Janssen Inc.

19 Green Belt Drive
Toronto, ON M3C 1L9
1.800.387.8781 toll free
416.449.9444 tel
416.449.2658 fax

www.janssen.ca

December 5, 2022

Dr. Mélanie Bourassa Forcier
Vice-Chair, Patented Medicine Prices Review Board (PMPRB)
Box L40
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Re: *Notice and Comment – 2022 Proposed updates to the PMPRB Guidelines* (October 6, 2022)

Dear Dr. Bourassa Forcier,

Janssen Inc. (Janssen) appreciates the opportunity to participate in this ongoing consultation process. Janssen is strongly opposed to the Proposed Guidelines as they represent a sharp shift from the Board's mandate as identified in the *Patent Act*. Furthermore, Janssen fully endorses the submissions by our industry associations, Innovative Medicines Canada (IMC) and BIOTECanada. This letter provides an overview of our concerns followed by a more in-depth examination of specific elements of the proposal.[1]

Summary:

There is a disconnect between the Proposed Guidelines and the federal government's Biomanufacturing and Life Sciences Sector Strategy, and the Drugs for Rare Disease Strategy.

Ensuring timely access for Canadian patients to innovative new drugs and breakthrough therapies is at the heart of the federal government's Biomanufacturing and Life Sciences Sector Strategy (BLSS). Patient access is also a key driver of Canada's anticipated Drugs for Rare Disease Strategy, and the Life Sciences Sector Strategies of the Governments of Ontario and Quebec. Nevertheless, the PMPRB has chosen to propose guidelines that will add significant new barriers for innovative drug and therapy launches in Canada. The Board has yet to offer any rationale or justification for this approach and has not provided any sort of impact assessment.

[1] Janssen understands that the Proposed Guidelines are intended to operationalize amendments to the *Patented Medicines Regulations* which came into force on July 1, 2022. Janssen is committed to constructive engagement with the PMPRB, but states for the record that its engagement should not be interpreted as supporting the validity of the amended *Regulations* which remain, as of the date of this submission, under review by the Federal Court of Appeal in docket A-215-20. Nor should Janssen's participation in the consultation be taken as a waiver of the right to object to any aspect of the amended *Regulations*, Proposed Guidelines, or other decision that exceeds the jurisdiction of the Board, or which raises constitutional division of powers concerns, or which is otherwise open to lawful objection.

Increased uncertainty and lack of predictability will negatively impact new drug launches and patient access.

Janssen is concerned about the unprecedented degree of uncertainty introduced by these proposals. Compared to previous guidelines, the PMPRB is proposing to replace bright-line price thresholds with vague "investigation criteria,"[2] which leave absolute discretion with Board Staff. In recent webinars, Board Staff have outlined scenarios in which they might require a new innovative medicine to be priced below the lowest international price (LIP), or at a price equivalent to a generic medicine. This approach undermines the very purpose of the *Patent Act*, namely encouraging and recognizing patented innovations. Not only does the PMPRB plan to disband the independent scientific review group, Human Drug Advisory Panel (HDAP), under the Proposed Guidelines, they have also eliminated the role of innovation and science by removing any consideration of therapeutic improvement for the patient.

The Proposed Guidelines go beyond the PMPRB mandate to focus on excessive pricing.

The Board's chosen path is also at odds with recent jurisprudence, which constrains the role of the PMPRB to the prevention of excessive pricing and patent abuse. In many cases, patentees will be forced into Board hearings that last several years and cost millions of dollars, only for the Federal Court or a provincial Superior Court to quash that decision on judicial review.

Our Proposal:

Janssen recommends that the PMPRB withdraw these Proposed Guidelines and engage with industry in the development of a new approach that contemplates the practical implications of future PMPRB proposals on government objectives, patient access to new therapies, and the health of Canada's economy.

Discussion points:

These Proposed Guidelines represent a sharp shift from the Board's mandate of ensuring prices for patented medicines are not excessive, and instead establishes an unprecedented degree of revenue control and price setting. In addition, the Proposed Guidelines deviate significantly from many of the PMPRB's first principles, including: i) a mandate to regulate excessive pricing of patented medicines; ii) predictability and clarity for patentees; and iii) consideration for innovation. If implemented, the Proposed Guidelines will pose significant hurdles for new drugs coming to Canada.

Mandate of Excessive Pricing for Patented Medicines:

In contrast to the current PMPRB Guidelines, the Proposed Guidelines do not provide clear "excessive" price tests. Rather, they merely provide "…criteria that may trigger an investigation,"[3] as well as events that may occur if an investigation is triggered (i.e., negotiations and/or potential price reductions, or hearings).

