September 11, 2024

Patented Medicine Prices Review Board
Box L40 Standard Life Centre
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Re: Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines

Dear Patented Medicine Prices Review Board,

On behalf of McKesson Canada Corporation ("McKesson Canada"), we would like to provide our input on the Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines issued by the Patented Medicine Prices Review Board ("PMPRB").

McKesson Canada is one of the country's largest healthcare companies and the largest distributor of pharmaceutical products. Uniquely positioned within the Canadian healthcare system, our role as a pharmaceutical wholesale distributor, the largest supporter of independent pharmacy in the country, owner of Rexall pharmacies, and provider of end-to-end supports for patients on complex therapies (e.g., patient support programs, specialty pharmacy, and infusion clinics) 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. We employ over 12,000 people across Canada.

McKesson Canada Recommendations

McKesson Canada takes note that the Discussion Guide states that supply chain concerns (raised by pharmacies, pharmacy associations, and distributors) lie beyond the Board's decision-making authority and will not be addressed in the Board's upcoming Guidelines.

However, we would like to reiterate that the actions of the PMPRB's legislated mandate will result in consequences for the pharmaceutical supply chain, and ultimately timely access to vital medicines for Canadians. Funding for both distribution and patient services within the broader pharmacy sector and supply chain are a function of the underlying price, and any reductions in that underlying price will reduce funding (in the absence of compensatory financial mechanisms to offset this). **With this in mind, we have framed our response to the Discussion Guide questions in terms of the anticipated consequences on the predictability and stability of the pharmaceutical supply chain, highlighting the options that would minimize such impacts. It is our hope that our highlighted options will also allow the PMPRB to achieve its mandate as well.**

Thus, with respect to the 7 topics and associated PMPRB-proposed options included in the Discussion Guide, McKesson Canada would like to share the following recommendations that would support predictability and stability in the pharmaceutical supply chain:

Topic 1: Price level within the PMPRB11 in the initial and post-initial price review:

- **Highest International Price (HIP) (option 2)**

Topic 2: The length of time Staff should wait, following the implementation of the Guidelines, to determine whether the IPC identification criteria for an existing medicine is met:

- **Three years (option 3)**

Topic 3: In-depth review based on CPI increase criteria:

- **If the cumulative increase in list price over the last two years is above the combined CPI for the past two years and the increase only took place within the last year (i.e. no increase in price in the first of the two years, followed by an increase on the second year) (option 2)**

Topic 4: The individuals/groups permitted to submit a complaint:

- **Limit complaints to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts (option 1)**

Topic 5: Expanding the list of products that would only be subject to an in-depth review following a complaint to include biosimilars and/or vaccines:

- **The PMPRB will only open an in-depth review for biosimilars and/or vaccines when a complaint is received (option 2)**

Topic 6: Use of clinical evidence to contextualize the degree of similarity of comparators identified for the Therapeutic Class Comparison (TCC):

- **Each comparator will be assigned a level of similarity (option 2)**

Topic 7: Future role of the Human Drug Advisory Panel (HDAP):

- **HDAP will be used only on an ad hoc basis when deemed necessary by Staff (option 1)**

Topic 1: Price level within the PMPRB11 to be used in the initial and post-initial price review

McKesson Canada recommendation: HIP (option 2)

HIP should be used as it is a price test that offers most predictability and stability for Canada's medicine ecosystem. Tables 1 and 2 below show McKesson Canada's estimates of the impact of the PMPRB's three IPC options (HIP; Median International Price (MIP)/HIP midpoint; MIP) on wholesale and retail pharmacy funding. The analysis demonstrates the **HIP will have the least impact on the stability of the medicine supply chain and retail pharmacy, resulting in the least disruptions in patient access to patented medicines across the country.**

Table 1: Impact of PMPRB IPC options on wholesale funding (annual)

Indirect (Wholesale) Brand Sales 2023 (IQVIA)	**$ 21.2 B**
Estimated Current Funding for Brand Distribution via Wholesale Upcharges	$ 474 M
Wholesale Funding Impact of IPC = HIP	**$ (37.9 M)** or -8.0%
Wholesale Funding Impact of IPC = MIP/HIP midpoint	**$ (61.6 M)** or -13.0%
Wholesale Funding Impact of IPC = MIP	**$ (109 M)** or -23.0%

Table 2: Impact of PMPRB IPC options on retail pharmacy funding (annual)

