Boehringer Ingelheim (Canada) Ltd/Ltée - Burlington, Ontario

Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
K1P 1C1

Boehringer Ingelheim (Canada) Ltd/Ltée

Human Pharma
Market Access

December 4, 2022

Carole Bradley-Kennedy
Telephone 905-631-4515
Mobile 289-208-0907
E-Mail carole.bradley@boehringer-ingelheim.com
5180 South Service Road
Burlington, Ontario, Canada
L7L 5H4
Telephone 905-639-0333
Telefax 905-639-3769
www.boehringer-ingelheim.com

Re: Patented Medicine Prices Review Board (PMPRB) Draft Guidelines 2022 Consultation

Submitted via online portal

Boehringer Ingelheim (Canada) Ltd/ltée ("BICL") would like to thank the Patented Medicine Prices Review Board ("PMPRB") for its engagement with stakeholders on the draft guidelines that were issued on October 6th, 2022. BICL continues to engage in constructive dialogue on the new guidelines and maintains that our participation in the consultation process should not be interpreted as acceptance of the draft guidelines in its current form.

In the November 3rd, 2022, Industry Webinar briefing and Backgrounder regarding the proposed Guidelines, PMPRB staff commented that the proposed Guidelines allows for an "apples-to-apples" comparison of domestic and international list prices. BICL agrees that an "apples-to-apples" approach should be undertaken and that for a true "apples-to-apples" comparison of the price of medicines to be made, the Board must also consider the period of market exclusivity (i.e., *effective patent protection period)* allowed by Canada relative to each of the PMPRB11 basket countries.

In addition to local market dynamics, the list price of medicines in a country is impacted by the time frame in which that medicine can be sold prior to the introduction of generic versions. When assessing this extremely important factor, significant differences exist between Canada and all the PMPRB11 comparator countries. Whereas medicines in all PMPRB11

comparator countries are eligible for patent term extension up to 5 years via the issuance of a Certificate of Supplementary Protection (CSP), in Canada such extension is capped at 2 years or not available at all. This additional 3 to 5 years of market exclusivity from generics in PMPRB11 countries can have a significant impact on the pricing of a medicine, allowing for lower list prices as the revenue to the patentee is extended.

Outlined in the 'Elements' throughout this document are BICL's comments and recommendations particularly surrounding the operationalization, staff powers, clarity, transparency, high uncertainty, and apparent lack of recognition for innovation.

ELEMENT 1. Patent abuse versus Price control

The proposed guidance appears to be aimed at lowering prices generally in Canada rather than controlling patent abuse through the excessive pricing provisions of the *Patent Act*. Appellate court at both the federal and provincial levels have recently clarified the limits of PMPRB jurisdiction and cautioned the Board against helping itself to powers beyond the limits of its mandate. The current draft Guidelines provide no justification for choosing the median of the PMPRB11 prices as an investigation trigger, nor was justification provided for potential investigational triggers for medicines that are priced below the lowest of the PMPRB11 prices. Guidelines that are anchored in patent-abuse would rather seek to ensure that Canadian prices do not exceed the price of any international reference price without justification.

If the PMPRB's mandate is to ensure that there is no patent abuse, there is no rationale provided as to how the median price of international comparator countries aligns with this mandate. This appears to be a clear and deliberate mechanism to enforce price control. Recent court decisions have directed the Board to restrict their assessments away from price control towards ensuring that Canada's prices are not the highest in the world. It is not clear how a price can be deemed to be excessive if it is already lower than comparator countries that have pricing controls. The Board continues to assess the price of products that have generic competitors. How can these products be considered excessive?

Benchmarking to a median (or lower) international price is outside of the mandate to ensure that there is no patent abuse. Implementing a ceiling price through such a mechanism is an advertent price control. Furthermore, BICL does not agree with the concept that a medicine whose price remains unchanged in Canada can oscillate from being non-excessive to excessive from year-to-year due solely to external factors or the launch of a new indication. Constant re-benchmarking as international prices fluctuate (due to exchange rate volatility) could result in price erosion over time of patented medicines. Continual re-benchmarking is not only inefficient from an added administrative workload perspective, but also a disincentive for manufacturers to launch new medicines and/or new indications that could significantly improve the health of Canadians.

Guidelines anchored in patent abuse would further require a factual basis to attribute an alleged excessive price to a market exclusivity conferred by a relevant patent. In a multisource environment where a generic or biosimilar version of a medicine is available along side of the innovator product, it is not clear that the conditions for patent abuse through excessive pricing provisions of the Patent Act can ever be established, as there is no market monopoly.

