March 19, 2025

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,

BIOTECanada is providing written feedback on the Patented Medicine Prices Review Board's (PMPRB) Draft Guidelines for PMPRB Staff: Administrative Process for Excessive Price Hearing Recommendation ("the Draft Guidelines") published on December 19, 2024.

BIOTECanada is the national industry association for Canada's health, industrial and agricultural biotechnology sectors. The association consists of more than 230 members, primarily patentees, that are dedicated to bringing life changing therapies to Canadian patients. Our association's membership is representative of the Canadian biotechnology ecosystem, including emerging research-focused small and medium sized enterprises, universities, investors, incubator, and accelerator organizations, as well as multi-national companies. Our members are at the forefront of producing the next generation of health care solutions and biologic based medicines, including vaccines, therapies for rare diseases, cell and gene therapies, and many new dynamic technologies holding great promise for the future of healthcare.

The Canadian biopharmaceutical ecosystem has changed significantly since the PMPRB's 2010 Guidelines were instituted. The biotechnology industry has achieved significant advancements in numerous therapeutic areas such that previously untreated conditions now have the possibility of a cure. Canadian pricing and reimbursement institutions, including Canada's Drug Agency, l'Institut national d'excellence en santé et services sociaux, the pan-Canadian Pharmaceutical Alliance, and the private insurance and benefits industry, each with mandates and existing mechanisms to assess the value of medicines, continue to evolve to reflect this changing ecosystem.

BIOTECanada remains committed to engaging in constructive dialogue with the PMPRB during this period of transition. Our submission is offered with a focus on identifying and addressing outstanding areas of concern to reinforce the stability, transparency, and predictability of the PMPRB's processes. The following sections outline our recommendations to ensure that the final Guidelines strike a balance between the PMPRB's mandate and the imperative to support innovation and maintain patient access to transformative and cutting-edge therapies.

Draft Guidelines

Initial and Annual Review

In this submission, we reaffirm our longstanding position that the review processes must be anchored in clear benchmarks that fall within the scope of the PMPRB's legislated mandate.

As such, **PMPRB should adopt the Highest International Price (HIP) as proposed in the Guidelines as the sole review criterion at a medicine's launch.** Canadian ex-factory prices that do not exceed the

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PMPRB11 countries, all of whom have some form of price regulation in place, are not excessively priced according to the Patent Act and thus should not be seen as priorities for further scrutiny.

Similarly, the adoption of a cumulative Consumer Price Index (CPI) framework for price adjustments aligns with the need for predictability and stability. Price adjustment based on CPI are critical to allow companies to adapt their pricing according to Canadian economic conditions that evolve over time.

However, the current Guideline proposal suggests that during an Annual Review, any Canadian List Price exceeding the HIP or CPI-adjusted benchmark would immediately trigger an In-Depth Review. PMPRB Staff should not "re-benchmark" prices based on evolving foreign market or regulatory conditions – factors that should have no bearing on whether a price is excessive in Canada. This is particularly relevant given the current Guideline proposal would extend In-Depth Reviews to all 'associated DINs'. **Once the price of a medicine is reviewed at launch and considered acceptable according to the applicable thresholds, that price should not be subject to further review against any factors other than the allowable CPI increase.** This approach provides the predictability and stability the sector requires to invest in new technologies that have very long discovery and development timelines. It also aligns with PMPRB's stated objectives, which are to enhance the Board's administrative efficiency, and to provide transparency and predictability to Rights-holders.

For New Medicines, initiating an In-Depth Review should ideally be deferred until prices are available in a minimum of five countries or once three years of sales have passed. This helps address issues of evolving international pricing early in a product's lifecycle. Only the product or products significantly exceeding the review criteria should proceed to an In-Depth Review, rather than automatically including all associated DINs.

To optimize resourcing, we emphasize the need for mechanisms that distinguish between meaningful pricing concerns from minor or transient fluctuations, especially in consideration of the current uncertain economic climate. This approach would prevent minor issues from escalating into lengthy resource intensive In-Depth Reviews.

Existing Medicines

The current proposal in the Draft Guidelines is to provide Existing Medicines, i.e. those first sold prior to July 1st, 2022, a one-year transition period before their first Annual Review.

Our longstanding position has been that for Existing Medicines—those already reviewed and found compliant with the PMPRB's framework—the application of the new basket of reference countries is both inappropriate and disruptive. Patentees set their prices at launch, in part, to comply with the Guidelines in effect, and then entered reimbursement, distribution, and dispensing agreements based upon those prices. By voluntarily complying with the Guidelines set out by the PMPRB previously in effect and the NEAP determined by the PMPRB, patentees had a reasonable expectation that prices of Existing Medicines were non-excessive.

