BIOTECANADA SUBMISSION TO THE PMPRB
DRAFT GUIDELINES 2022 CONSULTATION

Executive Summary

- A major priority for the government in its response to the COVID-19 pandemic is the pursuit of a Biomanufacturing and Life Sciences Sector Strategy to rebuild and grow the domestic biomanufacturing sector. The government is also on the verge of adopting a national strategy on drugs for rare diseases. The uncertainty created by these new proposed guidelines will undermine these government priorities which are building significant momentum in the biotechnology industry to provide economic and healthcare solutions for Canadians.
- The PMPRB proposes to abandon its voluntary compliance policy and instead is proposing a non-transparent case-by-case approach to investigations without a rationale for doing so nor an analysis of the implications. Creating significant uncertainty, this approach is contrary to good regulatory practice and PMPRB's repeatedly-stated objective to provide predictable "bright line" guidance.
- The proposed guidelines are not aligned with the PMPRB's mandate under the *Patent Act* to remedy instances of ***excessive*** pricing of patented medicines. Recent jurisprudence has reinforced the need for the PMPRB to respect and work within its statutory mandate.
- As per the *Patent Act* and case law, the PMPRB's mandate does not include assessing "affordable" prices, but the proposed "investigation criteria" would set triggers related to "median" foreign prices and prices even lower. The PMPRB has failed to establish a rationale for doing so and how such an approach is consistent with the Act.
- The proposed guidelines, including the "investigation triggers," are inappropriately biased against the most innovative therapies and smaller companies.
- In summary,
    - the proposed guidelines are not aligned with the government's industrial and healthcare priorities,
    - they go beyond the scope and mandate of the PMPRB,
    - they would disadvantage Canadians' access to optimal health care by creating new barriers to innovative therapies and by discouraging the supply of breakthrough treatments.
- The PMPRB should not make any changes to its guidelines until it conducts a more robust consultation, including sharing of data analysis and rationale to support its proposals.

December 5th, 2022

Douglas Clark, Executive Director
Patented Medicine Prices Review Board (PMPRB)
Box L40 | Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario, K1P 1C1

Dear Mr. Clark,

In May of this year, the government passed amendments to the *Patented Medicines Regulations* following a period of close to seven years of policy development and litigation. Over that time the government and the PMPRB have conducted a number of consultations on policy options to which BIOTECanada has contributed significant efforts to participate actively.

The proposed PMPRB Guidelines 2022 published in October contain novel concepts. They go beyond what was necessary as a result of the government's policy direction in the amendments to the Regulations and changes in the basket of countries. The proposed new case-by-case approach would establish significant uncertainty to the market and pricing framework for patented medicines in Canada.

The Biotechnology Ecosystem

Canada's intellectual property regime forms part of the biotechnology ecosystem. It is well-established the objective of patent policy is to reward and encourage innovation across all sectors, including health care. The PMPRB's role in this system is very specific – to prevent those granted patent rights for medicines from abusing those rights. 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. The PMPRB's guidelines should align with its statutory mandate and not detract from government priorities in this sector.

BIOTECanada is the national industry association with over 240 members located around the country, reflecting the diverse nature of Canada's health, industrial and agricultural biotechnology sectors. In addition to providing significant health benefits for Canadians, the biotechnology industry has quickly become an essential part of the transformation of many traditional cornerstones of the Canadian economy including manufacturing, automotive, energy, aerospace and forestry industries.

Biotechnology is becoming more central to supporting the economic and environmental transformation of Canada's traditional economic cornerstone and job intensive industries. Canada has a diverse biotech ecosystem with clusters in every province, in which small- and medium-sized biotech companies work with universities, research institutes and hospitals, regulatory authorities and multinationals to bring their innovations to the global market.

The Canadian biotech ecosystem is an economic strength positioning Canada to successfully deliver innovation to a world looking for solutions to domestic and global challenges in industries such as agriculture, energy production, environmental remediation, and healthcare. With unprecedented global issues including climate change, food security and health needs, the biotechnology industry is a vital

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contributor towards solving these challenges while delivering significant economic benefits, including investment and employment. Biotechnology is becoming especially relevant in government priority areas such as economic development, innovation, and healthcare.

The biotech ecosystem was crucial to the public health response during the COVID-19 pandemic and a catalyst for advancing research and innovation through industry collaborations and partnerships. Since the onset of the pandemic, BIOTECanada members have worked closely with governments to develop and bring to market the essential vaccines and treatments and they supported regulatory changes to accelerate access while maintaining the integrity of regulatory systems. BIOTECanada continues to work closely with governments to develop and support federal and provincial life sciences strategies and improvements in health care.

