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CAPDM Submission to the PMPRB
December 2022 Revised Guidelines Consultation

December 5, 2022

PMPRB Consultation Submission Portal

This submission is made on behalf of members of the Canadian Association for Pharmacy Distribution Management (CAPDM), in response to the 2022 proposed updates to the PMPRB Guidelines (Draft Guidelines). CAPDM is the national trade association for distributors that supply pharmacies and hospitals with over 95% of all medicines consumed in Canada. Pharmaceutical distributors ensure the safe, secure, and timely access of prescription and over-the-counter medications to every corner of the nation, servicing and supporting over 12,500 pharmacies and hospitals. This efficient, accurate, and reliable supply chain ensures physical accessibility to medicines for all Canadians.

Recommendation

CAPDM members support medicine affordability, but not at the cost of accessibility. Pharmaceutical distribution is largely funded based on a percentage of drug prices; the price of the product includes the costs to physically bring the product to the patient. After more than a decade of reduced funding as a direct result of steadily lower drug prices, distributors are facing issues of sustainability. Further reductions in drug prices put at risk the very infrastructure that ensures physical access of medications to Canadians and principles of *The Canada Health Act*. Despite that, to our knowledge, the PMPRB has conducted no impact assessments on supporting infrastructure funded by drug prices nor alerted government partners about the supply chain vulnerabilities that will result from the Draft Guidelines.

We urge you to suspend the current consultation process and undertake comprehensive consultation with all supply chain stakeholders, patients, and other players in the ecosystem and conduct impact assessments to inform affordability and accessibility.

The PMPRB must develop a comprehensive approach to medicine affordability ***and*** accessibility with its partners that enables an alternative funding model for distribution to compensate for the changes imposed by the PMPRB. We welcome opportunity to work with the PMPRB, the federal, provincial, and territorial governments to ensure the sustainability of medicine accessibility.

Price Compression and Impacts on Pharmaceutical Distribution

Pharmaceutical distributors operate in a controlled market where all partners want lower prices for medicines thus reducing distribution funding, while operating and regulatory costs increase annually.

Pricing policy changes over the last 15 years have dramatically eroded funding for distribution. As successive federal, provincial, and territorial governments have undertaken different efforts to reduce drug prices, an unintended consequence has been the erosion of funding for their distribution. The PMPRB's proposed changes are estimated by industry to reduce average prices of existing brand drugs by 5-7%, double-to-triple the PMPRB's own estimates, which would result in the reduction of distribution funding by over $20 million per year. This is on top of the 70% reduction in generic drug prices in Canada since 2007, which reduced distribution funding by an estimated $50 million per year.

At the same time, distributor operating costs have increased at least 2.5 times faster than distribution volumes in the past five years. Inflation, fuel costs, and labour costs continue to rise. Compliance with Health Canada's 2020 ambient transportation requirements costs the industry an estimated $20 million per year. Further, distributors handle an average of over 100 drug shortages every week, an uncompensated activity that costs over $3 million per year.

The cumulative impact of price reductions and increased regulatory and operating costs are estimated to be over $100 million annually. Adding the residual and ongoing impacts of the pandemic and increasingly frequent drug shortages, the fiscal sustainability of Canada's pharmaceutical distribution network becomes a glaring question. We are at a precipice.

There are few, if any, options left for distributors to absorb further funding erosion through cost reductions without cutting service levels that will impact patients. Sustainable offsets to further price reductions and increased costs require significant changes and are likely to:

- 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 ability to prevent or mitigate drug shortages.

We believe that Canadians should have affordable access to the medications they need, when and where they need them. We also believe that looking at the issue through the narrow lens of lowest cost contributes to an unintended and crippling impact across the supply chain and will lead to inequity in drug access for Canadians. The changes that will result from further drug price reductions are counter to two of the key principles of *The Canada Health Act*: universality and accessibility. The PMPRB's Draft Guidelines fail to produce a mechanism to reduce drug prices and also protect physical access. The potential savings resulting from the Draft Guidelines will come at a very steep price.

