Neighbourhood Pharmacy Association of Canada
Association canadienne des pharmacies de quartier

1205-3230 Yonge Street
Toronto, ON M4N 3P6
T: 416.226.9100
F: 416.226.9185
info@neighbourhoodpharmacies.ca
neighbourhoodpharmacies.ca

Guiding Principles on Biosimilars Transition Policies

Biologic drugs come from living organisms or from their cells and are generally larger and more complex in composition than chemically produced pharmaceutical drugs. They are often used to treat complex diseases and conditions. A biosimilar is highly similar to a reference biologic that was already authorized for sale; with no expected clinically meaningful differences in efficacy and safety. A biosimilar may enter the market after the expiry of the reference biologic drug's patents and data protection. The provincially led pan-Canadian Pharmaceutical Alliance (pCPA) negotiates prices for biosimilar drugs for its member jurisdictions, typically with a discount of 25%–50%. This is via a different framework than is used to negotiate prices for generic drugs.

Beginning in 2019, jurisdictions began implementing “Non-Medical Biosimilar Switching Policies” in an effort to reduce public drug costs. Under these policies, public payers only provide coverage for biosimilars instead of their reference biologic, resulting in patients having to change to (or begin) a new biosimilar medication. This is not to be confused with the substitution of a generic medication for its functionally identical brand name equivalent. Transitions can be difficult for these complex patients due to the complicated nature of biologic and biosimilar medications; patients may have experienced therapeutic failures in the past and often require considerable assistance to effectively transition to a new therapy. Changing therapies can also mean a change in patient support services associated with that therapy, which can put a significant burden on patients themselves.

The Neighbourhood Pharmacy Association of Canada is a national not-for-profit trade association representing the business of pharmacy. We advocate for pharmacy's role as a community health hub to improve Canadians’ health and contribute as sustainable partners to the shared vision of a robust, resilient health system. We believe all Canadians should have access to affordable medications. The current funding model that supports pharmacy’s capacity to serve patients is dependent on drug pricing; therefore policies designed to reduce drug costs will ultimately impact pharmacy’s ability to provide medications, care and services to Canadians.

In order to minimize the risks of potential negative consequences to Canadians, we believe that any **non-medical biosimilar transition policies** implemented by public and/or private payers must:

1) Include a minimum of 12 months transition window for any imposed transition policy to ensure all patients have adequate time for dialogue, care coaching, monitoring and medication optimization

2) Consider the clinical outcomes and associated risks that may arise from substitution of complex therapies and allow for patient exemptions where appropriate, e.g., for high-risk populations

3) Allow for patient centric decision-making that includes convenient access to medications, existing care and service relationships.

4) Encourage communication and collaboration between prescriber and pharmacist to support optimal patient experiences and outcomes.

5) Recognize that biosimilars involved in transition policies may have different levels of complexity and associated service requirements than originator biologics, and build in adaptable milestones and timelines for transition that further:

    a) Supports appropriate pharmacy fees for care and services required to facilitate patient transitions from biologics to biosimilars

    b) Recognizes that pharmacy may be required to fill gaps in care as biosimilar medications will require similar or enhanced levels of clinical or patient support services that may no longer be available, or covered, through programs tied to originator biologics

    c) Incentivizes healthcare providers in the patient's circle of care to begin the transition process early on in transition window.

6) Provide clear guidelines enabling pharmacists in the patients circle of care to use their scope of practice, professional judgement, and competency to initiate the prescribing process of substituting a patient's biologic medication with a biosimilar and manage and monitor these transitions.

7) Acknowledges and considers mitigation strategies for the potential supply chain and inventory issues that may be a result of switching policies:

    a) The potential for shortages of biosimilars medications implicated in switching policies

    b) The logistical challenges pharmacies and suppliers may face if required to carry, dispense and provide care for a wider array of products to serve patients transitioning from biologics