March 19, 2025

Patented Medicine Prices Review Board
Box L40 Standard Life Centre
333 Laurier Avenue West, Suite 1400, Ottawa, ON, K1P 1C1Email:
PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Re: December 2024 Draft Guidelines Consultation

Dear Patented Medicine Prices Review Board,

On behalf of McKesson Canada and our 4,900 employees across the country, please accept our input into the Patented Medicine Prices Review Board (PMPRB) new Draft Guidelines.

McKesson Canada is the leading healthcare solutions provider in the country. As one of the few organizations that not only understands, but also works across the healthcare system, **McKesson Canada is focused on streamlining and expediting patient access to the vital medications they need.** As the largest pharmaceutical distributor, we deliver pharmaceutical products across Canada within 24 hours to 98% of our hospital and pharmacy customers, and within 48 hours for the remaining 2%. We are also the largest supporter of independent pharmacy, supporting over 2,600 pharmacist owners with services to support their store operations, so that they can focus on patient care. We also support patients on complex therapies with an end-to-end specialty health care model, such that they can start treatment sooner and reach their desired clinical endpoints.

We appreciate the opportunity to provide input into the draft guidelines. We anticipate a number of significant impacts on McKesson Canada, our fellow pharmaceutical distributors, and the broader pharmacy & pharmaceutical industries if these Draft Guidelines are implemented as written. **We hope our input will identify opportunities for PMPRB to still achieve its mandate while ensuring that the unintended consequences of annual pricing instability are minimized, during this challenging and uncertain operating environment arising from US tariff policy.**

Summary of Recommendations

Our key recommendations are as follows, and additional details are found in the body of our submission:

1. The PMPRB should take into consideration the current global upheaval in the pharmaceutical industry caused by volatile US tariff policy, which will lead to an unpredictable pricing & supply environment. We recommend that **implementation of the Draft Guidelines be held off until the pricing impacts of tariff policy stabilizes (such as 2028, to coincide with the end of the current administration in the US).**
    - If the PMPRB does intend to proceed in implementing the Draft Guidelines, they should **provide clarity on the timing of when existing vs. new medicine patent holders would be subject to the first round of annual price testing (e.g., end of 2027? 2028?).**

2. The PMPRB should **stagger the Annual Review for existing vs. new medicines on a biannual basis,** continuing the staggered implementation schedule (such as new medicines in odd years, existing medicines in even years)
    - In addition to reducing the burden on manufacturers & distributors to potentially manage a large volume of year-end price changes every year, this will also reduce the workload for the PMPRB staff

3. The PMPRB should **collaborate with provincial drug plans, private payers, and manufacturers to create more predictability for price changes to minimize interruptions to patient access**:
    - **Designate November 15th each year as "P-Day", which patent holders will notify all stakeholders of their anticipated price changes for Dec. 31st**, which will provide 1.5 months of advance notice for public & private payers, distributors, and pharmacies on patented medicines price changes, creating more predictability for distributor staffing and pharmacy inventory management
    - **When the Annual Review is done, compare each patent holder's MLP on Dec. 31st with the HIP of Nov. 15th** to avoid penalizing them for HIP fluctuations (from exchange rates, etc.) during the annual implementation period
        - **Alternatively, if the HIP of Nov. 15th must be used by the PMPRB for annual price testing, we suggest that all patent holders be given until the end of the first quarter of the calendar year to correct their MLP** (if it does end up being higher than HIP due to unforeseen circumstances, such as exchange rate fluctuations or unexpected prices changes within the PMPRB11)
    - Finally, **PMPRB should ask public and private payers to allow a 1-month washout period (i.e., the month of January)** to allow pharmacies to sell through any on-hand patented drug inventories following any price reductions

4. The PMPRB should **encourage provinces to reinvest PMPRB-driven savings to strengthen distribution & pharmacy funding (i.e., reinvest ~8.6% of savings on patented drugs** into pharmacy & distribution funding)

5. If possible, the PMPRB should **provide visibility on which patent holders are under In-Depth investigations** such that distributors can plan procurement activities

US Tariff Policy Will Create Instability in Canada's Pharmaceutical Supply Chain

US tariff policy, which is specifically targeting pharmaceuticals and the Canadian economy, could have a transformative impact on the global drug supply chain. When tariffs wall off the largest pharmaceutical market in the world or result in higher-cost pharmaceutical inputs for US-based production, manufacturers around the world will be making difficult decisions on where their pharmaceuticals are manufactured, where they are sold, and which drugs will continue to be made. **As a result, we anticipate a period of global pricing and supply instability in pharmaceuticals that would have direct and indirect repercussions on the Canadian market, which has cost implications on both manufacturers and distributors that serve our country.**