Benchmarking Structure

The Draft Guidelines' use of the Highest International Price Comparison (HIPC) structure for benchmarking, which amounts to an estimated 5-7% price reduction for existing medicines, will be harmful to supply chain stakeholders and patients across Canada.

As a result of this change to the guidelines, CAPDM anticipates a deepening funding erosion for downstream pharmaceutical partners (distributors and pharmacies). Distributors alone are estimated to have to absorb at least $70 million in funding reductions per year. Industry estimates this benchmarking structure could have an estimated industry-wide negative impact of $1.3 billion once the transition to PMPRB11 HIPC occurs.

Just as concerning, the PMPRB has not produced any impact assessment on the Draft Guidelines, which is inconceivable in modern, evidence-based policy development. It is critical to comprehend the financial impact of policy changes on all points from drug development to dispensation and to make compensatory adjustments to the supply chain stakeholders that ensure accessibility and sustainability.

As it stands, there is significant misalignment on the amount of the actual price reductions and its subsequent impact. Industry data indicates there will be a 5-7% price reduction as a result of the Draft Guidelines, whereas PMPRB's own assessment projected 2-2.5%. This suggests an error and or/inaccuracy in PMPRB's own reference data, and causes uncertainty in quantifying and planning for the Draft Guidelines' impact at a time when Canadians are looking for strength in the supply chain.

Risk Exposure from Use of Foreign Exchange

The Draft Guidelines set up a regime that exposes distributors to significant risk related to foreign exchange. Through this, drug prices, and subsequently the funding of distribution, will be dependent on the fluctuation of the currencies of a basket of countries, which include the GBP, Euro, SEK, AUD, and JPY. This means that that industry will lack predictable prices and funding. The distribution network has seen the legal and regulatory framework evolve rapidly in recent years, triggering the need for significant investments. The industry needs predictability and stability in the supply chain, not the turbulence and uncertainty of a structure specifically designed to fluctuate over time.

Twelve-Month Transition Period

The Draft Guidelines contemplate a twelve-month transition period for grandfathered and gap medicines, which requires certainty in its start date. The transition should begin at point of implementation and not before, given the many successive steps and participants in the transition. Manufacturers first need to announce the pricing changes, and only then can distributors, and then and pharmacies, update their product and patient pricing files. Distributors and pharmacies alike have thousands of customer pricing files to update. **To ensure all parties transition properly, efficiently, and accurately and without loss in quality of customer service, a *minimum* of 12 months is needed from the date the decision is taken, and not before**.

Conclusion

We strongly urge the PMPRB to suspend its current process and engage in meaningful consultations with all supply chain stakeholders and patients. The PMPRB needs to not only look at monetary accessibility of medications, but also at physical accessibility through the distribution supply chain. Repeatedly, CAPDM has urged the PMPRB likewise. Despite these efforts, the PMPRB has not engaged meaningfully with our industry, and that is reflected in the Draft Guidelines.

CAPDM understands from previous conversations with the PMPRB that pharmaceutical distribution is out of the PMPRB's scope. With this in mind, we urge the PMPRB to include language in the consultation report that recognizes and highlights the significant negative consequences on pharmaceutical distribution and on equitable access to medicines for Canadians, and to alert government partners to the supply chain vulnerabilities the Draft Guidelines present and the need for compensatory measures.

The pharmaceutical supply chain **cannot** withstand further reductions in funding without impacting service levels and quality, and ultimately, access for Canadians. If the PMPRB does not suspend its process and begin a new, comprehensive consultation process with all supply chain stakeholders and patients, it is not only pharmaceutical distributors that will bear unintended ramifications, but regrettably, so too will Canadian patients.

cc: The Honourable Jean-Yves Duclos, Minister of Health
Stephen Lucas, Deputy Minister of Health