July 18, 2022

Ms. Tanya Potashnik
A/Executive Director
Patented Medicine Prices Review Board
1400 - 333 Laurier Avenue West
Ottawa, ON K1P 1C1

RE: Roche Canada Input on PMPRB Price Review Approach During the Interim Period following publication of Amendments to the Patented Medicines Regulations

Dear Ms. Potashnik:

On behalf of Hoffmann-La Roche Limited ("Roche"), please find enclosed feedback to the Patented Medicines Prices Review Board ("PMPRB") in response to the June 30, 2022 Notice and Comment.

Roche understands that the PMPRB intends to apply Guidelines within the framework of amendments to the *Patented Medicines Regulations* (Regulations), which came into force on July 1, 2022. While Roche is committed to constructive engagement with the PMPRB, Roche's engagement should not be interpreted as supporting the validity of the amended Regulations, which remain, as of the date of this submission, under review by the Federal Court of Appeal in Court File No. A-215-20. Roche reserves the right to oppose any aspect of the amended Regulations, Guidelines, or other decision that exceeds the jurisdiction of the Board.

Status Quo Approach for the Interim Period

PMPRB's Proposal	**Roche's Recommendation**
In the period between the coming into force of the new *Patented Medicines Regulations* and the final publication of a corresponding set of guidelines ("Interim Period"), the PMPRB is proposing to adopt a "*status quo*" approach to carrying out its regulatory mandate. However, under the described PMPRB "*status quo*" approach, an existing patented medicine will no longer be permitted to take a CPI-adjusted price increase during the interim period.	The *Patent Act* requires the PMPRB to consider changes in Consumer Price Index in assessing excessive prices and the *2017 Compendium of Policies, Guidelines and Procedures* allow the prices of patented medicines to increase by no more than the increase in the CPI calculated over a 3 year period. In the interim period, the current policy of allowing for CPI adjustments would allow manufacturers to take into account higher inflationary costs. The PMPRB should adopt a true status quo approach which permits existing medicines to take the necessary CPI-adjusted price increases.

Pricing for New Medicines during the Interim Period

PMPRB's Proposal	Roche's Recommendation
The PMPRB is proposing to not conduct a price review of any new patented medicines or open any investigations in respect of them until the new guidelines come into effect. In effect, PMPRB's "*status quo*" approach provides no pricing guidance for medicines launching after July 1, 2022. This means that the patentees will have to launch at risk with no understanding of how PMPRB will review these medicines to establish price ceilings and how it will calculate excess revenues.	Timely access to innovative medicines requires predictability. The PMPRB's role is to protect against patent abuse and both its current and future approaches must be anchored to an "excessive price" standard. Moreover, retroactive policies that impose monetary penalties raise serious procedural fairness concerns. Roche is of the position that if patentees launch without pricing guidance during the Interim Period, they should not be retroactively penalized when new price tests are introduced. As long as the rationale supporting a new product's price is within the PMPRB11 basket, the price should be deemed non-excessive and excess revenues should not be sought. This is essential to ensure patentees can continue to launch products in absence of any pricing guidance. Additionally, a full twelve-month transition period will still be required following the finalization of the new Guidelines.

We hope that our feedback on the proposed approach, including our recommendations, will be carefully considered by the PMPRB.

Regards,

HOFFMANN-LA ROCHE LIMITED

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