IMC Response to the PMPRB's 2023

Scoping paper for the consultations on the Board's Guidelines

December 20, 2023

Submitted via the PMPRB Website: Consultation Submission Portal

This submission is made on behalf of Innovative Medicines Canada (IMC) in response to the November 2023 Scoping paper for the consultations on the Board's Guidelines.[i]

IMC is the national association of biopharmaceutical and vaccine companies representing the majority of rights holders subject to the Patented Medicine Prices Review Board's (PMPRB) jurisdiction. The association advocates for policies that enable the discovery, development, and delivery of innovative medicines and vaccines to improve the lives of all Canadians and supports the members' commitment to being a valued partner in the Canadian healthcare system. Collectively, our sector supports more than 107,000 high-value jobs, invests upwards of $2.4 billion in R&D annually, and contributes nearly $16 billion to Canada's knowledge-based economy.

Background and context

IMC and its members believe that timely access to innovative medicines is a major Canadian public policy issue, given that patients have less access to these treatments than patients in other G7 nations and in many OECD comparator nations. This is due to many factors, including without limitation regulatory inefficiencies and duplication, narrow and inflexible Health Technology Assessment (HTA) recommendations, and the application of processes designed for conventional pharmaceutical products to complex new technologies.

The PMPRB's Guidelines must be considered in this broader access context and the range of government pharmaceutical policies and priorities. Access and availability, together with other important sectoral policies such as the Agile Licensing, the Biomanufacturing and Life Sciences Strategy, and the National Strategy for Drugs for Rare Diseases, will be enhanced and supported by a clear and appropriately limited excessive pricing regime.

In this context, IMC looks forward to engaging in a productive dialogue with the PMPRB to jointly develop Guidelines that are consistent with the Board's mandate while meeting the needs of the government, rights holders, and other stakeholders.

The Guidelines Scoping Document was more granular than expected as the basis for a "first principles" discussion. Therefore, it will be difficult for rights holders and others to provide responses to all of the specific questions. Many of the questions require some knowledge of the PMPRB's overarching

Guideline approach (e.g. questions on 'expedited' versus 'full' price reviews) while others relate to policy areas that are beyond the scope of an excessive pricing regime (e.g. questions on coordinating with CADTH, pCPA, and other entities).

As such, IMC respectfully limits its present comments to the key issues that are most critical at this stage of the Guidelines development process. We welcome additional technical dialogue to explore key themes and granular policy details further via working groups with rights holders.

Consistency with an excessive price standard

The revised PMPRB 11 schedule removed two higher price jurisdictions while adding several lower cost jurisdictions, which has the effect of constraining the ceiling price of New Medicines. Given its excessive pricing mandate, the PMPRB should not further constrain prices by selecting the median international price (MIP) of the PMPRB11 as the ceiling price in future Guidelines.

As previously discussed, the median price point identified in the September 2023 amended Interim Guidance was adopted without reference to the PMPRB's mandate regarding excessive prices and the detection of specific instances of patent abuse. IMC maintains that the MIP is inappropriate as a future mandated standard in conjunction with the revised schedule of international reference countries.[ii] In our view, the highest international price (HIP) is most consistent with an excessive pricing standard.[iii]

For this reason, IMC would suggest that caution is warranted with respect to reusing elements of the PMPRB's 2010 Guidelines. These Guidelines relied heavily on the median, which is not aligned with an excessive pricing role under the revised PMPRB11 schedule. The selection of the median is not required for its implementation, and alternatives more consistent with jurisprudence on the Board's excessive price mandate can and should be considered.

With regard to the PMPRB's December 5-6th 2023 roundtable, there were Board questions related to a potential differentiation between "excessive pricing" and "patent abuse." IMC notes the recent detailed Federal and Québec court jurisprudence with respect to the PMPRB's mandate. A detailed review of the jurisprudence is beyond the scope of our present comments. However, and in response to this line of questioning, IMC would strongly caution against any suggestion that different pricing policies could be derived from, or informed by, a differentiation of "excessive" versus "abuse" terminology.

Full grandfathering for existing products is required

During the recent roundtable, Board members requested input regarding what authority could be invoked to support the grandfathering of existing product prices. The revised schedule of PMPRB11 countries in the amended *Patented Medicines Regulations* (Regulations) is strictly a regulatory reporting requirement and in no way requires that the Board intervene in the market to reset the price of existing

medicines. In other words, no specific authority is needed because no adjustment is required under the revised Regulations. Grandfathering these products would be most consistent with the Board's excessive price mandate given that existing products were already compliant and therefore non-excessive with the applicable legislation and Guidelines, and the amended Regulations did not change the excessive price factors under the *Patent Act*.