In 2021, the Government of Canada announced over $2 billion to develop the Biomanufacturing and Life Sciences Strategy (BLSS)[1] to rebuild and grow the domestic biomanufacturing sector, to see through investments made throughout the pandemic, and to resolve any immediate supply chain challenges.

In its 2019 budget, the government announced an investment of up to $1 billion over two years for Canadians to access treatments for rare conditions, starting in 2022-2023.[2] The 2021 federal budget maintained this pledge and in the most recent mandate letter to the Minister of Health, the government committed to advance a national strategy on drugs for rare diseases.[3]

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 the investment network have helped to drive unprecedented early success in attracting record levels of investment into the sector in recent years. This includes multinational pharma, who not only with new direct research and development infrastructure, have also established critical licensing and research partnership throughout the Canadian SME biotechnology community.

Canada is competing with other jurisdictions to attract investors and talent to the sector. The convergence of life science innovation, financing, and operational growth with technologies including artificial intelligence, advanced cell and gene therapies, big data, and platform technologies such as 3D printing will lead the Canadian economy. 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.

[1] https://ised-isde.canada.ca/site/biomanufacturing/en/canadas-biomanufacturing-and-life-sciences-strategy
[2] https://www.budget.canada.ca/2019/docs/themes/pharmacare-assurance-medicaments-en.html
[3] https://pm.gc.ca/en/mandate-letters/2021/12/16/minister-health-mandate-letter

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Objectives of Proposed Guidelines

The proposed guidelines are intended to implement the amendments to the *Patented Medicines Regulations* effective July 1, 2022, which changed the basket of countries for which patentees are to file prices, creating the new PMPRB11: Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United Kingdom. The new regulation excludes the United States and Switzerland and adds six new countries with lower prices than Canada. The 2019 Regulatory Impact Analysis Statement estimated the changes in the basket would lower expenditures on patented drugs by $2.9 billion (present value) over 10 years.[4]

However, the proposed guidelines include many changes reaching far beyond the new basket of countries suggesting the Board has additional, unstated, objectives. The proposed investigation triggers imply that the Board expects that each new patented drug be priced at levels not exceeding the median of the PMPRB11 and that many would be lower. These triggers are inconsistent with the PMPRB's statutory mandate and with the government's policy intention.

In previous guidelines, the Board has stated its objective and principles. The Compliance and Enforcement Policy which was published online until 2017 states:

> **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. (Emphasis added)
>
> 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.[5]

BIOTECanada invites the PMPRB to consult on its objectives and principles for new guidelines. It should start by reviewing previous principles and asking whether and how they should be amended; it should ensure its objectives and principles for the proposed guidelines fit squarely within its mandate and are aligned with broader government policies and priorities.

[4] https://www.gazette.gc.ca/rp-pr/p2/2022/2022-07-06/html/sor-dors162-eng.html
[5] PMPRB 2014 https://www.pmprb-cepmb.gc.ca/view.asp?ccid=529#803

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Case-by-Case Approach

In the virtual webinar on November 3, Board Staff confirmed the proposed guidelines published October 6, 2022, intend to establish a new approach; staff confirmed the proposed guidelines intend to establish a "case by case" process for staff review of prices instead of the long-standing approach of voluntary compliance based on clear price guidelines. There had been no prior indication of this proposed change nor engagement with industry and other stakeholders on it. Board Staff described a scenario where once an investigation has been commenced, they would engage in discussions with the patentee to establish an acceptable price (not a non-excessive price). This proposal represents a significant reversal of the PMPRB's long-standing approach of voluntary compliance. It also came without warning as it had not been raised in the discussions of PMPRB reform over the past seven years.

In 1988 the Board decided against a case-by-case approach and adopted a voluntary compliance policy. It opted for:

> … clear, understandable guidelines that provide, to the maximum extent possible, certainty and predictability for patentees in the definition of excessive price.[6]

The PMPRB has not provided a rationale for suddenly moving to a case-by-case approach today; it is in no way related to the recent amendments to the regulations. In fact, it has been well accepted the approach of voluntary compliance with the Excessive Price Guidelines has been effective throughout the Board's history. The voluntary compliance approach acknowledges our members aim to comply with the pricing provisions of the *Patent Act*. It is corporate policy of all members to respect and comply with the law. The presence of the PMPRB's Excessive Price Guidelines has, for the most part, provided significant certainty to manufacturers to allow them to make business decisions to market their products in Canada, and to minimize the need for protracted and costly legal proceedings.

