



August 14th, 2023

Patented Medicine Prices Review Board
Standard Life Centre, Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

Subject: Lundbeck Canada Inc. response to the PMPRB's 2023 Interim Guidance Consultation

To Whom It May Concern,

Lundbeck Canada Inc. (Lundbeck) appreciates the opportunity to provide input on the 2023 Proposed Amendment to the Interim Guidance. Lundbeck also supports the position of Innovative Medicines Canada (IMC), our industry association, on this consultation. The purpose of our submission is to highlight specific challenges that we believe the Proposed Amendment to the Interim Guidance represents for patented medicines in Canada.

1. Selection of Price Reference Point

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 constraining the ceiling price of New Medicines. The PMPRB should not further constrain prices by selecting the median as a reference point either for this Interim Guidance, or in future Guidelines. Lundbeck recommends that the PMPRB considers New Medicines as reviewed provided the submitted Canadian prices are within the range of available prices of the revised PMPRB11 schedule.

2. Predictability for Reviewed Medicines

While Lundbeck acknowledges PMPRB's intent to provide rights holders of New Medicines with greater predictability, we believe that the proposed methodology to establish a "reviewed" and "under review" status cannot fully address predictability and risk for patentees. The Proposed Amendment does not specify whether the PMPRB could re-assess a "reviewed" New Medicine over time and re-classify it as "under review". Lundbeck recommends that the PMPRB issues a statement in the Interim Guidance that "once a product is determined to be "reviewed," PMPRB Staff will not reassess or 're-benchmark' the product, provided the rights holder does not increase its price by more than the Consumer Price Index."

3. Consumer Price Index Adjustments

In the 2023 Proposed Amendment to the Interim Guidance, the PMPRB has maintained the proposed approach related to list price increase for patented medicines with a MAPP or projected NEAP as of July 1st, 2022¹. It states that "During the interim period, the price of a patented medicine will not trigger an investigation if [...] its list price does not increase"¹. Changes in the Consumer Price Index (CPI) are specifically referenced in the Patent Act². Lundbeck recommends that the PMPRB amends the Interim Guidance to state that a price increase within the range of CPI for 2023 and ongoing, would not automatically cause a product to be "under review" or "trigger an investigation".

¹ Patented Medicine Prices Review Board. (2023). *Notice and Comment - Amendment to the Interim Guidance re: New Medicines*. Retrieved from: [Notice and Comment - Amendment to the Interim Guidance re: New Medicines - Canada.ca](https://www.pmprb.ca/notice-and-comment-amendment-to-the-interim-guidance-re-new-medicines-canada-ca)

² Government of Canada. (2023). *Patent Act - R.S.C., 1985, c. P-4 (Section 85 (1) (d))*. Retrieved from: [Patent Act \(justice.gc.ca\)](https://www.justice.gc.ca/patent-act)



Thank you for your consideration of our submission, and we look forward to collaborative discussions on this critical issue for our industry, governments, stakeholders, and Canadian patients.

Sincerely,

A handwritten signature in black ink, appearing to read "Michal Juul Sørensen". The signature is fluid and cursive, with a long horizontal stroke at the end.

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