August 4, 2020

Patented Medicine Prices Review Board
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To Whom It May Concern,

On behalf of McKesson Canada Corporation (“McKesson Canada”) and our 12,000+ employees across the country, we would like to provide our input on the June 2020 Draft Guidelines (“the revised guidelines”) of the Patented Medicine Prices Review Board (“PMPRB”).

McKesson Canada is one of the country’s largest health care companies & the largest distributor of pharmaceutical products. Uniquely positioned within the Canadian healthcare system, our role as a pharmaceutical wholesale distributor, pharmacy banner operator, patient-care innovator, and specialty solutions provider makes us one of the few companies that operates in and touches every aspect of the healthcare system. This provides us with a 360° view to help improve the cost and quality of healthcare delivery in almost every setting.
McKesson Canada’s Perspective on the Revised Guidelines

McKesson Canada appreciates how the PMPRB has responded to the feedback it received from the draft guidelines consultation that ended earlier this year and its engagement with the pharmaceutical distribution industry.

Overall, we are cautiously optimistic of the positive changes that we see in the revised guidelines.

We have reviewed the revised guidelines and would like to update our recommendations from our first submission:

1. **The PMPRB identify further opportunities to enable patent holders to be compliant with new price ceilings under the revised guidelines, such as**
   - Providing patent holders the latitude to incorporate essential supply chain costs, such as manufacturer-borne distribution fees and patient services costs, into the calculation of net prices
   - Stay the course in allowing patent holders to be deemed compliant to MLP if no excessive revenues are calculated at the net price level

2. **Given PMPRB’s 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.**

3. **The PMPRB provide the previously proposed 18-month grace period before compliance is enforced to ensure sufficient windows for the industry to manage a potentially high volume of price changes, to adjust business and service models to the new environment, and to help mitigate potential disruptions from subsequent waves of COVID-19**

McKesson Canada Comment on the Revised Guidelines

A. **Price Test for Grandfathered Drugs**

Basing the MLP for Grandfathered Drugs on the lesser of HIP or NEAP is perhaps the most impactful change from the perspective of McKesson Canada and its essential pharmaceutical distribution services and end-to-end specialty patient services. Under
the previous Median International Price (MIP) test, it was estimated that this would have reduced the national funding for pharmaceutical distribution services by $67 M/year. This would have threatened the sustainability of an industry already challenged by revenue reductions due to a >70% reduction in generic drug prices over the past decade and increased operational costs, including rising investments in cold-chain infrastructure, new Health Canada ambient transportation requirements, and of course, COVID-19 and its associated higher operational costs. There also would have been a similar significant impact on the funding for essential end-to-end support services we provide to patients on complex therapies.

With the move to the HIP test for Grandfathered Drugs, there will still be an impact on the pharmaceutical distribution industry in terms of an average 3-5% price reduction in Grandfathered Drugs, which would still translate into a $14-23 M/year loss of pharmaceutical distribution funding nationally. Though any further erosion of distribution funding would best be avoided, this is a marked improvement than the potential doomsday scenario arising from the MIP price test from the draft guidelines.

This change adds 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 compliance costs. With the new reality of COVID-19, McKesson Canada and other pharmaceutical distributors are investing millions into personal protective equipment and social distancing measures to protect staff and customers, as well as higher inventories and more robust IT systems to better react to the huge swings in demand we have seen 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.

We were pleased to hear during the July 16 meeting with CAPDM 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, which should hopefully further minimize the impact of the revised guidelines on Grandfathered Drugs. We hope that there will be opportunities for patent holders to incorporate the cost of essential supply chain and patient services costs into their net price calculations to provide a clearer picture of true net prices.

Recommendations

1. The PMPRB identify further opportunities to enable patent holders to be compliant with new price ceilings under the revised guidelines, such as:
   - Providing patent holders the latitude to incorporate essential supply chain costs, such as manufacturer-borne distribution fees and patient services costs, into the calculation of net prices
• Stay the course in allowing patent holders to be deemed compliant to MLP if no excessive revenues are calculated at the net price level

2. Given PMPRB’s 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.

B. Status of the Previously Proposed 18-month Grace Period

From a timeline perspective, we are also curious as to the absence of the 18-month grace period (for new & grandfathered drugs to be compliant with the revised guidelines) that had been proposed by PMPRB during the consultations on the November 2019 Draft Guidelines. The revised guidelines state that Grandfathered Drugs would need to be compliant by the end of 2021. If the planned timeline for publication of the Final Guidelines is delayed beyond the planned September 2021 release, there could be a very short window for patent holders of Grandfathered Drugs to be compliant within this time window.

As we have stated previously, a fast rollout of draft guidelines would also impact McKesson Canada’s ability to effectively implement price changes and protect itself from inventory deflation. McKesson Canada currently maintains pricing for 35,000 unique prescription drug products, with separate pricing files set up for each province/territory and market (e.g., retail vs. hospital contracts). Typically, if there are a large volume of price changes (such as the pCPA/CGPA agreement that reduced 70 generic drug prices on April 1, 2018), we are notified by governments 2-3 months ahead of time, which gives us time to confirm pricing with manufacturers, negotiate floor stock protection (i.e., be compensated for the lost value of drug inventories that decreased in price), and staff up for implementation. Similarly, our pharmacy customers need time to prepare for price adjustments, including ‘washout’ of old higher-priced inventory.

We remain concerned about our ability to receive a large volume of price adjustments in a timely manner from manufacturers and having the capacity to implement them. This concern is compounded by the COVID-induced unpredictability of supply and demand that we have been dealing with, as well as the numerous process and system changes being made over the next 12 months to improve our responsiveness & resiliency to new pandemic-driven operating demands.
Recommendation

3. The PMPRB provide the previously proposed 18-month grace period before compliance is enforced to ensure sufficient windows for the industry to manage a potentially high volume of price changes, to adjust business and service models to the new environment, and to help mitigate potential disruptions from subsequent waves of COVID-19

Closing Remarks

Thank you again for the opportunity to evaluate and consider our recommendations for the revised guidelines, and we look forward to more opportunities to inform the PMPRB’s thinking in the coming months. If in the interim you have any questions about McKesson Canada, our submission, or require any assistance on any other issue, please do not hesitate to contact me directly.

Sincerely,

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