



Sent via email: pmprb.consultations.cepmb@pmprb-cepmb.gc.ca

Re: Notice and Comment - On the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions

The Canadian Pharmacists Association (CPhA) would like to take this opportunity to highlight our ongoing concern with the government's intent and approach with the planned Patented Medicines Pricing Review Board (PMPRB) regulatory changes, currently scheduled for implementation on January 1, 2022. Over the past number of years, CPhA has actively participated in several consultations led by the government and the PMPRB to convey pharmacists' unique perspective as they ensure the safe and effective use of medications. Throughout these consultations we have raised concerns that the forthcoming pricing regulations may have potential impacts on the availability of medications in Canada. Despite the feedback provided and delays in the implementation of the reforms, neither the PMPRB nor the government have provided any further clarity on the anticipated impact or predictability of outcomes of these reforms. These concerns are further compounded by this most recent notice and comment period regarding the PMPRB guidelines, specifically the PMPRB's intent to re-benchmark Grandfathered medicines and the median price of the PMPRB7. From a pharmacy perspective, we are concerned that the impact on patients will be severe and that the implementation of either the regulations or guidelines during the pandemic will add undue burden on pharmacists and pharmacy staff as they navigate the financial impact of these changes on pharmacy operations.

Two Primary Concerns

PMPRB has not undertaken an impact assessment that includes the supply chain: Based on the limited information provided by the PMPRB on the projected impacts, we anticipate the impact to be somewhere in the range of \$140M–\$220M, a substantial increase from the initial projected \$79M. This total is more than any previous proposal put forth by the PMPRB to date, with little rationale, policy objectives or anticipated outcomes identified. These changes come after the pharmacy sector absorbed approximately \$1B in cost cuts from governments over the past number of years through other policy changes intended to drive down the cost of drugs. It is also being



implemented in the midst of the pandemic when pharmacies have had to invest considerably in safety protocols to keep their staff and patients safe. As a result of these guidelines, we anticipate significant downstream consequences to pharmacies. Canadians rely heavily upon the services delivered by pharmacies to ensure timely and consistent access to medicines, as well as trusted and reliable counsel on the safety and effectiveness of their medicines. These services are critical to ensuring that patients receive the best possible outcomes from the medicines they are prescribed. These negative impacts will not only affect the sustainability of supply chain stakeholders, but could also disrupt patient services and quality of care.

Guideline proposal out of step with current environment: Of particular concern is the timing of these proposed changes and of the consultation itself. Without any discernable rationale or context, these new proposed guidelines were released two weeks after Health Canada delayed the implementation the regulations to January 1, 2022. This new guideline proposal was unexpected and created confusion and uncertainty for our members, and for the more than 11,000 pharmacies across the country. Additionally, the consultation period for the new proposed guidelines is very short, falls in the middle the summer, during a federal election and, most importantly, comes at a time when pharmacies are consumed by pandemic efforts and vaccine deployment. This situation has been incredibly disruptive to pharmaceutical supply chain stakeholders and to the Canadians who rely on our services.

Key Considerations

There are several considerations specific to the pharmacy sector that should be examined as the PMPRB reflects upon this latest guideline proposal. Throughout the consultation we have always expressed concerns with re-benching and re-pricing drugs already on the Canadian market. These concerns were highlighted on a number of occasions by the Guidelines Steering Committee due to the potential for disruption for patients:

- **Drug shortages or drug disruptions:** Drug shortages, recalls and disruptions have been a long-standing problem for pharmacists and patients. This issue has been exacerbated during COVID, with several instances of drug supply needing to be very carefully managed



at the pharmacy and distributor levels.¹ Managing drug supply issues takes time and resources away from direct patient care. Pharmacists report spending up to 20% of their shifts managing shortages, tracking down supply and working with physicians to identify and provide appropriate drug therapy alternatives so that patients can continue to receive the best care possible. Most pharmacists report that drug shortages have increased in the last 3 to 5 years, with the vast majority (79%) indicating that shortages have greatly increased.² One of the contributing factors to drug shortages are business decisions from companies removing products from the market when they are no longer profitable. The proposed changes to medications already on the market threaten to reduce prices significantly enough to potentially result in removal from the market, threatening access for patients.

- **Management of existing drug inventory:** Pharmacies must navigate price changes in order to manage their inventories effectively. Any pricing changes require a sufficient transition period and clear communications and timelines to allow floor stock protection at the pharmacy and distributor levels. Ideally, price changes should be implemented with a single, designated day for all price changes to occur across all provinces/territories and a consistent washout period and floor stock protection policy (which would require collaboration and planning by multiple stakeholder sectors, including the PMPRB, provincial/territorial drug plans, manufacturers, distributors and pharmacies). This coordination will minimize supply disruptions as pharmacies can confidently continue to purchase, sell and distribute medications to Canadians as the compliance date approaches, which is particularly important for high-cost drugs that are purchased by pharmacies.

At this time, **CPhA is urging the PMPRB to pause the ongoing consultation and subsequent implementation of the regulatory framework until such a time that assurances can be provided to stakeholders on the full downstream impact of the changes**, with consideration of the current pandemic climate that has demonstrated the importance of a healthy life sciences industry and

¹ <https://www.pharmacists.ca/news-events/news/pharmacists-continue-to-have-difficulty-sourcing-certain-medications-amidst-the-covid-19-pandemic/>

² <https://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/CPhADrugShortagesandRecallsSurvey2018.pdf>



supply chain by both the PMPRB and government. We wish to remind the PMPRB and the federal government that pharmacies purchase drugs – governments do not. Pharmacies and the professionals that manage drug supply are therefore a critical stakeholder to engage in this process and impacts on the sector must be considered when identifying these policy options.

The pandemic has shown us the importance of accessing life saving drugs and vaccines. As a country we must look to the future and ensure that policies and regulations support broad access to existing and new and innovative therapies for all Canadians. We would be pleased to convene with government and the PMPRB on how best to reflect on these reforms in the context of Canada's priorities.

Regards,

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CEO