December 20, 2023

Board Secretariat
Patented Medicine Prices Review Board Box L40
Standard Life Centre
333 Laurier Avenue West, Suite 1400 Ottawa, ON, K1P 1C1
PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

RE: Scoping Paper for the Consultations on the Board's Guidelines

Dear Board Secretariat,

On behalf of McKesson Canada ("McKesson Canada") and our thousands of employees across Canada, we would like to provide our input on the themes and questions posed in the "Scoping Paper for the Consultations on the Board's Guidelines" ("Scoping Paper") issued on November 12, 2023.

McKesson Canada is one of the country's largest healthcare companies and its largest distributor of pharmaceutical products. Uniquely positioned within the Canadian healthcare system, our role as a pharmaceutical distributor, pharmacy banner operator, patient-care innovator, and specialty solutions provider makes us one of the few companies that operates in 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.

Given this perspective, this submission focuses comments on the following themes and questions developed in the scoping paper:[1]

- Theme 2: Transition to PMPRB11 – New versus Existing Medicines
- Theme 5: Relation to pan-Canadian Health Partners, Insurers (Private and Public); and Alignment with Broader Government Initiatives
- Theme 6: Engaging with Patients, Health Practitioners, Pharmacy, and other Stakeholders

To avoid the unintended further erosion of essential funding for the distribution and community pharmacy sectors, McKesson Canada is offering five recommendations:

1. **We encourage the PMPRB to comprehensively document the likely impact of its reform on the broader pharmacy ecosystem, as per the express wishes of the previous health minister.**
2. **The government should consider a 'whole of government' approach to this issue, ensuring a clear understanding of the impact of these reforms on the government's national pharmacare strategy, its life sciences strategy, and its drug supply chain strength strategy.**
3. **We encourage the PMPRB to declare all medications introduced prior to new reforms as "existing drugs," subjecting their maximum list price to the highest international price comparison, not the median international price comparison.**
4. **We recommend that Health Canada lead an exercise with provincial governments to identify opportunities to reinvest in the drug distribution and pharmacy systems to mitigate the negative impact of this reform.**

[1] McKesson Canada representatives presented the comments below PMPRB board during the December 6, 2023 Policy Roundtable. A copy of the presentation slides is available in Appendix I of this submission.

5. **We recommend that the PMPRB establish a Working Group consisting of provincial drug plan representatives, manufacturers, distributors, pharmacies and patient groups to develop new Guidelines and identify a common protocol for the establishment of new prices.** This will ensure a seamless transition for the thousands of medications that may be subject to price changes due to this initiative and avoid unnecessary supply interruptions as pharmacies seek to protect the value of their inventory.

Theme 2: Transition to PMPRB11 – New versus Existing Medicines

Question 2.1: Should the Guidelines distinguish between medicines that existed as of July 2022 (existing medicines) and medicines introduced afterwards (new medicines)?

Question 2.2: What approach should the Board take with respect to existing medicines with prices above the HIP of the PMPRB11? Should the Board review these prices, and if so, how soon?

Unfortunately, prescription drug policy discussion in Canada typically reflects a lack of understanding about how pharmacy funding and reimbursement works in Canada. Pharmacy funding is established by provincial governments as a set percentage of a drug's list price. This amount, referred to as a distribution fee/upcharge or markup, provides the envelope of funding to support drug distribution and community pharmacy services (pharmacists also receive a dispensing fee for every medication they dispense). **Thus, there is a direct link between the price of drugs and the funding for Canada's drug supply and community pharmacy services.**

It is important to note that while each province determines the specifics of its reimbursement framework, the principle is the same: pharmaceutical distributors and pharmacies receive funding that is set as a pre-determined percentage of the ex-factory list price of the drug – not the net price that may have been negotiated by the provinces via the pan-Canadian Pharmaceutical Alliance (pCPA).

Since provincial drug plans typically negotiate confidential price agreements with patented drug manufacturers via the pCPA (resulting in back-end rebates paid on the list price to achieve a net price), **the listed price of medications in Canada serves primarily to establish the funding envelope for drug distribution and community pharmacy services.** Any reduction in list prices leads to a corresponding reduction in this funding envelope. If the new list price still exceeds the existing net price negotiated between a provincial drug plan and a manufacturer, the only public drug plan savings generated would likely be from the distribution and pharmacy sectors, while the manufacturer likely continues to honour the original net price negotiated by the province, leaving the manufacturer no better or worse off.

