December 5th, 2022

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 2022

Dear Professor Bourassa Forcier,

Lundbeck Canada Inc. (Lundbeck) appreciates the opportunity to provide input on the PMPRB Draft Guidelines 2022. Lundbeck supports and has had an opportunity to contribute to the input from the Danish Life Sciences Forum (DLSF) and the *Fédération des chambres de commerce du Québec* (FCCQ), of which we are members. Lundbeck also endorses the submission from Innovative Medicines Canada (IMC), our industry association. The purpose of our submission is to highlight specific challenges that we believe the new PMPRB Draft Guidelines are creating and that we think would have the inevitable consequence of creating inequities and delaying or compromising patient access to innovative treatments in Canada.

1. **Criteria that may trigger an investigation for new medicines**

In paragraph 35 of the Draft Guidelines 2022, the PMPRB stipulates that a price exceeding the median international price for the PMPRB11 or the top of the domestic therapeutic class comparator prices (which may only include generic prices) may trigger an investigation.[1] These proposed criteria apply to all new medicines, irrespective of their therapeutic improvement level. Lundbeck believes that creating such rules, under which a price that falls below the median and even the lowest international price could still trigger an investigation and be exposed to being 'excessive', the PMPRB is introducing the risk of creating inequities and even delaying or compromising patient access to future innovative treatments in Canada.

Lundbeck recommends revising the criteria that may trigger an investigation for new medicines as follows:

- *The list price exceeds the **highest** international price for the PMPRB11; or*
- *The list price falls between the **highest** and the **median** international price for the PMPRB11, but exceeds the top of the domestic therapeutic class comparator prices (" dTCC ").*

2. **Absence of criteria that justify the termination of an investigation**

Although the criteria that may trigger an investigation listed in paragraphs 33, 34 and 35 of the Draft Guidelines 2022 are relatively clear, there is no information as to the criteria that determine the termination of an investigation, or that determine the need to hold a hearing. This lack of information, combined with the fact that an investigation may be triggered by a complaint received regarding the pricing of any patented medicine sold in Canada[2], creates a lot of uncertainty for manufacturers as they attempt to introduce innovative drugs in the Canadian market at a price predicted to be compliant. Lundbeck recommends that the PMPRB clarifies the criteria related to the closure of an investigation as well as the holding of a hearing in order to promote clear, transparent and predictable regulations.

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[1] Patented Medicine Prices Review Board. (2022). *PMPRB Draft Guidelines 2022* (p. 11, para. 35). Retrieved from: Draft-Guidelines-2022.pdf (canada.ca)

[2] Patented Medicine Prices Review Board. (2022). *PMPRB Draft Guidelines 2022* (p. 11, para. 33). Retrieved from: Draft-Guidelines-2022.pdf (canada.ca)

3. Methodologies for CPI adjustment and price sources

a) CPI-adjustment methodology: In paragraph 33 of the Draft Guidelines 2022, the PMPRB stipulates that a list price increasing by more than the changes in the Consumer Price Index (CPI) may trigger an investigation.[3] However, the PMPRB does not specify how the CPI adjustment will be applied. Lundbeck recommends adding more precision on the methodology the PMPRB intends to use, as it was the case in the Compendium of Policies, Guidelines and Procedures (updated February 2017)[4].

b) Price sources methodology: In the Draft Guidelines 2022, the PMPRB does not specify which sources will be used for both domestic and international prices. During its Public Webinar on November 3, 2022, the PMPRB Staff expressed its intent to allow for "apples to apples" price comparisons with domestic and international list prices[5]. Some medicines sold in Canada are only reimbursed by private insurers and do not have a published list price that is publicly verifiable. As such, to allow for "apples to apples" price comparisons, Lundbeck believes that the PMPRB should accept domestic and international ex-factory prices even though they are non-reimbursed or not publicly listed.

In its February 18, 2022 decision, the Quebec Court of Appeal emphasized that "it is important to note that the Board's mandate under the Patent Act is not to set prices for patented medicines, nor does it regulate the revenues earned by patentees. The Board only exercises its price control mandate when it finds that a patentee has abused its monopoly and is charging excessive prices. It is our view that the Guidelines proposed here are contrary to the February 18, 2022 Quebec Court of Appeal decision, in that they are intended to regulate the prices of medicines sold in Canada, rather than to control excessive drug pricing resulting from an abuse of monopoly, as is the PMPRB's mandate.

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 2022, as currently drafted, runs the risk of creating inequities and even delaying or compromising patient access to new innovative medicines in Canada, hence interfering with the achievement of the aforementioned objectives.

Sincerely,

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

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[3] Patented Medicine Prices Review Board. (2022). *PMPRB Draft Guidelines 2022* (p. 11, para. 33). Retrieved from: Draft-Guidelines-2022.pdf (canada.ca)

[4] Patented Medicine Prices Review Board. (2017). *Compendium of Policies, Guidelines and Procedures – Updated February 2017* (p. 45, Schedule 9). Retrieved from: Compendium_Feb_2017_EN.pdf (pmprb-cepmb.gc.ca)

[5] Patented Medicine Prices Review Board. (2022). *PMPRB Public Webinar – Draft Guidelines 2022* (slide 11). Retrieved from: Revised PMPRB Guidelines Overview of key changes (canada.ca)