Response to the Patented Medicine Prices Review Board (PMPRB) Draft Guidelines- December 2024 Version for Consultation

Novo Nordisk Canada Inc.
March 19, 2025

Ms. Anie Perrault
Acting Chairperson Patented Medicine Prices Review Board
Standard Life Centre, Suite 1400
333 Laurier Avenue West
Ottawa, Ontario K1P 7C1

Dear Ms. Perrault,

This submission is made on behalf of Novo Nordisk Canada Inc. (NNCI) in response to the Draft Guidelines for PMPRB Staff: Administrative Process for Excessive Price Hearing Recommendation ("the Draft Guidelines") published on December 19, 2024.

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.

Here in Canada, we serve more than 1.7 million patients, conduct pan-Canadian clinical research trials, and invest in community-based chronic disease prevention initiatives. Novo Nordisk is also a proud supporter of Canada's life sciences ecosystem, investing over $4B CAD in eighteen months to enable innovative Canadian life science companies to scale up their operations.

The aim of the new guidelines is to provide a transparent, predictable, and procedurally fair process around price review for patentees. NNCI appreciates the Board's openness to input and believes our analysis and recommendations will help ensure the new guidelines effectively balance the mandate of the PMPRB with the need to foster innovation and maintain patient access to existing medicines in Canada.

NNCI supports the decision of the PMPRB to use the Highest International Price (HIP) as the sole review criterion for new medicines at launch. However, we are concerned about the application of this metric in ongoing annual reviews. Anticipated re-benchmarking, as outlined in the proposed annual price reviews and in-depth reviews, presents the potential for arbitrary price reductions, as evidenced in the PMPRB's examination of price reviews during the Product Life Cycle 2023 Scoping document, Box 3, Pricing trends in Canada versus the PMPRB11. The data suggests that such re-benchmarking would constitute a manifestation of price control over time, deviating from the intended excessive pricing mandate. The PMPRB could continue to regularly oversee and confirm adherence to the CPI-adjusted price benchmark set when a medicine is introduced, without the need to re-benchmark prices annually.

Substantial concerns remain regarding transparency and predictability within the processes put forth in the Draft Guidelines, particularly in the application of the Therapeutic Class Comparison (TCC). We

strongly believe that the formation of technical working group(s) including experts representing rights holders is a critical step in the guideline development process. Additionally, as an Innovative Medicines Canada (IMC) member company, NNCI endorses the recommendations submitted by IMC to the PMPRB.

Existing medicines- Grandfathering is essential for predictability.

The 2024 PMPRB draft Guidelines outline a one-year transition period for existing medicines, defined as those first sold before July 1st, 2022, prior to their first Annual Review. Under the new rules established in the Draft Guidelines, patentees are expected to align the pricing of existing medicines with the Highest International Price (HIP) among the new basket of countries (PMPRB11). These products have already been reviewed by PMPRB, and their prices were set to comply with the Guidelines in effect at that time. Negotiations and agreements for reimbursement, distribution, and dispensing were based on these established prices. The application of a new threshold or a variation thereof (i.e., the application of the new basket of reference countries) should not, under any circumstances, transform a non-excessive price into an excessive one.

Recommendation:

The price of an existing medicine that was found to be non-excessive under the previous Guidelines should only be re-examined if that price increases beyond allowable CPI adjustments.

CPI- Former PMPRB practices should be reinstated.

The Draft Guidelines propose the use of the one-year lagged CPI, ensuring that adjustments reflect economic conditions as referenced in the Patent Act (s.85(1)(d)). Allowable price adjustment based on CPI are critical as it allows pharmaceutical companies to adapt and align their pricing strategies with Canadian economic realities, providing a buffer against inflationary pressures. The prior method of the two-year lagged CPI aligned the publication of the allowable factor with the timing required by payors to receive price increase submissions. The one-year lagged CPI would be available for publishing at the earliest, mid-January but several provinces require planned price increases from manufacturers a month prior to that date.

Transparency is essential to ensure that stakeholders can make informed decisions. The Draft Guidelines fall short in providing clarity and predictability regarding the methodologies used for CPI adjustments, leaving stakeholders without a comprehensive understanding of how these factors are calculated and applied.

Recommendations:

NNCI reiterates our previous recommendation regarding the reinstatement of former PMPRB practices specifically concerning the publishing of CPI-Based Price-Adjustment Factors by the PMPRB and the use of a lagged-CPI approach that allows for increases based on the cumulative increase in list price over the last two years.

A detailed review of former CPI methodology and those proposed in the Draft Guidelines, including the rationale for any potential changes, would be an invaluable topic for discussion during a technical working group.

Complaints- The role of complaints should be minimal and streamlined, focusing on products most at risk of excessive pricing.

The current Draft Guidelines present a framework that inadvertently encourages complaints. Public and private payers can submit complaints that trigger an In-Depth Review without providing detailed supporting evidence, even in cases where the price falls below the HIP. This process risks overwhelming the PMPRB review process with potentially misconceived complaints from a variety of stakeholders. Furthermore, there is no clarity on if/how complaints will be prioritized. The absence of a structured mechanism to prioritize complaints is inefficient and could put an unnecessary strain on PMPRB resources, raising concerns about the agency's capacity to efficiently identify and address genuine pricing issues.

The initiation of in-depth reviews also imposes a substantial burden on manufacturers. Navigating this process will require significant resource allocation for comprehensive submissions and results in a prolonged period of pricing uncertainty. Measures should be implemented to mitigate the risk of manufacturers being drawn into in-depth reviews due to misconceived complaints.

