Arthritis Talks: Understanding Biosimilars

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Presenters

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Webinar tips

- Use the **Q&A** section to ask the presenters your questions. Some of the questions will be chosen for the live question period at the end of the webinar.
- Click on the **Chat** box to connect with other participants and the Arthritis Society's chat moderator.
- If you have further issues, email arthritistalks@arthritis.ca

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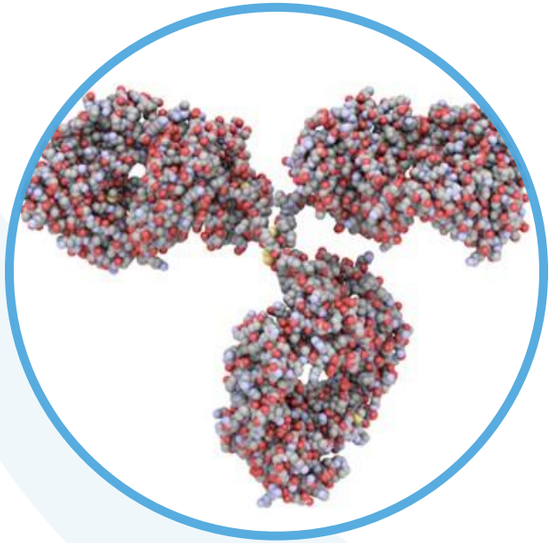
Overview

[1]
Overview of Biosimilars



[2]
Transition Process

[3]
Q&A

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What are biosimilars?

What is a biologic?

- Used to treat serious and life-threatening rheumatic diseases in Canada and around the world for >20 years
- Unlike most small molecule medications, biologics are large, very specific proteins, usually made by a cell
- Biologics are similar to antibodies that stop inflammation by clearing inflammatory proteins from the body
- Highly specific for their target, making them very unlikely to have side-effects unrelated to the target
- Given by injection under the skin or through IV
- Used after one or more conventional anti-rheumatic drugs (DMARDs) is either not effective or not well-tolerated

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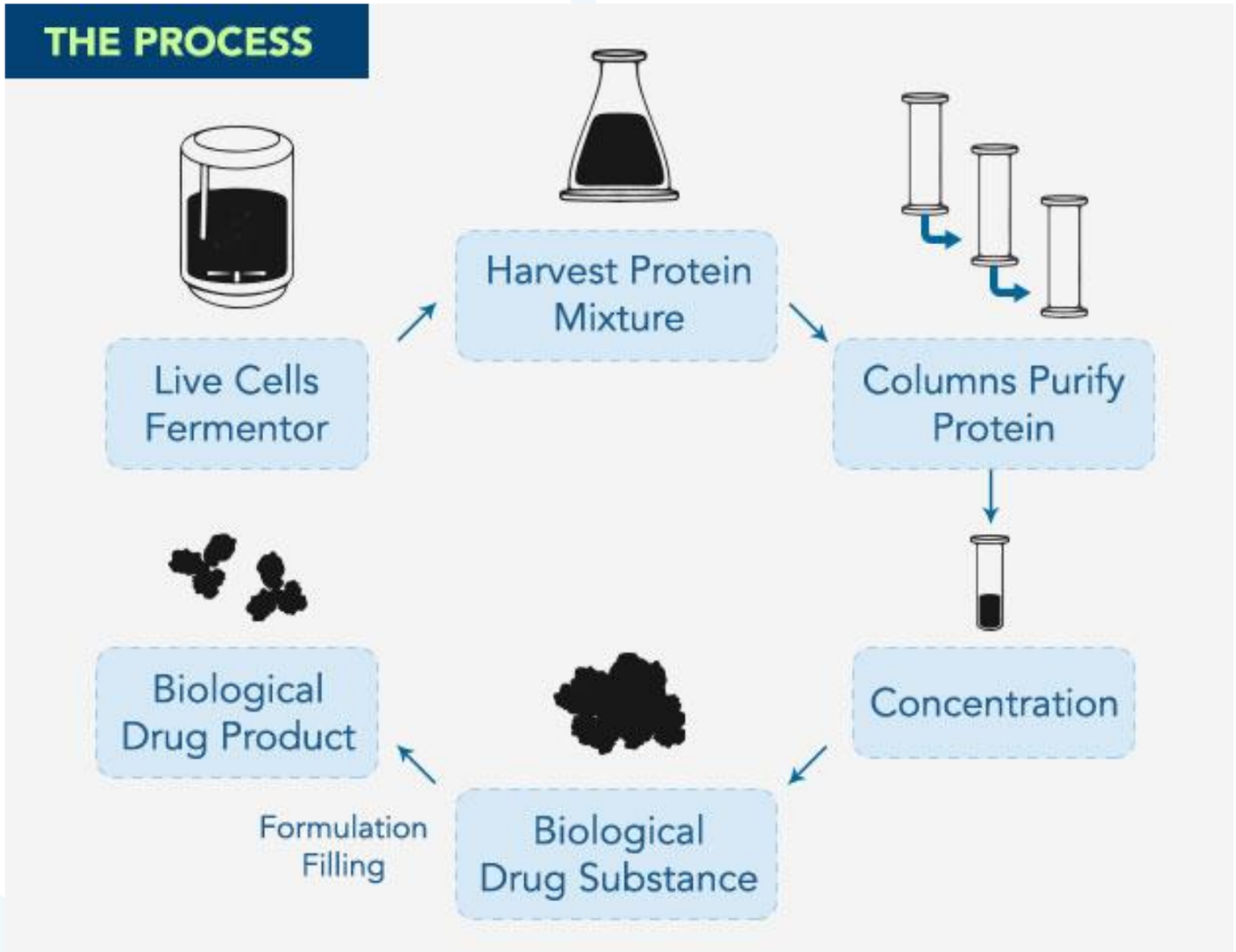