From the manufacturer perspective, Canada represents only 2% of global pharmaceutical demand and will need to "punch above its weight" to ensure that manufacturers would be willing to continue selling into our country, or even establishing domestic manufacturing facilities, amidst an increasingly fraught environment. Aside from being a small market, there are already numerous barriers that discourage manufacturers from serving Canada, such as a restrictive reimbursement environment, unique Health Canada regulatory requirements, unique labeling requirements, etc. **The new draft guidelines, which create a new systematic approach to price testing and greater risk for patent holders, will only further discourage manufacturers from not only entering Canada, but to continue selling in Canada, at a time when our country's drug supply faces instability threats not seen since the COVID-19 pandemic.**

Meanwhile pharmaceutical distributors have endured almost two decades of shrinking distribution funding driven by successive rounds of generic price compression (>70% since 2007), increasing Health Canada regulatory requirements, and rising costs. **The estimated "wholesale funding gap" for the distribution industry is about $100 M/year.** The pharmaceutical distribution industry has already reduced costs as much as possible while minimizing direct patient impacts, but such cost cutting has manifested itself in the form of reduced safety stock, less frequent deliveries to hospitals/pharmacies in rural/remote areas, and a 40% reduction in total number of distribution centres. **A trade war with the United States, along with the subsequent weakening of the Canadian dollar, will further drive up the operating costs (particularly fuel) and threaten the sustainability of pharmaceutical distributors.** And though the distribution sector was not intentionally targeted in Canada's proposed retaliatory tariffs, some of the items included in the first $30 B of those tariffs would have had a significant impact on McKesson Canada, such as wrapping/packaging machines, refrigerators & freezers (for housing vaccines and specialized therapies), and even building materials for a new distribution centre that is currently under construction.

The PMPRB should also take into consideration the current global upheaval in the pharmaceutical industry caused by volatile US tariff policy, which will lead to an unpredictable pricing & supply environment. We recommend that implementation be held off until the pricing impacts of tariff policy stabilizes (such as 2028, to coincide with the end of the current administration in the US). We believe that this will help mitigate the risk of manufacturers being discouraged from entering or continuing to supply the Canadian market, as well as the ongoing sustainability challenges facing pharmaceutical distributors.

However, if the PMPRB does intend to proceed in implementing the Draft Guidelines, they should provide clarity on the timing of when existing vs. new medicine patent holders would be subject to the first round of annual price testing (e.g., end of 2027? 2028?).

The Draft Guidelines Will Create Annual Pricing Instability

Based on our understanding of the new Draft Guidelines, the Annual Review every January will require patent holders to submit their highest manufacturer list price (MLP) in Canada as of December 31st. The PMPRB will then compare this MLP with the highest international price (HIP) among the PMPRB11 countries from December 31st, along with the previous years' MLPs and the CPI.

If the MLP is higher than the HIP (or the price increases taken are higher than CPI or a complaint has been filed by an authorized party), the patent holder will be subject to an In-Depth Review, which is now a lengthy and riskier process with only a short initial window for submitting supporting documentation.

The overall impact of this new process would be to create annual brand pricing instability. The HIP among the PMPRB11 countries will fluctuate from year-to-year due to exchange rates, new market entrants, and deflationary domestic drug pricing policies in the PMPRB11 countries. PDCI has estimated that annual price reductions are common across the PMPRB11 countries and the median price reductions can be as high as 18%.

As a result, **patent holders will need to decide at the end of each year if their highest MLP in Canada needs to be adjusted to stay under the current HIP, particularly if they want to avoid a far riskier In-Depth Review.** These decisions will also have to be made during the November/December timeframe, as the pricing adjustments will need to be communicated to and reflected in the monthly public drug plan formularies prior to the end of the year. Pharmaceutical distributors, pharmacy systems, and private payers will also need to update their pricing systems.

Unfortunately, all of this will be occurring during one of the busiest times of the year for pharmaceutical distributors and community pharmacies. **From a pharmaceutical distributor perspective, the initial implementation of the new Draft Guidelines would result in 367 drugs being reduced in price (32% of all patented medicines, as estimated by the PMPRB in 2023). This translates into about 2,900 distinct prices that would need to be adjusted (accounting for different strength/package size combinations and pricing across 13 provinces/territories), which would require about 290 hours of effort at each pharmaceutical distributor.** The traditional time of year for such a large volume of price changes is during the month of March, which usually requires a "blackout period" of several weeks in order to manage the workload. Thus, there will now be two "blackout periods" with the Draft Guidelines, a November/December one for patented medicines, and the traditional March one for non-patented brand drugs, as well as generics.

