Robbie's Rainbow Position Statement
Biosimilars

Historically, generic drugs have been used by millions of Canadians and have delivered a cost savings to patients and the health care system.

The creation of new biologic medications decades ago significantly altered the landscape of treatment and health outcomes for patients living with inflammatory bowel disease (IBD).
As patents for biologics expire, there is much discussion around the creation of generic versions of these drugs; however, the concept is more complicated and varies greatly from that of traditional generic medications.

Unlike generics, which are identical copies of chemically synthesized drugs, highly similar versions, called biosimilars, have been developed and approved by Health Canada. Biosimilars are similar to, but not identical to an original (reference) biologic drug. This is due to the complexities of their manufacturing process, which may be very difficult if not impossible to replicate exactly; therefore, the classification of "generic" cannot be applied.

Robbie's Rainbow believes that the needs of pediatric IBD patients must be at the centre of health policy decisions and there must be balance to ensure children living with IBD are supported to best meet their full health potential, in a cost-effective manner.

It is the position of Robbie's Rainbow that, while there may be benefit to biosimilars:

- The decision to select a therapy option should be between the IBD patient/caregiver and their gastroenterologist through a shared decision-making process
- Robbie's Rainbow supports the use of cost-effective therapies; however, safety and efficacy must remain a priority
- A biosimilar should not be automatically considered as an appropriate substitute or interchangeable with its reference biologic, given insufficient data to confirm equivalence.
- Patients should not be required to switch their treatment regimen given the lack of information on the effect of switching from a reference biologic to a biosimilar.
- There should be post marketing surveillance and safety reporting for biosimilars to ensure information about effectiveness and side effects is collected in a consistent manner.
- Biosimilars should have unique non-proprietary names to ensure clarity about the product being prescribed and administered. This will also ensure accurate attribution of side effects and effectiveness.