CANADIAN PHARMACISTS ASSOCIATION | ASSOCIATION DES PHARMACIENS DU CANADA

February 14, 2020

Douglas Clark
Executive Director
333 Laurier Avenue West Suite 1400
Ottawa, Ontario K1P 1C1

Dear Mr Clark,

On behalf of the Canadian Pharmacists Association (CPhA), please find below our input on the PMPRB Draft Guidelines. Over the past year, CPhA has actively participated in the Steering Committee to share the unique perspective of community pharmacists and pharmacy on the role of medications in the health and wellbeing of Canadians and the potential impact of proposed pricing regulations on patient care in Canada. We would like to take this opportunity to reiterate some of the observations that we have already provided and provide some additional feedback for consideration.

Consultation process

Throughout the consultation process, beginning in 2016 with the initial proposals for modernization, we have raised several questions about the impact of the regulations on patient access. While we appreciated the invitation to participate in the Guideline Steering Committee, the Committee was limited to providing feedback on the technical guidelines and there was no opportunity to have broader discussions about the regulations themselves and how they would impact the availability of medications in Canada, something that was raised by several stakeholders at the table. Many of our questions were left unanswered and we continue to have considerable concerns about the complexity of the proposed regulations.

Application of new PMPRB11 to existing medicines

The regulations state that grandfathered patented medicines will be subject to the new Schedule of comparator countries. What is less clear is how this review process will be initiated for those medications, over what time period and the impact that this will have on the availability of these medications in Canada. Given the current challenges that Canada is facing with a growing number of persistent shortages, our primary concern is that this process may result in manufacturers temporarily or permanently removing product from the market as they work through some of the administrative requirements.

We would also like to take this opportunity to highlight the impact that such changes will have on pharmacy practice and operations. Speciality drugs generally require enhanced infrastructure to manage the distribution and administration of these complex medications, including storage requirements, inventory management, drug injection/infusion services, patient management and adherence support to name a few. As governments move towards reducing the cost of these drugs, there has been no recognition that critical services are built into these prices such as patient support programs, and costs associated to drug managements, both supported by specialty pharmacies across the country.

Given the potential implications for patients who are currently using medications that will be subject to review, we would recommend that the government consider a phased in approach that would allow affected stakeholders to work with payers on an approach that would mitigate the negative impact on patient care.

Future access to new medications

The proposed guidelines outline various criteria to set the price of patented medicines that will likely have a considerable impact on medications for rare diseases and disorders. The complexity of the multiple factor analysis, combined with the pricing impact continues to raise concerns that this will delay the launch of innovative medicines into the Canadian market. While we continue to support governments implementing measures to ensure value for our drug spend, we also must recognize that in a time of unprecedented shortages, recalls and instability in the international drug supply, governments should take a cautious and incremental approach to this area to ensure supply and new entry of medication isn't negatively affected. The priority must always be ensuring Canadians access to medications they need to be healthy

Reassessment of medicines based on changes to market conditions

The price of patented medicines should remain stable to ensure that there is no disruption of supply to pharmacies. The proposed guidelines state the price of a patented medicine will be revisited if it receives a new indication which may alter the market size of the medicine and cost-effectiveness. This may lead to price fluctuations which bears the risk of affecting drug supply and potential shortages.

Pharmacoeconomic value threshold

According to the consultation backgrounder, the $60,000/QALY threshold is based on *preliminary* academic work commissioned by the PMPRB. However, it is known for certain medicines (e.g., oncology medicines) thresholds can exceed $100,000/QALY, disproportionally impacting patients with rare diseases in

particular. There is lack of clarity on whether the government will apply distinct threshold for oncology and other high cost medicines. In addition, it is unclear whether the proposed threshold will be adjusted for medicines marketed for high risk and/or unmet needs, demonstrates improvements over existing products and wider societal benefits.

Conclusion

Recognizing that the while the immediate mandate of the PMPRB is not focused on the downstream impact of pharmaceutical pricing changes, decisions must be made in full consideration of these impacts, and the gaps that may arise as a result should be addressed by working with affected stakeholders.

We hope the government will consider these critical issues before moving forward with implementing the new pricing guidelines and we will continue to participate in discussions related to the important role medications play in the life of Canadians.

Sincerely,

Glen Doucet
Chief Executive Officer

cc. The Honourable Patty Hajdu, P.C., M.P.