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

December 5, 2022

Tanya Potashnik
Director of the Policy and Economic Analysis Branch
Patented Medicines Pricing Review Board

Re: PMPRB Guidelines

Dear Tanya:

Thank you for the opportunity to review and provide comments on the new PMPRB guidelines. We have provided a summary and some insights below.

Summary of revisions to the PMPRB Guidelines for Excessive Pricing

- The criteria continue to focus on international benchmarking using the new basket of countries, PMPRB11: Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden and the United Kingdom. For context the previous basket, PMPRB7, were France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States.
- In this current draft of the PMPRB guidelines, the factors have now been pared down, the economic factors (e.g., cost effectiveness) have now been removed.
- The approach for international benchmarking is detailed follows: *Staff convert local currency prices filed for the PMPRB11 into Canadian dollars using exchange rates calculated as the simple average of the thirty-six (36) monthly average noon spot exchange rates for each country as published by the Bank of Canada.*
- In addition to international pricing, there will also be domestic within class comparisons of available treatments

referred to as: *domestic therapeutic class comparator prices ("dTCC")*

- Identification of domestic comparators, is described as follows:
  - *The World Health Organization (WHO) Collaborating Centre for Drug Statistics Methodology's Anatomical Therapeutic Chemical (ATC) Classification System is often used by Staff in the selection of medicines to be used for comparison purposes.*
  - *The medicines used for comparison purposes will typically be those identified under the ATC classification system at the sub-class level above the single chemical substance. This will normally be the fourth sub-class level but could include the next higher subclass or another sub-class. In some instances, it may be appropriate to select from the fifth or single chemical substance level.*
  - *A medicine of the same ATC therapeutic class as the patented medicine under review may be omitted if it is unsuitable for comparison.*

Implications for CADTH

- As a result of the changes to the economic requirements (now only looking only at international and domestic price comparisons), CADTH recognizes that implications and potential need for alignment on economic aspects is no longer required.
- CADTH often receives questions regarding the comparator that is chosen in our clinical reviews and economic analyses. As such, it would be helpful for our organizations to be aligned with respect to the definition of a suitable comparator.
- The PMPRB's method for choosing suitable comparators is not available publicly. CADTH recommends that PMPRB to make this information public or allow for an opportunity for CADTH to request this information.

We appreciate the opportunity to review this important document. Please do not hesitate to contact us should you require any clarification or additional information.

Sincerely,

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