https://www.medpagetoday.com/resource-centers/biosimilars/biologics-and-biosimilars/28

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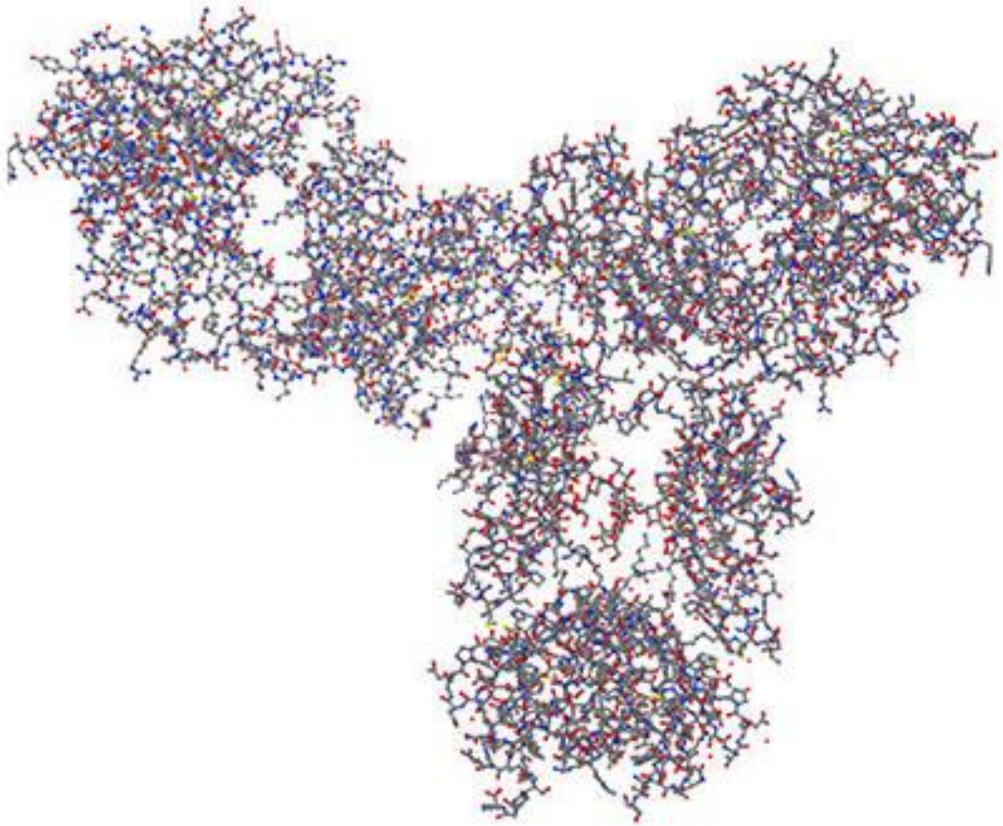
A COMPARISON OF SIZE AND COMPLEXITY

Aspirin 180 Da



Monoclonal Antibody ~150,000 Da

https://www.medpagetoday.com/resource-centers/biosimilars/biologics-and-biosimilars/28

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What is a biosimilar?

- Biosimilars are biologics!
- Based on the same (“originator”) biologics
- Allowed to be manufactured after the originator biologic’s patent runs out
- Biosimilars work on the same target as the originator biologic
- Manufactured by the same process as the originator biologic

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ADALIMUMAB biosimilars in Canada – an example

Type	Adalimumab Brand	First Approved by Health Canada	Canadian Distributor
Originator	Humira	July 2006	Abbvie
Biosimilar	Hadlima	May 2018	Merck
Biosimilar	Idacio	October 2020	Fresenius Kabi
Biosimilar	Amgevita	November 2020	Amgen
Biosimilar	Hyrimoz	November 2020	Sandoz
Biosimilar	Hulio	November 2020	Mylan

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How do we know biosimilars are safe?

