Response to Scoping Paper for the Consultations on the Board's Guidelines

Novo Nordisk Canada Inc.
December 20, 2023

Submitted via PMPRB Online Consultation Submission Portal

This submission is made on behalf of Novo Nordisk Canada Inc. (NNCI) in response to the PMPRB's *Scoping Paper for the Consultations on the Board's Guidelines* ("the Scoping Paper") published on November 10, 2023. Our written submission builds on the comments presented on December 5th, 2023, as part of the Policy Roundtable.

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) and BIOTECanada in their most recent submissions to the PMPRB regarding the Scoping Paper, particularly with respect to the formation of technical working group(s) and the need for predictability in the future Guidelines.

We appreciate the request for input on various topics that form the foundation of the future Guidelines. The answer to many of the questions within the Scoping Paper are highly dependent on the Guideline's policy objectives and the structure of the framework. To answer questions regarding the weighting of factors, the investigation triggers, the categorization of medicines, etc. would be disingenuous at this point as each one presupposes other aspect of the Guidelines. It is for this reason we request the formation of technical working group(s).

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NNCI recommends the formation of technical working group(s).

We support IMC's comments within the roundtable that ensuring an effective process is more important to long-term success than expediting implementation of a sub-optimal process. Key considerations include the following:

- Improved Efficiencies: Working Groups provide efficiencies by ensuring that feedback is incorporated during the drafting, thereby reducing the level of subsequent changes that occur when each draft is provided for broader consultation. The iterative process ensures that the factors, triggers and remedies within the Guidelines are aligned.

- Quantification of Impact: Working Groups provide access to broader resources which provides greater insights and transparency during the consultation period. This minimizes potential unintended consequences to patients, payers, patentees and the drug supply ecosystem.

We are hopeful that the collaborative development of Guidelines with the PMPRB, patentees and other stakeholders involved establishes a clear framework and certainty for government, industry, and Canadian patients who depend on innovative medicines.

Predictability in pricing is integral for ensuring timely access to innovative drugs.

As mentioned by several speakers during the PMRPB roundtable sessions on December 5th and 6th, predictability is necessary to ensure timely access to new innovations. Pricing uncertainty jeopardizes access to drugs for Canadians. This predictability comes in three forms;

1) Clearly defined excessive pricing tests at launch
2) Stability over the lifetime of the drug
    a) This was previously accomplished by allowing for lagged-CPI increases while a drug remained below the HIP. Two factors which were relatively stable and known in advance of provincial pricing deadlines.
3) Grandfathering drugs to the Guidelines/basket that was approved and in place when each drug had its first sale. The treatment of existing drugs today indicates what will happen in the future. If there is no certainty in grandfathering, there is no certainty that a drug won't be re-evaluated to new tests if Guidelines were to change again in the future. That jeopardizes the stability discussed in the prior bullet, and ultimately impacts a manufacturer's decision to launch an innovative medication in Canada.
    a) Under the previous regime, decisions to launch a drug in Canada were made using the Guideline information known at the time. Changes to Guidelines that result in significant impacts

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to the price of a drug could result in a company needing to withdraw that drug from the Canadian market. This has been seen in other countries and we encourage the Board to look to international examples.

b) In addition, for current drugs, listing agreements with public and private payers have already addressed budget impact and cost-effectiveness, based on a previously established non-excessive price. Guideline changes that decrease list prices will place these agreements in jeopardy and potentially result in less value to provide to individual payers.

Overall, the ability for a manufacturer to predict pricing levels at launch, and over the lifecycle of a drug, are critical factors in the decisions to launch and continue to sell a drug in a given country. Lack of predictability will impact access for patients.

Future Guidelines must align with the mandate provided for in the *Patent* Act.

The PMPRB is one step in the pricing of a patented medicine in Canada and the mandate of the Board is to ensure prices are not excessive. Excessive implies above the level appropriate comparators. Within the context of the *Patent* Act there are comparisons to international prices and the PMPRB has defined 11 countries as appropriate comparators. We would then submit that in alignment with the mandate, any drug at or below the highest international price within that basket would be defined as non-excessive. Similarly, the *Patent* Act also considers domestic prices in the therapeutic class and if a drug is at or below the highest price of this domestic therapeutic class comparison, then the price would be non-excessive.

The PMPRB is limited to reviewing transparent list prices, and there are confidential net prices in place with public and private payers in Canada, resulting in a lower average price across all payers. These competitive contracts and non-transparent prices result in the lowering of average prices over time. Therefore, the comparison of domestic and international prices in the PMPRB-11 is inappropriate at any time beyond launch as the levels of transparency vary between countries and an analysis comparing the two should not be used to justify limiting a factor in the *Patent* Act (CPI).

Novo Nordisk appreciates the opportunity to comment on the Scoping Paper. We reiterate our support for technical working groups to create Guidelines with a transparent, predictable definition of excessive which will facilitate the same high level of compliance as was experienced under the prior Guidelines.

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