14 February 2020

Douglas Clark
Executive Director, Patented Medicine Prices Review Board of Canada
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, ON
K1P 1C1

Patented Medicine Prices Review Board (PMPRB) Draft Guidelines Consultation Questions

Thank you for the opportunity to provide feedback on you draft changes to the PMPRB guidelines for patented drugs in Canada. The Canadian Association of Provincial Cancer Agencies (CAPCA) includes leaders of all cancer programs across Canada. CAPCA provides a forum for these leaders to discuss issues that affect cancer control delivery. Cancer drug sustainability is one of our top priorities at this time and we are working together to ensure patients are able to access the most effective cancer drugs in a timely and cost effective manner. PMPRB's plays a vital role in ensuring the price of patented drugs in Canada are accessible and sustainable for Canadians.

While we did provide you with some verbal feedback at our most recent Board of Directors meeting in February 2020, on behalf of the CEO's of each of the cancer programs across Canada, please find below some written feedback and points of consideration on your new draft guidelines.

General comments and questions for your consideration:

Overall the new process appears to be a much more complex process for PMPRB. Will PMPRB be adequately resourced to undertake the additional work in a timely manner?

Have PMPRB considered how they will monitor the potential impact on access to drugs in Canada and impact on other aspects like clinical trials and patient support programs? There may be potentially a lot of biased analysis in play. Will there be indicators developed before the changes?

The basket of proposed pricing comparators countries appears to be more reasonable and on par with Canada's model of healthcare funding.

- **Guideline change: Pertaining to the MRP calculation, the ICER will be compared against applicable Pharmacoeconomic Value Threshold ("PVT") of $60,000 per QALY.**

1. **Is this appropriate for cancer medicines, or should a different threshold be used?**

   Currently, during pCPA negotiations for oncology medicines, we strive to reach an agreement for value <$100,000 per QALY. Moving to a threshold of $60,000 per QALY would achieve higher value for P/T's and would set a benchmark at the beginning of negotiations that is known to manufacturers and pCPA. The challenge is that there is significant uncertainty and often wide ranges in the ICER estimates provided by CADTH, and manufacturers will be arguing for the lower range of the estimate and pCPA will be arguing for the higher range of the estimate – this often occurs now and is the most challenging part of negotiations.

   Another consideration is that INESSS often has different ICER estimates, so it shows there is uncertainty in any economic modelling based on comparators used, assumptions in the model, lack of good data, short follow up in the clinical trials, etc. There is concern that some negotiations may not ever be able to result in meeting the threshold, as the price reduction would be >95%.

   There is concern that manufacturers will delay or not bring new medicines to market (especially where there is an unmet treatment need) due to concerns over lost revenue – we have seen one manufacturer withdraw two submissions to pCODR citing concerns and uncertainty about the PMPRB regulations.

   Our suggestion is not to move to a threshold of $60,000 per QALY, but rather a threshold of $100,000 or $120,000 per QALY may be more reasonable. If treatment is potentially curative (e.g. CAR T-cells), an even higher threshold may be warranted.

2. **Should medicines indicated for rare types of cancer have a different threshold?**

   Yes, we should consider a different threshold for rare cancer drugs as the cost for these medicines will be higher. However, we could benefit from a Canadian definition for rare types of cancer, as there is no standard definition.

   In the current PMPRB draft guidelines, there is an escalator to allow a ceiling price of $90,000 per QALY for rare diseases. This seems appropriate, although in current pCPA negotiations for "rare"

oncology diseases (usually if the national budget impact is <$10 million) we have sometimes used a cost >$100,000 per QALY as directed by the Governing Council (ADM's) of pCPA.

Guideline change: Pertaining to Market Size Adjustment, a market size adjustment is applied to Category I patented medicines with quantities sold such that annual revenues would exceed $25 million across all dosage forms and strengths of the medicine (i.e., all DINs combined) when priced at the MRP(s) set by the pharmacoeconomic price (PEP). This adjustment will be applied annually to determine the MRP.

1. **Is the $25M trigger for the listing of a Category I product appropriate for cancer drugs? Or do you foresee issues with a $25M trigger for cancer drug products?**
   A target of $25M for the listing of Category I products will likely be reached quickly for expensive cancer drugs and may paint a false picture of market size. Our suggestion is to increase this trigger threshold.

   Another considerations is that how this will be tracked and managed, and additional rebates provided to P/T's is of
   interest?

2. **Given the treatment cost of the new cancer medicines, most are expected to trigger Category I, should they all be treated as high-risk, requiring a non-transparent price ceiling?**
   The rules should be applied equally and fairly to all new medicines.

Guideline change: For grandfathered drugs, the PMPRB proposes establishing a ceiling that is in line with the median international price as opposed to the highest international price. Would you see that appropriate?

Using the median international price rather than the highest international price for the new comparator price makes sense. However, if the difference between the current and new transparent price goes beyond current rebated price, it will represent a loss in revenue that companies may look for ways to mitigate. Some of the grandfathered drugs have a significant expenditure for cancer budgets. For example, it would be estimated that Lenalidomide spending in Canada may be >$300 million and Pembrolizumab is estimated to be >$400 million in a few years. We support using the median international prices for the ceiling of the transparent list

price, however, we would like to see some pharmacoeconomic adjustments based on market size (if it isn't already applied to the grandfathered drugs) due to the significant impact on cancer budgets.

Guideline change: Do you think the PMPRB should regulate biosimilars of oncology medicines in the same way as originator medicines, or should the PMPRB employ a complaints based approach?

Biosimilars should be treated similarly to generic drugs in terms of regulating the market, but should have an introductory transparent list price at least 25% lower than the originator. Because biosimilars are introduced after the originator patent has expired and are expected to result in savings due to increased competition, it may be appropriate to employ a complaints based approach rather than regulate it in the same way as the originator medicines.

We would be happy to review our feedback with you or provide clarification if desired. If we can be of further assistance, please do not hesitate to contact us. Thank you again for the opportunity to provide input into the changes to the PMPRB guidelines.

Regards,

Gunita Mitera
Executive Director, CAPCA

Eshwar Kumar
Chair, Board of Directors, CAPCA