Biosimilars
Updated Position Statement (July 2016)

ourbelief

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

theissue

People living with Inflammatory Arthritis are prescribed many different medications to manage their disease. 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 patients these first line treatments are ineffective or stop working, and the next treatment is called a biologic, which is a drug that is a much more complex, very large molecule. The first biologic was approved by Health Canada in 2000.

When patents expire on NSAIDS and DMARDS, 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. Patents are now beginning to expire on biologics and, as happened with generics, new drugs are being created to compete with the biologics in the marketplace. These drugs are called biosimilar (or subsequent entry biologics or SEBs). Biologics are large molecules (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.

whatis 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, cancer, or kidney disease.

whatis a biosimilar?

Biosimilars (or subsequent entry biologics or SEBs) 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, they have small differences. These small differences are because of differences in their production such as the type of cells used to produce them, the temperature, the pH, 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 (i.e. target the same biological pathway).

Health Canada states that:

Biosimilars are not “generic” biologics. Biosimilars are not considered to have pharmaceutical or therapeutic equivalence to the reference biologic drug.

http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/seb-pbu/seb-pbu_2010-eng.php#int

ourposition

1. Biosimilars have a role to play in providing additional treatment options for patients and potential cost savings to drug reimbursement programs **only** if prescribed appropriately following clinically-approved guidelines.

2. Biosimilars must not be considered for automatic substitution or interchangeable with the reference biologic Patients should not be forced to switch from one therapy to another when they are well managed on their current medication. 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.

3. Biosimilars should have unique and distinct names to ensure no accidental substitution by the pharmacy. This will ensure continued post-market surveillance of adverse drug reactions for the correct drug.

4. Biosimilars should be subject to rigorous Health Technology Assessment and to post-approval safety and efficacy monitoring.

5. Biosimilars should not be fast-tracked through the drug review process, that is, being reviewed before other, possibly more critical drugs that have been placed in a queue simply due to economic reasons.

6. Biosimilar manufacturers should be encouraged to put in place patient support programs similar to those that exist for reference biologic medications. These programs employ trained professionals to answer any questions patients may have about these complex drugs. This type of support is critical for patients to feel comfortable about and confident in taking their medication.