Canada's Drug and Health Technology Agency
L'Agence des médicaments et des technologies de la santé au Canada

Via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

December 14, 2023

Patented Medicine Prices Review Board

RE: Scoping Paper for the Consultations on the Board's Guidelines

Dear PMPRB,

We thank PMPRB for the opportunity to comment on the *Scoping Paper for the Consultations on the Board's Guidelines (November 2023)*. We have reviewed the document and feel that it would be most relevant to comment on Theme 5 (Relation to pan-Canadian Health Partners, insurers, etc.).

Role of CADTH Recommendations in Informing Drug Pricing

Through our reimbursement review process, CADTH issues recommendations to all federal, provincial, and territorial drug programs and cancer agencies that participate in CADTH's review processes and Canadian Blood Services. Recommendations from CADTH may include pricing conditions, such as a reduction in price (i.e., cost-effectiveness must be improved) or that the cost of the drug under review should not exceed the cost of appropriate comparators. In addition, CADTH evaluates the potential budget impact of new drugs, and our recommendations may note when there are concerns regarding the affordability of the drug under review. The issue of affordability is becoming increasingly prevalent as more technologies enter the market with a high cost per course of treatment.

One comment that was raised at the stakeholder session was that all older drugs should be grandfathered. While we understand the rationale for this statement, there have been instances where an older therapy is reintroduced for a new indication at a much higher cost and is not cost-effective. There should be situations where PMRPB can review an older product where there is a significant increase in price. Another area of concern raised by our customers and expert committees are when products are used for broader lines of use which expand the patient population, but the price is not adjusted accordingly. These pressures may be managed through pCPA negotiations and may be highlighted through an HTA review.

Following issuance of a recommendation from CADTH, the participating drug programs may undertake pricing negotiations with the drug manufacturer through the pan-Canadian Pharmaceutical Alliance process (pCPA). The pCPA enters into negotiations with manufacturers, from which, if successful, a letter of intent is created, listing the terms and conditions for funding a drug which are is then used to create a product listing agreement between each participating member jurisdiction and the drug manufacturer.

Determining Level of Therapeutic Improvement

We understand the value that PMPRB provides to address excessive prices in the Canadian market. Our reimbursement reviews expert committee members have often commented that the cost of a particular therapy may not align with its perceived therapeutic value. This concern is augmented when there is considerable uncertainty within the evidence included in the submitted package for review. We think that the work of the HDAP committee is important and that identifying the Level of Therapeutic Improvement is something that should be aligned across the various partners within the pharmaceutical system. If the work of HDAP continues, we would encourage that the outputs of this committee be publicly available. Often, it seems that various stakeholders have different opinions with respect to therapeutic value and if there is a common approach it could benefit several stakeholders. CADTH would be pleased to have further discussions on this area of work.

Co-ordination with pan-Canadian Health Partners

With respect to question 5.1, CADTH fully supports initiatives that would lead to closer co-ordination of activities and improve communications and consistency across all levels of the pharmaceutical review systems in Canada. For example, consistency with respect to therapeutic value for a new technology. In addition to the alignment of review timelines, CADTH would support initiatives that would allow all agencies within the health system to improve forecasting of the volume and complexity of new drugs that will enter the Canadian market. Joint collection and/or sharing of this information would enable PMPRB, CADTH, and our health system partners to better anticipate and plan for new and emerging therapies with the goal of accelerating decision making and access for patients.

Similar to that noted in the scoping paper, we recognize that more complex treatments are entering the Canadian market such as rare disease drugs. CADTH does consider unmet needs when assessing a drug's therapeutic value and the uncertainty of evidence, given constraints in collecting trial data. This may lead to challenges in calculating cost effectiveness and its overall value. It's not clear if these factors are considered in PMPRB's work when assessing therapeutic value. There may be opportunities for us to consider alignment on how we assess value for these complex therapies.

CADTH agrees with the input from stakeholders from PMPRB's Policy Round Table (held on December 5-6, 2023) who emphasized the importance of each of agency involved in pharmaceutical evaluation, regulation, and reimbursement staying within their own specified mandate to avoid generating confusion and/or duplication of effort.

Accelerating the Introduction of Innovative Medicines

CADTH notes that the PMPRB is seeking consultation on opportunities to accelerate the introduction of innovative medicines in Canada. CADTH has also recently engaged with the pharmaceutical industry and patient groups on opportunities to increase uptake of our parallel review process with Health Canada in an initiative called Target Zero. We would welcome the opportunity to discuss this with PMPRB on this or on any of a number of innovative initiatives that CADTH is planning for the year. As noted above, we fully support closer co-ordination and communication across the PMPRB and CADTH on important initiatives that could reduce the overall time to access for patients.

We would welcome the opportunity to discuss opportunities to collaborate with the PMPRB and would be pleased to arrange a meeting to discuss.

Should you have any questions, please feel free to contact Sudha Kutty at Sudha.Kutty@cadth.ca?

Sincerely,

Sudha Kutty,
Executive Vice President, Evidence, Products and Services, CADTH

cc. Suzanne McGurn, President and CEO, CADTH