guideline development. This attitude of openness and collaboration is a critical and much appreciated first step towards a more fulsome and inclusive discussion on how to achieve an affordable and equitable pharmaceutical ecosystem.

It remains imperative that the Board consider the interconnectivity among health care policies and the potential unintended consequences of policy development on Canadian's access to medications and care. We have been consistent in our recommendation for the Board to apply a 'whole-of-Government' approach to guideline development. Policies intended to protect Canadians against prohibitive drug costs, or to curtail public drug spending by switching to lower cost alternatives can have negative downstream consequences on medication availability. The impact and interdependencies of other national policies touching on other aspects of medication supply and access, such as the Biomanufacturing and Life Sciences Strategy and the new National Strategy for Drugs for Rare Diseases, must be reviewed and assessed. We are therefore pleased to see the Board's

deliberate identification of the theme of Relation to pan-Canadian Health Partners, Insurers (Private and Public), and Alignment with Broader Government Initiative in this consultation.

Under Theme 6, we are encouraged by the Board's recognition that the pricing review of drugs for rare diseases - that may be high-cost, complex and by nature of the rarity itself, have a limited body of the usual standard of evidence - may need additional consideration in terms of how they may be price-tested.

Rare diseases are likely to be complex conditions, and the medications to treat these conditions may be similarly complex, often having narrow therapeutic windows and significant side effects. Many of these medications require specialized handling, administration and monitoring, as well as additional clinical services to ensure effectiveness, safety and stability. Pharmacies rely significantly on markups dictated by list prices – continuously at risk of deflationary reductions – to fund the clinical services, capital investment, distribution, handling and inventory carrying costs these medications require.

We acknowledge that the market growth in high-cost complex medications is likely to accelerate, meaning that available funding to the pharmacy sector through markups might also increase. It is important to understand, however, that while markup is proportional to list price, the volume and extent of associated care may not be. For example, while a biosimilar drug may cost significantly less than its originator biologic, the infrastructure investment, and level of care and service required by the biosimilar to ensure patient safety, effective use, and adherence, will be the same or even greater than those associated with the originator biologic. As the market trends toward more complex medications, the infrastructure and resources to deliver and appropriately support patients on these medications is also growing.

It is important to note that Canadia is somewhat unique within the comparator countries in the PMPRB11, as pharmacies provide a significant amount of the specialized care and management of patients taking complex medications, as opposed to having such care take place in a hospital or institutional setting. For complex patients taking complex medications, we have recently estimated that Canadian pharmacies themselves directly invest and offset an estimated $1 billion, at minimum, in economic value to provide care and services which are not otherwise provided by the public health system.[6] Pharmacies are using markups to fill significant gaps in care for complex and vulnerable patients, such as those taking drugs for rare diseases. We recognize that it is not within the mandate of PMPRB to set prices, but given how the care that pharmacies provided to these patients is funded, **we urge the Board to refrain from using "lowest of" price tests for medications for rare diseases, as it has attempted to do in the past, and instead consider the complex and high stakes needs of patients in any deliberations relating to criteria for reviewing or price testing these medications.**

Summary

Community pharmacies have the distinction of being both the final drug distribution access point in the entire medication supply chain, as well as a sector whose ability to operate and provide medication-related clinical services is critically dependent on medication prices. We are pleased to have an 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.

Our comments can be summarized four main recommendations:

1. That the Board continue to advance their understanding of how pharmacy is funded, and what effects pricing reforms (without reinvestments by governments to offset their impacts) have on the pharmacy sector and therefore patients access to medication and associated pharmacy services;

2. That the Board continually apply a 'whole-of-Government' approach to guideline development, that considers the interconnectivity among health care policies and the potential unintended consequences of policy development on Canadian's access to medications and associated pharmacy services;

3. That the Board ensure that any new guidelines have provisions that guarantee that 'in market medications" (existing or reviewed before the publication of the final guidelines) will not be subject to reassessment against the PMPRB11 basket of comparator companies; and

4. That the Board to refrain from using "lowest of" price tests for medications for rare diseases, as it has attempted to do in the past, and instead consider the complex and high stakes needs of patients in any deliberations relating to criteria for reviewing or price testing these medications.

Our comments are intended to help the PMPRB minimize the negative downstream impacts that patented medicine pricing policy changes will have on Canadians' access to medication and care through their community pharmacies. The thoughtful development of the scoping themes and questions, the hosting of the first roundtables and this specific consultation are excellent first steps in the dialogue on considerations or principles that will support the next phases of guideline development.

Sincerely,

Sandra Hanna
CEO

References:

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3. Neighbourhood Pharmacy Association of Canada, The Generic Pricing Framework (October 2023) (Neighbourhood Pharmacies proprietary analysis)
4. Neighbourhood Pharmacy Association of Canada, Summer 2022 In The Know Horizons Report (August 2022) - maybe
5. Neighbourhood Pharmacy Association of Canada. Adapted from proprietary member data, February 2021
6. Neighbourhood Pharmacy Association of Canada, The Value of Specialty Pharmacy Services to the Healthcare Sector, Executive Summary (August 2023)