February 14, 2020

Patented Medicine Prices Review Board
Box L40
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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 proposed draft guidelines (“the draft guidelines”) of the Patented Medicine Prices Review Board (“PMPRB”).

McKesson Canada is one of the country’s largest health care services company & the largest distributor of pharmaceutical products, and we are uniquely positioned within healthcare. 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, offering us a unique 360° view and allowing us to improve the cost and quality of healthcare delivery in almost every setting:

**McKesson Canada at a Glance**

- **Distribution**
  - The largest pharmaceutical distributor in Canada, delivering over 1/3 of all medications across the country, ensuring timely patient access to vital medication

- **Community Pharmacy**
  - The largest supporter of Independent Pharmacy with 6 retail banners & franchises supporting 2,300+ independent community pharmacies
  - Best-in-class pharmacy care with 400+ Rexall pharmacies across Canada
  - Well.ca is Canada’s leading online destination for health, wellness, beauty and baby products

- **Specialty Health**
  - 13 specialty pharmacies & Canada’s only accredited network of 90 infusion clinics form our end-to-end solution for 18,000 patients on specialized therapies

- **Technology**
  - A leading provider of technology solutions that empower healthcare providers to deliver better care at a lower cost

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McKesson Canada’s Perspective on the Draft Guidelines

McKesson Canada recommends that:

1. The PMPRB identify opportunities to phase in and/or reduce the acuity of price compression for Grandfathered and new drugs to minimize the impact on distribution and patient services funding. Potential avenues to explore include:
   - A risk-based approach to focus only on Grandfathered Drugs that have a high risk of being excessively priced
   - Utilizing a less aggressive pricing test than the MIP for Grandfathered Drugs
   - 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
   - Allowing patent holders to be deemed compliant to MLP if no excessive revenues are calculated at the net price level

2. The PMPRB maintain the 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 and to adjust business and service models to a potentially reduced funding environment

After reviewing the draft guidelines and participation in the PMPRB’s consultation process, we are concerned that, if unaltered, the draft guidelines could have far reaching impacts on McKesson Canada’s ability to continue providing timely access to both essential distribution services for pharmaceuticals and end-to-end patient services for complex therapies.

Our essential Pharmaceutical Distribution Services provide next-day access to vital medications at most community and hospital pharmacies across Canada:

- Our 13 pharmaceutical distribution centres service 7,100+ community pharmacies and 1,350+ hospital pharmacies across all provinces and territories
- We are the only pharmaceutical distributor that still regularly supplies the Territories and other northern/remote communities
- Over 1/3 of all medications on the shelves of community and hospital pharmacies pass through our distribution centres
- We supply over 35,000 different prescription drugs and 20,000 consumer products in our distribution centres, fulfilling orders with over 99.95% accuracy and a fully ambient transportation network
- Next-day delivery available to most pharmacies in Canada means that if your local pharmacy is out of stock of a medication (whether it is a commonly
prescribed one or an obscure one), they can have it on their shelves the next day, thereby minimizing any treatment delay for a patient.

We also provide essential **End-to-End Patient Services** for patients on complex therapies that are not being met by traditional community pharmacies nor the healthcare system:

- **Our clinical services support both patients and their specialists by removing barriers to achieving the best clinical outcomes for complex therapies**, from patient education to reimbursement assistance to monitoring adherence to safeguarding against adverse events to administration support.
- We operate 15 specialty pharmacies and **Canada’s only accredited network of 80+ INVIVA infusion clinics**.
- We treat nearly **18,000 patients** and provide **130,000 infusions & injections annually** in multiple therapeutic areas, including gastroenterology, rheumatology, oncology, etc.

These essential services, which ensure timely access to medications and the best outcomes for complex therapies, are generally funded as a percentage of the underlying price or are dependent on manufacturers for funding:

- Distribution fees for Pharmaceutical Distribution Services are funded indirectly through pharmacy markups or directly via allowable wholesale upcharges (depending on the province).
- End-to-End Patient Services are subsidized by pharmacy markups paid by public & private payers, and some services (such as infusions and risk-management programs) are paid directly by manufacturers.

Any sudden change to the underlying price of a drug, such as what could occur to Grandfathered Drugs under the draft guidelines, would have a directly proportional impact on the funding of our Pharmaceutical Distribution Services and End-to-End Patient Services. For example, if the price of a Grandfathered patented drug drops by 20% tomorrow, we would still need to deliver the medication to Kapuskasing, albeit with 20% less funding.

Given the ‘pull system’ and regulated pricing environment in which we operate (i.e., the clinical decisions of prescribers determine the demand for medications, and drug prices are set by federal/provincial governments), McKesson Canada is unable to influence the prices paid nor the volumes sold to make up for the funding shortfall in distributing those drugs.
Impact on Pharmaceutical Distribution Services

Analysis by PDCI has estimated that the use of the Median International Price (MIP) for Grandfathered Drugs would result in an average 20% price compression, which would be devastating for McKesson Canada’s national pharmaceutical distribution network.

