CAPDM Driving | Healthcare

November 5, 2020

Dear Members of the House of Commons Standing Committee on Health

Re: Study on the Patented Medicine Prices Review Board's Final Guidelines issued on October 23, 2020

On behalf of the members of the Canadian Association of Pharmacy Distribution Management (CAPDM), we would like to thank you for considering our concerns and recommendations with respect to the implementation of amendments made to the *Patented Medicines Regulations* and the recently published PMPRB final guidelines.

We submit, for your consideration, three recommendations to protect the sustainability of critical pharmaceutical distribution infrastructure, which allows every patient in Canada equal and ready access to the medications they need, regardless of where they live:

1. **Adopt a New Funding Mechanism to Support Pharmaceutical Distribution**
2. **PMPRB Study and Report on the State of Pharmaceutical Distribution in Canada**
3. **Further Extension of PMPRB Reform Implementation**

Implementation of the PMPRB's regulatory changes and final guidelines will have a material impact on the pharmaceutical sector in Canada as a whole, and a significant impact on the pharmaceutical distribution industry. While the proposed reform may not be intended to harm the pharmaceutical distributors, the targeted price reduction of patented medicines will reduce the funding available to distributors given the reimbursement formula is a function of drug prices.

About CAPDM

CAPDM, founded in 1964, is a leading health care industry association. We represent participants in the world's most advanced pharmaceutical supply chain – serving as both a resource for Members, and an advocate for the industry.

The Canadian Association for Pharmacy Distribution Management (CAPDM) is the authoritative voice to manufacturers, pharmacy and governments for the safe, secure, and efficient distribution of pharmaceutical products in Canada. Our membership handles well over 95% of all drugs in Canada, and ensure timely patient access to a stable drug and vaccine supply across Canada's vast geography. A list of our distributor members can be found in Annex 1 below.

Pharmaceutical Distributors ensure that Canadians have timely access to vital medications in a safe, secure, and efficient manner. Pharmaceutical Distributors deliver prescription and over-the-counter medications to every corner of the nation, servicing and supporting over 10,000 pharmacies and hospitals across Canada. The low-cost, safe, accurate, and reliable pharmaceutical supply chain in Canada is a globally recognized gold standard, and our members are proud to contribute to its continuing success.

Canadians benefit every day from the critical 'invisible network' created by Pharmaceutical Distributors, as it makes the following possible:

- Next-day delivery to pharmacies, ensuring patients have timely access to vital medications that are out of stock or require a special order
- A short-term buffer against drug shortages with mechanisms for the equitable allocation of remaining supplies to counter potential hoarding
- Drug recalls being quickly executed
- Confidence in the integrity of all drugs, even for refrigerated products
- A $1.5 B system of extended credit that bankrolls pharmacies across the country
- Opportunities for the government to leverage our distribution networks to pharmacies for public health initiatives, such as public flu vaccines, pandemic drugs (such as during the 2009 H1N1 pandemic), and naloxone kits to counter the opioid crisis.

COVID-19 has highlighted the essential role that CAPDM members have played and continue to play during this pandemic. Despite many demand and supply challenges, pharmaceutical distributors have ensured patients have uninterrupted access to their medication.

Impact of PMPRB Regulatory Changes and Final Guidelines

The PMPRB's regulatory changes will have a significant impact on the pharmaceutical distribution industry. As the Final Guidelines suggest a shift to the HIP (highest international price) test for Grandfathered Drugs, there will still be a negative impact on funding to 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.

Given the current pandemic, pharmaceutical distributors are additionally investing millions into personal protective equipment and social distancing measures to protect staff and customers. Furthermore, higher inventories and more robust IT systems are required to better absorb important fluctuations in demand since the start of the pandemic.

Taken together, these pressures challenge the fiscal sustainability of the current pharmaceutical distribution funding model. 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.

The current funding model is misaligned as the pricing and reimbursement environment continues to erode distribution funding and the cost structures continue to escalate given regulatory policy changes and increases in operating costs.

On the funding side, reduction in drug prices has reduced distribution funding. At the provincial and pan-Canadian levels, generic drug prices in Canada have dropped >70% since 2007, reducing distribution funding by the same amount, which we estimate to be reduction of over $50 M/year. At the federal level, upcoming PMPRB reforms in 2021 are estimated to reduce distribution funding with average brand prices dropping 5%, resulting in $20 M/year loss of funding.