Nevertheless, the PMPRB could appropriately anchor a full grandfathering policy to the Consumer Price Index (CPI) provisions of the *Patent Act*. From a practical perspective, existing products could be determined as non-excessive going forward, provided their national average transaction price (N-ATP) does not exceed the most recent non-excessive average price (NEAP), as adjusted by the CPI for 2023, 2024 and onwards.[iv] This approach leverages core elements of the PMPRB's Interim Guidance approach to incorporate those CPI adjustments rooted in the *Patent Act* in the context of transition.

As noted by many participants during the recent roundtable, rights holders and other supply chain stakeholders (e.g., pharmacists, distributors, pharmacies and generic manufacturers) created and executed on business plans based upon the previous regime and should not be penalized for the ongoing uncertainty with respect to the creation and implementation of new Guidelines.

It is also important to note that some rights holders launched patented medicines "at risk" (in absence of final PMPRB Guidelines) following the enactment of revised Regulations on July 1, 2022. In the event of issues arising from the lack of final Guidelines, these products could be gradually transitioned to the Highest International Price (HIP) of the PMPRB11, or alternatively, rights holders could be afforded the opportunity to substantiate prices directly with the PMPRB. [v]

Predictability precludes price re-benchmarking

Predictability over time is among the most important issues in the current Guidelines discussion for rights holders. IMC recognises the PMPRB's stated objective to provide rights holders with greater predictability, and strongly supports the PMPRB's recent acknowledgement that it is "not a price regulator." The PMPRB can address predictability concerns by including a statement in the Guidelines that "once a product is determined to be 'compliant' or 'reviewed,' the PMPRB will not reassess or 're-benchmark' the product, provided the rights holder does not increase its price by more than CPI."

There has been considerable feedback from rights holders and stakeholders that any form of re-benchmarking (either through application of the international schedule, or therapeutic referencing) would pose significant predictability concerns. The PMPRB has functioned for decades without re-benchmarking and provincial product listing agreements and private payer agreements effectively control pricing over time.

Re-benchmarking would effectively create arbitrary price reductions over time which are foreseeable based on the PMPRB's analysis of price reviews during Product Life cycle (Scoping document, Box 3, Pricing trends in Canada versus the PMPRB11). Based on this data, re-benchmarking would clearly reflect price control over time that is beyond the purview of an excessive price review Board.

Reference was made during the roundtable to foreign jurisdictions which include various types of payer re-benchmarking in their respective systems. However, the PMPRB is not a payer, and these market factors are handled elsewhere in the pan-Canadian reimbursement system.[vi]

With respect to the third theme pertaining to the reviews during the life cycle of patented medicines, the Scoping Paper questions are very difficult to address without more information regarding the new Guidelines system or the function and implications of a price review. However, and as guiding principle, what rights holders need and expect is a predictable maximum non excessive price over the life of a product, subject to potential CPI adjustments. The PMPRB could still routinely monitor and validate compliance with the CPI-adjusted price benchmark established at a medicine's introduction without re-benchmarking prices.[vii]

Clinical performance is addressed elsewhere in Canada through pharmacoeconomic value assessment

It is premature to comment on timing and nature of scientific reviews, and indeed the future role of the Human Drug Advisory Panel (HDAP), without additional information on the future Guidelines envisioned by the PMPRB and how scientific review may or may not relate to the determination of excessive price.

Previous proposals for a domestic therapeutic class comparisons (dTCC) included inappropriate comparisons to generic medicines, unpredictable reassessments of the dTCC over time, 'lower-of' tests, and would have driven prices far below a non-excessive pricing standards based on international referencing. These proposals were particularly problematic and should be avoided. IMC believes that a simple and streamlined approach to implement the PMPRB11 international schedule would be best for all stakeholders and consistent with the PMPRB's excessive pricing mandate.

The *Patent Act* does not require the PMPRB to conduct a detailed examination of clinical performance.[viii] Health and safety regulators are tasked with evaluating clinical trials. Pharmacoeconomic value is considered elsewhere in the Canadian reimbursement system. Pharmacoeconomic value was ruled to be an unconstitutional price determination factor by the Quebec Court of Appeal in February 2022). It is therefore highly questionable whether the PMPRB is permitted to discharge its mandate on the basis of comparative clinical benefit assessments, which are the foundational analysis of pharmacoeconomic value assessments.

With reference to the fifth theme in the scoping paper, IMC notes that the mandates of Canada's Health Technology Assessment agencies, CADTH and INESSS, are separate and distinct from that of the PMPRB's excessive pricing role and from the PMPRB11 regulatory amendment that the new Guidelines are intended to operationalize. The PMPRB should avoid questions such has how a technology performs

following regulatory review, and is not well placed to examine the evolution of clinical evidence over time.

