

Robbie's Rainbow

We are a national charity dedicated to improving the health and quality of life of children living with inflammatory bowel disease. Treatment and care that attains remission is the first step in regaining health, the second step is learning to live optimally. Having a child diagnosed with a chronic illness can be scary and life changing, but it is a journey that doesn't have to be taken alone. Having someone to reach out to, someone who can mentor and guide can make all the difference in the world. Our mentor program has helped create strong bonds, friendships and a sense of community, an invaluable comfort when our love isn't always enough to take away the pain.

Along with great support, Robbie's Rainbow continues to build and provide educational resources. As we continue to learn more about IBD, we believe it is crucial to provide accurate and up to date information to patients and their caregivers. As treatments continue to evolve, it is important for families to know what lies on the horizon. This information brochure will help you understand the role of biologics and the emergence of biosimilars in Canada. From Robbie and our entire team, we wish you the best of health.

Kate Murray



Understanding the Role of Biologics

We have received a number of inquiries from parents about biologic medications, with specific questions about the difference between biologics and other available treatments such as steroids or immunosuppressants. We have also had some inquiries about subsequent entry biologics (SEB's), also called biosimilars, which are not approved in Canada for adults or children with IBD, but might be down the road.

In response to these important questions, we have put together some information that we hope you will find useful. Included, you will find the sources we used and invite you to read the information for further insights.

The Right Treatment For Your Child

Inflammatory bowel disease (IBD), including Crohn's and ulcerative colitis, is considered an autoimmune disease. This means the body's own immune system attacks elements of the digestive tract. Usually your child will start with one or more treatments like mesalamine with a steroid and/or an immunosuppressant, to help reduce inflammation and suppressing the immune system. If the disease remains uncontrolled, your child's healthcare team will suggest your child change or add other therapies, which could include a biologic medication like REMICADE.

Biologics, also called "large molecule" therapies. They interrupt the body's inflammatory response in IBD by targeting proteins that play a role in increasing inflammation. Having the ability to target the cause of inflammation means biologics are more effective than traditional medications like corticosteroids, which suppress the entire immune system and can cause unwanted side effects and secondary illness.

Biologics are genetically engineered using living cells, and are generally not prescribed right away because some children with IBD may respond quite well to more traditional chemical medications. Biologics tend to cost more than traditional medications because of the complex manufacturing process involved, in using recombinant DNA technology, bioreactor production, and multiple purification steps. The manufacturing process is key, this is how biologics actually work. One small change in the manufacturing process can result in a change in how the medication actually works. Other factors that contribute to the increased cost of biologics include: how this fragile treatment is transported, and how the biologic is administered- it's administered by injection or infusion, both of which require specialized devices and/or delivery systems.

This highly complex production and delivery process contributes to the higher cost of a biologic medication. With that said, the ability to provide targeted treatment, achieve remission and mucosal healing have made biologics a successful treatment for children, especially those who have tried and exhausted all traditional treatment options. Biologics have helped restore the health of many children with Crohn's or ulcerative colitis, allowing them to live happy, active lives.



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One child at a time.

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Understanding What Is On The Horizon

As parents of children with IBD, we often keep an eye out for new treatment options on the horizon, and some of you may have already heard of a new class of drugs called subsequent entry biologics (SEBs). At this time, SEBs are NOT approved by Health Canada for adults or children with IBD. However, an SEB was recently approved in Europe for use in adults and children with IBD. It's anticipated that this SEB may be approved in Canada in the near future, although it's unclear whether it will be approved to treat the same range of illnesses as in Europe. Regardless, we think it's a good idea to become informed about SEBs and what this might mean for Canadian children living with IBD.

