December 5, 2022

Douglas Clark
Executive Director
Patented Medicine Prices Review Board
1400 - 333 Laurier Avenue West
Ottawa, ON K1P 1C1

RE: Roche Canada input on proposed changes to the PMPRB's Guidelines

Dear Mr. Clark:

On behalf of Hoffmann-La Roche Limited ("Roche"), please find enclosed feedback to the Patented Medicines Prices Review Board ("PMPRB") in response to the proposed changes to the PMPRB's Guidelines which, if implemented, would give effect to recent amendments to *the Patented Medicines Regulations.* As a member of both Innovative Medicines Canada ("IMC") and BIOTECanada, Roche also endorses the industry associations' submissions.

About Roche and our pipeline

At Roche Canada, patients and science are at the heart of everything we do. For more than 125 years, we've been developing diagnostics and medicines for a wide range of chronic and life-threatening health conditions that continue to revolutionize healthcare. Most importantly, we're focused on helping patients live longer, better lives. In fact, many of our medicines which were developed decades ago still greatly benefit Canadian patients today. Yet despite all our successes, there is still a great need for medicines in therapeutic areas with some of the greatest challenges and unmet needs.

As it relates to our pipeline, our R&D activities are focused on applying excellent science to discover and develop potential new medicines with the goal of becoming first-in-class or best-in-class therapeutics. As we look ahead, our focus continues in several key areas, notably in neurological disorders and cancer care. Roche is rising to the challenge with one of the strongest neuroscience pipelines in the industry. In addition, our ultimate vision is to prevent and provide cures for cancer in all its forms. The next generation of pioneering medicines at Roche – with gene and cell therapy front and center – is blazing a path towards truly personalized healthcare. By combining our unique expertise in pharmaceuticals, diagnostics, and data-driven insights, we continue to move forward.

But life-changing innovation is only meaningful if it reaches those who need it. This is why we put access at the core of our business, and consider it a key part of our commitment to improving patient outcomes. Our mission is clear: to ensure that Roche, working together with healthcare systems, can deliver rapid, broad and sustainable patient access to our innovations. The Canadian regulatory and policy environment has a vital role to play in this mission.

Roche's concerns with the proposed Guidelines

The mandate of the PMPRB is to prevent pharmaceutical patentees from charging 'excessive prices' during the statutory monopoly period. The new draft Guidelines, including its triggers for investigation, appear to deviate from that mandate. Therefore, we would like to take the opportunity to highlight three fundamental areas of concern for Roche, each of which would impact our ability to deliver innovative products for Canadian patients.

1. Business uncertainty & unpredictability
    - For Canadian affiliates of global companies, having a predictable launch price is important for determining the commercial viability and timing of new medicines. Uncertain and unpredictable price ceilings may risk significant delays in the launching of innovative medicines in Canada or preclude the certainty businesses require to launch products.
    - The PMPRB's Guidelines have not proposed a predictable set of rules for determining whether a price of a new medicine can be found to be excessive. Rather than clear guidance, the PMPRB has proposed an open-ended set of powers for PMPRB staff to trigger investigations on a wide range of new medicines and to create rules on a product or situation-specific basis.
    - The proposed Guidelines lack critical information about both the investigative and the undertaking processes, which in turn empower PMPRB staff to operate more like a price negotiator, as opposed to acting as a safeguard against excessive pricing.
    - The proposed Guidelines empower PMPRB staff to conduct the scientific review previously conducted by an independent panel of experts. PMPRB staff appear to be empowered to decide what comparator medicines will be used for the domestic therapeutic class comparison test (dTCC), and whether any expert input is necessary. The Guidelines provide no clarity on how PMPRB staff will make either decision.
    - The draft Guidelines do not provide sufficient clarity and predictability to patentees on how investigations will be handled, or what prices are excessive. In the absence of clearly defined price tests used in the investigations, Roche is concerned that the investigation triggers will become the de facto price tests for excessiveness.

