To the Members of Standing Committee on Health,

Over the past years the Canadian Pharmacists Association (CPhA) has actively participated in discussions related to proposed PMPRB regulatory reforms as well as sitting on the Steering Committee tasked to provide input into the proposed Guidelines for the implementation of the regulations.

As the profession most directly involved in providing medication care to patients, we take a keen interest in any policies that could affect the availability of medications in Canada and thus the health and wellbeing of our patients.

The PMPRB proposed pricing regulation changes focuses on three key elements: (i) revised basket of comparator countries (PMPRB11), (ii) pharmacoeconomic value assessment for category 1 drugs to determine if the price is "excessive", and (iii) patentees have to report selling price to the PMPRB to account for rebates in price calculations.

While CPhA appreciates the context of reforming price regulation of patented medicines we would like to once again take this opportunity to highlight the potential impact of the proposed regulation on distribution, dispensing, and access to these medicines in Canada. From our perspective there are two main areas of concerns that we wish to bring to the Committee's attention:

1. The impact that the regulations may have on the availability of drugs that are currently on the Canadian market, and the impact on pharmacies.

2. The risk of delays for access to new and innovative drugs for Canadians

While pharmacies and other stakeholders were invited to provide feedback on the various iterations of the regulations and the guidelines, nowhere was there reference to the impact that these changes would have on the broader pharmaceutical supply chain, including many pharmacies across the country. Furthermore, as COVID-19 has demonstrated, Canada's supply chain is not immune to global drug supply disruptions. Over the past 3-5, 79% of pharmacists say that drug shortages have greatly increased, and during the pandemic, only 3% of pharmacists indicated that they were able to fill their entire orders. The potential for further drug disruptions is front and center for pharmacies and why we continue to recommend a cautious approach to drug pricing reform at this time.

Application of proposed regulations to grandfathered patented medicines

Grandfathered patented medicines (i.e. medications already on the Canadian market) will now be reassessed based on the new comparator (PMPRB11) countries with the goal of reducing the price of medications that are already in use by Canadians. This reassessment may lead to price adjustments that could cause a manufacturer to withdraw a product from the Canadian market or other decisions that have been made to distribute drugs to pharmacies across Canada. This may lead to misalignment between the priorities of manufacturers, distributors, pharmacies and that of the health care system resulting in various unfavorable impacts such as reduced investment on infrastructure as well as frequency of deliveries and services to rural areas. This can disrupt the supply of drugs to Canada's over 10,000 pharmacies and increases the risk of drug shortages.

We have previously recommended that the reassessment of grandfathered patented medicines be reserved to address specific issues for example, addressing complaints submitted in relation to the price of a medicine and that that price adjustments for grandfathered patented medicines be phased in to provide pharmacies sufficient time to adapt to the changing environment and to ensure patients maintain access to these medications.

Impact on specialty medications

Specialty medications are used to treat complex conditions and require special storage, handling, and administration. Despite high costs, these drugs significantly improve survival and quality of life of affected individuals. The pharmacy sector has heavily invested on infrastructures to store, distribute and administer specialized medicines to patients. The manufacturers provide patient assistance programs to partly fund the cost of these medications administered by pharmacies to alleviate the economic burden of patients. The proposed regulation based on new PMPRB11 comparator countries will lead to price adjustments (reductions) which may put already existing operational decisions and patient assistance programs at risk and access to these medications.

We recommend that the government should consider transition measures that will ensure timely access to specialty medications by Canadians.

Reassessment of new patented medicines in relation to market dynamics

The proposed guideline indicates various criteria where reassessment and adjustment of prices may be warranted such as, market size, updated cost-utility analysis, and a new indication for a patented medicine. Multiple reassessment of medicines and price fluctuations bears the risk of affecting drug supply to

Canadians. It is desirable to have drug prices stable over time to prevent disruption in the supply of medicines to pharmacies.

Access to new medications

Canada prides itself on its health care system. Canadians expect that they will receive the care that they need where and when they need it, including when it comes to the medications that they need to be healthy. Many innovative medications have proven to be life altering for so many Canadians and we believe that we must balance the need for affordability with access to therapies that can cure and drastically improve the quality of life for patients.

Several manufacturers have indicated that the new regulations would delay the launch of medications in Canada and negatively affect the availability of these medications in future. As pharmacists strive to provide the most optimal medications and therapies to their patients, such an outcome could ultimately have a negative impact on patient health.

Conclusions

CPhA appreciates the Committee's study of this issue. We recognize balancing affordability and accessibility is a complex process and one that should consider all of the potential downstream impacts across various stakeholders. We hope the government will consider the critical issues outlined above and continue to consult on the regulations to ensure that patients continue to have access to effective drug therapies into the future.