

February 12, 2021

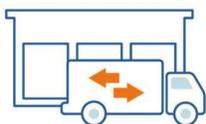
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Dear Sir or Madam:

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 Notice and Comment issued by the Patented Medicine Prices Review Board (“PMPRB” or the “Board”) on January 15, 2021, concerning the proposed consequential amendments to the January 1, 2021 guidelines.

McKesson Canada is one of the country’s largest health care companies and 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 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 Notice and Comment**

First, McKesson Canada would like to acknowledge the decision made at the end of 2020 to delay implementation of the implementation of the PMPRB final guidelines until July 1, 2021. **There remain several outstanding questions regarding the process for implementing these guidelines, which given their significance, will trigger a series of complex administrative processes.** Thus, McKesson Canada appreciates the Board's decision to postpone implementation until such time as these questions can be resolved and there is agreement between the Board and stakeholders on how these processes should function.

Regarding the proposed consequential amendments, McKesson Canada's perspective is as follows:

### ***Definition of Gap Medicines***

McKesson Canada supports aligning the definition of "Gap medicines" with the final guidelines' implementation schedule.

### ***Compliance Timelines for Grandfathered and Gap Medicines***

**McKesson Canada is concerned that the proposed revision to the compliance timeline will prove to be unworkable given the tight time constraints under which stakeholders will be operating.** While we appreciate the Board's desire to have the compliance timeline implemented according to the previous calendar, given the postponement of the coming-into-force of the guidelines announced at the end of 2020, we are concerned that the industry will be challenged to successfully implement pricing changes in such a compressed timeframe. We had also raised this concern in our submission to the 2020 consultation on the draft guidelines.

When the guidelines were planned for implementation at the start of 2021, the Board made the wise decision to allow manufacturers two compliance periods in which to implement their new prices. This timeline would have seen manufacturers receive their new maximum list price by end of March 2021, allowing them a reasonable timeframe to validate these new prices, conduct their own internal processes to update their list prices, and communicate them to distributors to ensure compliance by the end of December.

Given the Board's estimate that 34% of all grandfathered and gap medicines will have their MLPs changed, the original timeframe for ensuring compliance remains appropriate. The rationale for compressing this timeframe is not clear, and we are concerned that it will prove to be too rushed for an orderly transition to new prices.

In particular, we have three concerns related to the proposed compliance timeline:

1. **It is unclear when precisely manufacturers will receive information on the new MLPs, when they will be able to validate them internally and communicate them to distributors.** Initially, MLPs were set to be communicated in March 2021, however it is unclear whether that has been delayed until after the implementation of the guidelines in July 2021. It appears that it will be very challenging for manufacturers to be able to communicate new prices by December, just ahead of the proposed amended coming-into-force of the

compliance timeline. This increases the likelihood that the new list prices will be communicated on very short notice to distributors like McKesson Canada, who must conduct manual updates to our pricing system.

This will wind up occurring during the December holiday season when ordering volume typically increases as pharmacy customers conduct end-of-year buying and statutory holidays reduce available working hours.

- 2. There is currently no uniform process for the communication of list prices from manufacturers to distributors.** Existing commercial agreements did not contemplate mass updates to list prices, and thus only require very short notice period for the communication of new prices. In the absence of an agreed-upon, industry-wide timeframe, it is likely that manufacturers will only communicate their new prices to distributors at the very last minute, making it effectively impossible to update prices in time.

When new prices are communicated, distributors like McKesson Canada are occasionally able to provide automated updates to our internal systems; for example, when several dozen generic drug prices were changed in April 2018, our systems were quickly updated as the new prices were communicated in a single notice and, importantly, there was no variation in price from one jurisdiction to the next. When manufacturers change their prices now, the new information is communicated on very short notice on an ad hoc basis using a standard form. This information must be manually entered into McKesson Canada's pricing system.

Patients, pharmacy customers and distributors would benefit from a window of two to three months following the validation of the new MLPs by manufacturers to conduct the manual updates to pricing systems to reflect the new prices communicated to them. This timeframe would allow for manual updates and cross-verification with official sources (including manufacturers and the PMPRB), and to ensure clear and comprehensive communication to

### **New Grandfathered and Gap Medicine Rules Could Trigger 3,000-4,000 Price Changes**

It is worth noting that manufacturers typically vary the price of a drug from one province to another. The change in price of one drug usually entails multiple pricing changes in our systems. We anticipate that the number of actual price changes to implement as a result of the PMPRB reforms will far exceed the number of drugs that will have new MLPs.

These price changes, unless they are submitted in a batch file (which is unlikely to occur unless mandated by the PMPRB) will require manual updates to our systems. Depending on the complexity of the drug pricing change and any required verifications, these updates can take from several minutes to several hours.

**Our current estimates suggest that somewhere between 450 and 500 drugs will have their prices revised as a result of the new guidelines. If three-quarters of these drugs are priced differently from one province to the next, we anticipate between 3,000 and 4,000 price changes to implement. If each price change takes only an average of 10 minutes to complete, we anticipate requiring a total of between 300 and 400 hours to complete this work. To accomplish this, we anticipate needing up to 12 weeks of work time to ensure smooth, successful implementation.**

pharmacy customers and patients. McKesson Canada's understanding of the MLP process is that a six-month window is insufficient to ensure a minimum lead time of two months for distributors to adjust their systems and for pharmacy customers to manage their inventory.