The Canadian Association for Pharmacy Distribution Management (CAPDM) estimates that the cumulative impact of price reductions, as were proposed by **the last version of the PMPRB Guidelines, would have reduced funding for the drug distribution system by approximately $24 million annually, and for community pharmacy by approximately $100 million annually.**

Concurrently, the increasingly frequent drug shortages, inflationary pressures, and labour competition (shortages and wage increases) continue to rise and pose additional financial burdens on the entire pharmaceutical sector – from manufacturers, to distributors, to pharmacies. In the last five years, distributor operating costs have increased at least 2.5 times faster than distribution volumes. For example, compliance with Health Canada's 2020 ambient transportation requirements costs the industry an estimated $20 million per year, while handling drug shortages (100/week average)

continues as an uncompensated activity that costs over $3 million per year.

Although the argument can be made that there is increased funding in the sector due to market growth, these artificial 'gains' are offset by the complexity of drug therapies, their handling requirements, patient support needs, and use of alternative distribution channels. These requirements are putting additional strains for temperature-controlled infrastructure throughout the distribution and storage networks, as well as on pharmacy staff who are spending additional hours assisting patients with complex, increasingly more personalized drug therapies.

Furthermore, the pharmaceutical supply chain is increasingly being bypassed by new drugs, with more and more manufacturers of the highest-value specialty drugs shipping directly to pharmacies and hospitals, as a result of limited/controlled supply, restrictive public reimbursement policies, the need for cost efficiencies, or a combination thereof. **Thus, whatever new drugs that pharmaceutical distributors are able to distribute tend to be more expensive to handle, while they are missing out on the distribution funding from a growing number of drugs that utilize other channels.**

Since the cost of shipping drugs in Canada bears no direct relationship to the price at which they are sold, pharmaceutical distributors like McKesson Canada cannot meaningfully reduce operating costs to offset the anticipated reduction in distribution funding. In fact, distributors have observed a significant increase in costs in recent years due to more stringent regulatory requirements (such as the obligation to invest in ambient transport capacity), a shift in the pharmaceutical product mix towards specialty medications that require more expensive storage, handling, and transport, and inflationary adjustments to pricing across the supply chain.

The PMPRB's focus on price reductions – to the exclusion of system-level realities of what drug prices support – threatens the sustainability of our existing business model that ensures next day delivery to 98% of our pharmacies across Canada and a 48-hour delivery window for the remaining 2%.

As stated in previous submissions, McKesson Canada urges the PMPRB to thoroughly study the pharmaceutical ecosystem in its entirety and consider system-level implications of any proposed drug pricing reforms, understanding that a well-intentioned reform intended to regulate excessive drug prices will necessarily and unavoidably lead to a reduction, first and foremost, in funding for the country's drug supply and community pharmacies – without necessarily reducing the price provinces pay for medications.

This would risk further destabilizing an already fragile drug supply system, making access to medications for Canadians, particularly those in rural and remote areas, more challenging. Reduced drug prices become irrelevant to people who are unable to access them.

In light of these uniquely Canadian realities, and the scope of pharmaceutical distribution services that are covered exclusively through drug prices, the second question should focus on the validity of the PMPRB11 comparator countries, rather than the reviews of HIP and MIP prices. The geographic realities and population density challenges of Canada and PMPRB11 comparator countries are vastly different from a drug distribution perspective (see Figures 1-2).

Canada's distributors need to cover a geographic area of 9.98 million km² versus 11.03 million km² for *all other comparator countries combined.*[2] Only Australia has population density and distribution

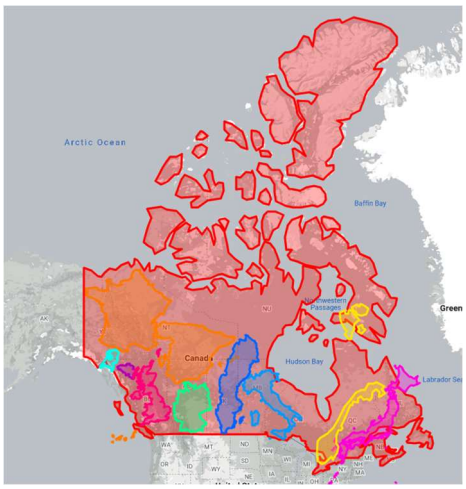
[2] Total combined area of all comparator countries excluding Australia: 3.41 million km², or 34% of Canada's area.

challenges comparable to Canada, albeit with only 76% of the territory and none of the seasonal weather-related challenges Canadian distributors contend with every year, with increasing frequency due to climate change-related emergencies.