Total Brand Sales 2023 (IQVIA)	$ 23.8 B
Estimated Current Funding for Patient Services via Pharmacy Markups	$ 2.14 B
Pharmacy Funding Impact of IPC = HIP	**$ (171 M)** or -8.0%
Pharmacy Funding Impact of IPC = MIP/HIP midpoint	**$ (278 M)** or -13.0%
Pharmacy Funding Impact of IPC = MIP	**$ (492 M)** or -23.0%

Even though HIP would have the least impact on distribution and pharmacy funding, there will still be a significant impact and it will be additive to significant price compression that has already impacted generic drugs. Based on McKesson Canada's estimates, the 2018 pCPA/CGPA agreement removed at least $45M/year wholesale funding and around $81M/year of pharmacy mark-up funding from the Canadian system (based on approximately $900M compression of public and private generic drug prices), which had a significant impact on the distribution and pharmacy sectors.

In addition, there are also practical concerns associated with using a median price-based criteria:

- The MIP and MIP/HIP midpoint price criteria proposed by the PMPRB are far more sensitive to market changes. To avoid triggering an in-depth review, patentees will need to repeatedly adjust their prices as the prevailing MIP or MIP/HIP midpoint fluctuates year to year. This has a disruptive effect downstream on wholesale and retail pharmacy (price change coordination, floor stock protection, and washout periods). On the other hand, the **HIP is a far more stable and predictable benchmark for the initial and post-initial review because it relies on a single price within the PMPRB11.**

- The PMPRB selected the PMPRB11 in line with the Board's mandate because these countries' pricing practices are considered reasonable and fair. Consequently, any pricing that falls within the range established by this set of PMPRB11 countries (i.e., less than

HIP) can be deemed justifiably appropriate, ensuring market and overall broader pharmaceutical ecosystem current and future stability.

- Canada's ecosystem currently has other mechanisms in place to establish drug affordability (e.g., CDA/ INESSS, pCPA).

The PMPRB's mandate is to ensure that a medicine's list price is non-excessive. Identifying the HIP as the maximum ceiling offers more transparency and predictability to Rights Holders during the crucial early stages of market access and throughout the patent life, thus also having a downstream impact on supply chain sector predictability.

Topic 2: The length of time Staff should wait, following the implementation of the Guidelines, to determine whether the IPC identification criteria for an Existing medicine is met

McKesson Canada recommendation: Three years (option 3)

We recommend that the PMPRB give Rights Holders a period of three years to adapt to the implementation of the Guidelines. A three-year period will support the development of a stable and predictable business environment that fosters support for business continuity and planning.

More immediate price testing could potentially lead to disruptions impacting the supply of existing medicines (pharmaceutical companies may be quickly forced to withdraw existing products from the market). A three-year period would allow Rights Holders and distributors to adapt, plan and forecast the drug supply, ensuring continuity of the medicine supply and access for Canadian patients.

Due to the potential volume of medicine price changes with the implementation of the new Guidelines, the three-year period will give distributors and pharmacies more time to coordinate a smooth transition for medicine inventory management without impacting the certainty of the marketplace and supply chain across Canada (i.e., floor-stock protection and washout periods against price deflation). It would also allow time for the industry and public drug plans to collaborate on a predictable and orderly schedule for implementing price changes arising from the new PMPRB Guidelines. **In the absence of a coordinated execution of price changes, floor stock protection, and washout periods, supply chain players will minimize on-hand inventories of patented medicines (to minimize potentially significant losses of inventory value from sudden price deflation), which would contribute to ongoing patient-facing supply constraints.**

Finally, the three-year period will provide manufacturers with not only concrete timelines but also with more lead time to communicate their new prices to distributors (existing commercial agreements between manufacturers and distributors did not contemplate mass updates to list prices, and therefore currently only require a very short notice period for the communication of new prices), contributing to a more stable transition ensuring continuity of medicine supply to Canadians.

Topic 3: In-depth review based on CPI increase criteria

McKesson Canada recommendation: If the cumulative increase in list price over the last two years is above the combined CPI for the past two years and the increase only took place within the last year (i.e. no increase in price in the first of the two years, followed by an increase on the second year) (option 2)

McKesson Canada recommends that the PMPRB use the combined 2-year CPI: this approach will help ensure certainty (i.e., use of the prior year's inflation), while aligning with broader economic conditions. Using a 2-year CPI average provides a more stable and predictable approach to medicine price regulation and Canada's medicine ecosystem, as well as reflects the current economy.

