

June 21, 2021

Patented Medicine Prices Review Board
Box L40, Standard Life Centre
Suite 1400-333 Laurier Avenue West
Ottawa, Ontario
K1P 1C1

Submitted via the [PMPRB Online Feedback Form](#)

To whom it may concern:

Response to the Guideline Monitoring and Evaluation Plan Consultation

On behalf of Elvium Life Sciences, we offer this response to the Patented Medicine Prices Review Board (PMPRB) proposed Guideline Monitoring and Evaluation Plan (GMEP). On this matter, we are fully supportive of the position, key recommendations, and concerns raised by our industry association, Innovative Medicines Canada (IMC). We further wish to highlight and reinforce that:

- a) Any future monitoring and evaluation activity of the PMPRB reform initiatives, including defining mandate, scope and metrics, should be done by an independent third-party organization so that it is not subject to internal bias.
- b) Much of the currently proposed monitoring activity goes beyond the PMPRB mandate of consumer price protection and encroaches on the roles of other government entities (e.g., CADTH, INESSS, pCPA) and should therefore be removed.
- c) The data sources and definitions used by PMPRB to monitor international prices and research and development should be relevant and updated to reflect an accurate representation of relative drug pricing and the substantial economic contribution of the biopharmaceutical industry to Canada.

We would also like to reiterate our overarching concern regarding the practicality and legality of the amended Regulations, which are the subject of ongoing legal challenge. Guidelines built on invalid and unconstitutional regulations provide no certainty to reporting patentees and risks patient access to new and innovative medicines. PMPRB should delay implementation of the regulatory changes and refocus on meaningful discussion with industry and patient groups on an alternative path towards a fair and balanced approach that supports innovation as well as addressing affordable drug pricing.

Thank you for the opportunity to provide comment.

Sincerely,

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