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20 December 2023

Submitted via the PMPRB Consultation Submission Portal, and via email to PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

2023 Scoping Paper for the Consultations on the Board's Guidelines

Dear Patented Medicines Prices Review Board:

Thank you for opening consultation on the 2023 Scoping Paper, and for both providing the Canadian Association for Pharmacy Distribution Management (CAPDM) opportunity to participate directly in the December Policy Roundtables and to submit this written response. We aim with this response to more fulsomely outline comments made at our December 5 presentation. Further, we respond from the distribution standpoint to Policy Roundtable discussions that may have suggested the wider supply chain is benefitting from significant market growth and high-cost medicines. Following that context, we provide response to specific questions in Themes 1, 2, and 6.

About CAPDM and the Pharmaceutical Distribution Supply Chain

Representing pharmacy supply chain stakeholders, CAPDM is the national trade association for the pharmaceutical distributors that supply pharmacies and hospitals with over 95% of medicines consumed in Canada. Pharmaceutical distributors ensure the safe, secure, and timely access of prescription and over-the-counter medications to over 11,500 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.**

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 licencing requirements and related regulations** for proper security of all ranges of products, including narcotics and cannabis.

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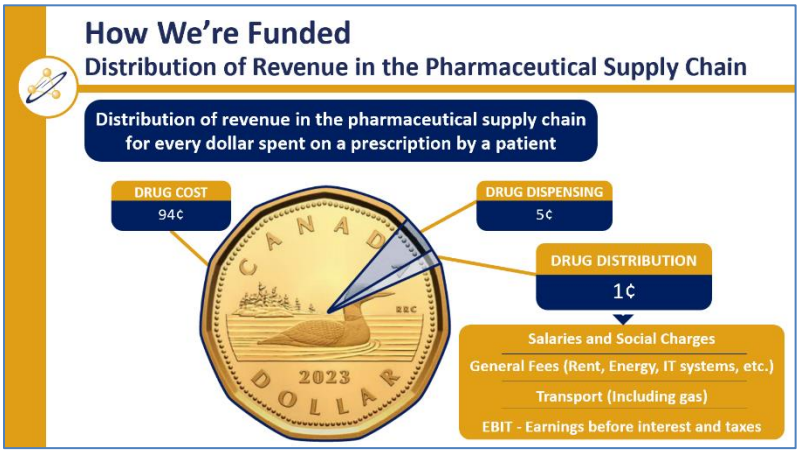
Interest in the PMPRB Guidelines: Distribution Funding, Costs, and Sustainability

Pharmaceutical distributors are directly impacted by any policy that seeks to reduce drug prices

In Canada's system today, drug prices and supply chain operability are inextricably linked. CAPDM strongly supports the affordability of medicines, but not at the expense of their physical accessibility.

Distributors operate in a market where funding is controlled, yet operating and regulatory costs are uncontrolled. Because of their thinning margins, pharmaceutical distributors are highly sensitive to changes in drug prices, given their funding is determined based on the listed price of medicines.



Funding: Funding for distribution is complex, and largely occurs either through (1) the framework of pharmacy reimbursement or (2) via agreements that distributors have with provinces. Either way, pharmaceutical distribution funding is a percentage of the provincially listed drug price, which is based on the federally allowed maximum drug price. This is so for both branded and generic medicines, given generic medicines are priced as a percentage of branded medicines, from 85% to as little as 10% depending on specific market conditions. As an illustration of the impact of drug price reductions, generic price reductions have reduced distribution funding by over $50 million annually, or $800 million since their downward trend began in 2007.

Costs: Costs have increased considerably with market forces. Operating costs such as fuel, labour, and property costs have increased with and beyond rates of inflation, and regulations have grown more stringent. As one example, the costs to adhere to Health Canada's GUI-0069 alone, which requires the continuous mapping and proof that storage and transportation temperature conditions are maintained throughout the drug supply chain, is estimated to have cost distributors $20 million annually.

Growth Clarification: During the Policy Roundtables, it was suggested that the distribution supply chain has benefitted from market growth and product innovation, which is not the case. While the overall market is shown to have grown, *the increase in costs is estimated to have eclipsed distribution volumes by 2.5 times***.** New products, despite their higher cost, often have higher distribution costs because of their perishability, temperature-controlled storage and transportation requirements, and other special handling needs, resulting in far lower-than-believed margins. Further, some high-cost products flow directly from manufacturer to the health care professional or to the patient themselves, and bypass pharmaceutical distributors altogether.