Recommendation:

Eligibility for making complaints should be limited to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts. Moreover, it should be a requirement that any complaints made be supported by evidence tied to one or more of the Section 85 price factors. These recommendations, in addition to having a clear and structured mechanism for prioritizing complaints will reduce resource burden by ensuring validity of a complaint prior to the initiation of an in-depth review.

Tender products undergo a competitive review and are solely purchased by organizations with the ability to negotiate to secure favorable terms and pricing. Because of this process, these drugs are at a low risk of “excessive” pricing.

Recommendation:

NNCI believes that the limited resources of the PMPRB could be more efficiently prioritized if all tendered products, including vaccines and blood products, were considered on a complaints-only basis, limited to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts.

In-depth Review Process- Clarity, consistency, and transparency is critical.

The current process for in-depth reviews proposed in the Draft Guidelines has been positioned as a work procedure, utilizing factors to assess therapeutic class comparability and price comparisons. Staff will make their recommendation to the Chairperson on whether a Notice of Hearing should be issued or not based on the Staff's analysis of the factors outlined in the Guidelines. It is acknowledged in the Draft Guidelines that, with the ‘case-by-case’ nature of the in-depth review process, individual cases may be subject to deviations from the general approach. It is concerning that there is considerable discretion granted to PMPRB staff in determining comparator relevance and weighing Patent Act factors, potentially leading to inconsistent outcomes. In-depth reviews will

be a key consideration when setting prices and planning launches. The lack of consistency and predictability creates challenges for Rights holders when making these decisions.

Similar to the concern regarding the prioritization of complaints previously outlined, there is no clarity on whether mechanisms will exist to prioritize in-depth reviews (i.e. complaint-based vs those triggered in initial or annual reviews, minor vs significant pricing concerns, etc.). Without a clear process for vetting and prioritizing, minor issues can escalate into lengthy In-Depth Reviews, tying up resources that could be used towards more important cases.

Undertakings are intended to be a tool to proactively and efficiently resolve In-Depth Reviews. The ability for Rights Holders to propose undertakings will help to streamline the resolution of certain reviews, thereby freeing up resources and allowing staff to prioritize more significant or complex cases. Under the new Guidelines, patentees will only be provided with the scientific review report, while the crucial price review report will be withheld. Without access to the price review report, Rights holders will not be able to effectively tailor proposed undertakings to address the specific issues identified in the review. This issue is further exacerbated by PMPRB staff not offering comments or assistance. Enhanced clarity and transparency in the review process is necessary for Rights holders to better support their strategic planning and contribute more effectively to the overarching goals of the PMPRB.

Recommendations:

Technical working groups with experts representing rights holders should be created to provide efficient and robust feedback on the In-Depth Review. More intricate and nuanced case studies than those presented will be needed and should be discussed through the technical working group(s). We believe that incorporating working groups into the process will result in a more transparent and consistent regulatory framework. These Working Groups need to be established, and their work completed before the Therapeutic Class Comparison test is included in the Guidelines, due to the significant uncertainty that currently exists.

Establishing mechanisms to differentiate between significant pricing concerns and minor or transient fluctuations (such as exchange rate variations or changes in international prices) will streamline the review process. Moreover, it is crucial that any delays stemming from prioritization or resource allocation issues do not result in undue penalties for Rights holders. A more structured approach to prioritization will ensure that resources are allocated efficiently, without burdening Rights Holders with unnecessary delays or penalties.

There are several significant concerns with the application of the TCC within the proposed in-depth review framework.

Generic or biosimilar (patented or otherwise) comparators may be included in the dTCC analysis, raising questions about the fairness and accuracy of price assessments. The guidelines also allow for unpredictable reassessments of the dTCC over time. An in-depth review could be triggered after the landscape has evolved with the introduction of new comparator or generic products in the market.

The Draft Guidelines specify that separate dTCC assessments will be prepared for each approved indication. There is no guidance provided to staff on the process to determine the appropriate price comparison if there are multiple indications and therefore multiple TCCs included in the review.

There is also no guidance provided to staff on the process to determine the price comparison if several comparators of equal quality have varying price points. Furthermore, it is unclear how the price of comparator products will be weighed in the decision to recommend a hearing based on the established level of comparability (low, vs. medium, vs. high).

Recommendations:

Inclusion of generic products or biosimilars in the TCC is inappropriate. Only branded comparators or fixed brand reference prices should be used to ensure consistency and accuracy.

TCC assessments should be conducted based on relevant comparators and indications at the time of the product's launch. This approach acknowledges that the future pricing decisions of comparator products are beyond the patentee's control and not relevant to the current price determination.

For scenarios involving multiple comparators of similar quality with varying price points, it is recommended that staff use the highest price point as a benchmark in their decision for recommending a hearing or not. This protects against undervaluation of new, innovative products and will allow for more consistency in recommendations. It is also consistent with the excessive pricing mandate of the PMPRB.

In cases where there are multiple indications involved, the indication with the higher price, reflecting the most significant therapeutic value of the product should be used for determining the risk of excessive pricing.

Lastly, publishing of TCCs from In-Depth reviews provides transparency and predictability for all stakeholders.

Conclusion

NNCI appreciates the opportunity to provide our insights and comments on the PMPRB Draft Guidelines. Throughout this process, we have consistently emphasized the significant advantages of incorporating technical working groups in the development of the guidelines. We believe these working groups would contribute valuable expertise and diverse perspectives and are an important step to ensure transparency, clarity, and applicability of the guidelines.

We remain committed to a constructive and collaborative engagement with the PMPRB and share the goal of achieving a balanced framework that ensures fair pricing while fostering innovation. We look forward to continued dialogue and partnership.

Regards,

Daneen Krinke

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Novo Nordisk Canada

Pricing & Analytics Associate Director