

August 4, 2020

PMPRB Draft Guidelines Consultation
Ottawa, ON
Submitted via the PMPRB Consultations online portal

To Whom it May Concern,

On behalf of Heart & Stroke, please find below some brief comments in response to the PMPRB Draft Guidelines Consultation. Overall, we acknowledge the importance of the new PMPRB regulations as a means of addressing runaway drug costs and setting the foundation for the development of a national universal pharmacare program in Canada. These guidelines are an opportunity for the PMPRB to protect consumers across Canada.

Although Heart & Stroke is supportive of the draft guidelines, we are disappointed with the postponement of the coming-into-force date of the amended regulations from July 2020 to January 2021. Canada pays the third highest drug prices among OECD countries and this delay further prolongs this unfortunate situation.

Additionally, in the 2019 Draft Guidelines, the Pharmacoeconomic Value (PV) threshold of \$60,000 per Quality-Adjusted-Life-Year (QALY) was used. The proposal in the 2020 Draft Guidelines has raised the PV thresholds to between \$150,000 and \$200,000/QALY. This increase seems quite drastic and unwarranted. We would ask that the PMPRB consider reducing this threshold back to the original \$60,000/QALY.

We are cognizant that the pharmaceutical regulatory environment has changed significantly over the last few decades – in particular, the shift from relatively low cost conventional, small molecule drugs for common diseases to high cost biologics and genetic therapies targeted to smaller patient populations. These new types of expensive therapeutics are also being developed for treatment of conditions such as high cholesterol or hypertension for those patients who have rarer variants of these very prevalent conditions or for those patients who have not responded well to first line therapies. The bottom line is that this shift in drug development has introduced a greater risk of excessive pricing. We also acknowledge that the industry practice of negotiating confidential rebates and discounts off public list prices in exchange for having their products reimbursed by public and private insurers can result in an uncertain price environment. To that end we were disappointed that the recent federal court ruling struck down the opportunity for PMPRB to address this particular issue.

Overall, Heart & Stroke supports the revised PMPRB regulations and draft guidelines, including the revised schedule of comparator countries - which includes countries that have similar consumer protection priorities as Canada. We see the revised PMPRB regulations and draft guidelines as an important means of protecting consumers, creating a pricing environment that is in line with the affordability constraints of the Canadian economy and setting the foundation for the development of a national universal pharmacare program in Canada. A national universal pharmacare program can in turn be an effective way of further ensuring reasonable drug prices.

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Why is a National Universal Pharmacare program important for Canada?

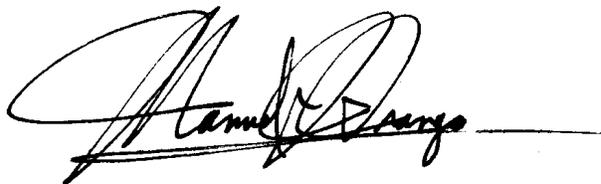
Canada is the only developed country with a universal health care system that does not provide universal coverage for prescription drugs and our multi-payer system for prescription drugs is among the most expensive in the world. Access to prescription medication remains an area of inequity, fragmentation and system failure of varying degrees across the country. Without a national pharmacare program, people in Canada do not truly have universal health coverage.

A national, universal pharmacare program is also critical because 7.5 million Canadians are either underinsured or have no drug coverage whatsoever. Among people in Canada, more than one in five report they or someone in their household has difficulty paying for prescription medications without insurance and one in 10 individuals have difficulty even if they have insurance. We also know that 16% of people in Canada go without their prescription medication for heart disease, high cholesterol or hypertension because of the cost. This situation may be worse now during the pandemic given the risk of reduced access to employer provided drug insurance that may have occurred as a result of job losses.

Heart & Stroke recommends the development and implementation of an equitable and universal pharmacare program, designed to improve access to cost-effective medicines for all people in Canada regardless of geography, age, or ability to pay. This program should include a robust common formulary for which the public payer is the first payer. This model would allow private payers to supplement the common formulary with brand name or other medications not available on the public plan. The public payer should always be the first payer to ensure cost efficiencies by containing drug costs, increasing buying and negotiating power and reducing the costs of administration.

In sum, Heart & Stroke is supportive of the draft PMPRB guidelines and regulations, including the revised schedule of comparator countries. These regulations and guidelines will help ensure a reasonable drug pricing environment and help pave the way towards a national universal pharmacare program.

Sincerely,

A handwritten signature in black ink, appearing to read 'Manuel Arango', with a horizontal line extending to the right.

Manuel Arango, MA, MHA
Director, Policy, Advocacy & Engagement