September 11, 2024

Thomas J. Digby
Patented Medicine Prices Review Board
1400 - 333 Laurier Avenue West
Ottawa, ON K1P 1C1

RE: Roche Canada input on Discussion Guide

Dear Mr. Digby,

Thank you for the opportunity to provide input into the Patented Medicine Prices Review Board's ("PMPRB") *Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines* published on June 26, 2024. Below, please find Hoffmann-La Roche Limited's ("Roche Canada") response to the Discussion Guide questions to aid the Board in its Guidelines consultation.

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. Roche is the leading pharmaceutical company in R&D spend. In 2022, globally we invested CHF 14.1 billion in research and development.

Our approach to pricing

We understand that healthcare systems are faced with rising costs and increased demands on 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 pricing of our medicines, that reflect 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 proposed approach to price reviews

Roche is pleased to see that the PMPRB has updated the Guidelines to reflect the recent jurisprudence and to simplify its framework. Furthermore, we are supportive of the stated objectives, which are to enhance the Board's administrative efficiency, and to provide transparency and predictability to Rights Holders. Roche supports making International Reference Price (IRP), Consumer Price Index (CPI) and complaints the primary screening factors that underpin a modernized, simple and efficient regulatory regime. However, the regime will not achieve the Board's stated objectives if:

- IRP levels used to screen medicines for in-depth reviews are set below HIP
- Prices are re-benched along the product life cycle
- Existing medicines are treated the same as new medicines

Topics for Discussion

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

- Roche recommends Option 2 - Highest International price (HIP) as the most appropriate international price test reflecting PMPRB's 'excessive price' mandate for both new medicines and existing medicines.
    - PMPRB11 is a pricing basket composed of countries (now excludes United States and Switzerland) that were selected because they regulate drug prices in a manner comparable to Canada. A price that is lower than HIP should not be subject to an In-Depth Review (I-DR).
    - The HIP is rooted in an excessive pricing standard, whereas lesser, arbitrary thresholds are consistent with price control, which would exceed the PMPRB's constitutional remit.[1]
- Median International Price (MIP) and midpoint (Mid) between the MIP and HIP are not appropriate benchmarks for a number of reasons:
    - These benchmarks will not achieve PMPRB's stated goal of administrative efficiency: approximately 78% of all DINs would be subject to an in-depth review if the IPC is set to MIP, and approximately 53% of all DINs would be subject to an in-depth review if the IPC is set to the midpoint between MIP and HIP, resulting in over 600 in-depth reviews and/or hearings, creating undue administrative burden.
    - These benchmarks are challenging to operationalize; MIP and the midpoint between MIP and HIP are dynamic benchmarks and are subject to change due to external factors, such as fluctuating exchange rates.

[1] *Merck Canada Inc. v. Attorney General of Canada*, 2023 QCCA 1540; *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2021 FCA 157.

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

- Roche recommends existing medicines (first sold before the final implementation date of the new Guidelines) be treated differently than new medicines.
    - For existing products, commercial, funding and contractual pricing decisions have been made by multiple stakeholders, at the time these medicines were introduced in Canada; therefore, it is critical to legacy these medicines to avoid any significant disruptions in the healthcare system (e.g. to existing Product Listing Agreements, Patient Support Programs, etc.).
    - According to PMPRB's latest Annual Report (2022), 92.3% of all medicines (1,138) reported to PMPRB have already been reviewed. Re-benching existing medicines against new Guidelines and Regulations does not align with PMPRB's stated goal of achieving administrative efficiency.
    - Roche recognizes that the new Regulations do not differentiate between established and new medicines. However, existing medicines are at a lower risk of excessive pricing. The Board had previously taken a position that it would be reasonable to differentiate how the factors set out in a new set of Regulations are applied during a price review process, depending on whether or not the medicine was on the market before the new Regulations were implemented (PMPRB Bulletin 1, July 1988). Similarly, it would be reasonable for the Board to place the greatest weight on the CPI factor when reviewing existing medicines.

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

- Roche recommends that Rights Holders be permitted to increase list prices in Canada in accordance with changes to CPI. An In-depth Review should not be triggered if a medicine's list price increase is below the CPI increase.

- Roche supports adopting the 3-year actual lagged CPI methodology from prior Guidelines for the following reasons:
    - To improve internal operations
    - To reduce uncertainty that could affect patentees´ pricing models and business planning for subsequent years
    - To provide predictability and certainty for patentees when they consider price increases

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

- Roche recommends Option 1: "limit complaints to the Federal Minister of Health or any of

his/her Provincial or Territorial counterparts ”

- An effective complaints mechanism requires a balance of inclusivity and transparency with administrative efficiency. Providing restrictions in Option 1 serves this purpose without overwhelming the board.
- Additionally, complaints that trigger In-depth Reviews must be valid and fall within the mandate and decision-making authority of the PMPRB (i.e. issues of excessive pricing and patent abuse). We would welcome clear pre-screening guidance to the Federal Minister of Health and his/her Provincial or Territorial counterparts on what would constitute a valid complaint to the PMPRB.