In short, the PMPRB11 basket of comparator countries does not accurately reflect the actual costs for getting drugs into the hands of patients in a geographically and climatically diverse country like Canada, prompting a further need for a more complete analysis of the implications of any future PMPRB pricing policies.

Figure 1. ***Area comparison – Canada and Australia***

Figure 2. ***Area comparison – Canada and PMPRB11 except Australia***



Theme 5: Relation to pan-Canadian Health Partners, Insurers (Private and Public); and Alignment with Broader Government Initiatives

Question 5.1: What efficiencies could be gained by co-ordinating decisions and timelines of the PMPRB with those of the Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et services sociaux (INESSS) and pan-Canadian Pharmaceutical Alliance (pCPA) or insurers (public and private)?

Question 5.2: How can the PMPRB optimize its presence within the Canadian bio/pharmaceutical ecosystem to support a whole of government approach to issues relating to patented medicines?

McKesson Canada and the associations that represent it (including the Canadian Association for Pharmacy Distribution Management, the Neighbourhood Pharmacy Association of Canada, the Canadian Pharmacists Association, and the Association québécoise des distributeurs en pharmacie – all of whom presented their remarks during this month's Policy Roundtables), have repeatedly pointed out that the PMPRB has not taken into consideration the direct impact price reforms will have on critical funding for pharmaceutical distribution and community pharmacy services in Canada.

It is important for the PMPRB in its next iteration to conduct a more fulsome overview of the drug

procurement and pricing situation in Canada, and to recognize the challenges presented by previous iterations of the Guidelines that risked impeding access to prescription medications for Canadians, at a time when we are navigating a series of difficult drug shortages that highlight the fragility of Canada's medication supply.

If the goal of PMPRB is to create stability and resilience for Canada's drug supply, then any proposed pricing reforms will need to consider the historical circumstances that have brought us to the current state, as well as the holistic effects of those reforms on the pharmaceutical ecosystem: federal, provincial and private drug plans, manufacturers, distributors, pharmacies, patient support programs, and patients.

What is missing from the conversation is a fundamental understanding of how pharmacy is being funded currently, and what effects pricing reforms (in the absence of concurrent compensatory policy changes) would have on the pharmacy sector as a whole – including manufacturers, distributors, pharmacies and, ultimately, patients' access to essential medication. Engagement with and understanding of the entire sector – not only a "whole of government," but a "whole of sector" approach – is essential to creating a fulsome picture of the effects of PMPRB decisions and policies.

In particular, there needs to be recognition that PMPRB pricing reforms do not exist in a vacuum. The federal and provincial governments have already implemented significant drug price compression reforms over the last 15+ years. These efforts include the pCPA's multiyear generic drug pricing reforms as well as mandatory biosimilar switch policies that most provinces have enacted in the last few years. **These policy choices have unintentionally reduced pharmacy supply chain funding without any significant reinvestments made by governments to offset their impact. In addition, the Government of Canada has also committed to introduce a national pharmacare program that will also likely reduce pharmacy supply chain funding.**

Our internal analysis, as well as those conducted by the industry associations mentioned above, conclude that the impact of the previously proposed Guidelines would result in a reduction in funding for pharmaceutical distribution and community pharmacy services of between 5% and 6%. This impact on pharmaceutical distribution and community pharmacy funding does not appear to have been taken into consideration in previous PMPRB analyses, and **in the seven years since the reforms were introduced, the PMPRB has not produced any data or insight into the impact of these reforms on the broader pharmacy ecosystem or patient access to medication.**

Similarly, community pharmacies rely on their economic viability to fund critical services that enable accessible healthcare. Pharmacies that will see their funding reduced because of price reforms will have no choice but to look to reduce expenditures in their stores potentially in the form of reduced healthcare services, hours of operation, and staffing. All this at a time when strained provincial health systems are relying more heavily on pharmacies to provide essential primary care to underserviced segments of the population from coast to coast to coast.

