From: HLTH PLBSD Correspondence Unit HLTH:EX <HLTHPSDCORR@gov.bc.ca>

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To: PMPRB Consultations / Consultations CEPMB < PMPRB. Consultations. CEPMB@pmprb-cepmb.gc.ca>

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Patented Medicine Prices Review Board Suite 1400 - 333 Laurier Ave W Ottawa ON K1P 1C1 pmprb.consultations.cepmb@pmprb-cepmb.gc.ca

To Whom it May Concern:

The Government of British Columbia is concerned about the latest round of consultations on the new Patented Medicines Prices Review Board (PMPRB) Guidelines. The open-ended nature of the questions being asked appear to signal that the PMPRB is moving backwards from previous positions on the regulation of transparent list prices in Canada.

The Government of British Columbia strongly urges the PMPRB to ensure it is both relevant and effective in protecting Canadians from excessive pricing and by failing to do so, will risk becoming irrelevant and reneging on its purpose to protect Canadians from excessive list prices.

Public drug plans and the pan-Canadian Pharmaceutical Alliance (pCPA) are not able to address the transparent list prices for drugs. List prices are important component of the Canadian pharmaceutical landscape, a majority of expenditures in Canada are private and not covered by the public drug plans. Public drug plans and the pCPA do not have the authority or the ability to ensure list prices are not excessive.

The PMPRB Guidelines should be strengthened in regards to the regulation of list prices:

- PMPRB11 list of countries as comparators should not be changed, the original rationale for the changes from PMPRB7 to PMPRB11 still stand.
- Excessive pricing should be considered anything above the highest price in the PMPRB11, it should be based on the median international price (MIP).
- CPI as a basis to allow list prices to increase over time should be reconsidered as drugs with patents are priced differently than any other consumer or commodity product.

• List prices should be checked again in future years to ensure they are not excessive over time, as manufacturers consistently increases the list price. Essential to examine and assess pricing against consistent parameters and criteria in the term.

British Columbia is confident that PMPRB will reaffirm its role in Canada as an effective and relevant price regulator to protect Canadian patients.

More specific answers to the consultation questions are below:

1. Efficient Monitoring of Prices without Price Setting

- Ensuring the price of patented medicine is not excessive, MIP should be used as the initial triage measure for commencing investigations, as 69 percent of all patented medicines had Canadian list prices higher than MIP of PMPRB11 in 2022 which represents 75 percent of the total sales.
- In the event that there's a few or no international prices, international prices of therapeutic class comparators should be used as reference.
- In addition, it's important that new Guidelines continue to categorize medicines by therapeutic class comparator characteristics such as Level of Therapeutic Improvement as it's critical to take into consideration of the level of therapeutic improvement.

2. Transition to PMPRB11 – New versus Existing Medicines

- The Guidelines should not distinguish between existing and new medicines.
- The PMPRB should review existing medicines with prices above the highest international price.
 - Only 24% of existing patented medicines and 34% of new patented medicines had Canadian list prices below or equal to the MIP of the PMPRB11 in January to June 2023.

3. Price Reviews during Product Life Cycle

- Price reviews should be conducted annually.
 - List prices of medicines in many countries decrease over time in general, and Canadian list prices of patented medicines were the third highest in the Organisation for Economic Co-operation and Development.
- Allowable CPI increase are not appropriate and applicable for list prices of patented medicines. Moreover, based on the long experience of using CPI increases has only allowed Canada to have some of the highest list prices in the world.

4. Relation to pan-Canadian Health Partners, Insurers (Private and Public), and Alignment with Broader Government Initiatives

- The Government of British Columbia, as a member of the pCPA, would support of the coordination of decisions and timelines with the PMPRB and the Canadian Agency for Drugs and Technologies in Health.
 - o For example, if a drug is currently being investigated for excessive list pricing, this is an important consideration during the pCPA price negotiation of that drug.
 - More efficient and effective from pCPA negotiation perspective when there is assurance that the list price of patented medicine is not excessive when comparing to international pricing; hence, the negotiation begins at a reasonable price point not an inflated price point.

Thank you for considering the perspective of British Columbia in your consultations. We are optimistic that the PMPRB will continue to be a relevant organization to help us manage the increasing cost of pharmaceuticals.

Sincerely,

Mitch Moneo Assistant Deputy Minister Pharmaceutical, Laboratory and Blood Services Division

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