July 31, 2020

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 Draft Guidelines 2020

Dear Dr. Levine and colleagues on the Patented Medicine Prices Review Board (PMPRB),

Lundbeck Canada Inc. (Lundbeck) appreciates the opportunity to provide input on the PMPRB Draft Guidelines 2020. Lundbeck supports and has had an opportunity to contribute to the input from our industry association, Innovative Medicines Canada (IMC). The purpose of our submission is to highlight a specific challenge that the new draft Guidelines are creating and that we think would have the inevitable consequence of introducing inequities and delaying patient access to innovative treatments in Canada.

First, we want to thank you for providing clarity on the intended review process in the situation where Canada would launch a new patented medicine before any of the PMPRB11 countries. However, we think that focusing only on the top of the domestic Therapeutic Class Comparison ("dTCC") to set the interim Maximum List Price ("iMLP") may delay patient access to innovative therapies in Canada and may unjustly penalize those innovations that are expected to generate value beyond available treatments and where the Median International Price ("MIP") of PMPRB11 countries ex-post facto exceeds the top of the dTCC by more than ten (10) percent.

In such case, the currently proposed methodology in the PMPRB Draft Guidelines 2020 limits the patentee's ability to adjust its MLP by more than the lagging change in consumer price index (CPI)[1]. An unintended consequence of this limitation would be to delay launches in Canada until price information in one or more of the PMPRB11 countries becomes available in a publicly available source that meets Staff requirements (see **Appendix**).

One potential solution would be to grant patentees a reasonable enough grace period until price information in one of the PMPRB11 countries becomes available before determining the iMLP. This approach would be more consistent with the PMPRB view that the MIP is the primary test for assessing the iMLP and the MLP of new patented medicines. It would also be consistent with the content of the Backgrounder 2020[2], in which the PMPRB explains that it has decided to forego certain approaches initially proposed in the Draft Guidelines 2019 for setting the MLP of new patented medicines since they would likely have the effect of pushing the MLP for certain medicines to the Lowest International Price ("LIP"). As shown in the example illustrated in the Appendix, the currently proposed methodology still poses a

[1] Patented Medicine Prices Review Board. (2020). *PMPRB Draft Guidelines 2020* (p. 13, para. 48). Retrieved from: https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/2020/PMPRB-Guidelines2020-en.pdf

[2] Patented Medicine Prices Review Board. (2020). *Backgrounder on June 2020 Draft Guidelines: Explanation of Changes from November 2019 Draft Guidelines* (p. 5). Retrieved from: https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/2020/PMPRB-Backgrounder2020-en.pdf

risk of pushing the MLP to below the LIP, which would result in significantly delayed patient access to innovative medicines, and potentially led to circumstances where a treatment can no longer be viably brought to Canada.

We reiterate the fact that Lundbeck fully supports a reform contributing to health system sustainability, and better and more affordable access to medicines for patients. However, we are concerned that the PMPRB Draft Guidelines 2020, as currently drafted, runs the risk of causing a delay in the launch of new innovative medicines into Canada and hence interfering with the achievement of the aforementioned objectives.

Sincerely,

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

Appendix
Illustrative Case Study

Please find below a fictitious example illustrating the potential impact of PMPRB Draft Guidelines 2020 on "Product A", a new patented medicine.

General attributes of Product A:

- DIN XXXXXXXX will be assigned after August 21, 2019;
- First sale in Canada will take place early in 2021;
- Annual treatment cost ≤ 150% GDP/capita;
- Maximum expected market size ≤ $50M.

New Patented Medicine

Category II

Launch sequence of Product A in PMPRB11 countries:

PMPRB11 countries	Estimated launch timelines	Estimated ex-factory & publicly available prices (in CAD)
Country 1	January 2023	$10.00
Country 2	July 2023	$10.00
Country 3	July 2023	$10.00
Country 4	October 2023	$13.00
Country 5	January 2024	$10.00
Country 6	January 2024	$10.00
Country 7	April 2024	$13.00
Country 8	July 2024	$10.00
Country 9	July 2024	$10.00
Country 10	July 2024	$10.00
Country 11	October 2024	$12.00

Pricing information:

- Top of dTCC based on Product A comparators in Canada: $5.00 CAD
- MIP of Product A (as it becomes known after Jan 2023): $10.00 CAD
- LIP of Product A (as it becomes known after Jan 2023): $10.00 CAD

MLP (in CAD) of Product A under proposed Draft Guidelines 2020 **(Canadian launch as expected)** *

2021 *interim*	**2022** *interim*	**2023** *interim*	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**
$5.00	$5.00	$5.00	$5.10	$5.20	$5.31	$5.41	$5.52	$5.63	$5.74

*Assuming an annual CPI adjustment factor of 2%

MLP (in CAD) of Product A under proposed Draft Guidelines 2020 **(Canadian launch delayed by 2 years)**

2021	**2022**	**2023** *interim*	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**
-	-	$10.00	$10.00	$10.00	$10.00	$10.00	$10.00	$10.00	$10.00