CAPDM Driving | Healthcare

February 6, 2020

CAPDM Submission to the PMPRB Draft Guidelines Consultation

On behalf of the members of the Canadian Association of Pharmacy Distribution Management (CAPDM) and as part of the consultations surrounding the PMPRB Draft Guidelines, we would like to submit a review of the projected impact of the proposed reform on the pharmaceutical distribution sector. We also endeavor to raise options, for your consideration, that would mitigate the unintended impact to our members and, more importantly, safeguard timely access to medications for Canadians, regardless of whether they live in remote or urban areas.

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.

Impact of Proposed PMPRB Regulatory Changes

We appreciate the opportunity to share our perspective and concerns with the proposed PMPRB reform and, in particular, the impact a 20% price reduction on grandfathered patented drugs would have on the sustainability of the pharmaceutical distribution sector. While CAPDM and our members appreciate the context for this reform, we feel compelled to share our perspective on the dangerous consequences (intended or unintended) of the proposed changes.

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. While the proposed changes may not appear to have a direct effect on the distribution of pharmaceutical drugs, the following corresponding critical impacts are worth considering.

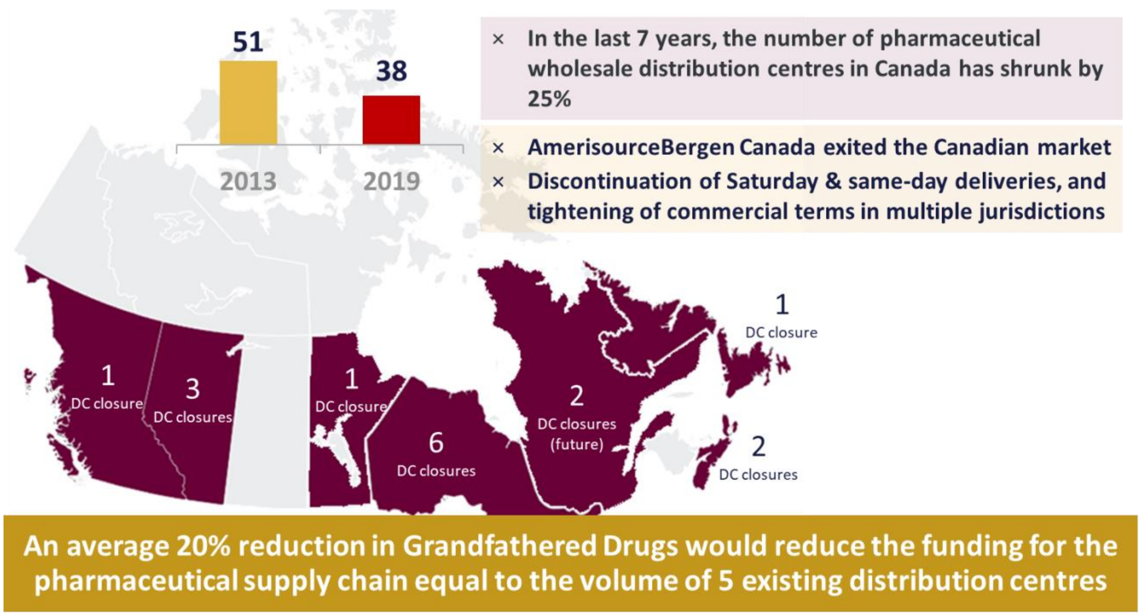
Specifically, the proposed revisions that aim to reduce the price of patented medicines in Canada will lead to a corresponding reduction in the reimbursement of pharmaceutical distribution, given that distribution rates are based on a percentage of the price of the medication being shipped. By changing the mix of comparator countries, the PMPRB is well-positioned to reduce the price of existing and new entrants to the marketplace. CAPDM estimates that the proposed "re-benchmarking" of existing medicines will lead to material price reductions of drugs already in circulation.

CAPDM members currently distribute ~$16.7 billion of patented drugs per year. This translates to $333 million of funding based on existing distributor reimbursement models across the provinces and territories.

Health Canada's Regulatory Impact Analysis Statement in May 2019 projected that sales of existing patented medicines would decrease by $788.5 million (present value) over the 10 years following implementation of the PMPRB reform. However, based on the assumption that PMPRB would target the median international list price of the new proposed 11 country basket, CAPDM believes that pricing of existing patented medicines would decrease by an average of 20% and result in a sales drop of $3.3 billion per year in the wholesale distribution channel. Our latest discussions with PMPRB suggest the latter scenario is more reflective of the impact of the current PMPRB draft guidelines. This would represent a $70 million per year erosion in supply chain funding.

