

## Biosimilars

### Updated Position Statement (September 2019)

#### our belief

The Canadian Arthritis Patient Alliance (CAPA) is a grass-roots, patient-driven, independent, national advocacy organization with members who are volunteers. CAPA's fundamental belief is that the first expert on arthritis is the person who lives with arthritis, and who provides a unique perspective that is all too often absent.

#### the issue

People living with Inflammatory Arthritis are prescribed many different medications to manage their disease over their lifetime. Typically patients begin treatment with small molecule drugs that are called non-steroidal anti-inflammatory drugs (NSAIDs) and/or disease modifying anti-rheumatic drugs (DMARDs). For some people these first-line treatments are sufficient to treat their arthritis, while for others, they are ineffective from the start or stop working after a period of time. There is currently no way to determine how one's arthritis will respond to different medications except for a trial and error approach. The next type of treatment after NSAIDs and DMARDs is called a biologic, which is a drug that is a much more complex, and very large molecule. The first biologic was approved by Health Canada in 2000.

When patents expire on small molecule medications, drugs that copy the original drug (that is, the 'reference,' 'originator,' or 'innovator' drug) and are less expensive to produce are brought to market – called generics. Generic drugs are exact copies of the original drugs with the identical medicinal ingredient, and are made through various chemical reaction steps. Biologics are coming off of patent protection, and as happened with small molecule drugs, new drugs are being created to compete with the biologics in the marketplace. These drugs are called biosimilars. Biologics are proteins that are produced by living organisms, and since their exact growth conditions are not made public, it is not possible to make an exact copy of them, so biosimilars are similar to, but not exact copies of biologics.

For more information on the differences between small molecules, generics, biologics, and biosimilars, see [CAPA's video](#) on this topic.

#### what is a biologic?

Biologics are a class of treatments derived from living cells (they are proteins) that target specific parts of the immune system, and which treat a growing list of diseases. Like other drugs, the same biologic may

be approved for treatment of psoriasis, psoriatic arthritis, Crohn's disease, rheumatoid arthritis, inflammatory bowel disease, ankylosing spondylitis, diabetes, cancer, or kidney disease.

## what is a biosimilar?

Biosimilars are similar but not identical versions of an existing biologic medication. The exact conditions for making biologics are not made public, so while biologics and biosimilars are the same protein as the original biologic, there are small differences. These small differences are a result in differences in their production, such as the type of cells used to produce them, the temperature at which the cells are grown, the pH at which the cells are grown, and the type of food provided to the cells. Unlike generics, where the active ingredient is identical to the brand name drug, biosimilars are the same protein as their brand name biologic counterpart with small differences. Biosimilars and biologics have the same mechanism of action meaning that they target the same biological pathway, and should result in the same benefits and risks associated with treatment. Even the original biologics have changed over time as small changes have been made to how they are grown or from batch to batch. For the original biologic and for biosimilars, these differences are monitored over time.

### Health Canada on:

#### Interchangeability:

"... often refers to the ability for a patient to be changed from one drug to another equivalent drug, by a pharmacist, without the intervention of the prescriber who wrote the prescription.

Health Canada's authorization of a biosimilar is not a declaration of equivalence to the reference biologic drug. The authority to declare two products interchangeable rests with each province and territory according to its own rules and regulations."

#### Switching:

"...Health Canada considers switching between authorized products to refer to a change from routine use of one specific product to routine use of another specific product.

Biosimilars are authorized by Health Canada for the indications listed in the Product Monograph. Patients and health care providers can have confidence that biosimilars are effective and safe for each of their authorized indications. No differences are expected in efficacy and safety following a change in routine use between a biosimilar and its reference biologic drug in an authorized indication."

#### Biosimilars and drug benefit programs:

"Funding through drug benefit programs is not guaranteed when Health Canada authorizes a biosimilar or other biologic drug for sale.

In Canada, drugs are reimbursed by federal, provincial and territorial public plans and by private plans. Each jurisdiction decides which drugs they will or will not cover, whether there are specific coverage criteria, and at what amount or percentage of cost is covered."



This information is quoted directly from Health Canada's fact sheet on biosimilars that can be accessed [here](#).

## our position

- 1 Biosimilars have a role to play in providing additional treatment options for patients and potential cost savings to drug reimbursement programs.
- 2 Treatment decisions need to be discussed and agreed upon between the physician and patient based on the best available evidence with the best health outcome for patients as the primary goal. If policies are adopted by private and public payers to support preference for biosimilars, educational information and supports to help patients with medication changes must be made available in terms that patients can understand and that meet their needs, and that have been co-developed with patients and/or patient organizations. Any **medication** changes should only be made when patients feel sufficiently informed and comfortable to make this decision. As with other medications, physicians should be able to seek exemptions to switching a patient's medication if it is in the best medical interest of the patient (e.g. in cases where the risks outweigh the benefits of change or for high-risk patients with life-threatening comorbidities who have experienced major challenges in finding a treatment to control their disease).
- 3 Biosimilars must have unique and distinct names to ensure accurate post-market surveillance. In Canada, all biologics are required by Health Canada to have a brand name, a non-proprietary name of the active ingredient (which is the same molecular name for a biologic and its biosimilar(s), a unique Drug Identification Number, and a specific lot number.
- 4 Biosimilars should be subject to rigorous post-approval safety and efficacy monitoring, including requiring the development of collection of real-world evidence databases, which is important for special populations such as children or pregnant women. In Canada, Health Canada has a number of ways that it monitors all medications.
- 5 Biosimilar manufacturers should have patient programs to support patients' needs while on these medications.
- 6 At least a portion of the savings enabled by the use of biosimilars should be re-invested in to the treatment of people with inflammatory arthritis (for example, providing access to treatments such as physical or occupational therapy, other novel therapeutics, educational programs, models of care for treatment, etc.). The arthritis community, including patient organizations, must be involved/consulted when making health care system and policy changes.

