March 14, 2025

Anie Perrault
Acting Chairperson
Patented Medicine Prices Review Board
1400 - 333 Laurier Avenue West
Ottawa, ON K1P 1C1

Dear Ms. Perrault,

RE: Roche Canada's Response to PMPRB's Draft Guidelines

We appreciate the opportunity to provide feedback on the new Draft Guidelines for PMPRB Staff published on December 19, 2024. Roche Canada is dedicated to working collaboratively with all regulatory bodies to ensure that Canadians have timely access to innovative and life-saving medicines while maintaining a sustainable healthcare system.

About Roche and our pipeline

At Roche Canada, patients and science are at the heart of everything we do. Our passion for science and our commitment to relentlessly pursuing the impossible for patients have made us one of the world's leading pharmaceutical, in-vitro diagnostics, and diabetes care management companies. With our combined strength in diagnostics and pharmaceuticals, we're driving healthcare forward; while ensuring we deliver meaningful benefits for patients and sustainable healthcare systems. In order to deliver true innovation, we must explore new research avenues and take significant risks. Our success not only allows us to sustain our investments in research and development (R&D), but it also empowers us to drive forward with the development of groundbreaking medical innovations for the future. In 2024, globally we invested over $20 billion in research and development.

Our approach to pricing

We understand that healthcare systems are faced with greater demands on their already strained finances. This drives our commitment to work with all partners in the healthcare system to find solutions to support access to our medicines in a way that can be sustainable for all.

At Roche, we take a value-based approach to the pricing of our medicines, that reflects the benefits they deliver to patients, their families, healthcare systems and society as a whole. Through this approach, we aim to support access to our medicines for as many patients as possible today, while at the same time ensuring we are able to continue investing into highly complex and risky areas of drug development to bring about the innovations of tomorrow.

Roche's perspective on the draft Guidelines for PMPRB Staff

Roche Canada acknowledges that the scope of the PMPRB's Guidelines has shifted to be directed towards Staff rather than Rights Holders. We appreciate this clarity from the PMPRB, as it enables us to provide constructive comments during the last phase of the consultation. We commend the selection of Highest International Price (HIP) as the initial screen. In our view, using HIP as a threshold for excessiveness is more consistent with the PMPRB's mandate than prior iterations of the draft guidelines. This aspect of the Guidelines must be retained in the final Guidelines.

There are a few areas in the current draft Guidelines that would benefit from further clarity or changes. Our recommendations follow.

1. Timing of the International Price Comparison (IPC) to allow for a robust analysis:

The draft Guidelines stipulate that the first semi-annual price filing for new products will be used to conduct the Initial Review against the Highest International Price. This process may pose a challenge in the situation where only one other country is anticipated to have an available price in the semi-annual period. Consequently, depending on the reference country, manufacturers may be forced to delay launching products in Canada until more countries have launched to allow for a more robust analysis.

We propose that the IPC for both initial and annual reviews should be deferred until the earlier of:

- Three (3) years from the date of the introduction of the patented medicine in Canada; or
- The date when the patentee has provided international price information for at least five (5) of the PMPRB11 countries.

2. Challenges with the Therapeutic Class Comparison (TCC) and Comparability Assessment:

The proposed comparability assessment takes into account a qualitative assessment and Anatomic Therapeutic Classification (ATC) grouping assessment to create a matrix, resulting in three comparability categories. The proposed methodology is challenging for the following reasons:

- The TCC qualitative assessment categories (e.g. comparable, less comparable, undetermined) are not based on well-defined, measurable criteria and are difficult to scientifically validate with available clinical data, and therefore will be subjective by nature
- The ATC grouping assessments are not appropriate as a means of establishing therapeutic comparability in this situation - the ATC classification system is based on molecular and anatomical systems, and not intended nor useful for the purposes of therapeutic comparisons; chemical and molecular structure similarities, in themselves, are not a scientifically validated way to assess therapeutic similarities or differences
- The complexity of a 16-cell matrix, followed by the simplicity of 3 categories of comparability are simultaneously an overcomplication and oversimplification of potentially nuanced situations

The key challenge is the lack of detail on the utilization of the comparability categories when it comes to pricing determinations and how these will inform the weighting of the TCC overall in the context of an In-Depth Review.