- 3. We anticipate floor-stock protection of inventory to be a significant priority for the smooth operation of the pharmaceutical sector.** It is likely that pharmacies will have inventory on hand that will see its value diminish significantly once the new pricing guidelines are implemented. Without any assurance that they will be credited for the difference in value between the purchase price (under the current pricing regime) and the eventual sale price (under the new pricing regime), customers may be unwilling to hold sufficient stock to meet the needs of their patients, potentially leading to drug shortages as the implementation date approaches. If there is no broad agreement on floor-stock protection, we anticipate customer service requests and complaints from thousands of pharmacy customers.

Similarly, at the distributor level, McKesson Canada will require inventory protection to ensure that it is able to carry sufficient stock of patented medicines to meet customer ordering needs without being subject to a significant decline in the value of this stock. Without careful consideration and planning, we may see unintended consequences related to the robustness of the country's drug supply leading up to implementation. Sector-wide coordination, however, can help ensure a smooth transition, avoiding disruptions in inventory management and providing a clear and shared understanding of the operationalization of the new guidelines among stakeholders.

Without sufficient time and coordination, we anticipate a significant "domino effect" to occur as inconsistent and mis-aligned floor-stock protection negotiations take place, cascading throughout the entire supply chain. Attempting to accomplish this without adequate time and agreed-upon parameters is likely to create uncertainty in the marketplace and could impact access to patented medicines across the country.

- 4. The compressed timeline will coincide with an unprecedented and exceptionally busy period for pharmaceutical distributors and community pharmacies, who are expected to be involved in the distribution and administration of both a COVID-19 vaccine and a seasonal influenza vaccine.** Moreover, given the scope of the changes resulting from the new guidelines, we anticipate the need to devote significant resources to supporting customers as they navigate through the impact of the guidelines.

## **Recommendations**

- 1. We recommend that the Board maintain its original compliance timeline, i.e., two compliance periods following the coming-into-force of the final guidelines on July 1, 2021, meaning the compliance timelines for Grandfathered and Gap medicines be maintained at July 1, 2022.** This will ensure manufacturers, distributors and pharmacists have enough time to conduct the complex process of updating hundreds of drug prices to ensure a smooth transition and optimal access to drugs for patients.
- 2. We recommend that the Board convene a working group comprised of representatives from the PMPRB, manufacturers, distributors and retail pharmacists to develop a process for implementing new list prices, including a**

**timeline for communication from manufacturers to the marketplace.** This timeline should reflect the unique and unprecedented volume of price changes that must be implemented by the coming-into-force of the compliance timeline. As such, consideration should be given to allowing a “listing update” period, whereby distributors would receive all updated list prices from manufacturers two to three months prior to the implementation of the new prices. This will allow distributors adequate time to properly process the thousands of changes to their systems and allow pharmacies to update their systems (assuming there are several hundred new MLPs, with most of the newly priced drugs being assigned prices that vary by province).

The recommendations of this working group should be applied to all manufacturers to ensure that price changes are implemented comprehensively and equitably.

This working group could be tasked with examining other technical and process-oriented challenges that may arise in the implementation of the final guidelines, such as management of floor-stock protection requests and related behaviour from retail customers. We recommend that the results of this group’s work ensure that distributors and pharmacy do not face financial penalties and losses and are credited the difference in value between pre- and post-implementation prices by manufacturers. Furthermore, the PMPRB should have measures in place so that distributors and pharmacies are fully supported to minimize any potential disruptions and shortages in the days and weeks leading up to implementation, and to ensure that the pharmaceutical supply chain continues to operate smoothly.

The working group should also consider implementing a “washout” period for pharmacy customers, to provide a window (at least 30 days following implementation) during which they can be reimbursed the actual acquisition cost for inventory purchased prior to the coming-into-force of the new list prices.

The working group should be able to complete its work prior to the July 1, 2021, implementation date.

3. The Board should consider postponing the implementation of the guidelines, particularly for Grandfathered and Gap medicines, to January 1, 2022, to ensure alignment with the Board’s compliance year calendar. The original guidelines, published in November 2019, proposed an 18-month period for patentees to be compliant with the new list prices for Grandfathered medicines.<sup>1</sup> This timeframe has already been reduced to 12 months, which is sufficient to ensure a smooth transition. It has now been shrunk to six months, which is simply too short to allow for compliance. While an extension to 12 months is necessary to ensure the sector has adequate time to implement these significant changes smoothly, it would have the unintended consequence of creating two different compliance regimes during a single compliance year, since the changes would be effective in July 2022. From an operational perspective for the sake of stakeholders, it would be beneficial to implement these changes at the start of the 2023 compliance year.
4. While the intent of this reform is the reduction of patented medicine prices in Canada, it is clear

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<sup>1</sup> “Patentees will be granted until the subsequent period after the MLP is set to ensure the List Price of the grandfathered medicine is lowered to a level that is no higher than the MLP” – *PMPRB Guidelines 2019*, p.15, accessed February 2021 at <https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/draft-guidelines-en.pdf>.

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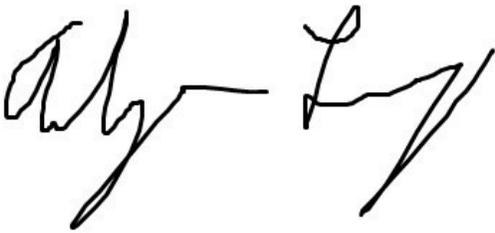
that there will be significant impact on the pharmaceutical distributors as well, since distribution funding is largely a function of drug prices. As a result, while not the intended effect of this reform, it will lead to a reduction in drug distribution and supply funding. Given the PMPRB's reporting 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 could 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. We note that an unintended consequence of the Board's reforms will be a reduction in pharmaceutical distribution funding.

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### **Closing Remarks**

Thank you again for the opportunity to evaluate and consider our recommendations for the proposed consequential amendments to the guidelines, and we look forward to more opportunities to inform the Board'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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