Dec 20th, 2023

Patented Medicine Prices Review Board (PMPRB)
Standard Life Centre, Suite 1400
333 Laurier Ave.
Ottawa, ON
K1P 1C1

RE: Response to November 2023 Scoping Paper re PMPRB Guidelines

Dear Mr. Digby,

On behalf of Viatris, please find enclosed information to be considered by the PMPRB in this first phase of consultations on its new Guidelines. We appreciate the opportunity to share our perspective on the new Guidelines, informed by Viatris' unique position, delivering both brand and generic products.

Canada's pharmaceutical sector is essential to the health and well-being of all Canadians, a fact highlighted by the COVID-19 pandemic, and requires a regulatory framework that encourages the sustainability of the industry and provides predictability for future investment and growth. Viatris is encouraged by the new PMPRB Board Chair giving the approach and content of these new Guidelines their due time and consideration, given how complex and critically important their subject matter is to the industry, and to the Canadian population.

Viatris is in full agreement with the response provided by the Canadian Generic Pharmaceutical Association (CGPA). In addition, we will focus on the following three themes raised in the PMPRB's scoping paper:

1. **Product Life Cycle** – evolution of PMPRB's role over the course of a product's life cycle
2. **Transition** – grandfathering of existing medicines; and
3. **Price Reviews** – appropriate benchmarks and comparators.

1. Product Life Cycle

The role of the PMPRB and the Guidelines ought to evolve over the course of a medicine's life cycle to remain relevant. As noted in the scoping paper, it is important to strike a balance that allows for ongoing monitoring without undue administrative burden. In Viatris' view, the current approach does not achieve that balance for established brand products late in their patented life cycle. Specifically, the requirement of a manufacturer to continue reporting to PMPRB for the duration of any patents "pertaining to" the medicine – whether or not said patents still confer exclusivity or are embodied in the marketed medicine – does not properly weigh the risk of excessive pricing against the administrative burden to manufacturers and, indeed, the PMPRB. In our submission, PMPRB's mandate should be (a) limited to patents embodied in the marketed medicine, and (b) extinguished upon loss of exclusivity ("LOE") by the patented brand medicine.

In the scoping paper it is noted that the list prices of medicines in many countries are often seen to decrease over time, whereas in Canada, list prices tend to remain static or increase. As addressed further below, we think this observation is misleading in that it does not reflect real-world pricing, which often includes rebates, discounts,

and other confidential pricing arrangements negotiated between drug manufacturers and payers. This is especially so for patented medicines late in their life cycle, that are already facing generic competition. Thus, while the list price may remain the same, the actual selling price in Canada decreases over the course of the medicines' life cycle, just like in other comparator countries that may have different pricing and reporting practices.

The mandate of the PMPRB is to monitor the prices of patented medicines in Canada to ensure that they are not excessive. That said, if a patent no longer offers protection from generic competition – whether from a successful patent challenge[1] or because the subject matter is not reflected in the marketed medicine – it no longer makes sense for the PMPRB to continue its price-monitoring mandate. Once there is generic competition, or when there are no longer any patents blocking generic entry, the PMPRB's mandate is accomplished. In these cases, where the patent does not provide the patentee with market exclusivity, there are several reasons for ending the PMPRB's jurisdiction:

