

**Written Submission for the Consultation on  
the PMPRB Draft Guidelines**

**By: Neighbourhood Pharmacy Association of  
Canada**



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## About Neighbourhood Pharmacies

The Neighbourhood Pharmacy Association of Canada (Neighbourhood Pharmacies) appreciates the opportunity to provide this Submission Brief to Health Canada on the PMPRB Draft Guidelines Consultation. This represents a terrific opportunity for us to formally share our thoughts with you following your in-person briefing to our team on December 17, 2019.

Neighbourhood Pharmacies represents Canada's leading pharmacy organizations who deliver high value, quality care to Canadians in all models including chain, banner, long-term care, specialty and independent pharmacies as well as grocery chains and mass merchandisers with pharmacies. Our members are home to the most trusted providers of drug therapies, pharmacy-based patient services and innovative healthcare solutions. We advocate for community-based care through our members' high accessibility and proven track record of providing optimal patient care closer to where patients live, work and play. By leveraging over 10,500 points of care with pharmacies conveniently located in every community across Canada, Neighbourhood Pharmacies aims to advance sustainable healthcare for all stakeholders.

## Introduction

Neighbourhood Pharmacies broadly supports the work the government is doing to create a healthier and safer Canada. As a key stakeholder in Canada's healthcare framework, Neighbourhood Pharmacies has engaged extensively with government as it has undertaken changes to improve individual and population health. We have offered our input to this government as it updates Canada's medical cannabis regime, develops a made-in-Canada pharmacare program, works to address the ongoing opioid crisis, and throughout the process of changing to the Patented Medicine Prices Review Board (PMPRB) Guidelines. We believe that solutions must be based on outcomes rather than on means to achieve those outcomes, so as not to introduce unnecessary red tape.

It is important for us to note, here, the context within which we provide these remarks. We are aware of ongoing court challenges that seek to address the specific issue of whether the regulations exceed the mandate of the PMPRB. We are not submitting this feedback on the guidelines in a manner that would contest whether the new regulations exceed the mandate of the PMPRB. Rather, we provide this feedback without conceding the legitimacy of the new regulations.

## **A Potential for Adverse Effects for Patients**

We would like to focus our comments on our area of greatest concern: the potential for unintended consequences of the proposed guidelines and how they will affect patients. Specifically, we are concerned about the impact on patient support programs (PSP) and services.

Patient support programs are partially funded by pharmaceutical manufacturers, and administered by pharmacies. They are designed to provide personalized patient care and support, anticipating the needs of patients with complex medication therapy, to ensure patients receive the greatest value out of the medicines they are prescribed. There is almost no government funded support for the medication management of these patients, beyond a basic dispensing fee.

Programs are executed with compassionate care and support, and ease the burden of care for patients and healthcare professionals. Care teams, comprised of nurses, pharmacists and other healthcare providers with experience in multiple disease states and therapeutic areas, oversee all elements of programs that include patient enrollment, reimbursement assistance, drug distribution and delivery through either a retail pharmacy or specialty pharmacy network, patient and healthcare professional education and training, and adherence support with robust data reporting.

Pharmacies specializing in this type of service have invested heavily in infusion clinics and other infrastructures to provide the level of patient care required. These investments in patients and patient services deliver tremendous economic value to the healthcare system. Specifically, patient services delivered by pharmacies help ensure more positive clinical outcomes and thus the best value-for-money in the pharmaceutical supply chain. The comprehensive management of drug usage through the close monitoring of patients, helps ensure that no expensive, prescribed medicine, is being wasted. As it stands, Provinces and Territories are not in a position to quickly assume responsibility for the patient services provided by the private sector and are reluctant to invest in the development of clinical infrastructure. A new reimbursement model – one centered on patient care – will take time to design and implement.

Given Canada's privately operated patient supports, international prices are not a fair comparison for the price of medications. Among the basket of comparator countries, only in Canada do PSP's and pharmacies provide the clinical infrastructure (such as through infusion clinics) and services required to safely deliver complex medications for rare conditions, meaning there is a false dichotomy in the comparison tool.