Any Existing Medicine's price that has been found to be non-excessive and compliant to the previous PMPRB Guidelines should only be re-examined if that price increases beyond allowable CPI adjustments or if a substantiated complaint is raised. This is consistent with the Existing Medicines provisions that were implemented when the Guidelines were last revised in 2010.

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New Medicines launched during the Interim Period (post-July 1st, 2022), and those which have not yet received a price review under the prior framework, should be provided with a transition period of at least one year before receiving their first review under the new framework.

Complaints

Complaints represent the third criteria that can trigger an In-Depth Review. The current proposal in the Draft Guidelines would allow public and private payers to submit complaints that trigger an In-Depth Review, even when prices are below the HIP and without detailed supporting evidence. The PMPRB should validate and resolve complaints where pricing is at or below the HIP. It is not appropriate for PMPRB to apply a different standard of review, and thus ultimately different price tests, to patented products, solely on the basis of a complaint. **BIOTECanada recommends the complaint mechanism should be refined to ensure that only prices that exceed the HIP and CPI factors should proceed to an In-Depth Review.**

In BIOTECanada's view, only Federal and Provincial Ministers of Health should be authorized to submit complaints, as they can balance the interests of all stakeholders and provide comprehensive, evidence-based assessments. The proposed complaints system should be manageable and predictable for rights-holders. Furthermore, details surrounding the complaints should be shared with the patentee, such that any supporting evidence can be generated to substantiate and inform dialogue with the PMPRB upon evaluation.

In-Depth Review

The new Guidelines clarify that the In-Depth Review process is not intended to serve as a final determination of whether a price is excessive. Instead, the In-Depth Review is an internal mechanism for PMPRB staff to evaluate whether to recommend to the Chair that a hearing be opened. In this context, the In-Depth Review is a tool for prioritizing resources toward products with a higher likelihood of excessive pricing.

Transparency in the In-Depth Review process is essential. BIOTECanada recommends full access to the scientific review report and the price review report, to help prevent errors or misunderstandings from escalating unnecessarily into a hearing.

In the current proposal, patentees receive only the scientific review report while the price review report is withheld. No justification or purpose is provided in the Draft Guidelines for withholding this document, especially since in the event of a Hearing, it is likely this report would be included in evidence and made public.

BIOTECanada recommends enhancing transparency in the decision-making process of In-Depth Reviews and adopting consistent and predictable policies. The current Draft Guidelines allow PMPRB Staff considerable discretion by enabling them to evaluate all indications and comparators—after assigning levels of similarity—and weighing the various Section 85 factors in determining whether to recommend a hearing. This raises concerns about consistency between reviews, especially when patentees do not receive the full price review report. Furthermore, prices which fall at or below the

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higher of HIP and the most expensive comparator in the TCC test should be presumed to be a low risk for excessive pricing. This will help ensure a more objective and consistent application of the review criteria.

The Draft Guidelines state that the purpose of an Undertaking accepted by the Chairperson is to resolve a specific In-Depth Review. The Guidelines should ensure that patentees have the information and assistance needed to propose Undertakings that directly address the issues identified in the review. The parameters of an acceptable Undertaking should be stated and understood by Patentees in advance. For example, excess revenue calculations should be retroactive only to the time an in-depth review is initiated. PMRPB Staff must be able to work with patentees so that Undertakings can be tailored to resolve the In-Depth Review and would allow PMRPB staff to prioritize more significant cases.

Conclusion

BIOTECanada recommends finalizing these Draft Guidelines to ensure a fair and predictable regulatory environment for the biotechnology sector. We believe that the sustainable growth of the Canadian biotech ecosystem is crucial not only for advancing patient care and fostering innovation within Canada but also for strengthening our global competitiveness in the life sciences.

We also recognize that Canada operates within a complex global landscape, where uncertain trade dynamics underscore the need for a flexible and resilient approach. It is essential that our pricing framework adapts to these uncertainties while maintaining a competitive edge for the Canadian biotech sector. By prioritizing collaborative solution-making, we will help ensure that the Canadian biopharmaceutical sector remains a leader in innovation and continues to attract the necessary investment for the therapies of tomorrow. BIOTECanada and its members appreciate the opportunity to provide feedback on the Draft Guidelines.

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