December 20, 2023

Thomas J. Digby
Chairperson Patented Medicine Prices Review Board
Standard Life Centre, Suite 1400
333 Laurier Avenue West
Ottawa, Ontario K1P 7C1

Dear Mr. Digby,

BIOTECanada is providing written feedback on the PMPRB's *Scoping Paper for the consultations on the Board's Guidelines* ("the Scoping Paper") published on November 10, 2023. This report builds on our comments presented orally as part of the Policy Roundtable on December 5th, 2023.

BIOTECanada consists of more than 240 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, which includes emerging research-focused small and medium sized enterprises, universities, investors, incubator, and accelerator organizations, and 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 therapies, and many new dynamic technologies holding great promise for the future of healthcare.

Many of the questions posed in the Board's Scoping Paper refer to specific technical aspects related to future Guidelines. BIOTECanada's view is that technical aspects would be best addressed while consulting on Guidelines, so that they can be evaluated in context.

Therefore, we have focused our written feedback on the following principles upon which the development of future guidelines must be based.

1. **New Guidelines must align with the current Canadian Biotechnology Ecosystem.**

The Canadian biopharmaceutical ecosystem has changed significantly since the PMPRB's 2010 Guidelines were instituted. The biotechnology industry achieved significant advancements in numerous therapeutic areas such that previously untreated conditions now have the possibility of a cure. Canadian pricing and reimbursement institutions, each with mandates distinct from the PMPRB, have evolved to reflect this changing ecosystem, which has included:

- Health Technology Assessments (HTA), conducted by the Canadian Agency for Drugs and Technologies in Health (CADTH) and l'Institut National d'Excellence en Santé et Services Sociaux (INESSS), are existing mechanisms to assess the value of medicines. Payers rely upon these findings of the relative clinical and cost effectiveness of new medicines and their reimbursement recommendations.

- The pan-Canadian Pharmaceutical Alliance (pCPA), established in 2010, has since negotiated over 500 listing agreements, typically with confidential net prices, and has transitioned to a stand-alone organization. Private payers have also come to routinely negotiate confidential net prices for new medicines.

Other countries, particularly those in the PMPRB7 and PMPRB11 countries, have likewise evolved their pricing and reimbursement systems to adapt to this changing ecosystem. This has changed the nature of international price referencing, with many foreign prices reflective of reimbursement agreements with government payers.

Although the PMPRB as a quasi-judicial body must operate at arms-length from these other players, the new Guidelines should reflect PMPRB's role in the biopharmaceutical ecosystem which is to ensure list prices are not excessive – the upper limit under which all other stakeholders are highly capable and well positioned to freely operate in the various markets for reimbursing and funding drug technologies in Canada.

Therefore, simply moving forward with the PMPRB11 countries inserted into the 2010 Guidelines is not an appropriate approach for a future framework. The previous method of price referencing often does not allow an apples-to-apples comparison of ex-factory prices. The least predictable elements of the prior guidelines - level of therapeutic improvement and the identification of domestic comparators - formed the most common price test applied to new medicines. Additionally, the PMPRB's assessment of therapeutic improvement and comparator medicines were often at odds with those of HTA bodies and the real-world experience of payers.

2. **Guidelines should not act in opposition to Canadian Government's broader objectives to grow the biotech sector.**

At a less technical level, the industry strongly encourages the PMPRB to align future Guidelines with the government's broader objectives to grow the Canadian biotech sector for purposes of economic and healthcare benefits to Canadians. This includes the federal government's National Strategy for Drugs for Rare Diseases, the federal Biomanufacturing and Life Sciences Strategy, and recommendations of the Health and Biosciences Economic Strategy Table Report all of which look to enhance Canada's competitiveness. Canada's health and biosciences sector are a globally competitive hub of innovation through more agile and streamlined regulatory approaches that support access to life saving medicines and vaccines needed by Canadians. Pillar 5 of the Biomanufacturing and Life Sciences Strategy speaks to a world-leading regulatory environment. The PMPRB must see itself as part of that environment.