For pharmacies, this end-of-year pricing instability will bring unpredictability to the inventory value of the patented drugs they purchase, as any inventory purchased today could decrease in value the following day or the following week. **This would in turn encourage pharmacies to reduce their on-hand inventories at year end to minimize losses from price deflation. This would subsequently**

impact patients reliant on those medications, who could experience delays in new therapy starts or interrupted treatment schedules.

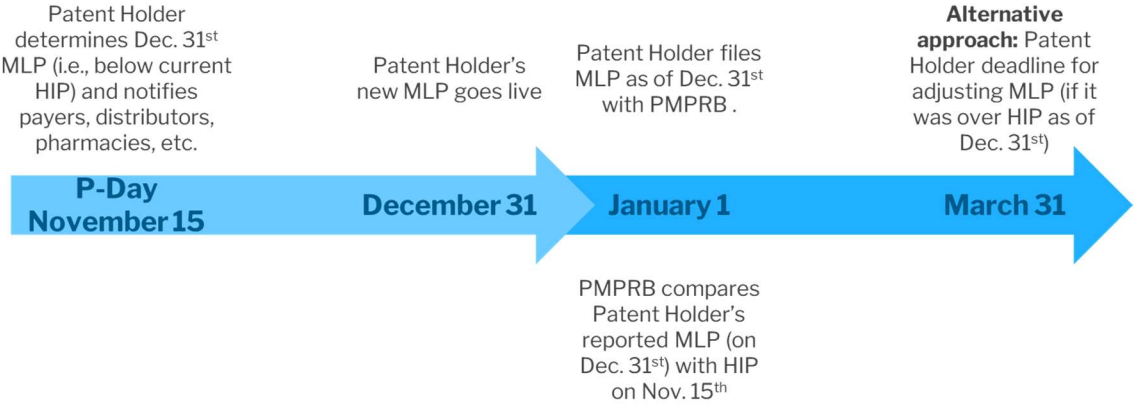
Thus, to mitigate the impact of this annual pricing instability on patent holders, pharmaceutical distributors, pharmacies, and ultimately patients, we recommend the following:

1. **The PMPRB should stagger the Annual Review for existing vs. new medicines on a biannual basis**, continuing the staggered implementation schedule proposed in the Draft Guidelines (such as new medicines price tested in odd years, existing medicines in even years). In addition to reducing the burden on manufacturers & distributors to potentially manage a large volume of year-end price changes every year, this will also reduce the workload for the PMPRB staff.

2. **The PMPRB should collaborate with provincial drug plans, private payers, and patent holders to create more predictability for price changes to minimize interruptions to patient access**

   - **Designate November 15th each year as "P-Day", which patent holders will notify all stakeholders of their anticipated price changes for Dec. 31st**, which will provide 1.5 months of advance notice for public & private payers, distributors, and pharmacies on patented medicines price changes, creating more predictability for payer & distributor staffing, as well as pharmacy inventory management

   - **When the annual price test is done, compare each patent holder's MLP on Dec. 31st with the HIP of Nov. 15th** to avoid penalizing them for HIP fluctuations (from exchange rates, etc.)



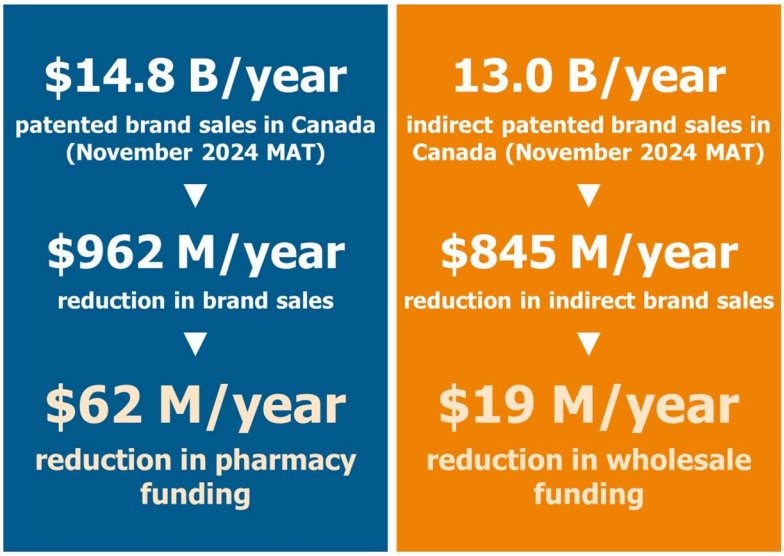
   - **Alternatively, if the HIP of Nov. 15th must be used by the PMPRB for the Annual Review, we suggest that all patent holders be given until the end of the first quarter of the calendar year to correct their MLP**—if it does end up being higher than HIP due to unforeseen circumstances, such as exchange rate fluctuations or unexpected prices changes within the PMPRB11