From the perspective of a rightsholder, the case-by-case approach establishes no clear path to compliance. Developing and marketing a new medicine requires a significant investment of human and financial resources and years of planning and forecasting. The proposed guidelines would give minimal guidance to patent-holding manufacturers as to what would be considered a non-excessive price by the Board Staff. If the patentee is unable to negotiate a satisfactory resolution with Board Staff, its only recourse is to proceed to a full public hearing and ultimate adjudication by a hearing panel.

The Independent Assessment of Health Canada's Cost-Benefit Analysis of the Impact of Proposed Amendments to the Patented Medicines Regulations by Dodge and Blomqvist stated:

> A regulatory agency such as the PMPRB in the Canadian system, however, does not play the role of a payer. In our system comprised of a multiplicity of public and private insurers, its mandate is to protect Canadians against "excessive" drug prices, ***not to negotiate with suppliers about prices and other conditions*** that will govern the future utilization of a given drug. Payers can do the latter. (Emphasis added)

This statement recognizes the drug pricing and reimbursement system in Canada is comprehensive and complex - involving many activities, programs, and levels of government, including Health Technology Assessment by the Canadian Agency for Drugs and Technologies in Health and l'*Institut National*

[6] PMPRB Bulletin 5, July 1988

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d'excellence en santé et services sociaux, pricing and listing negotiations for public plans through the pan-Canadian Pharmaceutical Alliance, and separate negotiations with both public and private payers. Although the PMPRB as a quasi-judicial body must operate at arms-length from these other players, it should not operate in a vacuum. Introducing negotiations or discussions on price with PMPRB Staff would create unnecessary overlap and duplication.

Given there has been no consultation on such a shift in the PMPRB's approach, BIOTECanada submits that the Board has an obligation to provide a clear rationale and objectives for doing so and, if it chooses to pursue this approach, that it conducts a separate and full consultation on the process to be applied.

Bias Against Innovative Therapies and Smaller Companies

The Board has stated one objective of PMPRB reform is to focus on drugs at "high risk" of excessive pricing. The Board has not defined "high risk."

In reducing reporting requirements for certain classes of drugs at "low risk," the government has applied a standard based on the nature and extent of competition in the market. The Board does not appear to have applied a similar standard. Instead, it appears to be targeting products based on their anticipated cost. In our submission, such an approach is inconsistent with the jurisprudence which emphasizes the Board's mandate is to assess excessive price in terms of patent abuse and not to assess what it may consider as "affordable" prices.

The proposed approach to "high risk" products appears designed, intentionally or not, to focus on the most innovative therapies that treat more specialized and less common conditions. For example, many new treatments coming to market will treat genetic and other rare conditions including many in oncology; these are often highly specialized and technologically advanced treatments. They are typically products for which evidence is continually being generated and ultimate optimal utilization is uncertain. We are concerned the Board's proposal will create greater uncertainty and delay for these innovations, running counter to the government's policies to support biotechnology and to provide greater access to innovative treatments for Canadians with rare disorders. The current proposal is also inconsistent with the historic approach of the Board to contemplate greater pricing flexibility for substantial improvement and breakthrough drugs.

A related concern is these products are often developed and brought to market by small, specialized companies whether based in Canada or in other countries. Without a broader portfolio they face a higher risk in coming to market in an unpredictable and complex, lengthy pricing system. Smaller companies are more likely to forego Canada due to this uncertainty as they may not possess the dedicated pricing and legal resources to navigate Board hearings and potential legal proceedings.

Proposed Guidelines Not Aligned with PMPRB Mandate

Instead of excessive price guidelines for patentees, the Board proposes to establish investigation triggers for Board Staff, i.e., price levels that would cause investigation, negotiation, and potential price reductions. Although they do not define "excessive" for purposes of the Act, these triggers give a clear indication of the intended starting point for further analysis and discussions with Board Staff.

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

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this context a number of the recent judicial decisions have helped to confirm the Board's mandate is to ensure that the price of a medicine protected by a patent not be excessive. 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.[7]

The proposed investigation triggers fall beyond the concept of "excessive." For example, by targeting prices above the median of the PMPRB 11, the Board is implicitly warning patentees that such prices would be considered excessive. It is one thing in the case of existing drugs for the Board to take the position that a price higher than the range of prices in the PMPRB 11 might be considered excessive, but it is quite another to propose prices for new medicines above the ***median*** would be considered excessive.