Any further drug price reductions, without a concomitant direct (re)investment into distribution and pharmacy services sectors, will only erode these sectors' abilities to maintain high service levels, particularly in rural and remote Canada, where distribution challenges and costs are highest. McKesson Canada's 48-hour delivery for the remotest 2% of pharmacy locations is often completed at a loss that is covered by the overall business model. Further reductions in drug distribution or pharmacy funding would be felt most acutely in the northern and indigenous populations that are already the most complex to serve.

McKesson Canada therefore urges the PMPRB Board to maintain engagement with the broader pharmaceutical sector and to consider the full impact of any pricing reforms such that distributors and pharmacies can continue to provide timely and appropriate levels of pharmaceutical services for all Canadians, regardless of geography.

Theme 6: Engaging with Patients, Health Practitioners, Pharmacy, and other Stakeholders

Question 6.1: What is your experience with innovative medicines and their list prices in Canada?

Question 6.2: What role do the PMPRB Guidelines play in your decision-making process in Canada and globally (if applicable)?

Question 6.3: Canada and the world are facing a generation of new high-priced drugs for the treatment of rare diseases.

i. Should the PMPRB view the question of whether the prices of these medicines are "excessive" through a different lens than other types of medicines?
ii. What quality of evidence should the Board consider when conducting its scientific review of these medicines?

Question 6.4: How can the PMPRB better engage with you?

McKesson Canada is encouraged by the recent steps taken by the new PMPRB Board to broaden its scope and recognize interdependencies within the pharmaceutical sector, by inviting a broader spectrum of stakeholders to present at the December Policy Roundtables. We were particularly pleased to hear from the Board Chair that the PMPRB's work going forward would not be bound by previous iterations of the Guidelines. This attitude of openness and collaboration is a critical and much appreciated first steps towards a more fulsome and inclusive discussion on how to achieve an affordable and equitable pharmaceutical ecosystem.

In recent years we have seen a growing appreciation among Canadians for the importance of a strong healthcare supply system. We have appreciated a strong supply chain that successfully rolled out COVID vaccines, just as we noticed the fragility of our system last year as we frantically tried to source children's analgesics and antibiotics. The lesson of the last few years is clear: our drug supply and pharmacy systems are essential to providing high quality healthcare in Canada. They also are increasingly fragile. Another round of cuts to the principal funding envelopes for these systems will have significant consequences for Canadians across the country, particularly those in remote, rural and Indigenous communities.

Within the already-strained pharmaceutical ecosystem, drug distributors and pharmacy operators assessing the potential impact of any major, permanent reduction in funding will have no choice but to consider how to manage their operations. Further reductions in drug prices put at risk the very infrastructure that ensures physical access of medications to Canadians in a manner consistent with the principles of The Canada Health Act, leaving few, if any, options for distributors to absorb additional funding erosion through cost reductions without cutting service levels that will impact patients.

For drug distributors like McKesson Canada, further funding cuts would force difficult choices about the sustainability of providing current service levels comprehensively across the country. **Such cuts would significantly reduce our ability to maintain frequent service to rural and remote areas and make it harder to carry a comprehensive range of products, as the distribution funding for many**

medications is already below the cost to carry and deliver them. Distributors will likely be forced to reduce 'safety stock' inventories, exposing Canadians to more drug shortages, and increasing the likelihood of more frequent and longer drug shortages in Canada.

At the community pharmacy level, where the twin challenges of high inflation and the healthcare human resource crisis are already threatening the sector's economic model, similar reductions in service and patient care are inevitable. Funding from drug dispensing enables pharmacies to invest in expanding their services to meet new scope of practice expectations. Funding cuts will mean less community-based pharmacy healthcare and service reductions in all pharmacy activity.

Furthermore, the implementation of the final guidelines will need to be coordinated to avoid patient access issues. With the possibility of thousands of deflationary price changes being made across hundreds of manufacturers on an uncertain schedule, there is a real risk of distributors and pharmacies maintaining low inventory levels of impacted patented drugs to minimize the risk of each unit in stock dropping in value by hundreds or thousands of dollars overnight. This would result in potentially a prolonged period where it may take longer for patients to receive their patented drugs until the uncertainty over pricing is over.