## **Impact of the Guidelines on Grandfathered Drugs**

Prices for Grandfathered Patented Medicines, i.e. those with a Notice of Compliance prior to Aug 21<sup>st</sup>, 2019, will be re-assessed based on the new PMPRB11 basket of countries. The consulting firm, PDCI, estimates that on average the new Median International Price (MIP) will be 20% lower than the current Maximum List Price (MLP). Thus, price reductions of 20% are anticipated for the majority of patented medicines, including those with a patient support program. Furthermore, these price reductions will directly affect the net profit of manufacturers which will force them to consider cost reductions in an effort to maintain their margins.

PSP's represent a significant cost for manufacturers and will most likely be targeted for cost reductions.

We ask the PMPRB to consider two unintended consequences which have the potential to affect patients:

1. Patient Support Programs for drugs already on the market have been developed based on current prices, and a price reduction will likely lead to a reduction in the amount of funding that manufacturers have allocated for patient support programs. Patients who rely upon PSP's for their drug therapy will see a reduction in the level of care provided. The current proposal does not allow sufficient time for manufacturers, provinces, and pharmacy to create a new plan for serving these patients.
2. Provinces and pharmacy need more time to develop a new reimbursement model which will ensure that patients continue to receive the services they need to remain healthy. Price decreases of 20% will also reduce pharmacy gross margins from markups by 20%. As previously noted, drugs for complex conditions require more intensive patient services and pharmacies are mainly compensated for their work with these patients through markups. A 20% reduction in gross margin will have a significant impact on the ability of pharmacies to effectively serve these patients.

## **Impact of the Guidelines on New Drugs**

Many of the same concerns regarding Grandfathered Drugs also apply to new drugs, since many of these drugs are aimed at difficult to treat conditions, which will require patient support programs in order to provide effective therapy.

We anticipate that manufacturers will be faced with difficult decisions regarding PSP's and the amount of funding they can allocate to ensure the best patient results. Unfortunately, the current guidelines could lead to annual recalculations of the Maximum Rebated Price (MRP) or MLP leading to a great deal of uncertainty for manufacturers and this will have a negative impact on the amount of funding available for a patient support program.

We submit that the PMPRB to consider the following:

1. The threshold of \$25 million ensures that almost all new drugs will fall into Category 1 and thus will face a battery of criteria designed to drive down the price. Many of these criteria (see item 2 below) will be difficult to predict, increasing the uncertainty manufacturers will face.
2. Many of the criterion manufacturers face will be difficult to predict, particularly:
  - Changes to the domestic Therapeutic Class Comparison (dTCC) as other manufacturers launch new products, change their prices, or introduce generics.
  - Market Size Adjustments due to increasing usage of the drug.
  - Changes to the MIP based on new international prices.
3. Lack of certainty will lead to underfunding or unstable funding of PSP's. In both cases patients will feel the impact.

This leads us to our three recommendations.

**Recommendation 1:** That Health Canada work with stakeholders to ensure a phased-in approach allowing more time for province, pharmacy and manufacturers of Grandfathered drugs with a patient support program, to determine how to maintain reimbursement for patient services.

**Recommendation 2:** Manufacturers be allowed to use the funds spent on patient support programs as an offset to the MLP for Grandfathered drugs.

**Recommendation 3:** That Health Canada consider amendments to the guidelines to allow more predictable pricing for Category 1 drugs, specifically through less frequent recalculation of MRP, MLP, or iMLP.

## Conclusion

Neighbourhood Pharmacies represents Canada's leading pharmacy brands who deliver high value, quality care to Canadians in all models including chain, banner, long-term care, specialty and independent pharmacies as well as grocery chains and mass merchandisers with pharmacies. Our members are home to the most trusted providers of drug therapies, pharmacy-based patient services and innovative healthcare solutions.

We are calling on the federal government to work with **all** stakeholders to move forward in a phased-in approach to ensure no patients, particularly those requiring additional assistance, are left behind due to unintended consequences to Patient Support Programs.

We look forward to working in partnership with Health Canada now and into the future to ensure that Canadians receive the health services that they need close to their homes.