- **Lack of exclusivity.** If a patent does not provide exclusivity, it no longer benefits the patentee and the requirement to report to PMPRB should be extinguished[2]. Under the current PMPRB regime, manufacturers like Viatris are forced to report on patented medicines that have been genericized for years with pricing dynamics that characterize generic competition.
- **Lack of subject matter.** Patents with subject matter not reflected in the marketed product also do not confer market exclusivity and should not fall within the PMPRB's jurisdiction. The test for whether a patent pertains to a medicine was thoroughly considered in the *Galderma*[3] case, but we respectfully submit that the PMPRB should take this opportunity to reconsider the utility of continuing to assert jurisdiction based on patents that have no real-world benefit to patentees and are not obstacles to generic competition.
- **Market competition and pricing.** Patents are intended to encourage innovation by granting inventors a period of market exclusivity to recoup their investment costs. However, when a patent offers no protection from generic competition, it indicates that the market is already competitive and there is no longer a need for regulatory oversight of the patented medicine pricing. The price of a patented medicine does not increase in the face of generic competition. Quite the opposite, the market will be driven even more forcefully to the generic alternative unless the patented medicine's price is decreased through rebates, product listing agreements and other confidential pricing arrangements.
- **Administrative burden to the PMPRB and manufacturers.** Removing irrelevant and ineffectual patents from the PMPRB's jurisdiction allows the board to focus its resources on patents that have a meaningful impact on the prices of patented medicines, thereby improving the efficiency and effectiveness of its regulatory efforts. By removing patents that offer no protection from generics from the PMPRB's

[1] We note that under the old *PM(NOC) Regulations*, there have been several cases where a second person's allegations of invalidity are held to be justified, allowing the generic to launch, but the patent remains valid in the Canadian Patent Office, albeit with no practical effect.

[2] While a patentee may choose to lapse its patents once exclusivity is lost, that route is cumbersome and not always an available option. In many cases, the brand manufacturer is not the owner of the relevant patents, but is only a licensee, whether explicit or implied. In those cases, it may not be open to the brand manufacturer to unilaterally lapse the patents at issue.

[3] 2019 FCA 196.

jurisdiction, the board can concentrate on its core mandate of ensuring that prices of patented medicines are not excessive, while allowing for a more efficient allocation of resources and regulatory oversight.

2. Transition to PMPRB11

Viatris strongly supports a grandfathering provision in the Guidelines for medicines existing as of July 2022 ("Existing Medicines") and those introduced afterward ("New Medicines"). Viatris does not agree with the inclusion of Existing Medicines in the new basket of international countries, the PMPRB 11. Viatris has consistently advocated for the complete grandfathering of Existing Medicines to reflect investments already made in Canada. This is a fair compromise given the reasonable expectations of the industry at the time that significant business decisions and investments were made.

In the alternative, if the PMPRB11 is to apply to Existing Medicines, then it is essential that the appropriate benchmarks and comparators are used, as further discussed below. At a minimum, if Existing Medicines are to be subject to the PMPRB11 basket of comparator countries, then the appropriate comparator is whether the national average selling price is less than the highest international price ("HIP").

3. Price Reviews

Price monitoring and reviews under the new PMPRB Guidelines ought to retain a number of the elements from the 2010 Guidelines and Section 85 of the *Patent Act*.

(a) Average Selling Price vs. List Price

The PMPRB should continue to use the national average transaction price – not the list price – under the new Guidelines.

- **Real-world pricing impact:** Referencing the national average transaction price provides a more accurate reflection of the actual prices paid for drugs in the Canadian market. List prices may not reflect the real-world prices negotiated between drug manufacturers and payers, which may include rebates, discounts, and other confidential pricing arrangements. Therefore, the national average transaction price provides a more realistic basis for assessing the affordability and reasonableness of drug prices. Using list prices as a basis for comparison could lead to misleading conclusions about the affordability of drugs and access to treatment.
- **International comparability:** Many international pricing benchmarks reference transaction prices rather than list prices. By maintaining the concept of the national average transaction price, the PMPRB can ensure that its pricing assessments remain consistent with international standards, facilitating comparisons with drug prices in other countries.
- **Transparency and fairness:** Using average transaction prices promotes transparency and fairness, as this approach aligns with real-world pricing dynamics and can facilitate a more equitable assessment of drug pricing practices. Maintaining the concept of the national average transaction price can provide a more accurate and comprehensive understanding of the actual cost of patented medicines in Canada, which is essential for the PMPRB's mandate to protect consumer interests, including patients, and ensure fair and reasonable drug pricing.