Operating costs have been growing 2.5 times faster than distribution volumes in the past 5 years. Part of the costs reflect higher regulatory hurdles such as:

- Compliance with Health Canada ambient transportation requirements costs the industry $20 M/year
- Other regulatory requirements (i.e. quality assurance resources, new precursor guidelines) have added $10 M/year in operating costs

Additional examples of rising costs and investment requirements are highlighted in the following table.

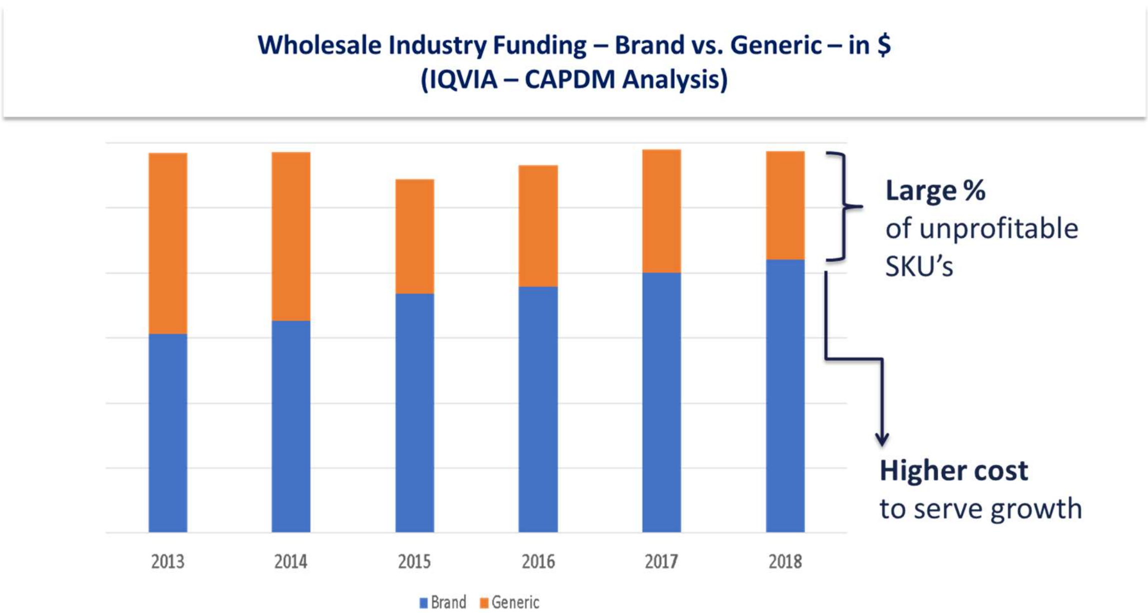
$20 M/year of new industry costs from Health Canada Ambient Transportation requirements	**$ 5 M/year** investment in cold-chain infrastructure
$3 M/year of labour & IT costs to manage more & more drug shortages	In 2019, Health Canada licensing fees increased by **3x**
2.4% CPI for energy costs over the past year	Canadian labour costs have increased **30%** over the past 10 years

In addition to rising costs, distributors play a critical role in an increasingly complex pharmaceutical eco-system. Distributors handle an average of approximately 100 drug shortages every week, an uncompensated activity that costs the industry $3+ M/year.

Changes in product mix are also driving up costs:

- The volume of cold-chain & specialized drugs have grown by 160% over the past decade, triggering necessary investments in infrastructure (e.g., larger walk-in fridges) and transportation costs (cold-chain packouts, which can cost up to $300)
- The low cost of generic drugs also leaves little funding to address the additional space & handling requirements arising from genericization and SKU proliferation

In the past 10 years, distributors have seen their activity level double with little change or decreases in funding overall. We are caught between rising volumes of unprofitable generics and rising volumes of high cost-to-serve brand drugs.



The significant negative impact that the PMPRB reforms will have on our sector's funding comes at a time when the wholesale distribution industry is facing increased regulatory costs (such as those related to ambient transport mentioned above), and additional costs from a shifting mix of pharmaceutical drugs as the share of specialty drugs (which cost more to store and ship than non-specialty drugs) continues to increase.