But the investigation triggers would go even further in that they would target prices ***below*** the median in many cases based on comparisons with the therapeutic class. The webinar presentation provided an example.

When PMPRB Guidelines propose thresholds characterized as lowest, lower of, or even median, midpoint or average, they are not consistent with the courts' determinations of what constitutes excessive pricing within the paradigm of patent abuse.

The Board has not provided clear objectives for the proposed guidelines. This contrasts with a long-standing position of the PMPRB under the previous regulations that it expected prices, ***on average***, would not exceed the median of international prices. By contrast, the proposed guidelines appear to intend the price of each new patented medicine does not exceed the international median with the result that prices on average would be below. Nothing in the Act, the new regulations or the case law supports that objective.

Barriers to New Drug Launches

The proposed guidelines will create added barriers to introduction of new drugs in Canada, especially breakthrough treatments, by creating lower price targets relative to our major trading partners and an unpredictable pricing regime. The latest PMPRB Annual Reports shows a decline of 45% in new patented drugs reported since 2018, with the 59 new drugs reported in 2021 the lowest annual total in PMPRB history.[8]

[7] Alexion Pharmaceuticals Inc. v. Canada (Attorney General) - 2017 FCA 241
[8] PMPRB 2021 Annual Report, Figure 2

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The PMPRB proposes for a new drug, any price above the median of the PMPRB11 will trigger an investigation that may in turn lead to a price lower than the median. The impact of this approach is the Board Staff will investigate a price at the level of prices in Italy, Germany, Sweden, Spain or Japan.[9] That investigation could result in Staff concluding the price should be lower than the foreign median as illustrated in the webinar presentation.[10] For a patentee introducing a new drug in Canada, there is no guidance on what price may be acceptable to Board Staff until after the drug is on the market and the patentee has reported price information to the Board.

There are concerns from throughout industry on the potential for frequent price reassessments by PMPRB triggered by the investigation criteria based on international prices and the dTCC. There is ambiguity on what would trigger a new dTCC assessment and concern that changes in the international median prices would create floating price ceilings. It is recognized the comparable foreign price may change frequently, either up or down, as a result of changes in the countries in which the drug is sold and fluctuations in exchange rates.

The proposed guidelines delegate wide discretion to Board Staff to select comparators and negotiate with the patentee but provide only limited direction on the criteria and factors to be applied. The Board Staff are not recognized as independent impartial experts in conducting therapeutic comparisons. The Board Staff will aim to negotiate an "acceptable" price, not a non-excessive one; the Board Staff will no longer seek a Voluntary Compliance Undertaking to comply with Excessive Price Guidelines but simply an undertaking to lower the price to some level "acceptable" to Board Staff.[11]

As proposed, it is evident the Board Staff may seek agreement on a price and undertaking at a level lower than what the Board would have found as a result of a hearing. In this context it must be recalled that Board Staff has exceptional leverage as they can recommend a Notice of Hearing; patentees take the threat of a public hearing very seriously, as it typically takes several years, with considerable expense and negative publicity.

In addition, the Board proposes that a complaint will automatically cause an investigation to be launched, whether or not the complaint provides any supporting evidence.

BIOTECanada members strive to bring medical innovations to patients in Canada in a timely manner; certainty in the Canadian pricing environment is a factor that impacts global product launch sequences, and the place Canada holds relative to countries with similar healthcare systems. All in all, if the proposed guidelines were to be adopted, patentees would face increased market uncertainty that will impact their decisions to invest and do business in Canada and to make new treatments available to Canadians.

[9] Based on slide 20 in the webinar presentation and the PMPRB's calculation of prices using IQVIA's MIDAS database. https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines-2022/PMPRB-Public-Webinar-2022-Draft-Guidelines-en.pdf

[10] Ibid., slide 22

[11] Proposed Guidelines, para 46: "If discussions result in an undertaking proposal the Staff believes will be acceptable to the Chairperson, it will be referred to them by the Executive Director for consideration."

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Next Steps: BIOTECanada Recommendations

The PMPRB should:

- Withdraw the proposed guidelines in their entirety pending further analysis and robust consultation;
- Abandon the proposal for a case-by-case approach and re-commit to follow a voluntary compliance policy in order to provide greater certainty to the Board, patentees and the health care system and to minimize the need for costly and lengthy legal proceedings; and,
- Before proposing any broader modifications to policies or guidelines, conduct a robust and transparent consultation around the PMPRB's guiding principles and objectives.

Sincerely,

Andrew Casey
President & CEO

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