



During the last 15 years, many new medications have been introduced that have helped people living with forms of arthritis such as Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis. These medications are called biologics because they are created using complex biologic processes in living cells.

Subsequent Entry Biologics

What are Subsequent Entry Biologics?

Subsequent Entry Biologics (SEBs) are sometimes referred to as “biosimilars.” They are intended to be sufficiently similar to their reference product (the original biologic medication) so there is not supposed to be clinically meaningful difference between them in terms of safety, purity and efficacy.

Are they interchangeable?

SEBs are not “generic” biologics. Currently, Health Canada’s position is that the authorization of an SEB is not a declaration of equivalence to the reference biologic. Health Canada has advised provincial and territorial authorities against substitution particularly without the advice of your physician.

Are they safe to use?

Currently, there is not enough data to answer this, particularly long-term data. Since an SEB cannot duplicate the complex manufacturing process of the original biologic, and is only similar to the original biologic drug, it may not have the same effect in the body as the original biologic drug.

What are the potential benefits and risks?

Clearly the benefit of biosimilars will be the reduction in cost to the payers, potentially in the range of 20-30%. Like all medications, there are potential side effects. It is important that you discuss these with your physician so that you have a full understanding of the benefits and potential risks of these novel medications. SEBs may not have been studied in the disease area where the reference biologic drug has been approved by Health Canada as safe and effective. A discussion with your health care professional is recommended to better understand the information supporting the safety and efficacy profile of all potential medication choices.

Summary message – Talk to your doctor, this is a joint decision.

These questions have been reviewed by Dr. Ed Keystone, Director, Rebecca MacDonald Centre for Arthritis and Autoimmune Disease at Mount Sinai Hospital in Toronto.

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