Recommendation:

- Rather than the current proposal, new and existing products should be assessed relative to the highest international price (HIP) of the PMPRB11.

ELEMENT 2. Uncertainty over interpretation of the draft guidelines

The draft Guidelines states:

> *"The Board does not set or mandate prices for patented medicine and these Guidelines are not intended to be read as pricing guidelines."*

In their attempt to develop "*more pragmatic, less prescriptive guidance*" the Board is significantly increasing the uncertainty associated with the pricing of new medicines in Canada and creating unnecessary administrative burden

Boehringer Ingelheim

for all stakeholders involved. This issue/concern is not new and was acknowledged in a previous PMPRB Bulletin (Issue No 5, December 1989):

> *"The alternative to issuing guidelines is to leave patentees with no guidance as to how the Board will generally interpret the factors in the Patent Act and to resolve each suspected case of excessive price in the hearing room. In the Board's opinion, this would not be in the best interest of the industry, the Board, or the public. This approach would be expensive, time consuming and confrontational rather than furthering the Board's objective of voluntary compliance. It would also be unfair to those patentees who wish to have established guidelines in order to facilitate compliance without public hearings. In this regard, the Board notes the views of some patentees who expressed a desire for more specific guidelines (i.e., more "bright-line tests") to facilitate compliance."*

The pharmaceutical industry cannot make decisions about the pricing and launch of new medicines in the absence of clear predictable guidelines. Launch sequencing of new innovative medicines is an important industry best practice as external reference pricing sets in motion the meticulous planning of how and when new medicines are launched world over. Given the high uncertainty and lack of predictability that will result from the draft guidelines; the pricing dependency in other regions; the proposed reassessment/re-benchmarking of prices and the inherent volatility in exchange rates, patentees may have no other option than to either not launch or to significantly delay the launch of new life-saving medicines in Canada.

The mandate of the PMPRB is to determine in a systematic and clearly defined manner if there is price related patent abuse and gross violation of the patent monopoly that patentees are granted; the mandate is not price setting nor is it ensuring that prices are reasonable. The draft guidelines in

its current form are a departure from the fundamental regulatory principles of feasibility, fairness, predictability, and transparency.

Recommendation:

- The Board should revert to the original mandate of ensuring that there is no patent abuse with respect to list prices and to remove the requirement for constant re-benchmarking.
- The Board should reinstate clear guidance in a similar fashion as was present in the original Compendium of Policies, Guidelines and Procedures.

ELEMENT 3. Extraordinary concentration and reliance on PMPRB Staff discretion to trigger investigations

The revised draft guidelines confer extraordinary authority to PMPRB staff members thereby creating significant uncertainty to patentees. Throughout the draft guidelines, the Board has made no mention of the procedures or rules that would be followed in the event of an investigation. There is great reliance on the "perception" and "consideration" of the staff rather than on clearly stated tests which would be to assess prices during investigations.

From an external lens this may be perceived as an attempt to create guidelines that are not susceptible to judicial review and creating a non-constitutional environment. This intent is supported by the fact that there are no *bright-line* price tests and only investigational triggers described.

The subjectivity throughout the guidelines regarding the jurisdiction of the Staff is not reassuring to patentees. Based on previous patentee experience (as obtained through an Access to Information request[1]) it is unclear how the same Staff will interpret the guidelines in an unbiased and fair manner. In a recent ruling it was noted[2]:

[1] Opinion: Is Ottawa prepared to call Big Pharma's bluff? - The Globe and Mail
[2] Alexion Pharmaceuticals Inc. v. Canada (Attorney General) - Federal Court of Appeal (fca-caf.gc.ca)

"By obfuscating, the Board has effectively put itself beyond review on this point, asking the Court to sign a blank cheque in its favour. But this Court does not sign blank cheques. Administrators cannot put themselves in a position where they are not accountable"

Recommendation:

- The jurisdiction and interpretation of Staff powers should be made rigorously clear. Price tests that the Staff will use once an investigation has been triggered should be explicitly described in the guidelines.

ELEMENT 4. Uncertainty due to investigation triggers

The draft guidelines make the distinction between "Existing" medicines and "New" medicines, however, the two-classification system is mute with respect to and appears to ignore the assessment and recognition of therapeutic benefit of New medicines to patients.

