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August 4, 2020

Tanya Potashnik
Director, Policy and Economics Analysis Branch
Patented Medicine Prices Review Board
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, ON, K1P 1C1

Dear Ms. Potashnik:

The Ministry of Health (the Ministry) would like to applaud the Patented Medicine Prices Review Board (PMPRB) for reviewing and modernizing an outdated regulatory framework. We acknowledge the high level of complexity and dedication involved in amending the regulatory framework that provides PMPRB with the tools and authority to effectively protect Canadian consumers from excessively priced patented medicines in today's environment.

The Ministry recognizes the challenge of finding a balance between keeping new patented medicines launches viable while ensuring that Canadians are paying a fair price for new drugs. As you know, the Ministry has been supportive of the PMPRB initiative since it was announced. Nevertheless, the Ministry is disappointed to learn that the June 2020 draft guideline is expected to result in pricing that will be less favorable for payers than the November 2019 draft guideline – as validated by a subsequent PMPRB report comparing the estimated price of select drugs between the November 2019 and June 2020 PMPRB draft guidelines. We believe that certain aspect of the June 2020 guideline revision may have been too generous, in particular the changes to the pharmacoeconomic value threshold (PVT).

Given the foregoing, BC is requesting that the PVT value be lowered, from $150,000 and $200,000 per QALY to $50,000 and $100,000 per QALY so that it is better aligned with international standards (see expanded rationale in Appendix A).

On behalf of the BC Ministry of Health, I want to thank you again for the efforts that you and your team has put in to modernize the regulatory framework. We sincerely hope that you will take our recommendation under advisement as you finalize the guidelines. We are looking forward to the positive changes on January 1, 2021.

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Ministry of Health

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Should you have any follow up questions, please feel free to contact Dominic Tan (dominic.tan@gov.bc.ca).

Sincerely,

Mitch Moneo
Assistant Deputy Minister
Pharmaceutical Services Division

APPENDIX A: Rationale for Pharmacoeconomic Value Threshold Change:

There is little consensus regarding the ICER threshold that a country should use. This is well described in Appendix D of the 2020 ICER Value Framework from the Institute for Clinical and Economic Review. In this, they conclude "…reflecting on the most recent conceptual and empirical research, reducing the health-benefit price benchmark range to $50,000-$100,000 per QALY could be contemplated" acknowledging that in previous frameworks they had discussed thresholds as high as $150,000 to $200,000 per QALY, including for treatments of ultra-rare disorders. The report states "…we believe it remains premature to seek to create a separate series of cost-effectiveness thresholds related to severity, burden of illness, or need." In reflection of their $150,000 to $200,000 per QALY thresholds, they state "…in today's market environment, it only takes $100,000 per treatment course, multiplied by a mere 10,000 patients, to provide $1 billion per year in revenue. We therefore judge that today it no longer seems necessary to make important exceptions to applying standard cost-effectiveness thresholds to analyzing the value of treatments of rare or ultra-rare condition."

The British Columbia Ministry of Health Pharmaceutical Services Division supports an ICER ceiling of $100,000 CAD for rare diseases and $50,000 CAD for the vast majority of medicines.

- The BC Ministry of Health recognizes that the ever-increasing expenditure on new medicines, most of which provide marginal incremental benefits is harmful to the overall health of Canadians on a population level due to opportunity costs (e.g. investments in education). With regards to ever increasing expenditures, the Institute for Clinical and Economic Review states "the opportunity costs are real, both within the health care system and beyond, and that our goal should be to recommend prices that will ensure that new interventions are adopted at a price that leads to a net increase in health over the entire population. It is not a matter of saving money; it is a commitment to improving health."
- To support the $50,000 CAD threshold, as a public payer it is reasonable to consider the median Canadian family after tax income of $61,400 CAD as an approximate threshold for willingness to pay for each additional QALY. With regards to opportunity costs, $50,000 approximates the mean after tax income of a registered nurse. Whether an individual believes an ICER threshold should be determined by willingness to pay or by opportunity costs, there is pragmatic justification for a $50,000 per QALY threshold. Of course, the $50,000 threshold also matches Claxton's work which is used by NICE in the United Kingdom.
- It is unclear to the BC Ministry of Health the exact evidence that has led the PMPRB to now adopt a $150,000 per QALY threshold. If this is based on the 2001 recommendation from the World Health Organization (WHO) of 1 to 3x the per capita GDP of a country per additional QALY ($46,195 for Canada according to the World Bank), the WHO has since expressed regret for this recommendation as it is unaffordable over the long-term. The classically cited case for how this threshold does not work is trastuzumab in Peru. Although the therapy is cost-effective according to the WHO threshold, adding trastuzumab would exceed Peru's entire budget for breast cancer treatments (Bertram et al. 2016).

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In conclusion, the British Columbia Ministry of Health Pharmaceutical Services Division supports an ICER ceiling of $100,000 CAD for rare diseases and $50,000 CAD for the vast majority of medicines in Canada. This is based on widely accepted work by Claxton, but it's also pragmatic and takes into consideration opportunity costs, acknowledging that the overall health of the Canadian population is dependent on much more than increasing expenditures on pharmaceuticals. Finally, deviating from a $50,000 per QALY threshold places our partners in the United Kingdom in difficult position, and it also appears to support a 20-year-old recommendation from the WHO that has since been walked back, but continues to cause affordability issues in developing countries.