Canadian law and jurisprudence have determined that factors cited in s. 85 of the *Patent Act* must form the basis of determining whether a price of a patented medicine is excessive. In addition, these factors must be applied consistently within the scope and mandate of the Board. In recent years,

[2] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/2022-proposed-updates-guidelines.html

[3] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/2022-proposed-updates-guidelines.html

several judicial decisions have established that the Board's mandate is to make certain that the price of a patented medicine is not excessive. In *Alexion v. Canada*, 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.*[4]

Furthermore, in *Merck v. Canada*, the Quebec Court of Appeal stated:

> *However, by imposing arbitrary price reductions of between 20% and 50% in some cases, and between 25% and 35% in others, the federal government is no longer acting within the framework of its jurisdiction over invention and discovery patents, since it is not seeking to regulate the price effects of the monopoly conferred by the patent, but rather the market itself* [translation from original].[5]

The Board's proposed investigation triggers expand their scope beyond excessive pricing, and into price control/market regulation. For example, the Proposed Guidelines state that if the list price of a new medicine exceeds the median international price (MIP) of the PMPRB11, an investigation may be triggered. However, the 2019 Regulatory Impact Analysis Statement determined that a change in basket alone (i.e., from PMPRB7 to PMPRB11) would lower expenditures on patented medicines by $2.9 billion over 10 years.[6] These are arbitrary reductions on the same order as those recently found to be invalid by the Quebec Court of Appeal. Therefore, if a patented medicine's price exceeds the MIP of the PMPRB11, it should **not** be considered to be excessive.

Furthermore, the Proposed Guidelines strongly imply that to avoid triggering an investigation, the patented medicine's list price must be the **lower of** the MIP of the PMPRB11 and the domestic therapeutic class comparator (dTCC). The very inclusion of language such as "median," "lower," and "lower of" clearly demonstrate that the Proposed Guidelines deviate from the PMPRB's mandate to prevent excessive pricing and patent abuse and are inconsistent with previous courts' rulings.

Lack of Predictability and Clarity for Patentees:

Janssen is concerned by the absence of clear definitions of price ceilings, and specific details for what will and will not trigger an investigation. These Proposed Guidelines are a marked departure from the bright-lines stakeholders had been promised.

In the PMPRB's webinar held on November 3, 2022, Board Staff confirmed that they intend to take a "case-by-case" approach when reviewing list prices as opposed to setting clear "excessive" price guidelines that support the principle of voluntary compliance. Board Staff described a scenario, and said that once an investigation is triggered, they would enter negotiations with the patentee to determine an "acceptable" list price (i.e., as opposed to a non-excessive price). Janssen is surprised by this deviation from current practice for two reasons:

[4] FCA Alexion 2021

[5] FCA Merck 2022

[6] https://www.gazette.gc.ca/rp-pr/p2/2022/2022-07-06/html/sor-dors162-eng.html

i) The PMPRB's role is not as a negotiator:

An independent Assessment of Health Canada's Cost-Benefit Analysis on the Impact of Proposed Amendments to the *Patented Medicines Regulations* stated that:

> 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.[7]

ii) The Board previously opted against a case-by-case approach in favour of voluntary compliance. Specifically, the Board elected to have:

> … clear, understandable guidelines that provide, to the maximum extent possible, certainty and predictability for patentees in the definition of excessive price.[8]

Throughout the course of its implementation, voluntary compliance with bright-line "excessive" price guidelines have been effective. This approach recognizes that all members aim to comply with the pricing provisions within the *Patent Act*, and with the law. By and large, the PMPRB's "excessive" pricing guidelines have provided manufacturers with enough clarity, predictability, and certainty so they could make pertinent business decisions. In contrast, the PMPRB's proposed case-by-case policy provides none of these important characteristics. In the absence of clear "excessive" price rules, patentees will have limited information as they attempt to establish an acceptable list price for their new innovative medicines which informs critical business decisions. This is problematic because decision-making in the pharmaceutical industry occurs over multi-year and sometimes multi-decade timelines. These decisions can be made only if there is sufficient certainty in the outcome.

The removal of "excessive" price tests and their replacement with criteria for investigation triggers result in greater discretion for PMPRB Staff. In addition, the Proposed Guidelines state that "In accordance with s. 96(4) of the Act, the Guidelines are not binding on Staff, the Chairperson, Hearing Panels or rights holders."[9] However, this statement does not align with either s. 96(4) of the *Patent Act* (i.e., "…guidelines are not binding on the Board or any rights holder or former rights holder," – it omits the term "Staff"),[10] nor section A.5.3 of the Compendium of Policies, Guidelines and Procedures.[11] It also conflicts with the Federal Court of Appeal's guidance in *Alexion*, which clearly states that even if the Guidelines are not formally binding, they must normally be followed by the Board, and departures must be justified. The Board itself recently confirmed this approach in *Horizon Pharma*, when it rejected multiple attempts by the Board Staff to depart from the Guidelines and use novel pricing tests. The Courts and the Board have both made clear that the Guidelines are expected to provide predictability and stability to excessive pricing hearings. The Proposed Guidelines are anything but.

The absence of price tests and clear guidelines, when combined with increased Board Staff discretion, creates a lack of predictability and uncertainty, and impedes global and local business

[7] http://www.raredisorders.ca/content/uploads/Dodge-Report-on-CBA-PMPRB-Aug-2018.pdf

[8] PMPRB Bulletin 5, July 1988

[9] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/2022-proposed-updates-guidelines.html

[10] Patent Act 1985

[11] https://www.pmprb-cepmb.gc.ca/view.asp?ccid=492

planning. Consequently, financial risk is increased, which is a disincentive to launching new drugs in Canada.