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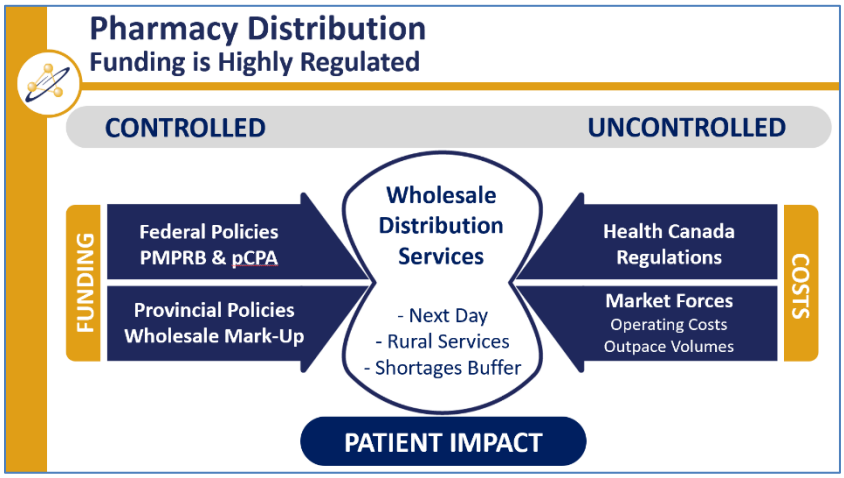
Pinch Point: The cumulative impact of price reductions and increased costs are estimated to be over $100 million annually, threatening the fiscal sustainability of Canada's pharmaceutical supply chain. There are few options available to distributors to ensure sustainability between funding and costs.



The pharmaceutical supply chain is at a precipice. Medicines might be affordable, but without also ensuring their accessibility, the debate could be moot, particularly for those living in areas that are most expensive to serve.

Theme 1 | Question 1.4: If international prices are used as the initial triage measure for commencing investigations, what price levels within the PMPRB11 should be used as the triage measure?

Given that distribution is funded based on a factor of the drug price, and the pinch point between falling funding and rising costs, CAPDM urges at ***least*** HIP be used as the initial triage measure for commencing investigations. Drug prices are the core number against which distributors are funded. In today's system, lowering drug prices, weakens the supply chain that makes medicines physically accessible.

In Canada, that weakness is exacerbated by our size. Simply as an illustration, all PMPRB11 countries aside from Australia could fit inside Canada's borders with room to spare. The costs of shipping medications across those individual countries is much different than in Canada. Traversing our country is enormously expensive, particularly guarding against Canada's seasonal weather extremes and in compliance with myriad regulations. *Funding to do that is not based on the actual costs but predicated on the price of drugs*.

Australia, which is closer to Canada's size and population density, recognized that challenge after a breaking point that threatened their own distribution supply chain. In 2006, Australia created performance-based supplementary funding of $200 million per year, *in addition* to funding based on drug price, to distributors who uphold "Community Service Obligations" for product mix, geographic coverage, time-to-delivery, and other standards their citizens expect. In their words, this fund was to make it ***commercially viable*** for distributors to supply medicines across their country.

Canada has no such supplemental funding structure. However, Australia's example underscores the costly challenge to serve a vast geography, and thus the importance of considering the supply chain stakeholders whose sustainability depend on the drug price. We urge for a triage measure ***at least*** HIP.

Theme 2 | Question 2.1: Should the Guidelines distinguish between medicines that existed as of July 2022 (existing medicines) and medicines introduced afterwards (new medicines)?

Theme 2 | Question 2.2: What approach should the Board take with respect to existing medicines with prices above the HIP? Should the Board review these prices, and if so, how soon?

Given distributors are highly sensitive to price reductions, which cause considerable administrative and cost burden, and further erode funding to an already strained supply chain, we urge that existing medicines be grandfathered, as they already have been evaluated as not excessive, and include an escalator linked to the Consumer Price Index.

In the earlier-mentioned generic medicine price decreases that reduced funding to distribution by over $50 million annually, distributors consequently had to eliminate expenses to stay in business. They optimized automation, closed distribution centres, eliminated daily deliveries to some areas, and more, and have done so with little to no impact to Canadians across this expansive geography *to this point*. However, because they run so efficiently, and amid the multiplicity of inflationary factors, further drug price reductions, will force further expense reductions, with few, if any, options that don't impact Canadians directly:

- **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.
- **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 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.

These cost reduction measures will impact every single step in the supply chain – manufacturers, distributors, pharmacists, health care professionals, and the patients and citizens we're aiming to serve – with those in rural areas first to experience the contraction of services. Thus, we urge that pricing of existing medicines be grandfathered, with an escalator linked to the Consumer Price Index.

Theme 6 | Question 6.4: How can the PMPRB better engage with you?

We acknowledge the many new Board members and supporting staff, and thank you for serving Canada after a most difficult period during which collective efforts failed to identify and achieve common objectives. We consider our reflections here to help inform the way forward.

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Our greatest challenge in recent years was the PMPRB's firm stance that lower drug pricing, and not the impact of it, was the PMPRB's only concern. The alarms CAPDM raised to the PMPRB failed to register or to generate enough concern to test with research the assertion that further drug price reductions would have deleterious impact on the supply chain responsible for physical access to medications.

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 a fragile supply chain powerless against further erosion and vulnerable communities even more vulnerable.

We recommend that the PMPRB:

1. Conduct an evidence-based impact assessment of the "Revised Guidelines" on the financial impact of policy changes on all aspects of the drug supply system, from drug development to dispensing, to the supporting infrastructures funded by drug prices.
2. Based on impact assessment outcomes, develop a comprehensive approach to medicine affordability and accessibility and make compensatory adjustments to the supply chain stakeholders for the changes imposed by the PMPRB that ensure accessibility and sustainability of the 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,
CANADIAN ASSOCIATION FOR PHARMACY DISTRIBUTION MANAGEMENT

Ms. Angelique Berg
President & CEO

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