August 31, 2021

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 the proposed changes to the July 1, 2021 Guidelines

Dear Ms. Potashnik:

On behalf of Hoffmann-La Roche Limited ("Roche Canada"), please find enclosed feedback to the Patented Medicines Prices Review Board ("PMPRB") as part of the consultation on three proposed consequential amendments to the July 1, 2021 PMPRB Guidelines resulting from the decision to delay the coming-into-force date of the Regulations Amending the Patented Medicines Regulations ("Regulations") a further six months, from July 1, 2021 to January 1, 2022.

Gap Medicine definition

Roche Canada accepts that changing the definition of a Gap medicine is logical given the delay in the implementation of Amended Regulations. Medicines for which a DIN was assigned on or after August 21, 2019 and prior to January 1, 2022 and first sold in Canada prior to January 1, 2022, *do* fall within a highly uncertain 'gap' period, marked by 3 consecutive delays in the coming-into-force of the Amended Regulations, several rounds of consultations and changes to the Guidelines.

Proposed price test (MIP PMPRB7) for Grandfathered Medicines and their Line Extensions

Proposing a new price test (i.e. MIP PMPRB7 as opposed to HIP PMPRB11) for Grandfathered Medicines and their Line Extensions a mere 6 months away from the implementation of Amended Regulations is arbitrary, hastily considered, and lacks a clear rationale. This unexpected proposal undermines the spirit of prior consultations and calls into question the openness of Board Members to consider submitted feedback in the development of the final Guidelines.

We emphasize that the latest delay in the implementation of the Amended Regulations was meant to provide industry with additional time to prepare for and comply with the changes already introduced. Roche Canada has already diverted significant time and resources to prepare for the anticipated price reductions, with business decisions made based on our best understanding of the July 1st, 2021 Guidelines. The newest proposed changes add another layer of significant business uncertainty, given that the impact to Roche Canada is expected to be significant. This hinders our ability to advocate for global investments into the Canadian life sciences sector, and to reassure our global counterparts that the Canadian Regulator is willing to work with industry to reduce barriers to introducing new innovations. We strongly urge PMPRB Board Members not to adopt these latest changes.

Compliance timelines

In addition to the unexpected changes to the price test for Grandfathered Medicines and their Line Extensions, the PMPRB also intends to reverse a prior decision that would allow patentees two reporting periods to comply with the new ceilings. As outlined in our submission to the PMPRB dated February 12, 2021, a 6 month transition period is not operationally feasible and will cause significant disruption to our pricing operations. For these reasons, Roche Canada supports the previously agreed upon transition plan of at least 2 filing periods.

Roche Canada urges the PMPRB to reconsider the proposed changes in order not to further exacerbate the business uncertainty and the regulatory instability for the life sciences sector in Canada. We would be willing to meet with PMPRB to open constructive dialogue, address any questions or provide further information upon request.

Regards,

David Shum

Director, Market Access and Pricing
Hoffmann-La Roche Limited