

Honourable Christian Dubé, MLA Ministère de la Santé et des Services sociaux Édifice Catherine-De Longpré 1075, chemin Sainte-Foy 15e étage Québec, QC G1S 2M1 ministre@msss.gouv.gc.ca

Dear Minister Dubé:

The Biosimilars Working Group (https://biosimilaroptions.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.

Michael Reilly, Executive Director

Alliance for Safe Biologic Medicines

execdir@safebiologics.org

Louise Gillis, President Canadian Council of the Blind ccbpresident@ccbnational.net

Durhane Wong-Rieger, President & CEO Canadian Organization for Rare Disorders

durhane@gmail.com

Mina Mawani, President & CEO Crohn's and Colitis Canada mmawani@crohnsandcolitis.ca

Gail Attara, President & CEO
Gastrointestinal Society, and President,
Canadian Society of Intestinal
Research

gail@badgut.org

Charlotte Rogers, Director **HS (hidradenitis suppurativa) Heroes**charlotterogers@hsheroes.ca

Jane M. Barratt, Secretary General International Federation on Ageing jbarratt@ifa.ngo

Dr. Alan Low, Executive Director

Medicines Access Coalition (formerly
the Better Pharmacare Coalition)
alow@medaccessbc.org

We thank you for the recent report from INESSS,¹ which concluded that there are certain populations who are taking biologics for which very little or no data are available regarding the safety of switching to biosimilars, and identifies significant concerns that clinicians have about non-medical switching. As patient groups, we share their concerns.

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 the BC government 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.

cc: Édith Godbout Edith.godbout@msss.gouv.qc.ca, Jonathan Valois jonathan.valois@msss.gouv.qc.ca, Sylvain Gobeil sylvain.gobeil@msss.gouv.qc.ca

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