CAPDM Driving | Healthcare

August 4, 2020

CAPDM Submission to the PMPRB June 2020 Revised Guidelines Consultation

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 submitted as part of the November 2019 Draft Guidelines consultation. We now submit for your consideration, as part of the consultations on the Revised Guidelines, further ideas to protect the sustainability of the drug distribution infrastructure. This infrastructure allows every patient in Canada equal and ready access to the medications they need, regardless of where they live.

The PMPRB's proposed regulatory changes and revised guidelines continue to have a material impact on the pharmaceutical sector in Canada as a whole, and on the pharmaceutical distribution industry in particular. While these proposed revisions 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.

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 '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 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.

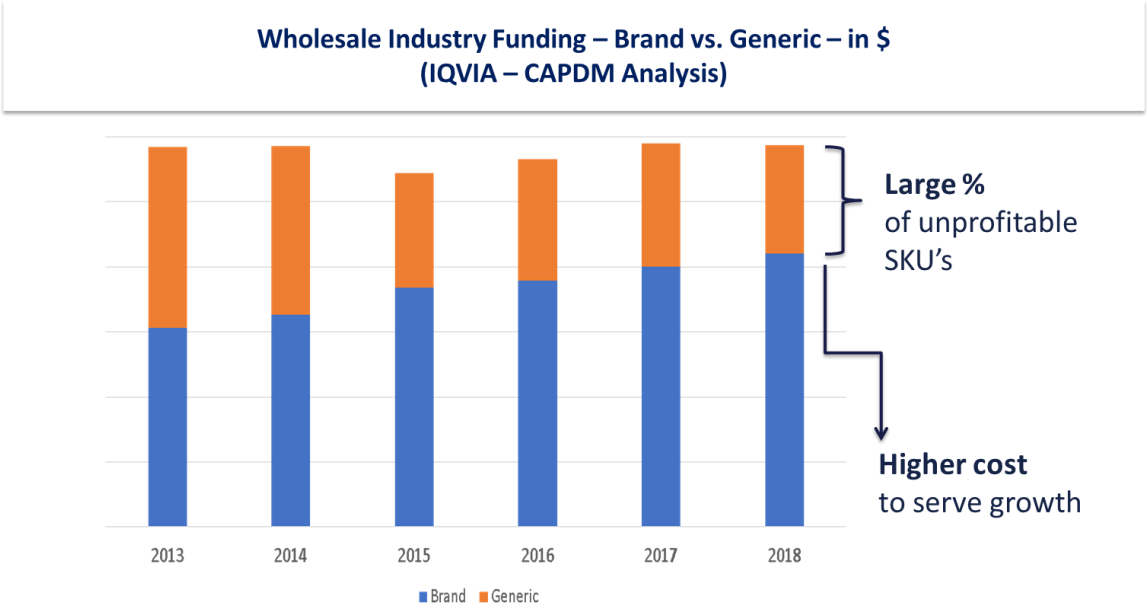
Given the current pandemic, pharmaceutical distributors are investing millions into personal protective equipment and social distancing measures to protect staff and customers. Furthermore, higher inventories and more robust IT systems are required to better absorb important fluctuations in demand since 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 funding model is misaligned as pricing and the resulting reimbursement continues to erode and the cost structures continue to escalate given regulatory policy changes. 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 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.



This dangerous PMPRB impact 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. The PMPRB reform would 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 provincially and federally regulated pricing. Our industry has few levers to restore funding, other than further reducing costs and services. If the price compression from the proposed regulations proceeds as is, distributors will have to confront the economic implications of this policy change, which would, though forewarned, have significant consequences to the distribution model and network in Canada. Remaining areas to target and their implications are:

- Reduce geographical reach and eliminate unsustainable regions
    - Patients in remote areas would need to travel to access their medication
    - Elimination of warehouse and delivery jobs

- Further reduce delivery frequencies
    - Patients could be delayed in accessing their medication if it is out-of-stock or requires a special order
    - Elimination of warehouse and delivery jobs
- Modify the product mix to eliminate money-losing products
    - Further increasing difficulty for patients to access certain drugs
    - Elimination of warehouse jobs
- Reduce inventory levels at the distributor level
    - Lower buffer inventory in case of drug shortages
- Eliminate credit for pharmacies
    - Increased financing and operating costs for pharmacies
    - Reduced inventories at the pharmacy level
    - Patients could be delayed in accessing their medication

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.

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.

CAPDM was pleased to hear during our recent July 16 meeting with the PMPRB that enforcement of Maximum List Price (MLP) for a patented drug will be undertaken if excessive revenues are actually incurred at the net price level. We support PMPRB in this approach and would ask that there be opportunities for patent holders to incorporate the cost of essential supply chain services into their net price calculations to provide a clearer picture of true net prices.

Beyond the distributor funding erosion, the PMPRB reform could have further knock-on effects that will impact our sector. The $20+ million per year funding decrease does not consider what effect 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 introduction 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 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).

Mitigating strategies should include:

- Exploring options where the net transaction price between manufacturers and distributors does not impact the pharmacy and wholesaler funding models with respect to existing products;
- In the event no alternative exists to deliver the above, collaborate with CAPDM to explore feasibility of 'make whole' provision in the revised guidelines given the reform did not have funding reduction for distributors and pharmacies as an objective (e.g. consideration for a flow-through 1% allowance above the MLP to fund distribution costs);
- Collaborate with CAPDM as part of PMPRB's Guideline Monitoring and Evaluation Plan to assess:
    - 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
- Work with Provinces and Territories on the above study via NPDUIS
- Support CAPDM's advocacy for a distributor reimbursement model that includes a minimum threshold similar to what is available in other like-minded countries that Canada is looking to join in a new 11-country basket.
- Extend 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.

CAPDM is very much interested in continuing the dialogue with PMPRB to find sustainable solutions for governments and drug supply chain actors. **As CAPDM advocates for Canada's pharmacy supply chain and more specifically the distributors supplying pharmacies and hospitals with essential and life-saving medicines, we request to be included in a forum to review potential 'make whole' provisions.**

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.

CAPDM and our members remain available to the PMPRB team to bring further clarification to points raised above and/or other elements of concern to PMPRB on the drug supply chain.

Sincerely,

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