February 12, 2021

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

RE: Roche Canada Input on PMPRB Guidelines Consultation

Dear Mr. Clark:

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 two proposed consequential amendments to the new 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 January 1, 2021 to July 1, 2021.

Definition of Gap Medicines:

The definition of Gap medicines under the new Guidelines applies to medicines for which a DIN was assigned on or after August 21, 2019 and that were first sold in Canada prior to January 1, 2021. The PMPRB is proposing to extend the date of first sale to the new coming-into-force date of July 1, 2021.

We fully endorse the expansion of the Gap medicine definition to account for the uncertainty patentees will be facing prior to the coming-into-force of the Guidelines. Roche Canada also recommends that PMPRB consider the application of HIP to Gap medicines once the new Guidelines do come into force. This will better align with the planned launch prices of some new medicines, which will now be re-classified as Gap medicines.

Compliance Timelines for Grandfathered and Gap Medicines:

With the decision to delay the implementation of the Regulations, the PMPRB is proposing to reduce the time to comply with the Maximum List Price (MLP) from two filing periods to one filing period, so that January 1, 2022 would remain the operative date for assessing compliance. This proposed change in timelines is not operationally feasible for the following reasons:

> First, Roche Canada expects to be notified of the new MLPs for Grandfathered and Gap medicines after the Regulations and Guidelines come into effect on July 1, 2021 and well into the second reporting period of the year (i.e. August - September 2021). PMPRB had committed to notifying patentees of new MLPs by March 2021 with the coming-into-force date of January 1, 2021. Manufacturers have the option to request a re-assessment (under section 75): with this re-assessment and exchange between manufacturers and PMPRB, the final re-adjusted MLPs for Grandfathered and Gap medicines will likely be available in October or November 2021. This would not provide manufacturers with enough time to

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seek global approval for the new list prices and submit the requests for a price change across the individual jurisdictions.

Second, this short notice does not allow enough time for implementation of price changes across individual jurisdictions in time to be compliant with the proposed deadline. A change in list price necessitates a change in official formulary listing and/or contractual obligations which need to be operationalized with enough lead time. For instance, Régie de l'assurance maladie du Québec requires a 2-3 month notice to implement any price decreases on its formulary. A longer implementation period is required across individual jurisdictions so that pharmacies, distributors and wholesalers have enough time to clear stock purchased at higher prices.

For these reasons, Roche Canada proposes to extend the compliance deadline to at least 2 filing periods (July 1, 2022). If PMPRB cannot assess compliance based on one mid-year filing, we propose to extend the compliance deadline to 3 filings periods (January 1, 2023).

Summary of Amendments:

<table>
<tr><th>Change</th><th>January 1, 2021 Guidelines</th><th>Roche Recommended Amendments for the July 1, 2021 Guidelines</th></tr>
<tr><td>Definition of Gap Medicines</td><td>35. Gap medicines are medicines for which a DIN was assigned on or after August 21, 2019 and first sold in Canada prior to January 1, 2021</td><td>35. Gap medicines are medicines for which a DIN was assigned on or after August 21, 2019 and first sold in Canada prior to July 1, 2021</td></tr>
<tr><td>Compliance Timelines with MLP</td><td>76. Patentees must comply with the MLP within one (1) reporting period of the MLP being set for Line Extension medicines and within two (2) reporting periods for Grandfathered or Gap medicines.</td><td>76. Patentees must comply with the MLP within two (2) reporting periods of the MLP being set for Line Extension medicines and for Grandfathered or Gap medicines.</td></tr>
<tr><td>Compliance Timelines with MLP</td><td>F. Summary of Compliance Timelines<table><tr><td>Patented Medicine Category</td><td>Compliance Assessment</td></tr><tr><td>Grandfathered</td><td>2 reporting periods</td></tr><tr><td>Gap</td><td>2 reporting periods (Dec. 2021)</td></tr></table></td><td>F. Summary of Compliance Timelines<table><tr><td>Patented Medicine Category</td><td>Compliance Assessment</td></tr><tr><td>Grandfathered</td><td>At least 2 reporting periods</td></tr><tr><td>Gap</td><td>At least 2 reporting periods</td></tr></table></td></tr>
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Regards,

David Shum
Director, Market Access and Pricing
Hoffmann-La Roche Limited