# Response to Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines

Novo Nordisk Canada Inc.
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*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 *Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines* ("the Discussion Guide").

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 their most recent submissions to the PMPRB regarding the Discussion Guide.

**Topic 1: Price levels within the PMPRB11 to be used in the initial and post-initial price review**

As outlined in the Discussion Guide, the PMPRB11 represents a more uniform price basket. While the PMPRB acknowledged two instances of prices surpassing the highest international price (HIP) resulting in hearings deeming them "excessive," it's important to note that these hearings occurred under the pre-2022 framework, before the shift to a more standardized price basket. Furthermore, the initial and post-initial assessments aim to optimize staff time by flagging prices that may necessitate thorough review and potential hearing recommendations. Throughout PMPRB's history, instances of drugs priced below HIP receiving an "excessive" ruling are uncommon. Products in compliance with the HIP are unlikely to require a hearing. Moreover, exceptions can be managed through the complaints process.

**Recommendation:** Use the Highest International Price in the initial and post-initial price review.

**Topic 2: The length of time Staff should wait, following the implementation of the Guidelines, to determine whether the IPC identification criteria for an Existing medicine is met**

Grandfathering for drugs with an existing Non-Excessive Average Price (NEAP) should be permitted. The application of a new threshold or a variation thereof should not transform a non-excessive price into an excessive one. Predictability throughout the product life cycle is essential.

**Recommendation:** Continue monitoring compliance for existing drugs based on Consumer Price Index (CPI) and NEAP.

**Topic 3: In depth review based on CPI increase criteria**

As per s.85(1)(d) of the Patent Act, the Board is required to consider changes in the CPI. The lagged-CPI approach offered predictability to all involved parties. We urge the PMPRB to uphold the same degree of certainty and openness that previously enabled strong compliance. To preserve this transparency, we ask the PMPRB to reintroduce its former practice of releasing updated CPI-Based Price-Adjustment Factors for Patented Drug Products.

**Recommendation:** CPI should continue to be based on the lagged CPI and published by the PMPRB. In-depth review should be based on the cumulative increase in list price over the last two years if it is above the combined CPI measure for the past two years and the increase only took place within the last year (i.e. no increase in price in the first of the two years, followed by an increase on the second year).

**Topic 4: The individuals/groups permitted to submit a complaint**

With transparent and predictable guidelines, the role of complaints in the determination of non-excessive pricing should be minimal. To preserve the integrity of the review process and safeguard PMPRB staff resources, we recommend limiting the groups permitted to submit a complaint to those referred to in the Patent Act – i.e., the 'Minister'.

**Recommendation:** Limit complaints to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts.

**Topic 5: Expanding the list of products that would only be subject to an in-depth review following a complaint to include biosimilars and/or vaccines**

As the Board is considering reducing reporting requirements for drugs with lower likelihood of excessive pricing due to their unique market characteristics (e.g., biosimilars and vaccines), we recommend expanding this list to include drugs sourced solely via tenders, such as hemophilia drugs.

**Recommendation:** The PMPRB will only open an in-depth review for biosimilars, vaccines and drugs sourced solely via tender (e.g., hemophilia drugs) when a complaint is received.

**Topic 6: Use of clinical evidence to contextualize the degree of similarity of comparators identified for the TCC**

**Topic 7: Future role of HDAP**

The lack of clarity provided in the Discussion Guide precludes us from offering an opinion on Topic 6 and Topic 7.

To offer a response to the appropriate application of "level of similarity" would require additional details on the fundamental role of such a comparability. The Discussion Guide highlights that one of the two main objectives for the guidelines is to *"…provide transparency and predictability to Rights Holders regarding the process typically engage in by PMPRB staff ("Staff")…"*. There is a lack of transparency and predictability inherently included in a process where broad discretion on the application of four factors within the Patent Act are applied/weighted.

Regarding the future role of the Human Drug Advisory Panel (HDAP) we are unable to comment on the timing and nature of scientific reviews without more information on the PMPRB's envisioned future guidelines and how scientific review and comparator weighting may or may not be linked to determining excessive prices. Additional investigation parameters will rely on the nature and complexity of the forthcoming PMPRB guidelines and can be further discussed through a technical working group.

**Recommendation:** Form a technical working group to provide efficient and robust feedback on the In-Depth Review.

**Next Steps**

Novo Nordisk appreciates the opportunity to comment on the Discussion Guide. We reiterate our earlier comments from our submission in response to the PMPRB's *Scoping Paper for the Consultations on the Board's Guidelines* regarding the benefits of including technical working group(s) in the guideline development.

Best Regards,

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