According to IQVIA, the annual volume of brand drugs distributed by the pharmaceutical wholesale channel is $16.7 B (MAT November 2019), which would be a rough proxy for the volume of Grandfathered patented drugs going through this channel. Pharmaceutical distribution is a very low-margin business, and this $16.7 B of Grandfathered Drugs volume would translate to just under $333 M/year (~2% net upcharge) of pharmaceutical distributor funding before costs are taking into consideration.

If the draft guidelines were to be implemented and the 20% average price compression were to occur, that would remove $67 M of distribution funding from our industry. This would be in addition to other regulatory impacts that our industry has had to manage over the past decade, including >70% reduction in generic prices, $20 M/year in new costs to meet new Health Canada standards for ambient transportation networks, $5 M/year investments in cold-chain infrastructure, etc.

To rebalance the business to 20% reduced distribution funding for Grandfathered Drugs, pharmaceutical distributors, like McKesson Canada, would have few options to shed cost, such as:

- **Reducing delivery frequency**, resulting in longer waits for patients to receive out-of-stock medications
- **Reducing geographical reach of deliveries**, which would mainly impact patients in rural areas
- Reducing the footprint of infrastructure, such as **closing distribution centres**, which has already happened, with 13 of the industry’s distribution centres, or about 25%, shutting their doors between 2012 and 2018 as a result of generic price compression
- **Reducing on-hand drug inventories**, which create a short-term buffer against drug shortages by smoothing fluctuations in supply and demand

The end result would be longer wait times, delayed starts, and interrupted therapies for patients, particularly in rural areas, and possibly more frequent drug shortages. On a longer term basis, pharmaceutical distributors, like McKesson Canada, would be challenged to continue making investments in distribution networks, with further negative impacts on timely service, increased risk of drug shortages, and access challenges for patients.
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 are concerned about our ability to receive a large volume of price adjustments in a timely manner from manufacturers and to be able to implement them on July 1, 2020, as well as the potential ongoing volatility of patented drug prices and the need for frequent price adjustments as price ceilings are recalculated or products switch categories.
Impact on End-to-End Patient Services

Similarly, funding for our End-to-End Patient Services would be impacted by a potential 20% average price reduction of Grandfathered Drugs, which would in turn proportionally reduce the pharmacy markup subsidization and reduce the funding available from manufacturers.

Our End-to-End Patient Services fill the ‘community care gap’ for patients on complex therapies. When the first of these complex therapies entered the Canadian market in the 2000s, we noticed that patients and their specialists had nowhere to turn for support with the additional complexities for these treatments, such as companion diagnostics, infusions & injection training, post-administration reporting, and reimbursement assistance. These additional requirements, which also ended up being barriers to access and treatment success, were beyond the capabilities of traditional community pharmacy practice and outside the scope of hospital-based care. Thus, we created an End-to-End Patient Services model to better support patients and their specialists, and this model is funded by a combination of pharmacy markup and manufacturer funding.

<table>
<thead>
<tr>
<th>Examples of How Our End-to-End Care Model Maximizes Patient Outcomes</th>
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<tbody>
<tr>
<td>Thalidomide for Oncology</td>
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<tr>
<td>▪ Manufacturer has committed ‘zero pregnancies’ to Health Canada for patients on this drug, so our staff ensures that negative pregnancy blood tests are confirmed prior to each dispense</td>
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<tr>
<td>Therapy for Autosomal Dominant Polycystic Kidney Disease</td>
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<tr>
<td>▪ Built a program with the manufacturer where we coordinate ongoing monitoring of liver enzyme blood work and validate lack of liver toxicity before each dispense</td>
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<tr>
<td>Cancer Care Ontario Awarding-winning Oral Chemotherapy Program</td>
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<tr>
<td>▪ Achieved &gt;99% compliance rate (versus typical 25% adherence rate) and low 1.1% drop-out rate</td>
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<tr>
<td>▪ 5% of baseline patient calls unearthed clinical issues that had to be referred to oncologists</td>
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<tr>
<td>▪ Hospital has more complete visibility to patient’s treatment progression</td>
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If such funding were to shrink in proportion to the 20% price compression anticipated under the draft guidelines, we would need to rebalance the services delivered to the lower funding levels, and potential options for cost containment could include:

- Reducing patient support services and capacity
- The use of more patient self-service options
- Scaling back of high-cost services (such as after-hours pharmacist support for patients to safeguard against toxic side effects)

The end result would be longer delays for patients to start complex therapies, more frustration as patients are forced to self-navigate, capacity-constrained specialists having to take significantly more time to assist patients, and patients less likely to achieve the best clinical outcomes of therapy (or potentially greater waste from treatment failures).
Recommendations

To avoid the unintended consequences outlined above, McKesson Canada recommends that:

1. The PMPRB identify opportunities to phase in and/or reduce the acuity of price compression for Grandfathered and new drugs to minimize the impact on distribution and patient services funding. Potential avenues to explore include:
   - A risk-based approach to focus only on Grandfathered Drugs that have a high risk of being excessively priced
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Closing Remarks

Thank you again for the opportunity to evaluate and consider our recommendations, 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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