For Existing medicines, the draft guidelines allow for the triggering of an investigation potentially leading to price reductions based on a single price in one PMPRB11 country. BICL believes that reference pricing based on one country (where the market dynamics and unmet needs may be completely different) is not a reasonable comparison, and that the price in a single market should not result in an investigation and/or price reduction. There is no clarity on when an investigation would be triggered if the medicine is not available in international jurisdiction at the time of launch in Canada.

Recommendation:

- The guidelines should include explicit assessment of the clinical benefit of New Medicines and/or new indications by the Human Drug Advisory Panel (HDAP).
- Prices of New and Existing medicines should only be assessed when a medicine's price is available at minimum in three PMPRB11 countries.
- Jurisdiction and interpretation of Staff powers should be made rigorously clear.
- Price tests that the Staff will use once an investigation has been triggered must be explicitly described in the guidelines.

ELEMENT 5. Challenging Interpretation of Therapeutic Class Comparison; Reference Strength Price and Unclear Scientific Review Process

Per the draft guidelines, the information detailed in the Appendices are *not-to-be relied* upon; however, operationally, information from the Appendices are the foundation for the criteria used to trigger investigations.

The identification of medicines and prices used for the Domestic Therapeutic Class Comparison (dTCC) is another example of how the Guidelines may be used as a price control mechanism versus ensuring that there is no patent abuse/excessive pricing. There is a very real possibility that the price of new highly innovative medicines will be benchmarked to those of older generic medicines with low-to-no therapeutic benefit. This is highly problematic and may serve as major disincentive to bringing new innovations to Canada.

The proposal to assess the price at which each dosage and strength form of an Existing medicine is or has been sold in any market in Canada or in any of the PMPRB11 countries may result in perverse situations where certain strengths of fixed dose combination (FDC) medicines that have been launched in a limited number of comparator countries may be reduced to price levels that are significantly lower than the individual components of the FDC. The draft guidelines are also silent with respect perverse pricing scenarios where the price of a higher strength/dosage of a medicine could be reduced to below a lower strength/dosage because of its availability in certain countries.

The proposed guidelines do not allow for flat pricing of New medicines. Flat pricing allows for a patient centric approach with efficacy and tolerability of medicines being the driving factor for prescription and not the cost of medicine. It has been a common practise for more than one dose of the medicine to be launched for the purpose of titration and adverse event management. Disallowing flat pricing of different strengths may result in suboptimal treatment of patients and delivering suboptimal clinical care.

Recommendation:

- Generic products should not be included in dTCC tests.
- Allow for flat pricing of medicines (irrespective of dosage and strength) and strike down the suggested linear pricing mechanism.
- Create a bright light rule where the price of FDCs cannot be forced below the price of individual components
- Create a bright light rule where the price of a higher dose cannot be forced below that of a lower dose

ELEMENT 6. Lack of recognition and greater disincentivizing of innovation

The draft guidelines make no attempt to acknowledge the scientific and therapeutic improvement of a medicine thereby failing to assess the innovation patentees are bringing to Canada. The disease landscape in Canada is rapidly changing particularly in the areas of rare disease and rare cancers; the draft guidelines fail to acknowledge the patient benefit incurred from the world class cutting-edge medicines that are launched in Canada.

The draft guidelines are mis-aligned with and undervalue the Federal, Provincial and Territorial plan of formalizing a drug for rare disease strategy in Canada and enable better access to new and innovative medicines to patients.

Recommendation:

- There needs to be a clearly defined, consistent and interpretable scientific evaluation process for all New medicines/indications.

ELEMENT 7. In highly uncertain economic time lack clear of CPI guidance to patent holders

The Consumer Price Index (CPI) calculation has been an essential mechanism to patentees for price increase calculations. Not only does the pharmaceutical industry rely on the CPI method as described in the Compendium of Policies, Guidelines and Procedures but provincial governments also rely on the method to establish price change. In the draft guidelines there is no explanation of how the CPI method will be implemented creating yet another source of operational uncertainty both for the government and industry.

Recommendation:

- Reinstate the CPI calculation mechanism as defined in the previous Compendium of Policies, Guidelines and Procedures.

In summary, Boehringer Ingelheim (Canada) Ltd requests that the PMPRB discard the proposed Guidelines and institute changes as recommended above. Such changes would serve to alleviate the concerns outlined in this document while still achieving the intent of preventing excessive pricing.

Yours truly,

Boehringer Ingelheim (Canada) Ltd.

Carole Bradley-Kennedy, MSc
Director Health Economics, Pricing and Outcomes Research