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

- Roche recommends Option 2: “The PMPRB will only open an In-depth Review for biosimilars and/or vaccines when a complaint is received”.
  - The proposed process is appropriate for classes of medicines that are at a low risk of patent abuse through excessive pricing (e.g. biosimilars, vaccines, tendered products).
  - Roche also requests that PMPRB consider expanding this list of products to also include branded medicines that have corresponding generics / biosimilars on the market for the same reasons (i.e. low risk of patent abuse due to competitive markets).

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

- Roche applauds PMPRB in making IRP the primary test that underpins a simple, predictable, and efficient voluntary compliance regime. If a list price of a medicine is above the HIP in PMPRB11 at introduction, assessment of the list price against other section 85 factors, including TCC, is appropriate. However, as in the prior Guidelines, application of TCC should only be done at introduction.
- The discussion guide lacks sufficient detail to understand how the application of TCC during an in-depth review will work in practice. Without the much needed context, it is challenging to offer our feedback on the use of clinical evidence to contextualize the degree of similarity (or difference) between comparators identified for the TCC. We can only offer that it would seem inappropriate to assign one level of similarity to a group of comparators as a whole, as this approach could miss critical context to understanding the multi-faceted value that the new medicine brings to Canadian patients, caregivers, and the broader healthcare system.
- Roche believes that to ensure Canadian patients have access to new medicines and health technologies, the assessments should take into consideration the unique value that new,

innovative options can bring and it is currently not clear how the application of TCC would allow for this.

Topic 7: Future role of HDAP

- The role of HDAP in this new process (wherein the levels of therapeutic improvement are no longer assessed) is unclear. Roche supports HDAP playing an independent advisory role to PMPRB Scientific Staff on an ad hoc basis. Specifically, HDAP review could be part of an escalation pathway in cases where rights holders and PMPRB Scientific Staff disagree.

Topics not raised in the Discussion Guide

In-depth reviews were not included as one of the discussion guide topics. However, given the importance of these reviews in the framework, we offer our considerations on the proposed approach:

- To achieve transparency and predictability, the details surrounding the implementation of an in-depth review should be published in the final Guidelines. Roche supports Guidelines that will be followed consistently for all reviews undertaken by PMPRB to ensure procedural fairness.

- The goal of any in-depth review should be to ensure that only cases where the price is likely to be considered excessive per the Regulations are recommended to a hearing. This is consistent with the mandate of the PMPRB and the goals of both manufacturers and the PMPRB to ensure limited resources are used effectively.

- There should be a recognition that in-depth reviews conducted after the initial review phase would have unique challenges due to changes in the market which are outside of the control of manufacturers. Re-assessing the list price in the middle of a product's lifecycle introduces significant unpredictability for patentees and complexity to the system. Careful consideration of how application of the factors may impact the conclusion is necessary in the context of assessing the risk of excessive pricing and patent abuse.

- In the absence of any changes to the price of a medicine over time (beyond the allowable CPI increase), in-depth reviews should not be required.

- To ensure procedural fairness, there should be consistency in the outcome of an in-depth review. It is important to understand the methodology by which products will be assessed in an in-depth review including (but not limited to):

    - How are each of the 4 factors weighted? Does the weighting differ for products that have an in-depth review during the initial review versus during the post initial review phase?

    - How will multiple indications be handled? How does the timing of these reviews (initial review or post-initial review) impact the process/criteria?

    - How will comparators be selected? How will "similarity" be assessed? When are comparators selected given that these will change over time and therefore could

impact the TCC?

  - How will fluctuations in currency exchange rates be managed (especially for products in the post-initial review period)? Will there be specific methods for addressing exchange rates to reduce the variability and/or avoid multiple reviews?
  - How will previous in-depth reviews be considered in the context of subsequent post-initial reviews?

- Given the potential complexity of the in-depth reviews, we recommend that this process be fully considered through a collaborative working-group to ensure transparency and predictability of the process. Technical working groups with experts representing rights holders should be struck to identify a path forward.

In conclusion, Roche supports making International Reference Price (IRP), Consumer Price Index (CPI) and Complaints the primary screens that underpin a modernized, simple and efficient regulatory regime. However, we remain concerned about three critical issues that were highlighted in this submission.

A summary of our recommendations are as follows:

- The initial and post-initial review screen should be set at HIP of PMPRB11
- Prices should not be re-benched after introduction
- Existing medicines should be legacied

We believe in working collaboratively to find solutions to achieve a future where the best healthcare innovations are embraced by and delivered within a sustainable and resilient healthcare system. We remain committed to working with all relevant stakeholders to build a system that is not only fair, but effective, efficient, and at the end of the day delivers what is best for all the people who live in Canada. We hope PMPRB finds our submission helpful and we thank you for your time and consideration through this process.

Regards,

David Shum
Director, Strategic Access & Pricing
Hoffmann-La Roche Limited