Thus, a coordinated approach to implementing price changes on a grand scale will be needed involving the PMPRB, public drug plan managers, manufacturers, pharmaceutical distributors, and pharmacies to identify a uniform target date for all price changes to occur, a notice period prior to this date for manufacturers to communicate price changes to all stakeholders, manufacturer floor stock protection policies, and provincial washout periods for older higher-priced inventories.

Thus, once again, McKesson Canada would like to encourage the PMPRB to strike a working group consisting of Board members, provincial drug plan managers, manufacturers, distributors, community pharmacists and patient groups, throughout the development of the new PMPRB Guidelines and particularly for the smooth implementation of the final guidelines. The PMPRB needs to not only look at monetary accessibility of medications, but also at physical accessibility through the distribution supply chain, and the additional patient support services that are covered through drug pricing.

We believe that Canadians should have affordable access to the medications they need, when and where they need them. We also believe that looking at the issue through the narrow lens of lowest cost contributes to an unintended and crippling impact across the supply chain and will lead to inequity in drug access for Canadians. The changes that will result from further drug price reductions are counter to two of the key principles of The Canada Health Act: universality and accessibility.

Recommendations

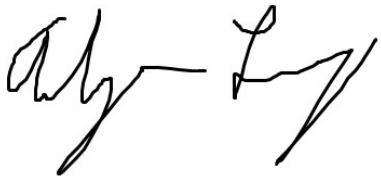
Understanding and appreciating the downstream system-level effects of drug pricing changes is imperative to the successful implementation of any future PMPRB Guidelines. To avoid further erosion of the distribution and community pharmacy sectors, McKesson Canada is offering five recommendations:

1. **We encourage the PMPRB to comprehensively document the likely impact of its reform on the broader pharmacy ecosystem, as per the express wishes of the previous health minister.**
2. **The government should consider a 'whole of government' approach to this issue, ensuring a clear understanding of the impact of these reforms on the government's national pharmacare strategy, its life sciences strategy, and its drug supply chain strength strategy.**
3. **We encourage the PMPRB to declare all medications introduced prior to new reforms as "existing drugs," subjecting their maximum list price to the highest international price comparison, not the median international price comparison.**
4. **We recommend that Health Canada lead an exercise with provincial governments to identify opportunities to reinvest in the drug distribution and pharmacy systems to mitigate the negative impact of this reform.**
5. **We recommend that the PMPRB establish a Working Group consisting of provincial drug plan representatives, manufacturers, distributors, pharmacies and patient groups to develop new Guidelines and identify a common protocol for the establishment of new prices.** This will ensure a seamless transition for the thousands of medications that may be subject to price changes due to this initiative and avoid unnecessary supply interruptions as pharmacies seek to protect the value of their inventory.

Thank you again for the opportunity to provide input on the "Scoping Paper for the Consultations on the Board's Guidelines" and participate in the Policy Roundtable on December 6, 2023. We urge the PMPRB to consider the holistic impact of any new Guidelines on the sustainability of Canada's pharmaceutical ecosystem moving forward.

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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Appendix I – Policy Roundtable slides – December 6, 2023 Session

McKESSON

PMRPB Policy Roundtable

Joseph Berger

December 6, 2023

McKesson Canada is the country's leading provider of healthcare solutions

Founded in 1905 and headquartered in Montreal, McKesson Canada plays a pivotal role in the Canadian healthcare supply chain providing solutions to hospitals, pharmacies, manufacturers and allied health providers

Our 12,000 employees streamline and expedite patient access to vital medications in Canada every day

Largest Pharmaceutical Distributor	Largest Pharmacy Retailer	Largest Provider of Complex Therapies
▪ Over 1/3 of medications in pharmacies & hospitals pass through our 15 distribution centres ▪ We deliver to 7,100+ pharmacies & 1,350+ hospitals every day with 99.8+% order accuracy ▪ 90% of our customers receive their orders on a next-day basis ▪ We help manufacturers manage drug shortages, from managing allocations to emergency importation	Guardian, I.D.A., Remedy's Rx, The Medicine Shoppe, uniprix, Proxim ▪ The largest supporter of independent pharmacy with 2,300+ pharmacies across Canada Rexall ▪ Best in-class retail pharmacy with hundreds of locations in Canada Well.ca Wellness Delivered ▪ Canada's leading online destination for health, wellness, beauty & baby	▪ Leading provider of end-to-end care support for patients on complex therapies, including rare disease drugs inviva ▪ The only nationally accredited infusion clinic operator with almost 90 locations across Canada