SEBs will become available in Canada as the patent on certain biologics expires, allowing other manufacturers to start producing copies of the original biologic medicines. While an SEB manufacturer will attempt to produce a product that is similar to the brand name biologic, the production process (how the medicine is made) will be different. The exact process by which each biologic is manufactured will not be known by SEB manufacturers and as a result, the SEB is considered similar to the branded version.^{1,2,3,4} For this reason, Health Canada, the government body responsible for approving new drugs to make sure they are safe and effective, does not categorize biologics and SEBs as being the same. This means that an SEB is NOT a generic version of the original, and an SEB will not be suitable to substitute in place of a biologic. We often see this with traditional drugs where a generic medication is given in place of the branded version.⁵ That said, switching or 'interchangeability' is determined by each province and not Health Canada, so interchangeability could occur depending on where you live. Health Canada also has the authority to approve an SEB for the treatment of a disease where a brand name drug has been approved, but the SEB will not have been studied in that disease. This would mean, Health Canada would rule the SEB is similar enough to the branded biologic drug^{6,7,8} to be used.

So why does that matter? At this point in time, no SEBs has been evaluated in clinical trials in patients with Crohn's or ulcerative colitis. This means that the outcome for any IBD patient prescribed an SEB is unknown – regardless of whether the patient was switched from a brand name biologic to an SEB or an SEB is used as a first biologic to be prescribed to the patient.

As of yet, no SEBs for IBD have been approved by Health Canada as a safe treatment option for our children, this is simply news to keep in mind. If and when this or other treatment options become available, Robbie's Rainbow will keep you informed and be sure to include useful details on our site.

Robbie's Rainbow Is Here To Help

It is important to keep in mind that your child's treatment needs may change over time. What works at one point during your child's illness may not be effective during a different stage. Maintaining an open dialogue and good communication with your child's doctor and health team is very important. Keep in mind your health team may try combinations of treatments to help your child best manage their illness, while also seeking to limit and reduce side effects.

These changes in treatment may result in an increase in cost, if the additional treatment is not fully covered by the government drug program or your insurance provider. If the cost is a barrier for your family, Robbie's Rainbow is here to help you find the financial and emotional support you need, including a variety of patient support programs offered by manufacturers.

If you have any questions about biologics or have thoughts on other topics we could cover on our website or newsletters, please let us know. We are here to help you.



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Sources

- Canadian Digestive Health Foundation - Guiding Your Gut.
<http://www.cdhf.ca/en/guiding-your-gut>
- Canadian Society of Intestinal Research- Gastrointestinal Society
www.badgut.org
- The Crohn's & Colitis Foundation of America
www.ccfca.org
- European Medicines Agency-Find Medicine-Pending EC Decisions
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/smop_search.jsp&mid=WC0b01ac058001d127

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¹ Kay J, et al., Health Canada/BIOTEC Canada Summit on regulatory and clinical topics related to subsequent entry biologics (biosimilars), Ottawa, Canada, 14 May 2012, *Biologicals*. (2012).

² Revers & Furczon, An introduction to biologics and biosimilars. Part II: Subsequent entry biologics: Biosame or biodifferent? *Canadian Pharmacists Journal*. July/Aug 2010 Vol. 143, No 4.

³ Dranitsaris et al., Biosimilars of Biological Drug Therapies - Regulatory, Clinical and Commercial Considerations. *Drugs*. 2011; 71 (12): 1-10.

⁴ Schellekens, How similar do 'biosimilars' need to be? *Nat Biotech*. Vol 22, No. 11 2004.

⁵ Letter from Health Canada to Provincial & Territorial Drug Plan Directors, July 29, 2010. <http://safebiologics.org/pdf/Health-Canada-Letter.pdf>

⁶ Health Products and Food Branch, Health Canada. Guidance for sponsors: information and submission requirements for subsequent entry biologics (SEBs). http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/seb-pbu/seb-pbu_2010-eng.php

Health Products and Food Branch, Health Canada. Questions & Answers To Accompany the Final Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs). <http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/seb-pbu/01-2010-seb-pbu-qa-qr-eng.php>

⁸ Kay J, et al., Health Canada/BIOTEC Canada Summit on regulatory and clinical topics related to subsequent entry biologics (biosimilars), Ottawa, Canada, 14 May 2012, *Biologicals*. (2012).



Biologics & Bio-Similars, Changes That May Affect Our IBD Children

This resource has been created by Robbie's Rainbow to help provide IBD families with an overview of BIOLOGICS, BIOSIMILARS, and future changes that may affect the type of treatment young IBD patients can access.



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