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Patented Medicine Prices Review Board
Box L40 Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, ON
K1P 1C1
PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Re: Consultation on New Draft Guidelines for PMPRB Staff

Dear Patented Medicine Prices Review Board,

On behalf of our pharmaceutical distribution members, the Canadian Association for Pharmacy Distribution Management (CAPDM) appreciates the opportunity to provide input on the 2025 draft Guidelines. Paying a fair price for medications is an objective that we support as an association of businesses, and as a community of individual taxpayers.

We continue to stress that while distributors are not directly targeted by the guidelines, they are nonetheless directly affected by them. Simply put, drug pricing does not exist in a vacuum, and the guardrails that the PMPRB imposes on the pharmaceutical industry have compelling economic implications downstream for drug access and supply that are overlooked. Since the distribution of medications is largely driven by listed drug prices, which are derived from the federally approved maximum price, the equation is simple: reduced distribution funding leads to lower inventory levels, which in turn reduces regional service capacity (particularly for remote communities), ultimately increasing the frequency and duration of drug shortages.

The draft Guidelines also come at challenging time for Canada's political and economic outlook, as the U.S. tariffs on Canada, China, and potentially other key markets (such as the European Union) create unprecedented uncertainty for stakeholders who manufacture and move medications. **More than ever, the pharmaceutical supply chain needs predictability and stability.** As proposed, the Guidelines would reflect a significant change in direction for the operation of the PMPRB. The Guidelines would move the PMPRB from a regime that encourages high voluntary compliance through predictable benchmarks, to a more open-ended regime where Guidelines are framed as review procedures for PMPRB staff, creating annual brand pricing instability. This uncertainty finds its way down the chain, from manufacturer to distributor; **so far, distributors have been able to shield patients from pricing volatility by maintaining dependable service levels and managing mounting drug shortages, but that could quickly unravel in a perfect storm of tariff headwinds, an unstable dollar, a mounting regulatory burden, and further pricing ambiguity.**

Our membership has estimated that, in the first years of implementation, Canadian brand sales will decrease by $962 million per year as patented medicine prices are reduced. **This would remove $19 million per year of distribution funding from the industry**, particularly at a time when the full 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, and other factors. 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 distribution infrastructure.

Given the above, **CAPDM recommends that implementation of the new Guidelines be held off until the pricing impacts of tariff policy stabilize.** If the PMPRB does intend to proceed with implementation, they should provide clarity on the timing of when existing versus new medicine patent holders would be subject to the first round of annual price testing (e.g., end of 2026 or 2027).

With respect to the new Guidelines, CAPDM proposes the following recommendations to avoid or reduce the scope of the negative downstream impacts to the supply chain:

1. **Maintain use of the Highest International Price (HIP) as International Price Comparison (IPC) for new patented drugs.**
   CAPDM was pleased to see that the PMPRB has anchored to the highest international price (HIP) of the revised PMPRB11 schedule of international comparators. We would like to emphasize that given funding for distribution is a function of the underlying drug price, any reductions in that underlying price will reduce funding for physical access for drugs (in the absence of compensatory financial mechanisms to mitigate this impact). As such, it is of critical importance that the HIP is maintained in the final Guideline.
2. **Grant full exemption for existing products.**
   CAPDM is disappointed that the PMPRB has not incorporated an exemption for existing products (e.g. grandfathering). Existing products were already compliant and therefore non-excessive with the applicable legislation and Guidelines, given that the amended Regulations did not change the excessive price factors under the *Patent Act*.
3. **Short of full exemption, stagger the Annual Review for existing versus new medicines on a biannual basis.**
   By continuing the staggered implementation schedule (such as new medicines in odd years, existing medicines in even years), not only will this reduce the workload for the PMPRB staff, but it will also reduce the burden on manufacturers and distributors to potentially manage a large volume of annual year-end price changes.
4. **Collaborate with provincial drug plans, private payers, and manufacturers to create more predictability for price changes to minimize interruptions to patient access.**
   Work with stakeholders to develop a process to provide adequate advance notice for distributors on patented medicines price changes, creating more predictability for distributor staffing, as well as pharmacy inventory management. This process could look like:
   - **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 and 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.

5. **Encourage provinces to reinvest PMPRB-driven savings to strengthen distribution funding.**
   A reinvestment of savings will be needed to mitigate the estimated $19 Million/year funding shortfall to distribution resulting from the new Guidelines. Without this reinvestment, the industry may not be able to continue:
   - Delivering to rural and remote regions, which are already financially unsustainable
   - Sustaining next-day deliveries five days/week
   - Maintaining the financial viability of cold-chain distribution
   - Carrying the full range of pharmaceutical products, including the unprofitable lower value items, and maintaining full safety stocks in the event of drug shortages.

The proposed changes to the Guidelines come at a time when the precariousness of the drug supply chain is already at its highest level, due to a multitude of factors that are beyond the direct control of the PMPRB. These include the US tariff threat, the deflation of generic drug prices, the increase of biosimilar products in the market, the non-indexation of government financial mechanisms overseeing distribution, the increase in operational costs (i.e. fuel, labour, increased regulation, the proliferation of refrigerated products, etc.), and many others.

We continue to encourage a holistic examination of the drug pricing system in Canada to ensure sustainable funding for Canada's medication supply system. While supply chain concerns lie beyond the Board's decision-making authority, **we recommend that the PMPRB convene a working group, with support from CAPDM, and in partnership with other government actors (such as CDA, pCPA, Health Canada, and provinces and territories) to investigate the role of pricing on dependable drug access and supply. The aim of the working group would be to publish a report that would inform a Canadian strategy on the sustainable physical access to medications and an analysis of the economic underpinnings of drug shortages.**

We have included a backgrounder on the state of pharmaceutical distribution at the end of this letter to help to contextualize our remarks.

