

Position Statement on Biosimilar Drugs

June 27, 2023

BACKGROUND

Over the past several years, medications for the treatment of eye diseases have evolved from drugs comprising single chemical entities to more complex drugs obtained from biological sources. These biologic drugs are usually based on recombinant DNA technology and are produced by organisms or living cell lines. As a result, they are complex molecules whose structure may vary depending on the exact method by which they are produced. As patents of existing biologics have expired, new manufacturers have developed biologics that are similar to the existing biologics but not identical. This means that biologics created by different manufacturing processes may be slightly different in structure while displaying similar clinical effectiveness.

All new biosimilars are required to obtain Health Canada approval before they can be marketed in Canada. This approval requires testing for safety and purity, as well as clinical efficacy in clinical trials comparing the biosimilar with the original innovative drug. Various provincial jurisdictions across Canada have issued rulings requiring mandatory substitution of a small number of non-ophthalmic biologics by their biosimilar drug.

The first biosimilar for the treatment of an eye disease was approved by Health Canada on March 8th, 2022, for the treatment of a number of retinal diseases. There are several other biosimilars under development that have not yet been approved for sale in Canada. As of the date of this policy statement, no government has mandated the substitution of a biologic drug with an ophthalmic biosimilar.

POSITION STATEMENT

1. Since biosimilar medications approved by Health Canada have been shown to be safe and effective treatments for eye diseases, the Canadian Council of the Blind (CCB) approves of their use as treatments for new patients, provided that it is within the professional opinion of the ophthalmologist that a biosimilar drug will be safe and effective for their treatment.
2. Since a patient's response to medication may be individualistic, the CCB recommends that patients who are stabilized on a given biological medication not be switched to a biosimilar medication unless it is within the professional opinion of the ophthalmologist who is treating that patient that treatment with the biosimilar medication will be safe and effective for the patient.
3. Since clinical studies of biosimilars are based on assessment of the primary outcome after four and/or eight weeks of treatment, the CCB recommends that it be within the discretion of the ophthalmologist that any patient not controlled on a biosimilar medication can be switched to a biologic drug.
4. Since clinical trials conducted on biosimilars are conducted on a relatively small number of patients, the CCB recommends that drug surveillance data continue to be collected for all new biosimilars in order to monitor their long-term effectiveness in a large population.

ABOUT THE CCB

The Canadian Council of the Blind (CCB) is the Voice of the Blind™ in Canada. It is a membership-based charity that brings together Canadians who are living with vision loss, including those who are blind, deaf-blind, and partially sighted. A tireless advocate for its members, the CCB works to promote a sense of purpose and self-esteem along with an enhanced quality of life for those living with vision loss through advocacy, research, education, profitable employment, and social association. The organization endeavours to create closer relationships between people who are blind or have low vision and the sighted community through information, education, and awareness.

The CCB provides education and awareness in preventing vision loss by promoting healthy living

and regular eye examinations. It collaborates with service providers and all levels of government in order to improve the current levels of service regarding accessibility and quality of life. The CCB is proud of its leadership role in initiatives that call for the provision of the very best in available medical treatments, research, and the fostering of patients' rights without limitation or discrimination. It does this all while recognizing that vision loss and blindness are preventable.

The CCB is supported by its members, volunteers, and donors, who contribute collectively over 30,000 hours of their time on an annual basis to help achieve the success of the CCB's programs and initiatives.