



**Neighbourhood  
Pharmacy**  
Association of Canada

Association canadienne  
**des pharmacies  
de quartier**

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Patented Medicine Prices Review Board  
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**RE: Proposed Consequential Amendments to the January 1, 2021 Guidelines**

The Neighbourhood Pharmacy Association of Canada (Neighbourhood Pharmacy) welcomes the opportunity to provide feedback, on behalf our members, to the proposed amendments to the Guidelines. 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.

Neighbourhood Pharmacies has repeatedly raised the concern that the timelines associated the implementation of Patented Medicines Regulation changes are insufficient to protect against significant unintended consequences that will negatively impact the drug distribution and front-line delivery network as well as, ultimately, Canadian patients. As such, our members appreciate and support Health Canada's decision to delay the coming-into-force date of the Amending Regulations – from July 1, 2020, to January 1, 2021 and now to July 1, 2021 – in recognition of industry's current need to focus on the pandemic response and for sufficient time to prepare for new obligations.

However, the subsequent proposal put forward by the Patented Medicine Prices Review Board (PMPRB) on January 15, 2021 to halve the Guidelines transition period for compliance from one year to six months for Gap and Grandfathered Medicines is unfounded and unsubstantiated.

The delayed coming-into-force date of the amended *Patented Medicines Regulations* is intended to provide industry, which is simultaneously grappling with the challenges wrought by COVID-19, additional time to prepare for the new reporting requirements. Reducing the compliance period from two to one filing period for the sole purpose of maintaining the operative date for assessing compliance is at cross purposes with the intent behind the amended coming-into-force date.

As the PMPRB rightly notes, the recent changes to its regulatory framework represents the most substantive and fundamental revision of the regime in more than 30 years. For their part, pharmaceutical manufacturers need a reasonable transition timetable to ensure they fully understand new requirements and Guidelines, and to operationalize corresponding changes.

The PMPRB has repeatedly committed that final Guidelines would include transitional measures to provide patentees sufficient time to take the necessary steps to come into voluntary compliance with the relevant price ceilings. Nonetheless, the arbitrary change proposed to the transition period has been made without regard to the extensive and detailed work required to ensure all parties involved in the reimbursement and distribution network – including payers, wholesalers, distributors, and pharmacies – are equally equipped for the transition and can minimize any potential supply chain disruptions.

Ultimately, it is patients, pharmacies and distributors who expect to bear a disproportionate burden of changes to Canada's drug pricing policy in a way that will wholly affect their businesses, services and quality of care. Along with manufacturers, pharmacy will also need time to work with both manufacturers and payors to have an orderly transition.

To this end, Neighbourhood Pharmacies continues to be deeply concerned that current plans for the implementation of Patented Medicines Regulation changes do not allow sufficient time for manufacturers, provinces, and pharmacy to create a new framework for reimbursement that ensures patient support programs continue to maintain the specialized care needed by patient with complex conditions.

Even in the most stable business environment, pharmaceutical manufacturers would require more than six months to adapt to the new regime. We respectfully submit that the PMPRB must revert to the two-reporting period, twelve-month timeline for compliance transition as a minimum benchmark for reasonableness.

Neighbourhood Pharmacies appreciates the ability to provide ongoing feedback on the PMPRB Guidelines and welcomes the opportunity to further discuss potential solutions to ensure that

Sincerely,

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

Sandra Hanna, RPh.  
Chief Executive Officer