POSITION PAPER

Access to Medication: Biosimilars

THE ARTHRITIS SOCIETY POSITION ON BIOSIMILARS

It is the Arthritis Society's position that:

- biosimilars have a role to play in the care and management of those living with inflammatory arthritis. Because of their shown efficacy and safety and their reduced cost, they may be preferable options for patients initiating a new treatment;

- biosimilars offer more choices for those living with inflammatory diseases and have the potential to lower health care costs and increase access to treatment;

- consistent, universal, unique biosimilar naming practices should be implemented to facilitate tracking of what specific medication is received by a patient;

- switching should not be forced on stable patients who are on an existing course of biologic treatment. The decision to switch should be at the discretion of the patient in consultation with their physician and following an informed, two-way discussion.

In terms of how biosimilars are implemented in the Canadian health care system, it is imperative that patient support and care needs are addressed. In particular, the Arthritis Society recommends that:

1. Patients on biosimilars and their physicians should have access to equivalent patient and physician support programs as those provided within existing innovator drug programs. These include bridge funding, copayment, sharps disposal, information lines and others.
2. Appropriate education and support materials must be developed and disseminated to ensure that patients and their healthcare professionals are well-informed about biosimilars.

3. A robust process for post-market surveillance and a registry of Real World Data that includes patient-reported and medical outcomes should be developed to follow and assess patients on all biologics. This requires coordinated action between governments, healthcare professionals, patient organizations, payers and pharmaceutical manufacturers.
4. If public or private payers adopt policies that preferably support biosimilars, rheumatologists should be able to identify and seek exemptions for patients who should not be switched to biosimilars based on medical criteria.
5. A gain-sharing model should be adopted to ensure that a portion of the savings resulting from the adoption of biosimilars be re-invested to improve access to treatments and/or to models of care for inflammatory arthritis.

BACKGROUND

What are biologics?

- Biologics are a class of medications designed to treat various inflammatory conditions including types of arthritis, such as rheumatoid arthritis, psoriatic arthritis, childhood arthritis and ankylosing spondylitis. In arthritis, biologics are used to suppress inflammation and help prevent damage to joints.
- Biologics are made by living cells from sources such as animals, bacteria, or yeast. They are larger, more variable and structurally complex than usual drugs that are made by a series of chemical reactions. The manufacturing process of biologics is highly sensitive due to the complexity of working with cells, requiring stringent manufacturing quality control measures to ensure product purity, consistency, safety and quality.
- Biologics are administered in two ways: infusion and injection. Infusion means the medicine will be given through a needle placed in a vein in the patient's arm and administered by a health care professional. The length of a typical infusion can vary from 30 minutes to 6 hours depending on the drug. Injection means the medicine will be

given by a needle under the skin of the patient's abdomen or thigh. Patients can receive training for self-administration of injections or injections may be provided by a health care professional. Both infusion and injection need to be regularly repeated at intervals depending on the medication.

How do biologics work?

- In people with arthritis, certain proteins may be present in the blood and joints in excessive amounts leading to increased inflammation (and consequently pain and swelling). Biologics work to suppress the body's immune system by blocking these proteins, and therefore their ability to create inflammation. Although this suppression can make it harder to fight off infections, it also helps to stabilize the overactive immune system in people with inflammatory arthritis.

What are biosimilars?

- When the patent on an original biologic (also called an "innovator" or "reference" drug) expires, other manufacturers can make their own version of this drug. These versions are called biosimilars.
- Biosimilars are sometimes mistakenly referred to as "generic" drugs. Because of their size, complexity, manufacturing process and the natural variability of a biologic, biosimilars are very similar, but not totally identical to the innovator drug; while generics are identical copies of chemically synthesized drugs.
- The term biosimilar is used by Health Canada to describe a drug that is demonstrated to be highly similar to a biologic drug that was already authorized for sale (known as the reference biologic drug) and that there are no clinically meaningful differences in safety and efficacy between them.[1]
- Biosimilars were also previously known as "subsequent entry biologics" (SEBs) or "follow-on biologics".

What is the terminology used around biosimilars?

Switching

- When speaking about the adoption of biosimilars, switching occurs when a patient change from one biologic to its biosimilar drug (e.g. switching between two different branded versions of infliximab).
- Health Canada generally refers to switching as a one-time change from a reference biologic drug to a biosimilar. Health Canada considers a well-controlled switch in an approved indication to be acceptable.[2]
- The Canadian Rheumatology Association recommends that switching from one biologic to its biosimilar, by someone other than the treating physician, must be avoided.[3]
- Health Canada also recommends that a decision to switch a patient to a biosimilar should be made by the treating physician in consultation with the patient and taking into account available clinical evidence and any policies of the relevant jurisdiction.[1]

Interchangeability

- Interchangeability refers to the ability of a pharmacist to provide an equivalent drug, without the intervention of the doctor who wrote the prescription. In Canada, the declaration of interchangeability rests with each province and territory according to its own rules and regulations.[1]
- The Canadian Rheumatology Association states that interchangeability for patients on established biologic therapy, with its biosimilars, is not supported at the present time.[2]

How does Health Canada address biosimilars?[1]

- When approving a biosimilar, Health Canada evaluates all the information provided to confirm that the biosimilar and the reference biologic drug are highly similar and that there are no clinically meaningful differences in safety and efficacy between them.
- Similarity is assessed by using a robust, science-based regulatory framework beginning with structural and functional studies and continuing with human clinical studies.
- Because the purpose of these studies is to demonstrate similarity, the type of data required to support biosimilar authorization differs from that required for an innovator biologic drug.
- Health Canada monitors the safety of all drugs on the market, including biosimilars; and asks manufacturers to report any new information received about serious side effects and provide a management plan for potential long-term side effects.

