

August 31, 2021

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

Response to: Notice and Comment posted July 15, 2021

To whom it may concern:

On behalf of Elvium Life Sciences, we write in response to the Patented Medicine Prices Review Board (PMPRB) proposal to change the international price tests for Grandfathered medicines and their line extensions. We fully support and endorse the response submitted by our industry group, Innovative Medicines Canada (IMC), which oppose the July 15, 2021 proposals.ⁱ In addition, Elvium Life Sciences would like to specifically emphasize the following points.

Implementing these proposals will have negative impacts

As expressed in previous submissions by our industry, investments associated with regulatory approval, distribution, patient assistance programs, listing agreements and ongoing research for existing products were all made based on the business case at existing price levels. The application of new set of rules with limited transition time fundamentally alters the business case of many medicines and creates the danger of pricing being reduced to a point that such programs could be at risk and supplying the Canadian market may become unviable.ⁱⁱ

The Elvium Life Sciences portfolio includes at least one medicine that would undergo an approximately 25% list price reduction under these proposed changes. This medicine is primarily used to prevent nausea and vomiting in a small group of pediatric patients (2 to 17 years old) undergoing chemotherapy. Elvium invested in commercialization of this product in response to the unique need for this specific formulation as identified by Canadian pediatric oncologists. We still believe it is the right thing to do. However, this level of negative revenue impact, with a limited market size, is simply unsustainable.

The significant changes to proposed by PMPRB lack clarity and rationale

We would also like to express our disappointment and frustration that these significant changes, yet again, shift dynamics and create great uncertainty to existing portfolios of products that entered the Canadian market in good faith and in compliance with the rules and regulations in place at the time of their market entry. No rationale for these changes have been provided, and PMPRB appears to be pushing through punitive measures to lower pricing while dismissing the potential direct and indirect consequences these changes will generate.

We further understand that PMPRB may proceed with this re-benchmarking of existing products even if the regulatory amendments do not come into force on January 1, 2022.ⁱ This leaves lots of unanswered questions about ongoing compliance and does not give patentees any predictability. Suggesting these dramatic changes, at any level, and particularly at a time when we need a strong and coordinated life science approach, is unfair to patients as well as to patentees who have already made significant investments based on business analyses done under an existing framework.

Alongside our industry, we continue to reiterate that existing patented medicines are not being 'grandfathered' under these significant changes. The term grandfathered would normally suggest that existing products would continue to follow the pricing rules in place at the time the product was first sold in Canada. Therefore, we request that PMPRB abandon these significant and harmful proposals to change the price tests for existing products.

Thank you for the opportunity to provide comment.

Sincerely,

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

ⁱ IMC Response to: Notice and Comment – On the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions. (August 31, 2021)

ⁱⁱ Based on its own internal analysis, the current PMPRB proposal will result in over 50% of existing medicines requiring a price reduction of, on average, 10% ([PMPRB Frequently Asked Questions, updated August 8, 2021](#))