Adopting a 2-year CPI average would smooth out short-term variances, providing a more accurate reflection of long-term economic trends (year-to-year CPI can fluctuate due to temporary economic conditions, such as supply chain disruptions, economic downturns, or sudden spikes in demand). By adopting a 2-year CPI average, the PMPRB would align with best practices and ensure that Canada's drug pricing framework remains stable and fair. This approach also demonstrates a commitment to a thoughtful and balanced drug regulatory process.

Topic 4: The individuals/groups permitted to submit a complaint

McKesson Canada recommendation: Limit complaints to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts (option 1)

Limiting complaints to the federal, provincial or territorial health ministers provides a fair oversight framework safeguarding the integrity of Canada's medicine pricing system, while also offering a balanced approach (reduced administrative burden for PMPRB Staff, safeguarding against misuse/ abuse of the complaints process, more predictability and stability for distributors, etc.) to help ensure that case-specific situations not captured by the PMPRB's price review process can be identified for an in-depth review when needed.

Topic 5: Expanding the list of products that would only be subject to an in-depth review following a complaint to include biosimilars and/or vaccines

McKesson Canada recommendation: The PMPRB will only open an in-depth review for biosimilars and/or vaccines when a complaint is received (option 2)

McKesson Canada recommends opening an in-depth review for biosimilars and/or vaccines only when a complaint is received – this approach balances fair oversight practices with allocating the Board's finite resources towards potential excessive pricing situations that have been brought to the Board's attention.

Biosimilar drugs pose a very low risk of excessive pricing in Canada: biosimilar medicines in Canada are priced significantly lower than the prices of their innovator reference products, therefore the prices of these medicines are not excessive. In addition, biosimilars in Canada face significant price competition with the other biosimilar products in the same class. Therefore, IPC should not be a relevant test for biosimilars.

For vaccines, the risk of excessive pricing is also low due to the vaccine procurement process in Canada. IPC for vaccines can be difficult due to confidential prices or differences in formulation (of note, TCC tends to be challenging for the same reason). A complaint for these products would likely come from the federal vaccine procurement agencies, which would have more validity.

Topic 6: Use of clinical evidence to contextualize the degree of similarity of comparators identified for the TCC

McKesson Canada recommendation: Each comparator will be assigned a level of similarity (option 2)

McKesson Canada asks the PMPRB to provide more explanatory information on this topic to help ensure clarity and mutual understanding.

Using common sense, implementing a system in which each comparator is assigned a level of similarity for the TCC would help support the precision, fairness, and relevance of drug price assessments. Not all comparators are equally similar to the drug under review: assigning a level of similarity to each comparator is a more sensitive approach that can reflect the therapeutic equivalence/ differences between the drugs. To our understanding, option 2 offers a granular approach that can ensure that the price of a new drug is compared to the prices of other drugs that are truly similar (e.g., in terms of therapeutic effect, clinical outcomes, patient use, etc.), leading to a more precise, trust-building, and reliable price assessment, which in turn would contribute to a more predictable and stable environment for the pharmaceutical supply chain.

Topic 7: Future role of HDAP

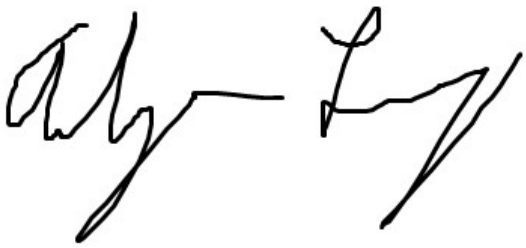
McKesson Canada recommendation: HDAP will be used only on an ad hoc basis when deemed necessary by Staff (option 1)

HDAP should continue to be used to help ensure credible, independent, and expert scientific advice to the PMPRB related to the scientific evaluation of patented medicines.

McKesson Canada asks the PMPRB to provide a rationale for the longer time it will take to review cases when engaging HDAP (8-10 months) - under the previous PMPRB Guidelines, the HDAP was engaged in reviewing all cases, with the review period being approximately 3-4 months despite meeting only 4 times per year.

Though the PMPRB is not bound to take into consideration the consequences of its policy decisions on the pharmaceutical supply chain and pharmacy sector, we hope that our recommendations point to options that would allow it to both exercise its legislated mandate while ensuring a predictable and stable environment for the industry, thereby safeguarding the timely access to vital medications that Canadians depend on. Please do not hesitate to contact me directly should you have questions about our submission or require assistance on any other issue.

Sincerely,



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