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PMPRB reform will have unintended consequences on timely patient access to medications

- Access to medications is already under pressure – more and more drug shortages of stronger intensity and duration, healthcare human resource crisis in pharmacies and throughout the healthcare system
- **The Canadian drug supply system and pharmacy services are funded on the basis of the ex-factory list price, hence this reform will directly impact funding for these sectors**
- Our internal analysis, which is consistent with analysis done by others in the sector, estimates the impact of the last version of PMPRB reforms *on existing medications alone* as reducing funding for drug distribution and pharmacy services by 5-6% which would result in:
  - **Distribution funding immediately reduced by $24 M/year**
  - **Pharmacy funding immediately reduced by ~$100 M/year**
- This would be **on top of the continuing 15-years of distribution and pharmacy funding erosion** from generic drug price compression, mandatory biosimilar switch policies, and provincial drug cost containment
- At the same time, supply chain operating expenses keep rising from new regulatory obligations (e.g., shipment temperature controls), a shift in the product mix towards more complex medications that have higher handling requirements, and the impact of inflation on wages, fuel, and other costs

Implications for patients

If the reforms proceed as planned, there will be less timely medication access

Pharmaceutical distribution potential impacts

- Limit or eliminate delivery to rural and remote regions, which are already financially unsustainable
- Reduction in delivery frequency, resulting in longer waits at your pharmacy for out-of-stock or special-order medications
- Fewer distributors will be able to carry a comprehensive range of products, eliminating money-losing products, which would make access to certain drugs more difficult for patients
- Reduce 'safety stock' inventory levels, which would further weaken the prevention/mitigation of drug shortages, which is a critical priority for the Government of Canada

End result: A weaker, geographically concentrated and more fragile Canadian drug supply

Pharmacy service potential impacts

- Reduced expansion into healthcare services – Canada's pharmacies rely on drug dispensing funding to sustain the critical healthcare services they provide in their communities (immunization, minor ailments prescribing, lab test ordering/analysis, etc.)
- Reduced hours of operation and reduced staff
- Reduction in funding for patient support programs that are critical for adherence to complex medications
- Weakened capacity for pharmacies to carry and dispense high-cost drugs, given the necessary capital investments

End result: More fragile access to medications and a reduction in pharmacy-based community healthcare

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Recommendations to minimize/mitigate the impact of PMPRB reform on Canada's drug supply and pharmacies (and ultimately patient access)

1. **Comprehensive analysis of the impact on the supply chain and pharmacy services:** To date, the PMPRB has refused to conduct a comprehensive analysis of the impact of the proposed reform on the drug distribution and pharmacy sectors, both of which rely on drug price-based funding to remain viable.
2. **Meaningfully embrace the 'whole of government' perspective:** We are encouraged that the current discussion document includes references to the a 'whole of government' approach to the Canadian pharmaceutical ecosystem. In practice, this should mean that patented medicines pricing decisions should be made in the context of trends and policy directives already in motion. Specifically, we propose that this reform be halted until the broader national pharmacare policy has been determined.
3. **Define all drugs launched in Canada prior to January 1, 2025, as "existing drugs,"** which would be subject to the HIP (and not MIP) of the PMPRB11, whereas any drugs launched on or after this date be considered "new drugs"
4. **Health Canada, in partnership with the provinces, reinvest a portion of the drug cost savings** from PMPRB reform to strengthen funding for drug distribution and pharmacy patient services
5. **Operationalization planning:** At implementation, the PMPRB reforms will consist of hundreds (potentially thousands) of individual price changes, which cannot be executed overnight. There is also the risk that pharmacies will simply stop ordering patented medicines as implementation draws near to avoid losses from devaluted inventory. We urge the PMPRB to strike a cross-industry & cross-government working group to establish guidelines for the application of these changes to avoid disruptions in the supply chain or the sudden devaluation of pharmacy-held medications. Furthermore, any further price changes outside of the initial implementation period be done so in a predictable, scheduled manner to allow the industry to adjust and manage the supply chain and pharmacy services impacts

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