



**Neighbourhood
Pharmacy**
Association of Canada

Association canadienne
**des pharmacies
de quartier**

Submission to the PMPRB Draft Guidelines Consultation

August 4, 2020



I. Introduction

The Neighbourhood Pharmacy Association of Canada (Neighbourhood Pharmacies) appreciates the opportunity to provide additional input to the Patented Medicines Prices Review Board's (PMPRB) Draft Guidelines consultation.

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 and aim to advance sustainable healthcare for all stakeholders by leveraging the 11,000 pharmacies in every community across Canada.

II. Maximum List Price (MLP) Test for Grandfathered Medicines

Neighbourhood Pharmacies is pleased that the PMPRB has acknowledged our greatest concern: the potential for unintended, negative impact to patient support programs.

Drugs for complex conditions require more intensive patient services. Patient support programs are administered by pharmacies who have invested heavily in infusion clinics and other infrastructure to provide the level of specialized patient care required and to ease the burden of care for patients and healthcare professionals. Patient support programs are funded by pharmaceutical manufacturers, so pricing and revenue expectations are an important factor.

The previous version of Draft Guidelines had the potential to threaten the patient services delivered by pharmacies as the application of the Median International List Price (MIP) test to Grandfathered medicines would have reduced the current Maximum List Price (MLP) by 20 per cent, on average, according to estimates by PDCI Market Access.

In shifting to an approach that applies a Highest International Price (HIP) test for Grandfathered medicines, the average MLP reduction under the updated Draft Guidelines is estimated to be 5 per cent. However, PMPRB analysis reveals that approximately one third of Grandfathered drugs – representing 20 per cent of sales – will experience a significant price decrease of 25¹ per cent or more.

Accordingly, Neighbourhood Pharmacies continue to be concerned about the potential impact such dramatic price decreases will have on the level of care accessible to patients dependent on support services for high cost, specialty medicines.

¹ PMPRB Public Webinar, July 8, 2020 slide 13

Unintended Consequences

Recent amendments to the Patented Medicines Regulations and corresponding guidelines are intended to reduce the price paid by Canadians for pharmaceuticals. This objective should be aligned with the PMPRB's mandate to prevent excessive drug prices. However, an unintended consequence is the negative economic impact on pharmacies and distributors which will impede their ability to deliver access to vital patient support services. These services are paid for by dispensing fees and markups. In the case of expensive drugs for complex conditions, funding for patient services relies almost exclusively on markups. Since markups are based on a percent of the drug price, pharmacies will experience a negative impact as a result of price reductions to Grandfathered medications. We estimate this impact at \$53 million² annually and these losses will be felt disproportionately by those pharmacies which serve the most complex patients. Pharmacies have limited ability to offset these losses since markups are dictated by public drug plans for much of the market.

Likewise, the services provided by pharmaceutical distributors are paid for through markups and will also be negatively affected by price reductions on grandfathered medications. The Canadian Association for Pharmaceutical Distribution Management estimates this impact at more than \$20 million annually. However, the losses experienced by distributors can be passed on to pharmacies through increased fees and markups. In this event, pharmacies can expect a negative impact of at least \$73 million.

Given the Federal Court's recent decision in the application for judicial review of the recent amendments to the Patented Medicines Amendments by Innovative Medicines Canada (IMC), the PMPRB will be unable to collect information on the rebates in the form of Product Listing Agreements (PLAs) negotiated by large payors from pharmaceutical manufacturers. As a result, even though list prices may be reduced for Grandfathered products, the net price after rebates will remain the same. Thus, it is questionable that the intention of lowering drug prices will result in any significant savings to provincial drug plans and large private payors. Paradoxically, the intended consequences of drug cost savings for payors may not be achieved while patients, pharmacies and distributors may experience serious adverse impact to their businesses, services and quality of care.

² Based on brand drugs sales of \$19 billion (IQVIA, MAT Sep2019), a 5% decrease in prices overall, and an average markup of 5.5%

III. Category I Threshold for New Drugs

Neighbourhood Pharmacies also appreciates the PMPRB's recognition that the threshold initially proposed to determine if a new patented medicine should be classified as Category I was too low and would result in the majority of new drugs falling into the category.

Our concerns about a potential negative impact on the amount of funding available for patient support programs extended to the categorization of new drugs as they are aimed at difficult to treat conditions, which will require patient support programs in order to provide effective therapy.

While we believe that the revised threshold will now exclude many drugs from Category I, the newly proposed Guidelines are far more complicated which will continue to contribute to uncertainty that has the potential to lead to underfunding or unstable funding of patient support programs.

IV. Recommendations

Recommendation 1: That the PMPRB and Health Canada work with stakeholders to ensure a phased-in approach allowing more time for province, pharmacy and manufacturers to fully assess the potential impact of the Guidelines on patient support programs and 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 the PMPRB consider additional amendments to the Guidelines to allow more predictable pricing for Category 1 drugs, specifically through less frequent recalculation of MRP, MLP, or iMLP.

Recommendation 4: That PMPRB estimate the impacts to pharmacies and distributors as part of its Guideline Monitoring and Evaluation Plan.