These commitments have helped to reposition Canada as a leading environment in which to invest and partner in developing the medicines of today, and importantly the next generation of health solutions. Global investors from throughout investment networks have helped to drive unprecedented early success in attracting record levels of investment into the sector in recent years. This includes multinational biopharma, who not only with new direct research and development infrastructure, have also established critical licensing and research partnership throughout the Canadian SME biotechnology community.

The Canadian biotech sector is experiencing a period of significant growth and investment as the pandemic has served to highlight the sector's economic, social, and health value. Indeed, 2023 has seen more than $4 billion dollars of investment through licensing, acquisitions, product development, and clinical trials secured from multinational partners into Canadian biotech companies including Bellus, Repare Therapeutics, Aspect Biosystems, Chinook, and most recently, Inversago Pharma.

Canada is competing with other jurisdictions to attract investors and talent to the sector. The world views Canadian biotechnology as an innovator in delivering ground-breaking solutions to the global marketplace. Recent successes can be found throughout the spectrum of innovation with hundreds of small start-up entrepreneurs striving to bring scientific discovery to the global marketplace. If Canada is unable to attract investors and talent, domestic innovations will be commercialized to countries whose markets incentivize growth and possess investment and talent capacity.

These new initiatives recognize the nature of a healthy biotechnology ecosystem that includes active investments and partnerships with multinational biopharmaceutical companies. Operating on a global scale, these companies rely on a competitive regulatory, reimbursement, and pricing environment granted by our governmental entities, including the PMPRB.

3. **New guidelines should align with the PMPRB's legislative mandate.**

The PMPRB's role in Canada is very specific: to ensure that the prices charged by patentees for patented medicines sold in Canada are not excessive. As the Federal Court of Appeal has recently stated, the PMPRB has not been authorized to act as a price regulator; that is an area of provincial jurisdiction.

It is well established in the law and jurisprudence that any finding by the Board of an excessive price must be based on the factors in the Act and be consistent with the scope and mandate of the Board. In this context, a number of recent judicial decisions have helped to confirm the Board's mandate. It is important to acknowledge that the term "excessive" is used in the context of legal rights granted under the Act and to address a potential abuse of those rights.

In the Alexion decision, the Federal Court of Appeal stated:

> Over and over again, authorities have stressed that the excessive pricing provisions in the Patent Act are directed at controlling patent abuse, not reasonable pricing, price-regulation, or consumer protection at large.
> ...
> Were the excessive pricing provisions of the federal Patent Act aimed at reasonable pricing, price-regulation, or consumer protection at large, they would be constitutionally suspect.[1]

The PMPRB's role is distinct from Canada's robust regulatory, reimbursement, and pricing frameworks for medicines, which ensure that Canadians have access to the most appropriate and optimal therapies at prices that support drug plan sustainability. The Board must ensure that their new Guidelines remain aligned with their mandate of ensuring patented drug prices are not excessive.

For the Board to develop effective new Guidelines, there must first be an agreement on the objectives the Guidelines seek to achieve. Only then can consulting stakeholders evaluate whether various mechanics or configurations of price tests are designed to effectively achieve these objectives.

A triage-based approach for commencing investigations would be of value so long as it closely aligns with the PMPRB's mandate and with the goals of an efficient administrative review – predictable bright-line tests could be developed to identify and investigate products with a potential excessive price. Patentees with products under investigation should then be able to rely upon well established Section 85 factors to justify the price.

The most appropriate mechanism at introduction to triage for potential excessive pricing is the Highest International Price Comparison (HIPC) test. Canadian ex-factory prices that do not exceed the PMPRB11 countries are not obviously excessively priced and should not be seen as priorities for investigations. After introduction, CPI-based increases to list prices should not trigger investigations. Moreover, once an initial review has been conducted following introduction, it should not be subject to re-benchmarking over time. This approach provides the predictability and stability the sector requires to invest in new technologies that have very long discovery and development timelines.

Another measure proposed in the Scoping Paper, the Median International Price Comparison (MIPC) test, is not appropriate for this purpose for a number of reasons. Use of the HIPC of new PMPRB11 basket of countries would already significantly constrain prices – a MIPC-based framework, which would presume that any price above the median may be excessive, does not align the PMPRB's mandate and crosses the line into price setting. Additionally, the use of the MIPC does not align with the purpose of Guidelines: to provide a framework for efficient administrative review which facilitates voluntary compliance. MIPs can significantly fluctuate year-to-year and would trigger a large number of investigations into prices once considered comfortably non-excessive.