Investigation thresholds – future technical discussion required

With respect to the fourth theme of investigations and referral to hearings, investigation thresholds are integral to the definition of excessive price (please see commentary above related to the HIP). The appropriateness of the 2010 criteria for commencing an investigation cannot be evaluated separately from the new Guidelines to be implemented. IMC maintains that the most effective excessive price review system would consist of transparent predictable Guidelines that provide price tests for medicines under its jurisdiction. If a price appears to exceed the ceiling set out by the price tests, then an investigation could be undertaken to determine if the test was appropriately applied in the circumstances. Procedural detail sufficient to ensure the principles of fairness, transparency, predictability, efficiency and voluntary compliance could be explored through a technical working group.

Other parameters around investigations will depend on the nature and complexity of the Guidelines proposed by the PMPRB and can also be discussed further through a technical working group. Provided that the HIP standard is clearly articulated, a high voluntary compliance outcome is foreseeable, and therefore investigations may only be needed in exceptional cases.

Consumer Price Index adjustments

The Consumer Price Index (CPI) is specifically referenced in the *Patent Act*. The PMPRB's Guidelines should be clear and acknowledge the allowability of CPI adjustments as permitted under the *Patent Act*. As a practical matter, the PMPRB must continue to update its *CPI-Based Price-Adjustment Factors for Patented Drug Products* on an ongoing basis.

Guidelines next steps

IMC looks forward to engaging closely with the PMPRB on next steps in the Guidelines development process, which should include technical working group(s) with rights holders and their trade association. While other stakeholder engagement opportunities would also be beneficial, this is distinct from a direct dialogue with the regulated parties.

While the current consultation does not reference specific Guideline proposals, we would reiterate that the Fall 2022 Proposed Guidelines, which included excessively complicated provisions, were fundamentally flawed, and should not form the starting point for future discussions.

Depending upon the complexity of the Guidelines proposed, detailed case studies may be needed and we would also suggest a prospective impact assessment as an integral part of the policy development and consultation process. The previously proposed retrospective Guideline Monitoring and Evaluation

Plan (GMEP) serves a distinct function and is not a substitute for policy impact assessment. However, both a prospective impact assessment, and detailed case studies, may be unnecessary if the PMPRB adopts the HIP rule proposed above, which is relatively simple to understand and to assess independently.

Thank you for your consideration of our submission. IMC looks forward to collaborative discussions on this critical issue for our industry, supply chain partners, governments, stakeholders, and Canadian patients.

---

[i] IMC understands that the PMPRB intends to issue Guidelines following amendments to the *Patented Medicines Regulations* (Regulations) which came into force July 1, 2022. While IMC is committed to constructive engagement with the PMPRB on the Guidelines, IMC's engagement is not intended and should not be interpreted as supporting the amendments to the Regulations, the August 2022 interim approach, the September 2023 amended interim approach, or the final Guidelines. IMC reserves the right to oppose any aspect of the amended Regulations, Guidance, or Guidelines that exceed the jurisdiction of the Board. There are a number of Guidelines-related issues that had been identified in previous IMC submissions that have not yet been addressed and which require future consultation (please see IMC's February 2020, August 2020, February 2021, August 2021, July 2022, December 2022 and August 2023 submissions).

[ii] In IMC's view, this is inconsistent with an excessive price standard, and recent appellate court decisions that have delineated the role of the PMPRB within its constitutional and legislative limits. Rights holders should be considered compliant with the new basket provided their submitted Canadian prices are within the range of available prices of the revised PMPRB11 schedule. The government has already removed the two higher-priced countries (Switzerland and the United States) from the international schedule, which has the effect of constraining the ceiling price of New Medicines. The PMPRB should not further constrain prices by selecting the median as a reference point in future Guidelines.

[iii] Prices above that level may be justifiable in some circumstances and rights holders should be afforded an opportunity to substantiate prices with the PMPRB.

[iv] Or other measure to ensure that products first sold prior to the amended regulations coming into force are reviewed against the PMPRB7 international schedule (e.g. those first sold before July 1, 2022, but that do not yet have a NEAP).

[v] IMC takes this opportunity to reiterate the PMPRB's commitment that "once new Guidelines are in place, no potential excess revenues will be calculated by staff retrospectively for any New Medicines for sales made during the interim period." https://www.canada.ca/en/patented-medicine-prices-review/services/legislation/interim-guidance.html

[vi] Furthermore, effective patent life is often shorter in Canada than in some international jurisdictions, making analytical comparisons and re-benchmarking provisions questionable.

[vii] We note that question 3.1 references average exclusivity period estimates that are not explicitly substantiated. As noted above, we do not believe that the PMPRB should re-benchmark products via price reviews during the product life cycle, nor generally, should the Guidelines provide different levels of PMPRB scrutiny based on type of molecule. We question: on what basis would the PMPRB establish such a differentiation?

[viii] Nor does it suggest the PMPRB should evaluate the evolution of clinical evidence over time (e.g. differences in clinical evidence at the time of medicine launch versus years after regulatory approval; Real-World Evidence).