THERAPEUTICS INITIATIVE Independent Healthcare Evidence

January 17, 2020

Douglas Clark
Executive Director
Patented Medicine Prices Review Board
Government of Canada
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RE: PMPRB Draft Guidelines, CDR and National Pharmacare

Dear Mr. Clark,

For 25 years, the UBC-based Therapeutics Initiative has been a strong and independent voice for rigorous scientific evaluation of drug evidence, supporting rational drug coverage and prescribing in British Columbia. We believe our independence over the years has enabled us to develop some of the best expertise in the world in evaluating the benefits and harms of drugs. We at the TI believe that it is essential our work remain free from drug industry bias and we therefore maintain a strong conflict of interest policy that shields us from industry influence.

In December 2019, we were pleased to meet with several representatives from the PMPRB who came to Victoria to discuss the new PMPRB regulations and to provide feedback on your draft guidelines. We are writing you to thank your staff for taking the time to brief us and to offer our congratulations on the thoughtful and important changes to PMPRB regulations. We think the proposed changes will set an international gold standard in regulating drug prices and will be envied by other nations interested in drug affordability and accessibility. With Canada currently having among the highest priced pharmaceuticals in the world, these reforms were not only overdue, but will be vitally important in making drug therapy more affordable for Canadians in the future.

We also want to take the opportunity to express our concerns of how these regulations might be operationalized as Health Canada, CADTH's Common Drug Review (CDR) and your office contribute to a future single drug agency which may some day support a national Pharmacare plan.

With PMPRB's new price regulations we believe that Canada will have more leverage to extract better value from its pharmaceutical budgets, but it concerns us that under the new regulations PMPRB will no longer be looking at the therapeutic value of new medicines. We think that determining therapeutic value is at the heart of setting prices on new patented drugs, and we believe the regulatory changes at PMPRB will need a strong and independent body to help rigorously assess therapeutic value.

From our vantage point, the greatest risk to the success of the new PMPRB regulations stems from potential bias in agencies which oversee the approval, assessment and coverage drugs. In particular we are very concerned about recent reforms to CDR's review processes, including a requirement that industry provide Systematic Reviews (SRs) for drug evaluations. We think that any proposed savings to CADTH staffing costs will be more than offset by the increased cost to Canadians of a weaker drug review process, poorer scrutiny of industry data, and a reduced level of validity and reliability of CDR drug assessments. It will also mean increased drug costs to provincial payers, in direct contrast to the promise of PMPRB reforms.

What good is it if Canadians are shielded from excessive drug costs by new PMPRB regulations if new drugs will be assessed through weaker, potentially industry-biased analyses of drug evidence? The British Columbia Ministry of Health has already voiced its concerns over these CDR changes and we share those concerns.

Even now, prior to these reforms we find that CDR assessments frequently disappoint. Too often their reviews are superficial reiterations of industry submissions shaped by the industry's narrative around the evidence. In particular, CDR reviews provide relatively little critical analyses of outcome measures and provide weak critical appraisal of clinical studies. This move to outsource even more of its expertise to industry means CDR is likely to produce new drug reviews that fail to fully and comprehensively consider a drug's harm. If industry does not submit evidence of harm in its submission, then this information is completely missed in a review.

We fully understand why drug manufacturers and the patient groups they fund are opposed to PMPRB's regulatory changes. Those who profess that PMPRB's changes will weaken drug investment in Canada and deny Canadians access to new drug therapies are making evidence-free statements which are unlikely to be true. A future landscape which is dominated by excessively high prices for orphan drugs will undoubtedly squeeze funding for other disease groups. As your reforms demonstrate, properly controlling these prices will be highly contentious, but very important. Equally vital, we would argue, is an evaluation process that judges drug evidence in an impartial and independent manner, based on rigorous evaluation of the evidence which is totally free of industry bias.

In Canada, too often public agencies set up biased processes for input and fail to make it easy for other civil society actors—especially non-profit groups, independent consumers organizations and others—to participate. We were pleased to see in your PMPRB consultations you provided financial aid to groups to participate and hence were rewarded with valuable commentary from independent organizations. We would hope the trust you placed in independent

organizations remains a pillar of Canadian drug approval and coverage decisions in the future.

Going forward we think that PMPRB's reforms must be carefully evaluated to ensure that the hoped-for outcomes of affordability and accessibility come to fruition. We hope that other agencies in Canada, especially CADTH and Health Canada, will see how vital it was for PMPRB to utilize clean and fair process for stakeholder input where the voices of independent organizations were heard, and the public interest could be properly captured.

In closing we hope you agree with us that CADTH's Common Drug Review, while not a regulatory agency, does have a key role in limiting industry influence on provincial drug funding decisions. As such, we hope the PMPRB's evaluation of its regulatory changes also incorporates a detailed, regular review of CADTH processes and procedures, including a requirement that changes to its procedures require clear documentation of the benefits and harms of those changes.

We recommend that the PMPRB consider these concerns and support our demand that process changes at CDR are subjected to a strong and independent evaluation so that Canadians can be confident that our drug plans are getting good value for money from their drug budgets.

Again, congratulations on the PMPRB reforms. If you wish to discuss our concerns in more detail, please don't hesitate to contact us.

Yours truly,

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