

Honourable Christine Elliott, MPP
5th Floor, College Park
Ministry of Health
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Dear Minister Elliott:

The Biosimilars Working Group (<https://biosimilarioptions.ca/>) is a key collaboration of diverse non-profit organizations, registered health charities, and healthcare advocacy coalitions who are dedicated to ensuring that good outcomes for patients are at the centre of health policy in Canada, specifically in the biologic medication treatment areas.

We have concerns regarding implementation of any policies that would switch patients stable on an originator biologic medication to its biosimilar. We have strong medical reasons and unaddressed issues that underpin our thoughts and conclusions.

In your upcoming deliberations, we request full consultations with patient groups before you reach any conclusions. This way, policy can be forged in a manner that keeps Canadians safe, especially during this current pandemic and beyond. There can be no one-size-fits-all approach and developing policy with fulsome input from those who will be directly impacted will help achieve the desired outcomes effectively.

A recent report from INESSS,¹ the Quebec health technology assessment body, concludes that there are certain populations on biologics for which very little or no data are available regarding the safety of biologics switching, and identifies significant concerns that clinicians have about non-medical switching. Most of the available scientific data have methodological limitations and raise significant uncertainties. Therefore, conducting adequate clinical studies with a larger number of individuals from these populations and greater homogeneity in the participants' baseline characteristics would be useful for better determining the impact of switching between biologics.

Of further note, most jurisdictions worldwide favour switching patients treated with a reference biologic drug to a biosimilar but **do not impose it for all patients**. Only a few European countries and one Canadian province (BC) have implemented policies that lead to a mandatory non-medical switch for most patients. Another province (Alberta) has an implementation date set for 2021. We have asked BC to partner with us on analyzing the switch data to date, as our groups have had many patients report adverse reactions to non-medical switching of their medication, with some requiring hospitalization.

Please provide us with the opportunity to meet with you in a meaningful way, so we can be part of the discussion informing your decisions on biosimilars policy. We have valuable experiences to share with you.

Thank you for your consideration.

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¹ <https://www.inesss.gc.ca/publications/repertoire-des-publications/publication/innocuite-de-la-substitution-et-de-linterchangeabilite-des-medicaments-biologiques.html>

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