Canada's Drug Agency
L'Agence des médicaments du Canada
Drugs. Health Technologies and Systems. Médicaments, technologies de la santé et systèmes.

March 17, 2025

Patented Medicine Prices Review Board

RE: Consultations on Draft Guidelines for PMPRB Staff

Dear PMPRB,

We thank PMPRB for the opportunity to comment on the *Draft Guidelines for PMPRB Staff*.

Please see comments from Canada's Drug Agency (CDA-AMC) below and we would welcome the opportunity to have a more in-depth discussion on these items.

Use of CDA-AMC and INESSS Documentation

The guidelines indicated that reports from CDA-AMC and/or INESSS may be used by PMPRB when establishing comparability ratings. We would appreciate further details on the following aspects of the proposal:

- **Reports or Recommendation:** Would PMPRB seek to apply the committee conclusions regarding the comparable clinical benefit of the drug in question (i.e., the committee's recommendation) or would PMPRB use the CDA-AMC reports as the source for the evaluation (e.g., assessment compiled by our review team before the committee deliberations).
- **Timing:** Would PMPRB seek to conduct their evaluation before, during, or after CDA-AMC has completed our review (e.g., only after the final reports have been published on our website).
- **Redactions:** Indirect treatment comparisons are frequently redacted from CDA-AMC reports. We would be interested if the redaction of that information poses downstream challenges for the PMPRB staff in their evaluation.

Paragraph 87: Staff May Consult the HDAP on an Ad Hoc Basis

CDA-AMC is interested in process initiatives that may help ease the burden on expert committee members and use their time and expertise in a manner that adds the greatest value for the health system. We have recently released new procedures for our reimbursement review process that allows recommendations to be issued by a subcommittee and not require deliberation by the full expert committee. We would be interested in learning more about the specific situations where the PMPRB would feel the need to convene HDAP to advise on a file (e.g., a flow diagram would be beneficial for clarifying the process).

Paragraph 89: Sources of Information Considered when Assigning Comparability Rating
CDA-AMC notes the list of potential sources of information to inform the comparability ratings is extensive and includes health technology assessment reports from domestic and international sources, regulatory documentation, domestic and international clinical practice guidelines, input from the DIN holder, and potential consultation with HDAP. As we begin to explore opportunities to streamline our reimbursement review processes for drugs within the same therapeutic class as existing alternatives, we would be interested in learning more about the methods used by the PMPRB. We appreciate the staff procedures are a high-level description of the methodology; however, additional details on how the evaluation is completed by PMPRB would be beneficial. We would also encourage the outputs from the staff review (with or without the participation of HDAP) to be publicly available.

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@cda-amc.ca.

Sincerely,

Sudha Kutty,
Executive Vice President, Evidence, Products and Services, Canada's Drug Agency

cc. Suzanne McGurn, President and CEO, Canada's Drug Agency