The Absence of any Consideration for Innovation:

The PMPRB has a long-standing history of considering levels of therapeutic improvement and recognizing innovation within the price review process. This practice is followed by other countries within the PMPRB11 (e.g., France, Germany, Italy, Japan). Indeed, the PMPRB temporarily removed therapeutic improvement from the November 2019 Draft Guidelines,[12] only to restore the importance of considering clinical innovation for the June 2020 Draft Guidelines after receiving feedback from stakeholders.[13] Therefore, Janssen was surprised and disappointed to see that the levels of therapeutic improvement were removed again from the Proposed Guidelines.

Not only has the PMPRB removed therapeutic improvement from the Proposed Guidelines, it also plans to continue using the dTCC when determining if an investigation may be triggered. Constraining the list price of new innovative medicines to existing domestic comparators is counter to the intended benefit of awarding a patent to the patentee. Furthermore, the selection of comparators will be left to the discretion of PMPRB Staff; a task that was previously undertaken within the scientific review by the HDAP. Under the Proposed Guidelines, the HDAP will be consulted on an *ad hoc* basis only, and its role restricted to the selection of comparators. This is problematic since Board Staff may not have the same level of formal clinical training, and thus the necessary expertise to make these decisions.

Moreover, the HDAP provided clarity on levels of innovation and domestic comparators early in the review process. This in turn increased predictability and allowed for long-term planning. Adopting a case-by-case approach or an evolving list of comparators does the opposite and makes informed long-term planning impossible.

Challenges for New Drugs Coming to Canada:

The lack of predictability and clarity in the definition of an excessive price, taken together with increases in Board Staff discretion, will create new challenges for patentees, and increase the barrier of entry for new drugs in Canada. Innovative drugs that deliver new levels of patient benefit will be disproportionately, and negatively impacted by the Proposed Guidelines. This will be especially apparent for breakthrough treatments, and personalized medicines (e.g., cell and gene therapies). Since these treatments will be given to a small and select group of patients, it is expected that their development costs, and consequently their prices, will be higher than those of standard-of-care. Furthermore, these novel therapies will be compared to inadequate, older treatments that are relatively lower priced.

The Proposed Guidelines strongly imply that a list price that exceeds the MIP or dTCC may trigger an investigation. Furthermore, the figure on page 11 of the Proposed Guidelines highlights instances in which a patented drug's list price may trigger an investigation even when it is lower than the LIP. If the Proposed Guidelines result in potential list prices that are significantly lower than international norms, patentees will either delay or not pursue launch in Canada. Overall, the Proposed Guidelines offer few details and great ambiguity over what may trigger an investigation, and how such an investigation may be resolved. In the recent joint IMC-BIOTECanada Meeting, PMPRB Staff stated that they are not looking to investigate all drugs, but the "outliers." Patentees are curious to know

[12] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines/draft-guidelines-2019.html

[13] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines.html

how the PMPRB identifies and defines an outlier, and how many future launches they might consider as such.

The use of conditional terms such as “may trigger” and “could potentially lead to a hearing” within the Proposed Guidelines offers patentees little assurance of the precise triggers for an investigation, or what may be an outlier. Rather, the Proposed Guidelines offer PMPRB Staff wide latitude. Patentees will not be able to accurately calculate non-excessive price thresholds for new products which is key in global business planning. Ultimately, this will have a negative impact on patient access to new medicines and treatments in Canada.

Conclusion:

Janssen is supportive of the federal government’s BLSS and its objective of enabling innovation by ensuring world class regulation and look forward to the imminent launch of its National Strategy for Drugs for Rare Diseases. The instability and unpredictability introduced by the PMPRB, through the Proposed Guidelines, will undermine the federal government’s efforts in these areas and are not consistent with its intent to “grow a strong and competitive domestic life sciences sector and ensure Canada’s readiness for future pandemics or other health emergencies.”[14] The Proposed Guidelines will compound the challenges created by the overlap and duplication in the system: Canada is the only country that uses a separate quasi-judicial body to regulate the list and net prices of patented drugs in addition to the price controls and negotiations conducted by public and private payers.

Janssen asserts that the Proposed Guidelines should not be implemented as drafted.

We will continue to strongly urge the PMPRB to work with industry to create a workable solution that maintains a predictable, understandable pricing system which preserves Canada’s international position for access to medicines and enhances efforts to grow Canada’s life sciences sector. Unfortunately, the Proposed Guidelines work at cross-purposes with that strategy and those efforts.

Sincerely,

Berkeley Vincent

Digitally signed by Berkeley Vincent
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Berkeley Vincent
President

cc. Rt. Hon. Justin Trudeau, Prime Minister of Canada
cc. Hon. Jean-Yves Duclos, Minister of Health
cc. Hon. Francois Phillipe Champagne, Minister of Innovation, Science and Economic Development
cc. Ms. Janice Charette, Clerk of the Privy Council and Secretary to Cabinet

[14] https://ised-isde.canada.ca/site/biomanufacturing/en/canadas-biomanufacturing-and-life-sciences-strategy