CANADIAN PHARMACISTS ASSOCIATION
ASSOCIATION DES PHARMACIENS DU CANADA

August 4, 2020

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

Dear Mr. Clark,

Over the past years the Canadian Pharmacists Association (CPhA) has actively participated in the Steering Committee to highlight the unique perspective of pharmacists and pharmacies on their role in ensuring safe and effective use of medications by Canadian and the potential impact of the forthcoming pricing regulations on the availability of medications in Canada. 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.

Application of proposed regulations to grandfathered patented medicines

Grandfathered patented medicines will be subject to maximum list price (MLP) calculation based on the new comparator (PMPRB11) countries. The proposed reassessment criteria are broad and does not clearly indicate how market dynamics (e.g., change in market size) will be factored in price adjustments on an ongoing basis. This reassessment may lead to price adjustments (reductions) which may not adequately take into consideration the existing decisions that have been made to distribute drugs to pharmacies across Canada. This may lead to misalignment between priorities of manufacturers, distributors, pharmacies and that of the health care system resulting in various unfavorable impacts such as reduced investment on infrastructure, operational plans, 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 would recommend 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.

We would also like to reiterate 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.

Maximum rebated price and pharmacoeconomic value assessment

Category 1 patented medicines will be subjected to maximum list price (MLP) and maximum rebated price (MRP) ceilings. The MRP will be based on the pharmacoeconomic (PE) price which in turn is determined against PE value threshold based on therapeutic criteria levels. To date, PE assessment is used to inform reimbursement decisions by payors as opposed to setting price ceilings. When PMPRB will review ceiling prices, manufactures may not have product listing agreements (PLAs) with drug plans. A PLA negotiates a reduced price (rebate) between a drug manufacturer and a drug plan resulting in a confidential net price. A recent Federal court ruling indicated PMPRB does not have jurisdiction beyond the factory-gate price of patented medicines.[1] Therefore, asking patentees to provide rebated prices to PMPRB is inconsistent with their mandate.[1] At this moment it is unclear what amendments PMPRB will make in repose to this court ruling.

Moreover, the proposed PE value assessment does not adequately take into consideration unique requirements of drugs for rare diseases (e.g., small patient population, lack of data, uncertainty with data). PE threshold for drugs of rare diseases can be well beyond the threshold values (e.g., $200K/QALY) presented in the proposed guidelines.

We would urge the government to reconsider this economic factor to set prices of patented medicines.

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 of category II medicines have exceeded predetermined threshold, updated cost-utility analysis of category I drugs, 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.

Impact on specialty medications

[1] Innovative Medicines Canada v. Canada (Attorney General), 2020 FC 725. https://decisions.fct-cf.gc.ca/fc-cf/decisions/en/item/481803/index.do

Speciality 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.

Conclusions

CPhA appreciates the efforts of PMPRB to work with stakeholders in Canada to ensure timely access to affordable medicines. We recognize balancing affordability and accessibility is a complex process. We recommend that the implementation of the proposed price regulation be undertaken in a phased in approach starting with the new comparator countries. The immediate mandate of PMPRB does not take into consideration downstream impact of the proposed changes; however, decisions should be made taking into consideration the full impact on drug distribution and dispensing. We hope the government will consider the critical issues outlined above while moving forward with implementing the proposed regulation. We will continue to participate in discussions to ensure Canadians' have timely access to patented medicines.