

**VIA PMPRB's Consultation Portal**

December 5, 2022

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

**Subject: Merck Canada Input on the October 2022 PMPRB Draft Guidelines**

On behalf of Merck Canada Inc. (Merck), thank you for the opportunity to provide comments on the October 2022 PMPRB draft Guidelines (the "Guidelines"). Our submission aims to complement those made by our industry associations, Innovative Medicines Canada and BIOTECanada.

After six years of discussions on the federal drug pricing reform, a global pandemic that demonstrated the importance of a strong life sciences sector, recent court cases clarifying the PMPRB's mandate, amendments to the *Patented Medicines Regulations* made last July and the launch and renewal of federal and provincial life sciences strategies to grow the sector, we were expecting the PMPRB to produce clear, predictable and transparent Guidelines that support innovation and access to new medicines while ensuring drug prices remain non-excessive.

We were therefore astonished and disappointed to see the PMPRB propose Guidelines that lack bright line tests, devalue innovation and run counter to the PMPRB's mandate and federal priorities.

In fact, the proposed approach represents a complete "paradigm shift", as acknowledged by the PMPRB staff, which has never been tested and which is expected to be finalized in only a matter of weeks (i.e., by the end of 2022). Such a significant change in approach warrants a robust consultation with the regulated sector and stakeholders and an assessment to understand the impact it will have on the sector, the health system and Canadians, prior to its implementation.

We have outlined in more detail below each of these concerns, which we hope will persuade the PMPRB to suspend the current process to allow time to carry out appropriate consultations and analysis. Ultimately, we need a regulatory environment that enables research and commercialization of medicines, and the proposed Guidelines fall short on this strategic imperative for Canada.

**1. No bright line tests**

The PMPRB is proposing to abandon its voluntary compliance policy based on clear price tests in favour of a "case-by-case" approach with arbitrary investigation triggers. The PMPRB staff will also be provided with unprecedentedly broad discretion and powers for assessing drug prices in the context of these investigations. Both these aspects are problematic.

**a. Arbitrary triggers**

The triggers for investigation in the draft Guidelines are lower thresholds than the prior price tests. For example, rather than using a price test which allows the higher of the Median International Price (MIP)

and domestic Therapeutic Class Comparison (dTCC), the trigger is instead any price which exceeds the lower of the MIP or the dTCC.

This is important because it will be difficult for patentees to launch their products in compliance with the investigative triggers. In short, this would mean that patentees can never price beyond the current domestic therapeutic comparators or if they do, then the price needs to be at least lower than any of the prices in the PMPRB11. It also runs counter to the stated goal of having fewer investigations than in the past, since the new criteria are much more likely to trigger investigations.

Because the PMPRB has said that the criteria are investigative triggers only and will not presume that a price is excessive even if beyond the triggers, then we appreciate that there may be some flexibility to price beyond the triggers, but the extent of the flexibility is unknown and so patentees will have no choice but to launch their products at risk or to stay below the very low investigative thresholds. This has important implications as further described below.

#### ***b. Broad discretion***

In its consultation webinars, the PMPRB staff indicated that if an investigation is triggered, they would engage in “discussions” on a price based on the factors outlined in section 85 of the *Patent Act*. The concept of a “discussion” in this case appears to understate the powers of the PMPRB staff, as it engages in negotiations for an undertaking by a patentee to avoid a hearing.

Based on our review of the recent Board Hearings, the PMPRB staff pushed for the lowest price ceilings possible. In both of the Board’s most recent excessive-price hearings (*Alexion*<sup>1</sup> and *Horizon Pharma*<sup>2</sup>), the staff adopted punitive pricing tests. This kind of litigation conduct suggests that the staff will pursue similar approaches in negotiations and the push for “lower-of” tests will undercut the ability of patentees to forecast revenues for the Canadian market.