2. Therapeutic value and innovation not recognized
    - The proposed Guidelines do not account for incremental therapeutic value or recognize innovation. The patent system is intended to encourage innovation; the proposed guidelines will deter it, in particular through the way in which the Guidelines propose to apply the dTCC.
    - Applying the dTCC test to all new medicines without considering incremental therapeutic value over chosen comparators will harm the commercial viability of some of the most clinically valuable medicines.

3. High administrative burden due to dynamic factors used to trigger investigations
    - Investigations are highly resource intensive for PMPRB and manufacturers, and this will be exacerbated by the proposed Guidelines, in particular for new medicines. In the past three years where rules of excessiveness and investigative procedures were clearly defined, the average time for PMPRB to close simple Roche product investigations was 427 days.
    - Further, the investigation triggers (i.e. dTCC and MIPC) can change from year to year which creates a floating target for manufacturers to monitor and react to, so as not to trigger any investigations. Potential scenarios where flat prices may be investigated based on changes in the external environment:
        - Foreign exchange rate fluctuations can place Canadian products above the MIPC one year and below the MIPC the next year, even when there were no price changes in PMPRB11 countries.
        - PMPRB11 countries launching or discontinuing a product can shift MIPC and push the Canadian product above the investigation threshold.

The overall impact of the proposed Guidelines

The proposed Guidelines will actively serve as a barrier to innovation and will have an negative impact on:

1. Roche's ability to launch some of the most clinically valuable medicines
2. Roche's ability to retain our priority spot in the global launch sequence
3. Roche's ability to continue to attract investments into Canada

With the proposed approach, the PMPRB is undermining the value and market viability of some of the most innovative future medicines. At Roche, such medicines could one day offer hope to patients living with a neurological disorder or cure cancer. We estimate that the majority of our new launches in underserved therapeutic areas will trigger PMPRB investigations in the next two years.

Roche Canada competes with the rest of the world in attracting clinical research investment. In 2021, our expenditure on Canadian R&D was $67 million. The risk and business uncertainty posed by the proposed Guidelines will have detrimental impacts on our continued ability to attract this investment. We fear that Canada's standard of clinical practice will be diminished as research and investment are directed to markets where regulations and policies supporting access to new therapies exist.

Roche's recommendations

The proposed Guidelines for new medicines are not supported by a clear rationale that is grounded in PMPRB's excessive price mandate. More importantly, the proposed Guidelines are not compatible with the National Strategy for Drugs for Rare Diseases, the National Life Sciences Strategy and the government's efforts to turn the page on years of PMPRB policy challenges. The Guidelines, if implemented, will prevent Canada from building a stronger life sciences sector and health system, which has become a clear imperative for both federal and provincial governments.

Roche recommends the following necessary adjustments to the draft Guidelines:

1. PMPRB must revise the Guidelines to ensure the clarity and predictability required to allow for business certainty and timely access to new medicines for Canadians.
2. PMPRB must ensure that the domestic therapeutic class comparison test is applied in a manner that is consistent with an excessive pricing mandate.

Given that PMPRB no longer intends to consider the incremental therapeutic value of innovative medicines over comparators, one potential way to address these recommendations is to modify the role of the dTCC test. For example, a price should not be considered excessive as long as the list price is at or below the higher of the HIPC PMPRB11 or the top of the dTCC. This approach avoids casting a wide net of uncertainty over the launch of clinically valuable medicines in Canada and aligns PMPRB's resources with its mandate to prevent pharmaceutical patentees from charging 'excessive prices'. Additionally, this approach provides the clarity and predictability required to allow for business certainty and timely access to new medicines for Canadians.

If our two recommendations cannot be adequately addressed in time for the implementation of the new Guidelines, Roche proposes that the PMPRB suspend the current consultation process and take the necessary time to work with industry and other stakeholders to find a better way to move forward.

Roche is committed to working collaboratively with all stakeholders in order to build a resilient and sustainable healthcare system for Canadians. We hope that our feedback on the proposed approach, including our recommendations, will be carefully considered by the PMPRB.

Regards,

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