What is the current situation with biosimilars?

- Manufacturing and monitoring technology has advanced significantly since the first biologics were introduced in Canada. While Health Canada does not require the same clinical data and testing as the innovator biologic, biosimilars are showing to be safe, efficient and of high quality and consistency.[1]
- Based on the current example of biosimilars, we expect that most public and private payers will mandated biosimilars for patients who have not previously received the innovator biologic in the interests of reducing costs to the health care system. In other cases, innovator biologics costs may be covered up to the cost of the biosimilar, with the patient responsible for the difference (this may vary from plan to plan and drug to drug).
- In some instances, where a patient and their physician have decided to change from a medication that is not working as intended, a biosimilar of a different medication may be an option.
- Multiple biosimilars of the same innovator biologic drugs have arrived on the Canadian market. No study has yet been made to evaluate the impact of switching from a biosimilar to another biosimilar of the same innovator biologic drug.

- A recent patient focus group study[4], conducted with the collaboration of five different inflammatory disease patient organizations, has provided the following insights:
  - Switching of a medication negatively impacts stress and anxiety levels. Participants were open to the role of biosimilars for new patients who had not been on the originator biologic, but were strongly opposed to the idea of people who are currently stable on an innovator biologic being switched to a biosimilar for non-medical reasons, until research determined that it was safe and effective.
  - Participants were concerned that switching would reopen access and coverage questions.
  - More education and awareness is needed around treatment options. Participants require a better understanding of the health care process and the treatment options available to them for their inflammatory disease, including biologics and biosimilars.

What are some specific issues regarding biosimilars?

Naming

- Most drugs are identified according to an International Non-proprietary Name (INN) issued by the World Health Organization (WHO). At this time, the innovator and biosimilar products are provided with the same INN.
- The major concern about biosimilars and innovator biologics having the same name is that this will make it difficult for patients, pharmacists and physicians to know the exact drug the patient received, and thus to differentiate them in post-marketing surveillance.
- The World Health Organization and Health Canada are developing their positions on the naming of biosimilars.

Switching

- Both Health Canada and the Canadian Rheumatology Association state that switching a patient to a biosimilar should be made by the treating physician in consultation with the patient.
- There might be situations, when it would be preferable for a patient to remain on its current treatment for medical reasons, such as, but not limited to, patients that have been hard to stabilize on its treatment, patient that have exhaust multiple treatment options and patient affected by severe anxiety or mental illness.
- Health Canada refers to switching as a one-time change from a reference biologic drug to a biosimilar. Since multiple biosimilars of the same innovator biologic drugs have arrived on the Canadian market, studies are needed to address the impact of switching from a biosimilar to another biosimilar of the same drug.

Information

- As reported in the patient focus group study, people affected by arthritis require a better understanding of biologics, biosimilars and the heath care process surrounding their access.
- The Arthritis Society believes that caregivers and any member of the patient treating team should have access to appropriate education and support material to ensure that they are well-informed about biologics and biosimilars.

Post-market Surveillance and Real-World Evidence

- Post-market surveillance and collection and use of Real Word Data will help to monitor the long-term efficacy and safety of biologics. They will also enable researchers and clinicians to better address issues such as the impacts of concomitant treatments or diseases (comorbidities), or to optimize treatments and improve patient outcomes.

Patient and Physician Support Programs

- In Canada, manufacturers marketing biologics provide a patient and physician support program related to their drugs. These include bridge funding, copayment, sharps disposal, information lines and others.
- Not all programs offer the same kind or quality of support.
- To increase cost reduction or for sustainability reasons, a manufacturer may reduce the quality or the offering include in those programs.

GUIDING PRINCIPLES

- Safety is paramount and a patient-centred approach is crucial.
- Decisions about switching must be in the hands of people living with arthritis and their physicians – not payers or policy makers.
- People affected by arthritis and their physicians need to be armed with the right information to make an informed and shared decision about treatments.

THE ARTHRITIS SOCIETY'S ROLE

- The Arthritis Society will fulfill its mission by educating individuals affected by arthritis about the complex and unique characteristics of biologics and biosimilars, so that they can make the most appropriate and informed choice of therapy in consultation with their prescribing physician.
- The Arthritis Society is committed to ensuring that government decision makers have a clear understanding of the impact of biosimilars on patients, and that public policy is implemented to support individuals affected by arthritis.

For further information, contact:

Ken Gagnon
Director, stakeholder relations
The Arthritis Society
380, rue St-Antoine O. Bureau 3120
Montréal (Québec) H2Y 3X7
514.846.8840 x2432
kgagnon@arthritis.ca

References

1. Government of Canada. Fact Sheet : Biosimilars. August 2017. Available at: https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html
2. Government of Canada. Health Canada's 2017 Biosimilars Workshop: Summary Report. August 2017. Available at: https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/biosimilars-workshop.html
3. Canadian Rheumatology Association. Canadian Position Statement on Biosimilars and Innovator Molecules. May 2017. Available at: https://rheum.ca/images/documents/Canadian_Position_Paper_on_Biosimilars_.pdf
4. Biosimilar Focus Group Report. March 2017. Available at: http://www.arthritis.ca/AS/media/pdf/About%20Arthritis/TAS_FocusGroupReport_Final_ENG_V5.pdf

Revised: January 2018