

Patented Medicine Prices Review Board  
333 Laurier Avenue West, Suite 1400  
Ottawa, Ontario  
K1P 1C1

August 4, 2020

**Re: PMPRB Draft Guidelines Consultation**

We are writing to you today on behalf of the Canadian Biosimilars Forum. The Forum is an alliance of companies who represent the breadth of the biosimilars industry and have come together to maximize the positive impact of biosimilars on patients, on clinicians and on the sustainability of Canada's health system. The Forum today encompasses Merck Canada, Pfizer Canada, Sandoz Canada, and Teva Canada and considers itself to be the leading voice on biosimilars policy across the country.

The Forum is focused on accomplishing three fundamental goals. First, raising awareness of biosimilars and serving as a credible resource for evidence-based information regarding biosimilars. Second, informing and supporting public policies that encourage access, awareness and adoption of biosimilars. Third, providing an opportunity for companies developing biosimilars for the Canadian market to work with key stakeholders – like the Patented Medicine Prices Review Board – on topics instrumental to biosimilars and patient care.

This letter serves as a follow-up to the submission the Forum provided to the PMPRB (the Board) in February 2020. The Forum was glad to see the release of the June 2020 draft guidelines, including many updates from the previous version. In particular, we were pleased to see how comprehensively the Board reflected our previous concerns about the need to ensure that any regulatory reforms didn't inadvertently weaken or undermine Canada's nascent biosimilars market.

As recommended by the Forum, the Board has made the appropriate and judicious decision to treat patented biosimilars the same way it treats generic medicines and medicines for veterinary use. With these Category II medicines only subject to investigation if a complaint is received by the PMPRB, the Board has taken steps to reduce the burden of automatic regulatory review for manufacturers of patented biosimilars. The Forum would also like to respectfully suggest that the PMPRB develop a set of criteria to assess the merit of any complaint it receives regarding a specific biosimilar. Given the current dynamics of the Canadian biosimilars market, we believe it is important for the Board to have transparent criteria it can rely on to ensure that its complaints process is not used frivolously or

disingenuously. Following the example of generic medicines, we believe that any complaint against a biosimilar should not be investigated if the drug in question has been subject of a pricing agreement with the pan-Canadian Pharmaceutical Alliance to which it is compliant. Taken together, these actions will encourage biosimilar manufacturers to continue launching biosimilars in Canada, and in so doing develop the kind of robust and sustainable pan-Canadian market required to lower the cost of biologic medicines across the country.

As we have emphasized before, the Forum commends the Board for its sustained focus on quantifying the savings that biosimilars could deliver to payers and policymakers across Canada, and we encourage you to continue providing this valuable analysis. We appreciate your commitment to helping create a sustainable and competitive biosimilars market – and to identifying ways to reduce the regulatory burden on medicines bringing system savings into Canada.

Thank you again for this opportunity to share our views in a more structured and formal way, and we look forward to continuing our engagement over the coming months. In the meantime, please don't hesitate to have your staff direct any questions or comments about the Forum or our positions to [secretariat@canadianbiosimilarsforum.ca](mailto:secretariat@canadianbiosimilarsforum.ca).

Yours sincerely,



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