September 9, 2024

Thomas J. Digby
Chairperson, Patented Medicine Prices Review Board
Standard Life Centre, Suite 1400
333 Laurier Avenue West
Ottawa, Ontario K1P 7C1

Subject: Patented Medicine Prices Review Board (PMPRB) 2024 Discussion Guide for Consultations on New Guidelines

Dear Mr. Digby:

On behalf of EMD Serono, a division of EMD Inc., Canada ("EMD Serono"), I write to provide input to the Discussion Guide for PMPRB Phase 2 Consultation on New Guidelines ("Discussion Guide").

EMD Serono, the Canadian biopharmaceutical business of Merck KGaA, Darmstadt, Germany, is committed to ensuring patients in Canada will benefit from innovative products in oncology, neurology, fertility, and endocrinology. Our pipeline includes investigational innovative therapies in neurology, oncology, and immuno-oncology. In Canada, we support research by sponsoring research studies in all therapeutic areas as well as through clinical trials in multiple sclerosis (MS) and oncology. EMD Serono has its headquarters located in Mississauga, Ontario and employs more than 100 people across Canada. At present, Canada is considered a strategic country for clinical trials and among the first wave of launch countries for Merck KGaA, Darmstadt, Germany.

EMD Serono, a member of Innovative Medicines Canada (IMC), fully supports the submission from its industry association. In this letter, I have provided feedback on each of the 7 'Topics for Discussion' included in the Discussion Guide and articulate the basis for each chosen option.

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Topic 1: IPC Criteria

Option 2: Highest International Price

Based on the Discussion Guide and in public webinars, the PMPRB affirms that it is only interested in conducting In-Depth Reviews for products that are at a high risk of excessive pricing – in other words, 'clear outliers'. The framework proposed in the Discussion Guide is meant to reflect this approach; therefore, if this framework will use the International Price Comparison (IPC) test to conduct this triage for excessive pricing, then the IPC should use the highest benchmark – Highest International Price (HIP) and not a Median or Midpoint price benchmark.

Any other benchmark, whether Median or Midpoint, cannot identify price outliers. In the case of the Median International Price (MIP), it would imply that prices in the upper half of the PMPRB11 markets would be considered 'outliers'. Both the MIP and Midpoint benchmarks can change year to year as products launch in new markets, new indications or competitors are approved, or market conditions change. A price below the IPC criteria in one year can exceed it in the following year without any actual change to the Canadian price. It is not reasonable to consider such a case as an 'outlier' at high risk of excessive pricing.

The rationale provided by the Government for the amendments made to the Patented Medicines Regulations in 2022 was to remove the 'outlier' reference countries (USA and Switzerland) and replace them with a more representative reference country basket. Medicines with Canadian prices that fall below any of those in the PMPRB11 cannot reasonably be considered outliers. Therefore, the Highest International Price is the only appropriate IPC benchmark that can be accurately used to achieve the PMBRB's updated mandate.

Topic 2: Transitional provisions for Existing Medicines

Option 3: 3-Year Transition Period

The PMPRB has been engaging in efforts to "modernize" its regulatory framework for nearly a decade. In June 2016, the PMPRB published the first "Discussion Paper" to consult on Guideline reform. This resulted in 8 years of pricing uncertainty for Canadian patent rights holders. Patent rights holders and stakeholders in the pharmaceutical industry, both in Canada and at the global level, needed to continually revise corporate planning as the PMPRB reversed and revised their framework proposals. To allow time for all stakeholders to prepare accurate price expectation, and in absence of full grandfathering for "Existing Medicines", patent rights holders should be given sufficient time to transition prices to the new framework.

A 3-year transition time has an additional advantage, in that a greater proportion of patented medicines will be "New Medicines" at the end of the transition period. These medicines will have been launched and priced with the expectations of the 2022 Patented Medicines Regulations and a new Guideline framework.

Topic 3: The CPI Factor

Option 2: Cumulative 2-Year Change to CPI

Option 2 proposed in the Discussion Guide offers advantages to nearly all stakeholders compared with the first option. The second option allows patentees to take increases in line with a 2-year cumulative change

to CPI. Under Option 1, if patentees wanted prices to keep up with inflation, they would be required to increase prices every year.

Incentivizing patent rights holders to take price increases every year creates an administrative burden to distributors, wholesalers, pharmacies, and payors. Each stakeholder must revise their price lists, account for stock purchased at prior prices, adjust listing agreements, and so on. Option 2 avoids this issue by allowing patent rights holders to keep up with inflation with fewer price adjustments.

Further, the Discussion Guide suggests that the CPI 'factors' to be considered would be based on 'actual' CPI changes instead of the 'lagged' approach of the previous Guidelines. The lagged approach gives patent rights holders much more certainty when planning price changes. Indeed, this was the reason the lagged-CPI approach was introduced in the first place. If CPI is to be used as a trigger for commencing an In-Depth Review, the PMPRB should continue with a 'lagged CPI' approach.

The PMPRB and payors have previously expressed a desire to avoid large year-over-year price increases. The proposed 2-Year approach represents a good balance.

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

Option 2A: Federal and Provincial Ministers of Health + Public Payors only

The previous PMPRB Guideline framework was based upon a well-defined series of price tests and price ceilings. Under that framework, an investigation into a complaint could easily be resolved by referring to the price tests explicitly set out in the Guidelines, so that there would be minimal impact to the patent rights holder where its medicine was not found to be priced excessively.