CAPDM has a strong history of collaborating with federal and provincial governments and agencies to better inform and shape policies and solutions to ensure safe, secure, and timely physical access to medicines for all Canadians. We look forward to the opportunity to collaborate with the PMPRB and to be part of solutions that ensure medicine affordability in balance with accessibility.

Sincerely,

Simona Zar
SVP, Government Relations
CAPDM
simona@capdm.ca
Mobile: (647) 965-4405

Angelique Berg
President & Chief Executive Officer
CAPDM
angelique@capdm.ca
Mobile: (416) 523-3814

About CAPDM

The Canadian Association for Pharmacy Distribution Management (CAPDM) is the national trade association representing Canada's healthcare supply chain, offering comprehensive end-to-end visibility of the pharmaceutical distribution network across the country. Our diverse members include distributors, drug manufacturers, and service providers. Together, our membership manages the complex infrastructure that supplies pharmacies and hospitals with more than 90 per cent of all medicines consumed in Canada—delivered on a next-day basis to most communities. CAPDM members streamline the ordering and delivery processes for over 15,000 product SKUs from hundreds of manufacturers to more than 12,000 dispensing locations across Canada. This highly efficient system saves the country over $1 billion each year while maintaining an accuracy rate of over 99.9%.

Background: Canadian Pharmaceutical Distribution

As a byproduct of the funding received from the listed price of a drug, pharmaceutical distributors can ensure reliable and predictable access to medications. Functionally, distributors:

- Service **all areas in Canada on a next day basis**, five days per week, **including rural communities**.
- Carry **buffer stock of multiple weeks** that often avoids shortages, reduces their scope or duration, or delays public impact, allowing health care professionals more time to prepare their patients.
- Ensure the **safety and security** of complex inventory of shelf-stable, perishable, and cold and ultra-cold chain products, ensuring optimal expiration management with minimal loss.
- Partner with **provincial governments for public health distribution initiatives**, such as seasonal flu vaccines; pandemic vaccines, drugs and testing kits; and naloxone kits to counter the opioid crisis.
- Adhere to **multiple licensing requirements and related regulations** for proper security of all ranges of products, including narcotics and cannabis.

Despite the steadfast continuity of service in times of stability and during a global pandemic, the distribution sector is now at a precipice. For nearly two decades, drug distributors have been

operating within an outdated financial model and legislative framework that has failed to adapt to changing clinical and market dynamics.

Distribution funding, largely a factor of listed drug prices, is controlled by government, while expenses are subject to market forces. As an illustration of that effect, generic price reductions have reduced distribution funding by over $50 million per year, or $800 million, since their downward trend began in 2007. It is a controlled market where funding is limited, yet operating and regulatory costs are uncontrolled, subject to market forces such as inflation, fuel costs, and labour costs.

Operating costs have been growing 2.5 times faster than distribution volume in the past five years, and this is coupled with an increase in the regulatory burden, central to this being Health Canada's GUI-0069, *Guidelines for environmental control of drugs during storage and transportation*, that cost the industry $20 million per year. Changes in product mix are also driving up costs: cold-chain and specialized drugs have grown by 160% in volume over the past decade, triggering necessary investments in infrastructure (e.g. larger walk-in fridges) and transportation costs (i.e. cold-chain pack-outs, which can cost up to $300 per shipment). Distributors handle over 100 drug shortages every week, an uncompensated activity that costs the industry $4+ million per year.

The cumulative impact of price reductions and increased costs are threatening the fiscal sustainability of Canada's pharmaceutical supply chain. In a market once comprised of over a dozen pharmaceutical wholesalers, there remain just five and only two of national scope. In 2013, the market had 51 distribution centres. Today, there are just 32. Distributors at one time maintained eight or more weeks of buffer stock inventory, which today is less than half.

Distributors now have few, if any, options to compensate for the knock-on effects of drug price compression, high operating costs, and an increasing regulatory burden without Canadians really feeling the impact. Given the current financial challenges and additional funding cuts, the following changes by distributors may be inevitable:

- **Limit or eliminate delivery to regions that are financially unsustainable**, which would necessitate patients in rural and remote areas to travel further to access their medications.
- **Reduce delivery frequency, particularly to rural and remote communities,** and thus disproportionately to Indigenous populations, which would cause patients delays in starting new medications or accessing refills if they are out-of-stock or require special order.
- **Eliminate money-losing products (those of the lowest cost)** to create a more sustainable product mix, which would make access to certain drugs difficult for patients.
- **Reduce 'safety stock' inventory levels,** which would all but eliminate any meaningful ability to prevent or mitigate drug shortages.

The above changes would initially impact regions that are financially unsustainable to service, resulting in patients needing to travel greater distances to access their medications. This would lead to delays in starting new therapies and obtaining refills. Fortunately, solutions that respect the PMPRB's mandate exist to address the concerns raised and limit the potential impacts resulting from the future adoption of the new guidelines.

As we consider how the PMPRB can better engage with our sector, we regard the PMPRB's dual mandate with optimism: protecting consumers by ensuring that the prices of patented medicines are not excessive and providing information on pricing trends. We assert that the mandate reasonably and responsibly includes predicting trends resulting from policies proposed by the PMPRB and that those be done proactively, rather than to leave an already fragile supply chain powerless against further erosion and vulnerable communities even more disadvantaged.