September 11, 2024

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: Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines

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 Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines issued by the Patented Medicine Prices Review Board (PMPRB). Paying a fair price for medications is an objective that we support as an association, and more importantly, as taxpayers. While distributors are not directly targeted by the guidelines, they are nonetheless directly affected by them.

Representing pharmacy supply chain stakeholders, CAPDM is the national trade association for the pharmaceutical distributors that supply pharmacies and hospitals with over 90% of medicines consumed in Canada. Pharmaceutical distributors ensure the safe, secure, and timely access of prescription and over-the-counter medications to over 12,000 hospitals and pharmacies, allowing vital medications to reach the great majority of our nation's communities on a next-day basis. With their trading partners, pharmaceutical distributors form the efficient, accurate, and reliable supply chain that ensures physical access to medicines for all Canadians.

This submission comes at a critical juncture for the pharmaceutical distribution sector, whose future sustainability is at risk. As you will notice in our submission, CAPDM expresses concerns similar to those raised in previous rounds of consultation. If the Board's ultimate concern is patient access, we are alarmed by the potential impact to access that the new guidelines will have on the drug distribution infrastructure in Canada, particularly for those in rural areas of the country. While we recognize the PMPRB's mandate and acknowledge the Board's response that "provincially listed prices ultimately dictate the overall impact on supply chain issues," we emphasize that these downstream effects stem from the PMPRB, as the listed prices are derived from the federally approved maximum drug price.

CAPDM Recommendations

Recent history has demonstrated the fragility of the drug supply chain. Global and domestic disruptions across all modes of transport, combined with ongoing geopolitical tensions and trade shocks, have led to unprecedented drug shortages. Faced with these current and future challenges, CAPDM firmly defends the priority of protecting access to medications for Canadians. With this priority at heart, we believe that **a reduction in the list price of drugs**

already on the market will not improve access to medications, but on the contrary, stands to reduce it. Since distribution is largely driven by listed drug prices, the equation is simple: reduced distribution funding leads to lower inventory levels, which in turn reduces regional service capacity, ultimately increasing the frequency and duration of shortages.

In addition, 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 deflation of generic drug prices, the increase of biosimilar products in the market, the significant increase in interest rates, the non-indexation of government financial mechanisms overseeing distribution, the increase in operational costs (i.e. fuel, labour, increased regulation, etc.), and many others. In short, adopting the guidelines in their current state would only exacerbate an already fragile situation.

We have noted that the Discussion Guide states that supply chain concerns (raised by pharmacies, pharmacy associations, and distributors) lie beyond the Board's decision-making authority and will not be addressed in the Board's upcoming Guidelines.

However, we would like to emphasize that the actions of the PMPRB's legislated mandate have serious consequences for the pharmaceutical supply chain, and ultimately for the reliable access to medications for Canadians. As funding for distribution is a function of the underlying drug price, any reductions in that underlying price will reduce funding (in the absence of compensatory financial mechanisms to mitigate this impact). As such, we encourage a holistic examination of drug pricing to ensure sustainable funding for Canada's medication supply system. **Without consideration of the costs of physical storage and delivery in contemplating drug pricing approaches, the proposed reforms will further destabilize an already fragile drug supply system, making access to medications for Canadians, particularly those in rural areas, more challenging.**

<u>We recommend that the PMPRB:</u>

1. Limit the application of the new guidelines to new drugs and grant full exemption for existing products.
2. Use the Highest International Price (HIP) as International Price Comparison (IPC) for new patented drugs.
3. Use the power to report to the Governor-in-Council, conferred on the Council by section 100 of the Patent Act, to examine and inform the government of the negative financial impacts on the various links in the drug supply chain, including pharmaceutical distributors, pharmacies, and patients.

State of Pharmacy 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:

- 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 over a decade, 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 ambient transportation requirements 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). 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 remain 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:

- **Eliminate product range and money-losing products**, which would unfortunately create access and supply challenges for pharmacists, patients, and prescribers.

- **Further lower inventory levels and the expense of "safety stock**," significantly reducing the ability to prevent or mitigate drug shortages.
- **Reduce overall service (frequency and speed)**, therefore increasing the need for pharmacies to take on inventory risks.

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.

<u>CAPDM proposes the following three recommendations to avoid or reduce the scope of the impacts previously mentioned:</u>

1. **Limit the application of the new guidelines to new drugs and grant full exemption for existing products.**

   Changing downward the price of drugs already on the market is the factor that would have the greatest impact on access, to the funding of distribution and patient services. The PMPRB has the option of excluding drugs already on the market, while respecting its mandate. Failing this measure, CAPDM proposes that the Board develop a mechanism specific to drugs already on the market, so that the application of the guidelines does not result in a change in the list price. Instead, a mechanism similar to a confidential listing agreement could be put in place, under which the difference between the list price and the price set by the guidelines would be the subject of revenue for the Receiver General, allowing the Governor-in-Council to then choose to compensate the players in the pharmaceutical chain via the provinces, thereby strengthening the drug supply chain and patient services. This would ensure access to medicines and continuity of services to patients, as permitted by section 103 of the Patent Act regarding Agreements with provinces.

   Regardless of pricing policy, we believe in the option to wait three years before existing medicines are subject to a price review. Due to the potential volume of drug price changes with the implementation of the new Guidelines, the three-year period will give distributors and pharmacies an opportunity to adapt and forecast the medicine supply. It would allow stakeholders more time to plan and coordinate a smooth transition for medicine inventory management without impacting the certainty of the marketplace and supply chain across Canada.

2. **Use the Highest International Price (HIP) as International Price Comparison (IPC) for new patented drugs, as it is fairer and limits the impact on access to medicines.**

   By setting prices based on the highest among a group of countries, this approach ensures competitive costs while preserving supply and wholesale margins, thereby avoiding potential drug shortages as much as possible. Importantly, this measure respects the PMPRB's mandate with respect to excessive prices, whereas the median price goes beyond the spirit of this mandate.

3. **Use the power to report to the Governor-in-Council, conferred on the Council by section 100 of the Patent Act, to inform the government of the negative financial impacts on the various links in the drug supply chain, including pharmaceutical distributors, pharmacies, and patients.**

   This approach would highlight the economic difficulties caused by the new guidelines and allow the government to choose to reinvest in drug distribution to compensate for the losses suffered by these essential players in the health system.

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,

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