Therefore, we propose a technical working group be established to address the challenges introduced by the Draft Guideline's application of TCC.

3. The complaint process introduces unpredictability for products post launch:

As reflected in Case Study 7 of the PMPRB Guidelines, a complaint can automatically trigger an In-Depth Review at any time in a product's life cycle by both public and private payers even when prices are below the HIP and without detailed supporting evidence thus creating unpredictability for products post launch.

We propose that a complaint screening process be implemented to ensure complaints are well substantiated before triggering an In-Depth Review. This would be aligned with PMPRB's Guideline's focus on administrative efficiency by helping to discourage frivolous complaints that lead to highly burdensome In-Depth Reviews for all parties, and consistent with the practices of other administrative decision-makers who conduct complaints-based reviews.

We further propose that private insurance companies be excluded from the list of organizations whose complaints can lead to an In-Depth Review, given the very different function of the private insurance market relative to public entities or individuals otherwise permitted access to the complaints process. Like other private parties, private insurers should advance concerns through an identified public official or body.

4. Fluctuating exchange rates may trigger unnecessary In-Depth Reviews during Annual Reviews:

Under the previous regime, PMPRB would assess non-excessiveness at introduction, and then monitor for compliance with the introductory price plus CPI. The proposed regime introduces a new approach: annual re-benching against the prevailing HIP. There has been much volatility in the strength of the Canadian dollar relative to other currencies due to factors outside of the control of manufacturers, such as interest rates, inflation, and the economy. Given this volatility, international prices can become higher or lower, inadvertently triggering In-Depth Reviews despite a product's price remaining unchanged.

Annual re-benching will vastly increase the administrative burden to both PMPRB and Rights Holders without a corresponding benefit to the Canadian public. This approach adds unnecessary complexity and significant uncertainty to the detriment of PMPRB, innovative medicines, and the Canadian public.

We propose that when an In-Depth Review is triggered, PMPRB's first assessment should be to ascertain if the review's initiation is solely due to a fluctuation in exchange rates. If this is the case, and the Rights Holder has not taken a Consumer Price Index (CPI) increase in the period of the annual review, then Staff should recommend the In-Depth Review be closed.

5. The absence of clear pricing compliance rules prevents a manufacturer from knowing if a price is excessive, putting historical revenues at risk:

Due to the nature of annual assessments and the complaint process moving products to In-Depth Reviews, and hearings at any time in a product's lifecycle, manufacturers may be pricing their products below international benchmarks for years in good faith compliance with the Guidelines when a hearing panel finds that a product has been excessively priced for a period of time, putting historical revenues at risk.

We propose that the Board and Guidelines be explicit in stating that repayment of excess revenues as a remedy for excessive pricing is limited to the period where a manufacturer is notified of an In-Depth Review due to either an annual review or after a complaint is received by the manufacturers. This approach will allow the manufacturer to account for the new financial risk introduced due to the lack of clear price compliance guidelines.

6. Timing of implementation does not give Rights Holders enough time to align processes and prices with the new Guidelines:

If New Medicines are reviewed immediately when the Guidelines go into effect, the next annual review could include sales data from up to 11 months prior to the effective Guideline date. This may create inconsistencies and challenges for manufacturers trying to align with the new Guideline processes.

We propose the PMPRB should provide the same one-year timeline before New Medicines are reviewed, similar to the timeline provided for Existing Medicines. This grace period would allow manufacturers sufficient time to secure necessary approvals and implement price changes that align with PMPRB's new Guideline processes.

Conclusion

Roche Canada is committed to working with the PMPRB through this consultation process. We believe that through constructive dialogue and collaboration, we can achieve a balanced outcome that ensures the availability of innovative medicines at fair prices while maintaining the sustainability of the healthcare system.

We look forward to continued discussions and thank you for considering our perspective.

Sincerely,

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