September 4th, 2024

Submitted via the PMPRB Website: Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines - Canada.ca

Subject: Lundbeck Canada Inc. response to the PMPRB's Discussion Guide Consultation

Lundbeck Canada Inc. (Lundbeck) appreciates the opportunity to provide input on the Discussion Guide in the context of the Phase 2 consultations on the New Guidelines. Lundbeck also supports the position of Innovative Medicines Canada (IMC), our industry association, on this consultation. The purpose of our submission is to reinforce specific elements which may impact access to patented medicines in Canada.

- **Topic 1: Price level within the PMPRB11 to be used in the initial and post-initial price review**

By implementing the PMPRB11 basket effective July 1st, 2022, the government has already removed the two higher-priced countries (Switzerland and the United States) from the international schedule, which has the effect of limiting the ceiling price of patented medicines in Canada. As noted in the Discussion Guide, 32% of all patented medicines had Canadian list prices higher than the highest international price (HIP) of the PMPRB11 in 2023. The PMPRB should not further constrain prices by selecting the median or the midpoint between the median and the highest as a reference point in future Guidelines. Lundbeck recommends that the PMPRB uses the Highest International Price of the PMPRB11 basket as a threshold to trigger an in-depth review in the initial and post-initial price review (**Option 2**).

- **Topic 2: The length of time Staff should wait, following the implementation of the Guidelines, to determine whether the IPC identification criteria for an Existing medicine is met**

The PMPRB has, under previous versions of the Draft Guidelines, provided a transition measure for existing products whereby existing products would be compared against the HIP of the PMPRB11. Lundbeck believes the PMPRB should uphold this previous commitment. Regardless, decreasing the list price of Existing medicines to comply with the IPC identification criteria, in applicable cases, can have several financial and logistical implications for Rights Holders and other supply chain stakeholders, as outlined in the IMC submission. In order to provide these stakeholders with a reasonable period of time to comply, Lundbeck recommends that the PMPRB waits three years before determining whether the IPC identification criteria for an Existing medicine is met (**Option 3**).

- **Topic 3: In depth review based on CPI increase criteria**

Lundbeck agrees with the PMPRB that using the one-year CPI is a predictable and transparent methodology. However, given that the provincial deadlines to submit list price increases are in most cases before the publication of the one-year actual CPI from Statistics Canada, it would make it easier from an implementation perspective if the PMPRB was to apply a methodology in line with the one in effect under the 2017 version of the Compendium of Policies, Guidelines and Procedures, by applying a cap on the maximum price increase in any one year equal to the change in the latest actual lagged CPI.[1] As a measure of practicality and transparency, Lundbeck also invites the PMPRB to continue updating its *CPI-Based Price-Adjustment Factors for Patented Drug Products* on an ongoing basis, even before the implementation of the New Guidelines, given that CPI adjustments are permitted under the Patent Act.

[1] Patented Medicine Prices Review Board. (2017). *Compendium of Policies, Guidelines and Procedures – Updated February 2017*. Schedule 9. Retrieved from: Compendium of Policies, Guidelines and Procedures - Updated February 2017 (pmprb-cepmb.gc.ca)

- **Topic 4: The individuals/groups permitted to submit a complaint**

Lundbeck believes the most effective excessive price review system consists of clear and predictable factors outlining when a price is excessive and triggers an investigation (e.g. HIP). In this context, the scope of complaints should be reduced, and complaints should be easier to administer. Lundbeck recommends that the list of individuals/groups eligible to submit a complaint should be narrow, consistent with s. 86(2) of the Patent Act, and restricted to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts (**Option 1**).

- **Topic 6: Use of clinical evidence to contextualize the degree of similarity of comparators identified for the TCC.**

Lundbeck is concerned about the broad discretion the PMPRB would be given to identify comparators for in-depth reviews. PMPRB staff may not have the scientific expertise to consider and weigh relevance of comparators during in-depth reviews. In line with IMC, Lundbeck believes that additional discussions with experts representing Rights Holders, in the form of technical working groups, be conducted on this topic.

- **Topic 7: Future role of HDAP**

Given all the uncertainty highlighted in this submission around the nature and complexity of the New Guidelines, and how the scientific review and the selection of comparators will relate to the determination of an excessive price, Lundbeck believes it is too early to comment on the future role of HDAP at this stage.

Thank you for your consideration of our submission.

Lundbeck appreciates the collaborative approach used by the PMPRB to conduct the consultation phases on the New Guidelines and looks forward to contributing to the next phases.

Sincerely,

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Lundbeck Canada Inc.