



Eye See You: Biosimilars in Ophthalmology

Position Statement

August 15, 2022

Background

Biologics are a class of medications produced by living cells using recombinant DNA technology and are used to treat conditions in rheumatology, oncology, gastroenterology, ophthalmology, and other areas of medicine.ⁱ At the same time that patents expire on originator biologic drugs, biosimilars engineered to be similar to the reference products are entering markets as a less costly and less time-consuming alternative to manufacture.ⁱⁱ Consequently, there is a growing movement towards the use of biosimilars globally, but policy to inform their introduction is generally lagging.

Biosimilars have been introduced in various countries with Europe being the most mature market, establishing policies in 2005, followed by Japan, India, Korea, Canada, and the United States.ⁱⁱⁱ In Canada, at the federal regulatory level, the Canadian Agency for Drugs and Technologies in Health (CADTH) announced in May 2019 that the Common Drug Review (CDR) and the pan-Canadian Oncology Drug Review (pCODR) no longer require evaluation of biosimilar drug submission upon approval from Health Canada.^{iv} Since then, in Canada only the Institut national d'excellence en santé et en services sociaux (INESSS) continues to review biosimilars in Quebec.^v

The vision health landscape in Canada is quickly emerging, with ophthalmic biosimilars approved for the treatment of retinal conditions, including wet age-related macular degeneration (wAMD) and diabetic retinopathy (DR), which affect more than 2 million Canadians.^{vi} Despite various federal and provincial consultations to inform biosimilars policies, significantly less attention has been given to the field of ophthalmology. As such, there is an increasing concern from patient and advocacy organizations regarding the basis for policies and the impact on current and future patients. This situation necessitates the voices of global experts, namely clinicians, patients, caregivers, and advocates to help inform the development of ophthalmic biosimilar policies alongside the urgent creation of evidence-based educational materials, guidelines, and protocols.

To address the growing concern, the International Federation on Ageing (IFA) launched the Eye See You (ESY) Biosimilars in Ophthalmology program. The ESY program calls on health policies that impact the treatment of eye conditions to be evidence-based and enable informed decision making. Clinical dialogue in conjunction with comprehensive patient education are foundational elements of a vision health plan and policy framework for the use of biosimilars in ophthalmology to achieve the goal of sustainable access and affordability. Patient choice in consultation with the treating physician, alongside the principles of safe, effective, and appropriate management and treatment must be the norm, not the exception.

As the development and implementation of biosimilars has implications for patient management and access to treatments, evidence-based information and education remain a focus to mobilize the ophthalmic and patient advocacy community. The ESY program is positioned to help build capacity across sectors and disciplines to address knowledge gaps and amplify collective voices of older Canadians with blinding eye diseases and their health professionals in calling for access to appropriate, safe, and effective vision treatments.

The IFA Position

Effective government policy is built on sound evidence that places the patient at the centre of management and treatment decisions specific to the nature and duration of the eye condition. Unlike other chronic diseases where biosimilars presents a treatment alternative, vision loss is often irreversible as small variations can lead to complications due to the nature of intravitreal administration. This is a fundamental consideration for patient and physician decision making.

Preserving vision in the management and treatment of retinal diseases is unlike other conditions where biosimilars may be applied and deserves special consideration. The invaluable experiences and guidance

of stakeholders in therapeutic areas, such as rheumatology, oncology, gastroenterology, and others can help inform the development of an appropriate policy framework for ophthalmic biosimilars. The ESY program is committed to raising awareness about emerging biosimilars in ophthalmology and connecting Canadians to experts and thought leaders in vision health.

Drawing on the experiences of people living with vision loss and following extensive consultations and feedback, the IFA, along with retinal specialists and allied patient organizations agree on a position related to biosimilars in ophthalmology that:

- Biosimilars can play an important role in Canada, improving access to treatments for retinal diseases.
- Choice of treatment should not be directed by cost but based on an informed discussion between the patient and their prescribing physician focused on treatment goals, safety, efficacy, and associated risks.
- Prescribing physicians should be able to request an exemption for a patient to remain on a biologic reference product.
- Appropriate data collection, systematic gold standard research, and public analysis is essential to better understand the use of ophthalmic biosimilars.

There is a need to continue efforts with and on behalf of the vision health community, as it relates to the introduction of biosimilars in ophthalmology:

- to centralize the patient in all discussions pertaining to biosimilars in ophthalmology, prioritizing patient care and access;
- to provide partners and the public with emerging intelligence to better understand biosimilars in this new therapeutic area; and
- to ensure government policies clearly understand the risks to patients and that a one size fits all policy approach is inappropriate.

List of Endorsers

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