(b) TCC using HIP is the Correct Approach

Currently, excessive prices through a therapeutic class comparison (TCC) are benchmarked against prices in the same therapeutic class. As long as a new market entrant is not priced higher than the class price (i.e., the top of the TCC or HIP) it is not considered excessive. The status quo 'top of the TCC' or HIP is the only TCC test consistent with an excessive price standard. Consideration of a median therapeutic class comparison, or Median International Price ("MIP"), is inconsistent with an excessive price standard as this would force products to be priced *lower* than products in the same therapeutic class, even if comparators are clinically inferior. A price should not be considered excessive just because it is "not lower" than half of the prices for similar drugs. The median TCC / MIP is an unreasonable test that is disconnected with the value and therapeutic improvement of a product and has no bearing on an 'excessive' distinction. Furthermore, the inclusion of generic drugs is of concern in the context of a possible median TCC as opposed to the highest of the TCC. As such, Viatris supports TCC tests and the need for the HIP of the TCC to remain the standard.

The PMPRB's consideration of International Therapeutic Class (iTCC) comparisons has the potential to significantly impact many patented products. Viatris is concerned that using products unavailable in Canada as relevant comparators for setting prices in the Canadian market creates the potential for an inaccurate understanding of what constitutes excessive pricing. There is also a lack of predictability associated with the iTCC and the median of medians concept. Differing criteria, labels, and other factors in foreign countries make it extremely challenging for a patentee to determine and comply with an iTCC. We recommend that the PMPRB maintain the current policy for the use and application of the iTCC, namely, only for informational purposes in the context of an investigation into potentially excessive prices.

(c) Changes in Consumer Price Index ("CPI")

Changes in the CPI are important and should continue to be reflected in the new Guidelines, as CPI can influence the pricing of patented medicines, namely:

- **Regulating price increases:** CPI is used to determine the maximum allowable price increase for a patented drug. If the CPI increases, a patented drug's price can also increase up to the same percentage. This has assisted drug pricing in keeping pace with inflation such that a given drug doesn't become more or less expensive relative to the market over time.
- **Establishing pricing guidelines:** CPI is used to establish pricing guidelines for new and existing patented drugs. Changes in the CPI can affect these guidelines and, consequently, the pricing of patented drugs.

In addition, changes in the CPI can provide the PMPRB with information about the general economic climate, including the rate of inflation, which can affect the affordability of patented medicines. Changes in the CPI can help the PMPRB to understand and anticipate these and other economic factors impacting affordability for consumers.

(d) Medications with Limited International Benchmarks

In reviewing patented medicines with limited international benchmarks, Viatris submits that the PMPRB should consider real world evidence and therapeutic value. We suggest using comparator countries with similar healthcare systems and allowing for a flexible pricing framework for innovative or rare-disease treatments.
Open and transparent communication between patentees and the PMPRB is essential for a better understanding

of specific challenges associated with medicines with limited international benchmarks. Highlighting the significant research and development costs associated with medicines with few international comparators emphasizes the need for fair pricing. A risk-benefit assessment acknowledging the inherent risks in developing novel therapies is crucial. Further, we propose the use of a cost-effectiveness analysis as a valuable tool in cases where international benchmarks are lacking.

Conclusion

In conclusion, Viatris appreciates the opportunity to contribute to the PMPRB Guidelines consultation. Aligned with the Canadian Generic Pharmaceutical Association, we emphasize the need for a balanced approach in the Product Life Cycle, proposing a refined mandate that considers the specificities of a medicine's life cycle to streamline regulatory efforts. Regarding the Transition to PMPRB11, we strongly support grandfathering provisions for Existing Medicines and advocate for careful consideration of appropriate benchmarks if included in the PMPRB11 basket. In Price Reviews, we recommend retaining key elements from prior guidelines, prioritizing the national average selling price for accurate assessments, and urging the use of the Therapeutic Class Comparison with the Highest International Price as the benchmark. Our suggestions aim to foster a framework that aligns with industry sustainability and regulatory efficiency, ensuring fair pricing while considering the complexities of the pharmaceutical sector, ultimately to the benefit of the Canadian patients.

Sincerely,

Jeffrey Long

Country Manager

VIATRIS™ Canada