Under the new framework envisioned in the Discussion Guide, any complaint will lead into a so-called 'In-Depth Review'. This review would apply all excessive price factors from Section 85 of the *Patent Act* – the balancing of these factors would be based on the discretion of PMPRB Staff on a case-by-case basis. Further, the Discussion Guide proposes that results of In-Depth Reviews would not be made public, would not result in a price ceiling (equivalent to a MAPP or NEAP), and would not establish any precedence for future reviews.

Under this framework, the impact of complaints is much greater. To counterbalance this, the standing to submit a complaint should be limited to stakeholders whose interests are to balance, on the one hand, the desire for lower medicine costs with, on the other hand, a mandate to provide care to patients. Therefore, complaints should be limited to either the Federal Minister of Health, his/her Provincial/Territorial counterparts, and Public Payors.

Topic 5: Special provisions for Biosimilars and Vaccines

Option 1: The PMPRB will treat patented biosimilars and/or vaccines the same as other medicines.

The framework proposed in the Discussion Guide does not appear to inappropriately affect biosimilar and vaccine products. There may be cases where an In-Depth Review would be warranted for these products.

Biosimilars: In most cases, an In-Depth Review triggered by the IPC test should be easily resolved by the Therapeutic Class Comparators (TCC) test – they will be highly similar to the more expensive brand product. Care should be taken to avoid discouraging the introduction of new biosimilar products. This can be accomplished by ensuring an efficient and rapid resolution to the In-Depth Review when warranted by the TCC tests.

Vaccines: It can be difficult to conduct an IPC test for many vaccine products purchased by a central public health authority due to confidential prices. These products are therefore unlikely to trigger In-Depth Reviews. However, there are vaccine products that are commercialized in a similar manner to other brand medicines. These are more likely to have publicly available international prices and therapeutic comparators. In these cases, IPC tests will be easier to carry out with the availability of such information.

Topic 6: Assessing Degree of Similarity

Option 2: Each Comparator will be assigned a Level of Similarity

The PMPRB has not provided sufficient information regarding any aspect of the 'In-Depth Review' in either the Discussion Guide or the subsequent webinar, making meaningful consultation on this topic difficult.

The Discussion Guide mentions that one metric, variously named as 'Level of Similarity', 'Degree of Similarity', and 'Similarity Grade', is distinct from the 'Level of Therapeutic Improvement' of the previous Guidelines. However, the Discussion Guide does list a few clinical evidence considerations that directly match the Primary and Secondary factors of the old 'Level of Therapeutic Improvement' framework, in describing the 'Level of Similarity' metric.

There are several potential problems in assigning a single Level of Similarity to a group of comparators that are not addressed in the Discussion Guide. The Discussion Guide does not describe how a single 'Level of Similarity' would be assessed for a group of diverse comparators – for instance, does the single Level of Similarity represent an average of the comparators? Or would the least similar comparator determine the level of similarity for the group? How would differing evidence quality between comparators be handled? Would comparators be assumed, absent evidence to the contrary, to be highly similar to the medicine under review (as with 'slight or no improvement' under the old framework), or would they be assumed to be highly dissimilar?

Given these inconsistencies, and the absence of clear examples and case studies from the PMPRB, it seems much more appropriate and straightforward to assign each comparator an individual Level of Similarity.

Topic 7: Future role of HDAP

Option 1: HDAP to continue to have a role in the Scientific Review

The framework proposed in the Discussion Guide delegates this responsibility to PMPRB Staff, who will only consult the Human Drug Advisory Panel (HDAP) on an as-needed basis determined by Board Staff themselves. Delegating PMPRB Staff with the authority to conduct scientific reviews opens the door for biased or uninformed decision making. To date, the PMPRB has not adequately explained why they have continually proposed the removal of the HDAP from its historical role in the price review process.

HDAP's involvement has two key advantages: its independence from the PMPRB Staff and pricing considerations, and the scientific and clinical expertise of its members. The HDAP-centered process of the previous Guidelines has been proven to work.

As such, we recommend the HDAP expert committee must continue to have a primary and regular role in the scientific review, rather than PMPRB Staff.

Conclusion

In our prior submissions to this consultation process, we have made clear that our primary ask has been for the Guidelines to reflect the limits of the PMPRB's mandate. This Discussion Guide includes many encouraging signs that this ask has been heard.

There remains, however, an area of serious concern: the In-Depth Review. The Board has stated that a main objective of the Guidelines is to "provide transparency and predictability to Rights Holders", at least on the processes Board Staff use to identify medicines for both In-Depth Reviews and Hearings. Transparency and predictability limited to only the Initial/post-Initial Review would be very narrow indeed. Under the prior framework, Investigations had to at least start with the standard price tests of the Guidelines – this gave both patent rights holders and Staff a common reference point from which to proceed.

An appropriate balance is required between improving the affordability of medicines, ensuring timely patient access to medicines, and creating a world-class innovative life sciences environment in Canada. We ask that the Board ensures that this balance, and the promised transparency and predictability, extends to all elements of the new Guidelines, including In-Depth Reviews.

We look forward to participating in the next phase of consultations on new PMPRB Guidelines.

Sincerely,

Henry Chak
Director, Patient Access & Government Affairs