

February 2019

Recently in the pages of The Vancouver Province, Michael Reilly from the US-based Alliance for Safe Biologic Medicines authored an Op-ed on a class of medicines called biosimilars that we found incomplete and inaccurate. There are at least three profound problems with article, which combine to leave readers with a misleading understanding of what we believe to be one of the most important advances impacting medicines in the last 10 years.

First, Reilly adopts a highly selective approach to referencing the position of Health Canada on biosimilars. Health Canada clearly states that its *“rigorous standards for authorization mean that patients and health care providers can have the same confidence in the quality, safety and efficacy of a biosimilar as any other biologic drug.”*¹ And yet rather than reinforcing this “confidence,” Reilly instead chose to highlight the very concerns Health Canada’s statement effectively dispels.

Health Canada also says *“it considers a well-controlled switch from reference biologic drug to biosimilar in an approved indication to be acceptable, and recommends that a decision to switch a patient being treated with a reference biologic drug to a biosimilar, or between any biologics, be made by the treating physician in consultation with the patient and take into account any policies of the relevant jurisdiction.”*² It’s disappointing that Reilly selectively omits the first part of Health Canada’s quote, which provides all-important background and context to the piece he did include.

Second, Mr. Reilly erroneously suggests that switching patients to a biosimilar is “prioritizing savings over health and safety.” Putting aside Health Canada’s definitive comments on safety

referenced above, Reilly fails to note that governments across the country (including in BC) have used the savings generated from biosimilars to not only expand access to transformative medicines but also support the sustainability of their public health care systems.

Finally, Mr. Reilly ignores the fact that a 2018 review of 90 biosimilar switch studies encompassing 14,225 patients found that *“while use of each biologic must be assessed individually, these results provide reassurance to healthcare professionals and the public that the risk of immunogenicity-related safety concerns or diminished efficacy is unchanged after switching from a reference biologic to a biosimilar medicine.”*³ Not only that, but biosimilars have been used across Europe for more than a decade, generating over 700 million days of patient experience⁴ and justifying the decision of the 13 European countries that have instituted biosimilar switching policies.⁵

In his Op-ed, Mr. Reilly missed an obvious and important opportunity to address some of the myths and disinformation that exist around biosimilars. It’s our hope that policymakers in BC – and across the country – will see biosimilars as an exceptional opportunity to deliver more life-changing treatments to more patients at a significantly lower cost.

The **Canadian Biosimilars Forum** is an alliance of companies who represent the breadth of the biosimilars industry and who are collectively working to increase awareness, access and adoption of biosimilars across Canada.

1 Health Canada, Fact Sheet: Biosimilars.

2 Health Canada, Health Canada’s 2017 Biosimilars Workshop: Summary Report.

3 Cohen, H.P., Blauvelt, A., Rifkin, R.M. et al. *Drugs* (2018) 78: 463. <https://doi.org/10.1007/s40265-018-0881-y>

4 <https://www.medicinesforeurope.com/biosimilar-medicines/>

5 <https://www.biopharma-reporter.com/Article/2017/03/21/Biosimilr-switching-interchangeability-and-substitution-the-EU-view>