Another source of uncertainty is the failure of the new Guidelines to lock-in comparators and prices at a certain point in time. Under the current draft, the maximum prices that companies can charge for their medicines will continuously fluctuate as a result of changes in the countries in which a medicine is sold, changes in exchange rates and shifts in domestic comparators and their prices. This is a complete departure from the PMPRB’s previous approach where products were assessed at time of first sale and were subsequently required not to exceed the highest international price of the basket of comparator countries (i.e., the PMPRB7). Instead, the PMPRB is now proposing to continuously and unpredictably reassess prices based on a floating median and subsequent indications of dTCC. This will not only generate significant uncertainty, but is also inconsistent with the PMPRB’s mandate, as further explained below.

Compliance is also rendered impossible by factors which have nothing to do with the pricing of a company’s medicines. For example, the draft Guidelines propose to automatically open investigations if there are no international comparator prices available. This means automatic investigations for products that launch first in Canada, or that launch first in the United States, followed by Canada. Companies that

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<sup>1</sup> *Alexion Pharmaceuticals v. Canada (Attorney General)*, 2021 FCA 157: <https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/500849/index.do>

<sup>2</sup> Board Decision - *Horizon Pharma and the Medicine “Procysbi”*, September 1, 2022 : <https://www.canada.ca/content/dam/pmprb-cepmb/documents/hearings/decisions-and-orders/PMPRB-Procysbi-Merits-Decision-Public-Version-EN.pdf>

would otherwise make Canada their #1 or #2 market will now be punished for doing so with automatic investigations regardless of their medicine pricing. As well, given that other markets reference Canadian prices, including the United States and European countries, this will deter companies from launching early in Canada for fear that it will erode their prices in other markets. This will therefore likely result in delayed Canadian launches or no-launch decisions.

Under the proposed approach, there will be no clear rules for how companies can price their medicines in Canada and therefore no clear path to compliance. Businesses cannot operate with this level of unpredictability, especially when it comes to regulatory compliance in an industry that deals with multi-year product pipelines. It will make it extremely challenging to commercialize new medicines.

As a result, the implementation of the proposed Guidelines will lead to the following negative consequences:

- **Decreased or delayed drug launches:** The new Guidelines will further exacerbate recent downward trends in the launch of new medicines in Canada. In particular, the number of globally-launched medicines that have been commercialized in Canada has declined every year since 2016, when the pricing reform was initiated.<sup>3</sup> Since mid-2019, more than half of all medicines approved by the USFDA have not been submitted to Health Canada for approval.<sup>4</sup>
- **Reduced research investments:** Research has also already been affected by the uncertainty of the price reform, as it is unethical to study a medicine in a jurisdiction where it may not be made commercially available once it is shown to be effective.<sup>5</sup> This trend will only worsen with the proposed pricing regime.

Moreover, in addition to pan-Canadian Pharmaceutical Alliance (pCPA) negotiations, manufacturers launching their medicines under the new approach will necessarily have to face another layer of negotiations with the PMPRB staff. This will likely result in more hearings and litigation, due to the uncertainty in the applicable price tests and discretion of the PMPRB staff. The cost of doing business in Canada will increase in this adversarial and litigious context.

This additional cost and administrative burden will be especially challenging for small businesses – small biotech companies – that may not have any experienced market access teams and that generally have more limited resources. These businesses, many of which are based here in Canada, are often the ones developing the most innovative solutions. These are businesses that the federal government is aiming to support and scale up through its Biomanufacturing and Life Sciences Strategy.

It is important to stress that the Board already considered adopting a “case-by-case” approach to price regulations and ultimately rejected that option for reasons outlined in the PMPRB Bulletin # 5 (1989):

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<sup>3</sup> <https://lifesciencesontario.ca/wp-content/uploads/2022/06/ENGLISH.pdf>

<sup>4</sup> Health Canada Drug and Health Product Submissions Under Review (SUR); Health Canada Notice of Compliance Database; FDA Drug Approvals and Database

<sup>5</sup> Clinical Trials in Canada: Worrying Signs Remain Despite PMPRB’s Superficial Response, Canadian Health Policy, March 2021: <https://www.canadianhealthpolicy.com/products/clinical-trials-in-canada--worrying-signs-remain-despite-pmprb---s-superficial-response.html>

Furthermore, while the guidelines may appear to be inflexible in that they provide “bright line tests”, it must be emphasized that the guidelines serve to trigger a review and do not represent the final determination of the Board on whether a price is excessive. 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. *[emphasis added]*

The case-by-case approach was demonstrated to be expensive, time consuming and confrontational and for the same reasons the PMPRB articulated at the time, this would still be the case today. The draft Guidelines and Background document do not provide any justification for departing from the Board’s 33-year-long approach of favouring bright line tests.

