March 17th, 2025

Submitted via the PMPRB Website: https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines-pmprb-staff.html

Subject: Response from Lundbeck Canada Inc. to PMPRB on Draft Guidelines 2025 Consultation

Lundbeck Canada Inc. (Lundbeck) appreciates the opportunity to provide input on the Draft Guidelines in the context of the Phase 3 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.

HIP

Lundbeck supports PMPRB's proposed approach of using the Highest International Price (HIP) of the revised PMPRB11 schedule of international comparators to conduct Initial Reviews and Annual Reviews, and believes it is critical that the HIP is maintained in the Final Guidelines. 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. 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.

CPI

Lundbeck supports PMPRB's proposed approach of reviewing list prices against the CPI and considering the total change in CPI over the last two years when Rights Holders did not take a list price increase in the first year and the increase in the second year is lower than or equal to the total change in CPI over those two years. However, given that some provinces have a deadline to submit price increase requests in December, and that the publication of the annual CPI by Statistics Canada is in January, Lundbeck suggests that the PMPRB uses a one-year lagged CPI in line with the methodology in effect under the 2017 version of the Compendium of Policies, Guidelines and Procedures.[1] For example, the Staff should compare list price increases taken in 2027 against the **2025** CPI factors, published by Statistics Canada in January 2026, instead of the 2026 CPI factors, published by Statistics Canada in January 2027. 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.

Transition Period

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 such, Lundbeck recommends that the PMPRB waits three years before determining whether the IPC identification criteria for an Existing medicine is met. Lundbeck also takes this opportunity to reiterate the PMPRB's commitment that "once new Guidelines are in place, no potential excess revenues will be calculated by staff retrospectively for any New Medicines for sales made during the interim period." Lundbeck believes that the interim period should be in effect until the Guidelines are

[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)

finalized in 2025 or 2026, and thus expects no financial impacts for Rights Holders for sales made during the current period, up to the date when the Guidelines are finalized plus an appropriate transition period.

Complaints

Lundbeck believes it is inappropriate to automatically trigger an in-depth review on the basis that a complaint has been made. This would lead to unnecessary review burden and unpredictability. Indeed, it would be challenging for rights holders to determine an allowable pricing given the possible evolving mix of therapeutic comparators throughout the product life cycle. Lundbeck believes that the PMPRB should validate complaints against the HIP and resolve complaints where pricing is at or below the HIP, before triggering an in-depth review. Lundbeck also believes that the list of individuals/groups eligible to submit a complaint should be narrow and transparent, consistent with s. 86(2) of the Patent Act, and therefore restricted to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts. As stated in the Discussion Guide, this would help ensure that key government officials with a vested interest in public health bring the most pertinent cases of potential price excessivity to the PMPRB's attention.

In-Depth Reviews

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.

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,

Michal Juul Sørensen
Vice President & General Manager
Lundbeck Canada Inc.