July 31, 2023

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

RE: Roche Canada Input on proposed revisions to the PMPRB Interim Guidelines

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 20, 2023 Notice and Comment. We look forward to working with the PMPRB on these Interim Guidelines as well as the development of the final Guidelines.

For patented medicines with a Maximum Average Potential Price (MAPP) or projected Non-Excessive Average Price (NEAP) as of July 1, 2022

The Patent Act requires the PMPRB to consider changes in Consumer Price Index (CPI) in assessing excessive prices and the 2017 Compendium of Policies, Guidelines and Procedures allowed 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 policy of allowing for CPI adjustments should be permitted and would allow manufacturers to take into account higher inflationary costs (see APPENDIX for Roche's recommendation). PMPRB should permit CPI-based adjustments taken after July 1, 2022 and issue CPI-based price adjustment factors for 2024.

For patented medicines without a MAPP or projected NEAP as of July 1, 2022 ("New Medicines")

The PMPRB's role is to protect against patent abuse and both its interim and final approaches must be anchored to an "excessive price" standard. Therefore, as long as the price of a new medicine does not exceed the PMPRB11 basket, the price should be deemed non-excessive (see APPENDIX for Roche's recommendation).

Roche is supportive of establishing temporary measures that provide more predictability to patentees during this interim period. We look forward to working collaboratively with the PMPRB on future guidelines that would allow Canada to build a stronger life sciences sector. 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 will be carefully considered by the PMPRB.

Regards,

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

APPENDIX

Issue	Interim period Final Decision, August 18, 2022	Interim period Proposed Amendment, June 2023	Roche Recommendation
For patented medicines with a MAPP or projected NEAP as of July 1, 2022	During the interim period, the price of a patented medicine will not trigger an investigation if: 1. its national average transaction price (N-ATP) remains at or below the NEAP (Non-Excessive Average Price) as projected in the most recent compliance letter from PMPRB staff to the relevant patentee, and; 2. its list price does not increase. For greater clarity, an increase in the list price of a medicine will not trigger an investigation if it was taken in accordance with the CPI-based price-adjustment factor during the first filing period of 2022. In cases where the N-ATP of a patented medicine is above the NEAP, the PMPRB will only open an investigation if this results in excess revenues greater than $50,000, as is currently the case.	[text remains the same]	During the interim period, the price of a patented medicine will not trigger an investigation if: 1. its national average transaction price (N-ATP) remains at or below the NEAP (Non-Excessive Average Price) as projected in the most recent compliance letter from PMPRB staff to the relevant patentee, and; 2. its list price does not increase. For greater clarity, an increase in the list price of a medicine will not trigger an investigation if it was taken in accordance with a CPI-based price-adjustment factor. In cases where the N-ATP of a patented medicine is above the NEAP, the PMPRB will only open an investigation if this results in excess revenues greater than $50,000, as is currently the case.
For patented medicines without a MAPP	Medicines without a MAPP (Maximum Average Potential Price) or NEAP (Non-Excessive Average Price) as of July 1,	Medicines without a MAPP (Maximum Average Potential Price) or NEAP (Non-Excessive Average Price) as of July 1,	Medicines without a MAPP (Maximum Average Potential Price) or NEAP (Non-Excessive Average Price) as of July 1,

Issue	Interim period Final Decision, August 18, 2022	Interim period Proposed Amendment, June 2023	Roche Recommendation
or projected NEAP as of July 1, 2022 ("New Medicines")	2022, will not be subject to price reviews by PMPRB staff during the interim period. Furthermore, once new guidelines are in place, no potentially excess revenues will be calculated by staff retrospectively for any such medicines for sales made during the interim period.	2022, are considered reviewed if their list price is below the median international price for the PMPRB11 countries. The rights holders of these products will receive a Status Report letter once the assessment is completed. Medicines that do not meet this criterion, are considered "under review" until new guidelines are in place. 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.	2022, are considered reviewed if their list price is below the highest international price for the PMPRB11 countries. The rights holders of these products will receive a Status Report letter once the assessment is completed. Medicines that do not meet this criterion, are considered "under review" until new guidelines are in place. 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.