Despite efficiencies achieved over the past decade through labour reductions, automation and other cost rationalizations, the funding erosion has continued unabated with no signs of relief in sight. Implementing the PMPRB reforms will continue this pronounced downward funding trend for distributors.

Pharmaceutical distributors have limited ability to affect demand for the goods they sell or the price at which they are sold. They operate in a pull system with federally and provincially

regulated pricing. Our industry has few levers to restore funding, other than further reducing costs and services.

Should price compression from the PMPRB reforms proceed as is, distributors will have to confront the economic implications of this policy change, which would have significant consequences to the distribution model and network in Canada and have a direct impact on Canadian patients. Remaining levers to target and their implications are highlighted below:

Tool to Address Distribution Funding Gap/	**Impact on Patients**
Reduce geographical reach and eliminate unsustainable regions	▪ Patients in rural and remote areas need to travel further to access their medication
Reduce delivery frequency, particularly in rural/remote communities	▪ Patients, particularly Indigenous populations, could be delayed in accessing their medication if it is out-of-stock or requires special order
Modify the product mix to eliminate money-losing products	▪ Increased difficulty for patients to access certain drugs
Reduce 'safety stock' inventory levels at the distributor level	▪ Lower buffer inventory in case of drug shortages
Reduce credit terms to pharmacies & hospitals	▪ Increased financing and operating costs for pharmacies while reducing inventories at the pharmacy level
Reduce/postpone infrastructure/IT investments	▪ Lower system resiliency to supply/demand shocks

None of these scenarios are favoured by the pharmaceutical distributors as they all have negative consequences for patients. Further threatening the sustainability of the drug supply chain is an undesirable policy outcome. Any of the above actions would have amplified negative impacts for patients in the context of COVID-19 and in future pandemic scenarios.

While CAPDM and its members recognize the PMPRB's 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 for pharmaceutical distribution. This has allowed distributors to continue servicing otherwise unsustainable regions with products that do not make economic sense.

Beyond the distributor funding erosion, the PMPRB reform could have further knock-on effects that will impact our sector. Our estimated $20+ million per year funding decrease does not consider future impacts of overall lower launch prices will have on industry decisions to bring products to market.

Significant uncertainty remains for the pricing of new medicines and this will likely delay or prevent their launch in Canada. If lower price ceilings lead to fewer overall product launches, it represents an opportunity cost for distributors who might otherwise offset part of the funding erosion with volume from new product introductions. It is also anticipated that as patents for existing (and eventually new) drugs expire, the generic prices will be lower and create more strain for the sustainability of the distribution model.

Another important consideration is the impact the PMPRB reform will have on the pharmacy sector who also receives much of its funding on a percentage of drug prices. Distributors who sell to pharmacies also provide a significant amount of financing to them through credit terms. As price erosion also threatens the viability of pharmacies, distributors risk having their pharmacy customers default on their payment for drugs and supplies. As distributors work on very low margins, it would take an incremental 100 orders of similar size and value to offset the non-payment of one single invoice.

Lastly, drug shortages remain a major area of concern for all healthcare stakeholders. CAPDM fears that the proposed reforms will not improve drug shortages and may otherwise make them worse if market authorization holders deem the new prices less attractive than in other jurisdictions and allocate limited supplies to foreign markets.

Recommendations

CAPDM would recommend that PMPRB and the federal government continue to work with industry stakeholders to find a balanced framework that would meet policy objectives while ensuring patient access to medications. As mentioned previously, price decreases on existing medicines would further destabilize Canada's critical pharmaceutical distribution network. As we have seen with the 2018 generic price decreases, such price compression initiatives benefit payers but threatens timely access for patients (drug shortages, reduced investments in inventory, reduced service levels, impact on remote and rural areas of the country).

1. Adopt a New Funding Mechanism to Support Pharmaceutical Distribution

A key tenet of our recommendations is the adoption of a **new funding mechanism** to address immediate challenges facing pharmaceutical distribution and will promote the sustainability and resiliency of critical healthcare infrastructure by complementing the current reimbursement framework.

Pharmaceutical distribution is a strategic industry in Canada's healthcare system that is critical for the stability of Canada's drug supply. It provides critical infrastructure that the federal government needs to 'build back better' to safeguard the health of Canadians, now and in the

face of future emergencies and pandemics, and will ensure timely and equitable access to medications, particularly in rural/remote and Indigenous areas.