## 2. Devaluing and blocking innovation

The proposed Guidelines include the concept of therapeutic referencing based on a dTCC to lower prices well below the median of international prices. As a result, breakthrough medicines or major improvements could be compared to older medicines, including low-cost generics, resulting in significant price reductions. The approach, which is intended to focus on “high risk” medicines, will disproportionately negatively impact the most innovative treatments that address significant unmet clinical needs, including in the areas of cancer, rare diseases and antimicrobial resistance (AMR).

We also want to stress the concern that the PMPRB staff, who may not have the appropriate level of clinical expertise in the therapeutic area under review, will have unfettered discretion to select comparators. There is no mechanism either for patentees to challenge this determination. There is also arguably a risk of bias, since it is the same PMPRB staff who are conducting price assessments. The PMPRB Board in *Horizon Pharma*<sup>6</sup> criticized the Board staff for reverse-engineering price tests to achieve desired price reductions; the same concern would arise from Board staff reverse-engineering clinical comparators to achieve a similar outcome.

Comparing breakthrough innovations to older, genericized products undermines the value of innovation and patents. Patents are intended to reward innovation and the proposed approach would curtail this intellectual property protection, which is the cornerstone for developing new medicines.

Accordingly, we recommend that the PMPRB not use domestic comparators to further reduce prices as proposed in the draft Guidelines.

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<sup>6</sup> Supra note 2.

### 3. Inconsistent with PMPRB's mandate and federal priorities

The draft Guidelines are disconnected from the PMPRB's mandate, which the courts have said is limited to ensuring drug prices are non-excessive as a function of patent abuse. The courts have clearly indicated that the PMPRB's mandate does not extend to price control.<sup>7</sup> However, this is precisely what the PMPRB is intending to do by adopting a new approach that will unreasonably drive down the prices of new medicines.

More specifically, the PMPRB cannot use its powers to push prices below an already non-excessive level, because this would be unconstitutional.<sup>8</sup> Yet the draft Guidelines do precisely that by using the dTCC to reduce prices from the median to a lower non excessive price. In fact, the Guidelines specifically state that the dTCC can be used to push prices below the level of the lowest international price.

The concept of therapeutic class referencing and investigation triggers relying on "lowest" or "lower than" are therefore completely out of scope of the PMPRB's mandate.

The PMPRB has also failed to justify why the price of a medicine above the median of international prices would automatically be considered "excessive" and an abuse of patent. The Board has long held the position that prices should not, on average, exceed the median of international prices (i.e., the median of the PMPRB7).<sup>9</sup> However, the requirement that each medicine not exceed the median means that many treatments will have to be well below this threshold. It should also be stressed that the new basket of countries (i.e., the PMPRB11) now includes countries with much lower drug prices than those that were included in the previous basket. This is an important aspect for the PMPRB to consider when establishing pricing thresholds to ensure they set the bar at the appropriate level (i.e., to ensure non-excessive prices rather than to control prices). Patentees already negotiate prices with both public and private payers to achieve value, which drives billions of dollars in annual savings for the system.

Further, the uncertainty generated by the proposed approach, the way it devalues new medicines and its anticipated impacts (i.e., less research and fewer and delayed medicine launches) will also undermine Canada's broader governmental goals of growing the sector under the Biomanufacturing and Life Sciences Strategy and improving access to rare disease medicines through the national strategy, which is currently being developed by Health Canada.