   - Finally, **PMPRB should ask public and private payers to allow a 1-month washout period (i.e., the month of January)** to allow pharmacies to sell through any on-hand patented drug inventories following any price reductions

The Draft Guidelines Will Further Reduce Essential Pharmaceutical Distribution & Pharmacy Services Funding

The new Draft Guidelines will further reduce funding for essential pharmaceutical distribution & pharmacy services as the price of patented medicines are compressed. Based on PMPRB's 2023 annual report cross-referenced with IQVIA data, patented medicines account for about 57% of brand sales in Canada. PDCI has previously estimated that the use of HIP as the international price comparator would reduce patented medicine prices by 6.5%.

Thus, in the first years of implementation, we have estimated that Canadian brand sales will decrease by $962 M/year as patented medicine prices are reduced. **This would remove $62 M/year of pharmacy funding and $19 M/year of distribution funding from the industry, particularly at a time when the impacts of US tariff policy on Canada's drug supply are still unknown.**



These estimated funding losses would likely be larger as patent holders looking to avoid In-Depth Reviews would likely set their MLP well below the HIP to ensure that there is a buffer to account for currency exchange fluctuations, unforeseen market changes, etc. And as the HIP declines from year-to-year, and patent holders are subject to In-Depth Reviews, prices would decrease further, exacerbating the impact on the pharmaceutical distribution and pharmacy industries.

For pharmaceutical distributors, there will be further funding pressures on pharmaceutical distribution services, leading to a weaker, geographically concentrated, and more fragile Canadian drug supply, which will already be under pressure from US tariff policy:

- Deliveries to rural and remote regions, which are already financially unsustainable
- Sustainability of next-day deliveries 5 days/week, resulting in longer waits at your pharmacy for out-of-stock or special-order medications
- Financial viability of cold-chain distribution, particularly with the growth in unsustainable volumes of GLP-1s
- The ability for distributors to carry the full range of pharmaceutical products and maintain full safety stocks

For community pharmacies, the funding reductions would lead to more fragile access to medications and a reduction in pharmacy-based community healthcare:

- Reduced expansion into patient care services that are backfilling capacity constraints in Canada's primary & acute care systems (e.g., minor ailments prescribing, immunizations, etc.)
- Reduced hours of operation and reduced staff
- Weakened capacity for pharmacies to carry and dispense high-cost drugs, given the necessary capital investments
- Reduction in funding for patient support programs that are critical for adherence to complex therapies

We recommend that the PMPRB encourage provinces to reinvest PMPRB-driven savings to strengthen distribution & pharmacy funding (i.e., reinvest ~8.6% of savings on patented drugs into pharmacy & distribution funding)

Miscellaneous Recommendations

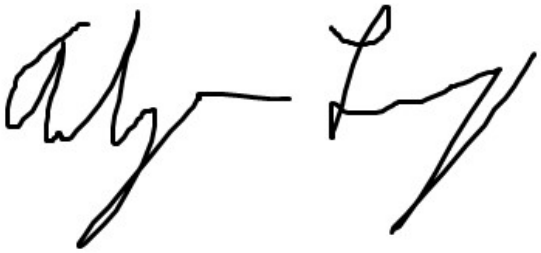
If possible, the PMPRB should provide visibility on which patent holders are under In-Depth investigations such that distributors can plan procurement activities.

Closing

With the threat of US tariff policies disrupting the global pharmaceutical industry, and the potential direct & indirect impacts on Canada's drug supply, the launch of new Draft Guidelines by the PMPRB will only add further uncertainty to the industry, Canada's drug supply, and ultimately patient access to vital medications. We hope that our input has highlighted the risks posed by implementing the new Draft Guidelines at such a precarious time, as well as identified potential approaches that could minimize the disruption to the pharmaceutical supply chain and patient access to patented medications.

If you have any questions or would like to discuss our submission further, we would be happy to organize a meeting with you.

Sincerely,



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