CAPDM and its members propose to introduce a public or **community service obligation funding model** as the means for the federal government to invest in and support ongoing maintenance of our industry's critical infrastructure and would include:

- An agreement between the federal government and pharmaceutical distributors to ensure resilient and sustainable pharmaceutical distribution across Canada
- Establish **minimum level of standards for pharmaceutical distribution in Canada**, ensuring all Canadians have timely, equitable access to the medication they need regardless of where they live
- Provide **stable, predictable funding** in the form of a funding pool and make funding available to distributors based on market share to encourage industry investment in comprehensive distribution services
- Enable **transparency in pharmaceutical funding** and **support the critical infrastructure of Canada's drug supply**

Implementing such a framework will provide stable, predictable and transparent funding floor needed to maintain this critical infrastructure, ensuring the system is able to respond to Canadians' needs, now and in the future. By ensuring industry sustainability, our members will be able to:

- Ensure continuity of supply during system shocks, such as COVID-19 and ongoing drug shortages
- Support future critical distribution needs, such as COVID-19 vaccines
- Maintain comprehensive distribution services (full line distribution) to Canadians across the country, particularly those in rural/remote areas and Indigenous communities
- Support the increasingly complex logistics needs of drug therapies

This framework would promote investments in new cold-chain capabilities to deliver vaccines and in IT systems to improve inventory tracking and ensuring appropriate regional distribution of vaccines, drugs and other therapies. Ultimately, the proposed funding model would improve the sustainability of drug supply and reduce the impact of future drug shortages.

The benefits of a Community Service Obligation to strengthen critical pharmaceutical distribution infrastructure

Resilient Drug Supply

- In the absence of dedicated, transparent funding, the Canadian drug supply relies on fleeting and shrinking funding sources
- Incentivizes investment in critical infrastructure, ensures rural/remote and Indigenous communities are treated fairly, and improves system resiliency to system shocks

Dedicated Funding

- Dedicated distribution funding ensures the viability of drug supply service to all parts of Canada, especially rural, remote and Indigenous communities
- Decouples distribution funding from pharmaceutical pricing, increasing resiliency of the country's drug supply

Accountability

- A transparent pan-Canadian distribution funding mechanism ensures governments have an accurate understanding of where their funding goes
- Ensures regular reporting on drug supply and distribution service levels

2. PMPRB Study and Report on the State of Pharmaceutical Distribution in Canada

CAPDM recommends 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.**

As part of PMPRB's Guideline Monitoring and Evaluation Plan, collaboration with CAPDM is recommended to assess:

- Continuity of supply during system shocks, such as COVID-19 and ongoing drug shortages
- The economic impact of the reform on distributors and their service model
- The effect on patients' access to medication
- Alternative international approaches to distribution funding in a drug price compression environment

This study can consider the changing pharmaceutical eco-system and its impacts on 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 overall funding model to be better aligned with securing

a drug distribution infrastructure that will allow Canadians fair and equitable access to their medications regardless of where they live.

3. **Further Extension of PMPRB Reform Implementation**

CAPDM also requests extending the implementation timetable beyond the 12 months transition (January 1, 2021 to January 1, 2022) to recognize the uncertainty and resources required to deal with the current pandemic. This would allow distribution stakeholders to focus their energy and leadership on ensuring pharmacies and patients are well served during these difficult times.

Conclusion

Pharmaceutical distribution is a strategic industry that is critical for the stability of Canada's drug supply. The pandemic has demonstrated, more so than ever, the need for a strong and resilient healthcare system, including drug and vaccine distribution.

The cumulative impact of policy-driven pharmaceutical price compression and higher regulatory and operating costs is currently estimated to be $100+ M per year, challenging the fiscal sustainability of Canada's pharmaceutical distributors. With limited ability to restore funding, pharmaceutical distributors have limited tools to balance reduced funding with higher operating costs, all with potential to impact the health of Canadians.

While we have raised these concerns during recent PMPRB consultations, our sector is at further risk given their final guidelines published on October 23, 2020. We welcome the opportunity to share our perspective with the House of Commons Standing Committee on Health.

Without action, critical infrastructure that the healthcare system and Canadians rely on is in jeopardy of further erosion, putting our health and economy at risk.

Sincerely,

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Annex 1

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