Health Canada's Regulatory Impact Analysis Statement (RIAS), which accompanied the recent regulatory amendments, expressly references ongoing federal initiatives, including the Biomanufacturing and Life Sciences Strategy and the national rare disease drug strategy, as part of the rationale for making the regulation changes. It states that "the Government is now moving ahead with a suite of initiatives related to improving access to quality medicines and ensuring the sustainability of the healthcare system, while

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<sup>7</sup> Merck Canada Inc. et al v. Canada (Attorney General) et al, Quebec Court of Appeal, decision rendered Feb. 18, 2022: <https://www.canlii.org/fr/qc/qcca/doc/2022/2022qcca240/2022qcca240.html?resultIndex=1>; Alexion Pharmaceuticals v. Canada (Attorney General), 2021 FCA 157: <https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/500849/index.do>

<sup>8</sup> Merck Canada v. Canada, 2022 QCCA 208 ¶154, 161-162, 227, 244

<sup>9</sup> PMPRB 2022-23 Departmental Plan, p. 11: [https://www.canada.ca/content/dam/pmprb-cepmb/documents/transparency/departmental-plan/2022-23\\_Departmental\\_Plan\\_EN.pdf](https://www.canada.ca/content/dam/pmprb-cepmb/documents/transparency/departmental-plan/2022-23_Departmental_Plan_EN.pdf)

supporting innovation and investment in the pharmaceutical sector” *[emphasis added]*.<sup>10</sup> The Guidelines therefore run counter to the policy intent outlined in the RIAS.

#### 4. No impact analysis and insufficient consultations

When proposing a new policy, a regulator should first provide a clear rationale for a changed approach and conduct due diligence to analyze the impact the policy will have on the sector it regulates.

It is very concerning that the PMPRB has opted not to do so in this case. No substantive rationale for the new approach has been provided by the PMPRB. As well, the PMPRB is punting any impact analysis to a future evaluation plan (the Guideline Monitoring and Evaluation Plan).

Further, in our July 2022 submission to the Board, we recommended that future Guidelines consultations include working groups with industry to carefully review how the new approach would work in practice and to look at a range of case studies. We were disappointed that the Board chose instead to move forward with a limited consultation process with no opportunity to workshop the changes. The limited turnaround time for finalizing the Guidelines post-submission deadline also indicate the Board’s intention to push through a pre-determined solution without much consideration for stakeholder input.

In contrast, previous consultations on smaller technical changes to the Guidelines involved much more robust consultations. For instance, consultations related to changes to the DIP methodology, which allowed for the provision of compassionate free goods without affecting the list prices, included working tables with industry as well as direct engagement opportunities with Board Members.

In closing, we want to reiterate our request that the PMPRB suspend the Guidelines process to allow more time to develop a clear, transparent and predictable pricing framework that falls within the scope of its mandate and is aligned with the federal priorities of growing the life sciences sector and improving access to medicines. The PMPRB and the federal government are at an important inflection point of making a decision that will ultimately determine what type of life sciences sector and health system they want to build in Canada. Other countries, such as the UK, France and Australia, are stepping up with new measures and incentives to rebuild their health systems and expand the life sciences sector post-pandemic. If the PMPRB moves forward on the PMPRB’s draft Guidelines, this will hold Canada back compared to its peers and undermine efforts to rebuild our economy and health system.

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<sup>10</sup> Regulatory Impact Analysis Statement, July 6, 2022, Canada Gazette Part II, Vol. 156, No. 14: <https://www.gazette.gc.ca/rp-pr/p2/2022/2022-07-06/pdf/g2-15614.pdf>

We thank you for the opportunity to provide our comments. Please do not hesitate to contact me should you have any questions about this submission.

Sincerely,



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Merck Canada Inc.

**Merck understands that the PMPRB intends to adopt new Guidelines to operationalize amendments to the *Patented Medicines Regulations* (Regulations), which came into force on July 1, 2022. While Merck is committed to constructive engagement with the PMPRB, Merck's 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 Court File No. A-215-20. Merck reserves the right to oppose any aspect of the amended Regulations, new Guidelines, or other decision that exceeds the jurisdiction of the Board or which raises constitutional division of powers concerns or which is otherwise unlawful.**