

June 21, 2021

**Re: PMPRB Consultation on the Guideline Monitoring and Evaluation Plan**

To whom it may concern;

The Canadian Association for Distribution Management (CAPDM) and its members are very much concerned with the proposed PMPRB regulatory reform and the unintended consequences on the downstream pharmaceutical supply chain stakeholders. As outlined in prior submissions to the PMPRB, eroding prices for existing medicines will reduce the funding available to pharmaceutical distributors to get drugs to all Canadians, regardless of where they live. As such, CAPDM strongly recommends the PMPRB to monitor and evaluate the impact of the new regulations and guidelines on pharmaceutical distributors and patient access to medications as part of assessing the ramifications on the broader healthcare ecosystem.

**Impact of Proposed PMPRB Regulatory Changes and Revised Guidelines**

The PMPRB's proposed regulatory changes will have a significant impact on the pharmaceutical sector in Canada as a whole, and on the pharmaceutical distribution industry in particular. As the revised guidelines suggest a shift to the HIP (highest international price) test for Grandfathered Drugs, there will still be a negative impact on the pharmaceutical distribution industry. An anticipated overall revenue and price decline of 5% for Grandfathered Drugs translates in a pharmaceutical distribution funding erosion of over \$20M/year nationally. This change would continue to add to the expanding 'wholesale funding gap' that has grown over the past decade as a result of generic drug price compression, rising infrastructure costs and increased Health Canada compliance costs. Taken together, these pressures challenge the fiscal sustainability of the current pharmaceutical distribution funding model.

It is also imperative to understand the risks of actions in one part of the ecosystem on other sectors. A manufacturer faced with a reduction in profitability could consider means to recoup the losses. There is the potential risk of manufacturers clawing back funds from distributors through changes in credit terms and cash discounts, or reducing credit provided for returns. If distributors were to experience such negative impacts, there would be a need to recover such downstream losses in whatever ways make sense to each distributor, whether through a reduction in service, or otherwise.

As these sustainability challenges impact access to medicines and health care delivery, it is critical to gather evidence and analyze the challenges of distribution compensation and develop policy solutions that are aligned with the new pricing environment in Canada.



Furthermore, given the ongoing pandemic, pharmaceutical distributors have invested millions into personal protective equipment and social distancing measures to protect staff and customers. Higher inventories and more robust IT systems were required to better absorb important fluctuations in demand since the start of the pandemic. These investments were made without compensation with the objective of safeguarding patient access to their medication and vaccines when needed.

### **The case for monitoring and evaluating broader ecosystem impacts**

While CAPDM and its members recognize the PMPRB objective of lowering the cost of medicines in Canada and aligning with prices in like-minded countries, policies should also reflect differences across the entire pharmaceutical eco-system, and particularly differences in how the drug supply chain varies in other countries. While the other proposed comparator countries have managed to lower prices, they have also ensured the sustainability of the distribution system by providing minimum thresholds of funding. This has allowed distributors to continue servicing otherwise unsustainable regions with products that do not make economic sense.

**As importantly, given PMPRB's monitoring and reporting role, we would ask that PMPRB or the National Prescription Drug Utilization Information System (NPDUIS) initiative, collaborate with provincial and territorial governments and the pharmaceutical distribution industry and its association, the Canadian Association for Pharmacy Distribution Management (CAPDM) to study and report on the current state of pharmaceutical distribution funding in Canada.** This study can consider the widening wholesale funding gap in Canada, make international comparisons (particularly in terms of how other countries address the knock-on effects of drug price compression), and recommend potential policy solutions to revamp the funding model to be better aligned with the amended Patented Medicines Regulations.

Calculating the reduction in distribution funding caused by the new PMPRB Guidelines would be a straightforward exercise in **tracking the average sale price per unit** of medication sold **for existing patented medicines**. As distributors' funding model is a percentage of the drug price in all provinces and territories, any price reduction will translate in funding erosion.

CAPDM and its members remain concerned with the risk that the new PMPRB regulations and guidelines **negatively impact patients' timely access to medication**. This could be monitored by tracking the following metrics:

- Patented medicines discontinuation in Canada
- Number of drug shortages in Canada
- Duration of drug shortages in Canada
- Number of days following FDA approval for new drugs to be launched in Canada, to determine whether patented medicine manufacturers de-prioritize the Canadian market for new launches



## Recommendations

The new PMPRB Regulations and Guidelines will bring material changes to the pharmaceutical industry. While the patented medicines manufacturers will be directly affected, the broader pharmaceutical ecosystem and particularly the downstream supply chain stakeholders such as distributors will be subject to unintended and negative consequences. The PMPRB's GMPEP should be conscious of the knock-on effects of the regulations and guidelines and strive to monitor them and evaluate their ultimate impact on Canadian patients. CAPDM is prepared to work with the PMPRB to track the impacts on the broader pharmaceutical ecosystem.

In light of the above, CAPDM recommends:

1. PMPRB form a multi-stakeholder group to plan an effective and consistent transition process (timing of changes, communication leadtime, and inventory transition processes). At this point, there is no aligned process for manufacturers to communicate new prices to market in a timely and orderly fashion. There are, more importantly, unresolved issues about floor-stock protection at the distributor and retail pharmacy levels, which will be required to prevent supply interruptions and unnecessary shortages around the compliance date. CAPDM is unaware of any engagement with provincial drug plans to consider whether 'washout' periods ought to be implemented to protect inventories purchased at higher prices being sold at lower prices. Failing protective measures, supply chain stakeholders may be inclined to minimize purchasing activities and on-hand inventories for a few weeks before anticipated price reductions to minimize potential inventory losses, which may create supply disruptions and patient access issues.
2. PMPRB to uphold commitment to evaluating and monitoring the impact of the reforms on the broader eco-system and particularly on the unintended consequences to the essential pharmaceutical distribution infrastructure

CAPDM and its members would be available to work with the PMPRB staff as part of a multi-stakeholder group to effectively plan such a transition as well as the ongoing monitoring and evaluation of the impacts of the new regulations and guidelines. We welcome the opportunity to submit our comments on the PMPRB's GMPEP and are available to meet to answer questions or provide further clarification.

Sincerely,

Daniel Chiasson  
President and CEO

---

### Canadian Association for Pharmacy Distribution Management

3800 Steeles Ave W • Suite 301A • Woodbridge • ON • L4L 4G9  
Tel: (905) 265-1706 • Fax: (905) 265-9372 • [capdm@capdm.ca](mailto:capdm@capdm.ca) • [www.capdm.ca](http://www.capdm.ca)