To provide context, this level of funding erosion would be greater than the generic drug price decrease in 2017/2018 following the pCPA/CGPA agreement and the generic manufacturers' agreement in Quebec. In order to rebalance the lower supply chain funding resulting from ongoing generic drug price compression, distributors have had to reduce costs and service levels. This included reduced delivery frequencies, particularly to rural/remote areas and lowering on-hand inventory levels. Reduced inventory levels create a smaller buffer against unexpected drug shortages.

Given the projected supply chain funding decrease that would result from the PMPRB reform, the sustainability of the pharmaceutical supply chain would be further threatened. Any sudden and pronounced reduction of the price of existing patented drugs would have serious repercussion on our industry as the infrastructure cannot shed costs that deeply and that quickly. In the past 7 years we have already seen the number of pharmaceutical distribution centres in Canada shrink by 25%. An average 20% reduction in the price of existing patented drugs would reduce the funding for the pharmaceutical supply chain equal to the volume of 5 existing distribution centres, which would represent the loss of a few regional distributors or the significant scaling back of a national distributor.



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

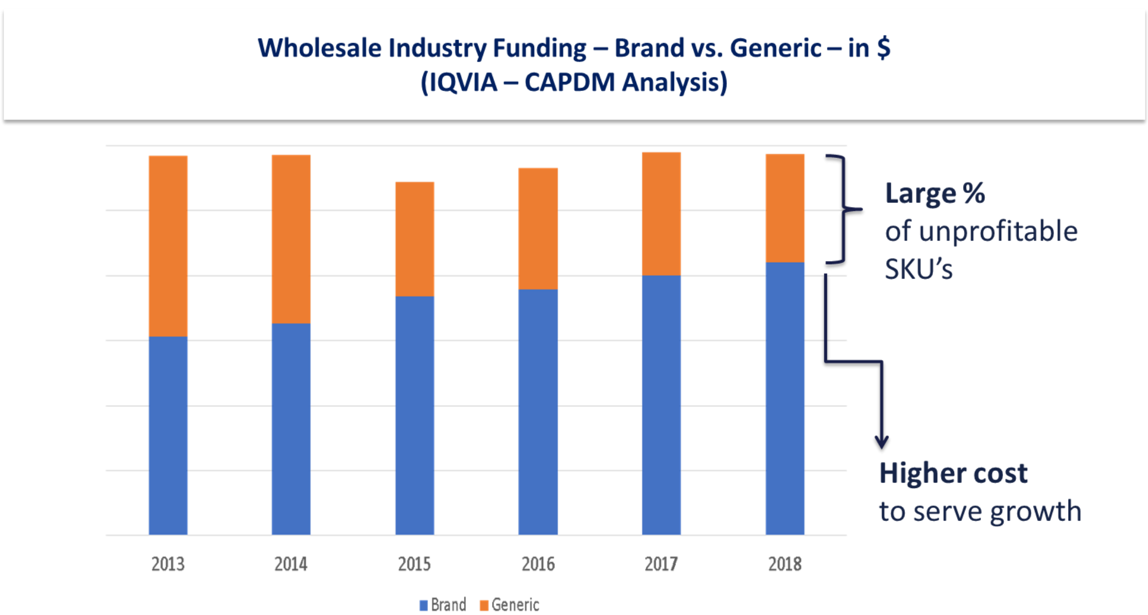
$3 M/year
of labour & IT costs to manage more & more drug shortages

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 significant price compression from the draft 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
- 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.

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.

Beyond the distributor funding erosion, the PMPRB reform could have further knock-on effects that will impact our sector. The $70 million per year funding decrease does not consider what effect overall lower launch prices will have on industry decisions to bring products to market. 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.

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, sudden and significant price decreases on grandfathered drugs 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 transaction price between manufacturers and distributors does not impact the pharmacy and wholesaler funding models;
- Shifting the median international price target to the highest international price target within the new 11 country basket;
- Phasing of implementation over 10 years and prioritizing drugs with the highest risk of being excessively priced;
- 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.

CAPDM is very much interested in continuing the dialogue with PMPRB to find sustainable solutions for governments and drug supply chain actors. We understand that PMPRB will host a policy forum with its Board after the February 14th, 2020 submission deadline and would invite stakeholders with unique and non-duplicative perspectives. **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 your upcoming policy forum and on-going working groups tackling implementation issues.**

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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