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# Response to Notice and Comment – Amendment to the Interim Guidance re: New Medicines

Novo Nordisk Canada Inc.
21 August 2023

*Submitted via PMPRB Online Consultation Submission Portal*

This submission is made on behalf of Novo Nordisk Canada Inc. (NNCI) in response to the 2023 Proposed Amendments to the Interim Guidance re: New Medicines (the draft Guidance).

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat serious chronic diseases, built upon our heritage in diabetes. Our treatments today are benefiting millions of people living with diabetes, obesity, and rare blood and endocrine diseases. From our labs to our factory floors, we are discovering and developing innovative biological medicines and making them accessible to patients around the world.

NNCI supports the recommendations put forward by Innovative Medicines Canada (IMC) in its most recent submission regarding the draft Guidance, particularly with respect to consistency with an excessive price standard. We are hopeful that the development of final Guidelines offers an opportunity for industry and the PMPRB to work collaboratively in the development of an approach that offers certainty for government, industry, and Canadian patients who depend on innovative medicines. In addition to the considerations raised by IMC, NNCI calls the Board's attention to a particular omission in the draft Interim Guidance which has the potential to result in negative consequences which could limit Canadians' access to these medicines.

**The TCC (Therapeutic Class Comparator) ensures that there is a comparable price within the same pricing system. Traditionally, the PMPRB has used the higher of Median International Price (MIP) or TCC as the highest price at which drugs can launch. NNCI is concerned that TCC has been removed from the Interim Guidance for several reasons outlined below:**

*Comparing to a transparent price in another system places vulnerable populations in Canada at risk*

The TCC ensures that there is a comparable price within the same pricing system. In Canada, vulnerable populations, including seniors, newcomers, and low-income Canadians, access medicine through a public payer, who negotiates a confidential price. While the PMPRB-11 offers a different degree of transparency, the removal of the TCC places the pricing structure in Canada at risk, and therefore has the potential to limit access to medicines for Canadians in greatest need.

*The proposed interim price test creates uncertainty*

The removal of the TCC is concerning for reasons outlined above and below, but also creates uncertainty as to whether it could be applied once a medicine undergoes a full review. In addition to concerns with respect to the absence of TCC, NNCI also seeks clarity as to what point in time Median International Price (MIP) would be assessed, and whether it would be reassessed going forward. For example, if a medicine launches in 3 out of PMPRB-11 countries and the price is set under the current MIP, clarification is required to understand if the price would be reassessed at the time of subsequent launches.

*The rules established in the interim period exclude fundamental criteria of the Patent Act*

The TCC is referenced in Section 85 (1) (a) and (b) of the *Patent Act* and should not be arbitrarily dismissed as part of the review process during the interim period. A more reasonable course of action would be to continue under the prior Guidance until new Guidance is implemented, respecting the criteria outlined in the *Patent Act*.

Novo Nordisk appreciates the opportunity to comment on the draft Guidance. We reiterate our support for IMC's position and suggest that for the sake of clarity and predictability, interim products should be reviewed under the previous Guidelines until the new Guidelines are finalized.