ELVIUM LIFE SCIENCES

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February 15, 2021

Patented Medicine Prices Review Board
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Submitted via email to: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

To whom it may concern:

Response to: Notice and Comment - On the change to the definition of Gap medicines and the timeline for compliance

On behalf of Elvium Life Sciences, we write in response to the Patented Medicine Prices Review Board (PMPRB) proposal to shorten the timeline for compliance for Grandfathered and Gap medicines from 12 months to six months.

With respect to the current consultation, Elvium Life Sciences supports Innovative Medicine Canada (IMC)'s position. We agree that a minimum of 12 months is a reasonable transition period from the date that the regulations come into force, and we want to draw your attention to the following additional concerns with a six-month transition period.

By shortening the timeline for compliance with the Guidelines to one reporting period, it effectively leaves only one month for patentees to operationalize price changes, on the assumption that the patentee does not wish to challenge the PMPRB decision on the MLP adjustment.

Patentees must file their first half 2021 sales report by July 30, 2021. However, patentees do not receive a compliance report with information on the new price ceiling until mid-September at the earliest. Should the patentee be required to file evidence for a Maximum List Price (MLP) adjustment based on the reporting of benefits, the new list price ceiling may only be communicated to patentees by mid-November at the earliest. From this point, internal company approvals must occur followed by communications with customers and formularies. Amending product listing agreements and commercial contracts would also be necessary. This is not feasible within a month.

A significantly compressed timeline is unworkable and creates a high administrative burden at a time when our collective efforts and resources should be focused on addressing the COVID-19 pandemic and ensuring the continued supply of essential medicines for Canadian patients.

Even if a reasonable and operationally feasible transition period can be agreed to, we still note the Guidelines have not been revised in light of the recent decisions of the Federal Court in *Innovative*

Medicines Canada v. Canada (Attorney General), 2020 FC 725 and the Superior Court of Quebec in *Merck et al. v. Attorney General of Canada*, Court File No. 500-17-109270-192, in which the amended *Regulations* were found to be invalid, and unconstitutional, respectively for requiring patentees to report confidential third-party pricing information. Guidelines built on invalid and unconstitutional regulations provide no certainty to reporting patentees. Rather than continuing to implement these Guidelines, the PMPRB should delay implementation of the to permit appellate decisions of these cases, and potentially to revise Guidelines built on invalid and unconstitutional Regulations.

Thank you for the opportunity to provide comment.

Sincerely,

Melanie Milburn
V.P. Market Access, Elvium Life Sciences