The prices of Existing Medicines must be grandfathered and not subject to additional price review in the new Guidelines. Grandfathering should be defined as follows: medicines and their line extensions sold at non-excessive prices prior to implementation of the new Guidelines should be presumed to be non-excessive moving forward. This is consistent with the grandfathering provisions when the Guidelines were last revised in 2010.

Grandfathering ensures crucial predictability to both existing patentees and to stakeholders more broadly. Patentees set these prices, in part, to comply with the prior Guidelines and then entered into reimbursement,

[1] Alexion Pharmaceuticals Inc. v. Canada (Attorney General) - 2017 FCA 241

distribution, and dispensing agreements based upon those prices. Patentees and the other stakeholders had a reasonable expectation that these prices would, for the most part, remain non-excessive in the future. As the Scoping Paper notes, 76% of existing medicines, which were deemed compliant under the PMPRB7 and 2010 Guidelines, are currently priced above the Median International Price. Forcing price reductions to these products, which represent 85% of patented medicine sales, by changing reference countries would be a significant disruption to stakeholders and is a form of price control beyond the PMPRB's mandate.

Other efficiencies should be included in a triage-based Guidelines approach. Vaccine products have a low risk of excessive pricing due to a centralized procurement process. These low-risk products should be regulated on a complaint basis much like veterinary, OTC, and generic products.

4. Development of New Guidelines should be a Collaborative Effort

In previous versions of the Guidelines, the Board included a statement of purpose and principles that the Guidelines were meant to achieve. The most recent Compendium of Policies, Guidelines and Procedures (2017) identified fairness, transparency, openness, and predictability as guiding principles[2].

The Compliance and Enforcement Policy, which was published in prior versions of the Compendium[3], stated:

> **1. Purpose**
>
> **1.1** The purpose of this policy is to ensure that the prices of patented medicines are not excessive by encouraging and facilitating voluntary compliance by pharmaceutical patentees with the Act.
>
> **1.2** The policy is based on the following principles:
>
> a) Consultation with all interested parties, including patentees and ministers of health, on the development of Regulations, Guidelines, and other policies of the Board.
>
> b) Clear Regulations and Guidelines to provide certainty concerning the filing requirements and price review criteria.
>
> c) Transparency of the PMPRB's policies and activities to the extent consistent with the provisions of the Act.
>
> d) Fair proceedings in accordance with the principles of natural justice.
>
> e) Timely and effective enforcement to remedy instances of excessive pricing, deter noncompliance with the Act, and penalize, when appropriate, activities contrary to the Act.

The purpose of the Guidelines, as stated above, is to provide patentees with an operational, transparent, and predictable framework that facilitates voluntary compliance. BIOTECanada requests that the PMPRB establish meaningful Working Groups when developing the new Guidelines. For example, the 2011 DIP Technical Working Group, which consisted of representative stakeholders and PMPRB Staff, provides an important model of an effective working group and should be emulated. Experienced members would be able to "stress-test" the Guidelines in a Working Group structure and help develop clear language to prevent ambiguity, contradiction, and unforeseen or counter-productive outcomes before the Guidelines are published.

Guideline proposals from the PMPRB should be accompanied by financial impact assessments and with detailed case examples of applying the various elements of the Guidelines to drug prices.

[2] PMPRB 2017 https://www.pmprb-cepmb.gc.ca/view.asp?ccid=492
[3] PMPRB 2014 https://www.pmprb-cepmb.gc.ca/view.asp?ccid=529#803

BIOTECanada strongly encourages the PMPRB to continue the current level of communication and collaboration with stakeholders. It is through effective and transparent collaboration that durable Guidelines can be developed to provide patentees with the predictability and clarity needed for compliance and ensure a sustainable Canadian biotechnology ecosystem.

BIOTECanada and its members appreciate the opportunity to provide feedback on the Scoping Paper. Collectively, we are eager to work cooperatively with the PMPRB to establish drug pricing policies that prioritize the health of Canadians and ensures a sustainable health care system.

Sincerely,

Andrew Casey
President & CEO