Biosimilar safety

- Biosimilars must be tested before they are approved
- Must have the same efficacy to the originator for at least one major indication with a similar safety profile
- To date, more than 170 published studies in rheumatology, gastroenterology and dermatology that demonstrate no meaningful differences in safety or efficacy of biosimilars compared to originators

- Biosimilars in the EU: Information guide for healthcare professionals
- https://www.ema.europa.eu/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals_en.pdf

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Variability of biosimilars is kept within strict limits

“The range of variability allowed for a biosimilar is the same as that allowed between batches of the reference medicine.”

“This is achieved with a robust manufacturing process to ensure that all batches of the medicine are of proven quality.”

Biosimilars in the EU: Information guide for healthcare professionals

https://www.ema.europa.eu/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals_en.pdf

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Regulation of biosimilars

Health Canada

"A biosimilar is a biologic drug that obtains market authorization subsequent to a version previously authorized in Canada, with **demonstrated similarity to a reference biologic drug**. A biosimilar relies in part on prior information regarding safety, efficacy and effectiveness that is deemed relevant due to the demonstration of similarity to the reference biologic drug."[1]

FDA

"A biosimilar is a biological product **highly similar to the reference product notwithstanding minor differences** in clinically inactive components and for which there are **no clinically meaningful differences** in terms of the safety, purity, and potency of the product."[2]

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

"A biosimilar is a version of the active substance of an already authorised original biological medicinal product with **demonstrated similarity** in terms of quality characteristics, biological activity, safety and efficacy based on a comprehensive comparability exercise."[3]

1) Information and Submission Requirements for Biosimilar Biologic Drug, Health Canada 14 November 2016

2) Biologics Price Competition and Innovation Act, FDA 2009; 3) Guideline on Similar Biological Medicinal Products, EMA 23 October 2014;

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What is the difference between biosimilars and biologics?

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Biologics and biosimilars

Biologics and Biosimilars

BIOLOGIC

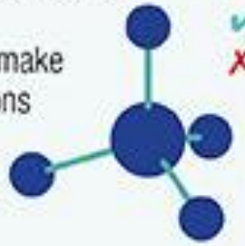
Brand name that discovered therapy

BIOSIMILAR

Brand that makes treatment after 20-year patent expires

Similarities between the two

- ✔ Proteins grown, isolated, and purified from living cells
- ✔ Complex and expensive to make
- ✔ Grown under strict conditions (temperature, pH, food)
- ✔ Cells programmed to make specific proteins



Results

- ✔ Same protein
- ✔ Work the same way
- ✗ Similar effect but small differences due to variations in growth conditions

What they're used to treat

- ✔ Inflammatory arthritis (including rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis)
- ✔ Inflammatory bowel disease
- ✔ Anemia (related to cancer treatment)
- ✔ Psoriasis
- ✔ Breast cancer

Health Canada approval requirements

- ✔✔ Safety data
- ✔✔ Efficacy data
- ✔✔ Post-market data
- ✔ Fewer clinical studies

Source: CAPA

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Differences between biosimilars and originator biologics

- A different version of the same thing
- Produced by a different manufacturer
- Use a different patient support program
- Lower cost to manufacture = lower cost to health systems
- Differences in the chemical features vs. originator are subtle
  - Differences between the first and subsequent batches of the originator biologic are often larger than between originator and biosimilar version

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Why are patients being transitioned to biosimilar medications and what does that transition process typically look like?

Why are patients being transitioned to biosimilars

- Biosimilars are lower in price than originator biologics
- Government of Canada Patented Medicines Prices Review Board estimates that private and public drug plans can save $332 million to $1.81 billion in the 3rd year after transition implemented
- Savings from transitions to biosimilars can be re-invested into other aspects of health care
- No clear medical reason (safety or efficacy) not to transition

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What is a biosimilar transition

- Transition = after a patient has been taking an originator biologic for some time, they switch to taking a biosimilar instead
- Transition does not mean interchangeability (switching back and forth biosimilar and originator, or between different biosimilars)

Transition process - what will I experience?

Medical transition

- If your disease is not well-controlled, you may decide with your rheumatologist to transition to a new biologic, which could be a biosimilar

Non-medical transition

- When public or private drug plan requires patients to transition from an originator biologic to its biosimilar because it is less expensive
- For e.g., several provinces are coordinating transitions for all patients receiving an originator biologic where a biosimilar is now available (infliximab, etanercept, adalimumab)

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Automatic biosimilar transitions in Canada

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Biosimilar transitions

Regardless of the reason for transition…

- Your rheumatologist/specialist will discuss with you and help you select a new biosimilar
- May be enrolled into the new patient support program (PSP) for that biosimilar (if applicable)
  - PSP helps to support obtaining access to the medication and coverage
- Patients and their rheumatologists will monitor the efficacy and safety of the transition in the coming weeks and months during routine care

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Any final thoughts or recommendations?

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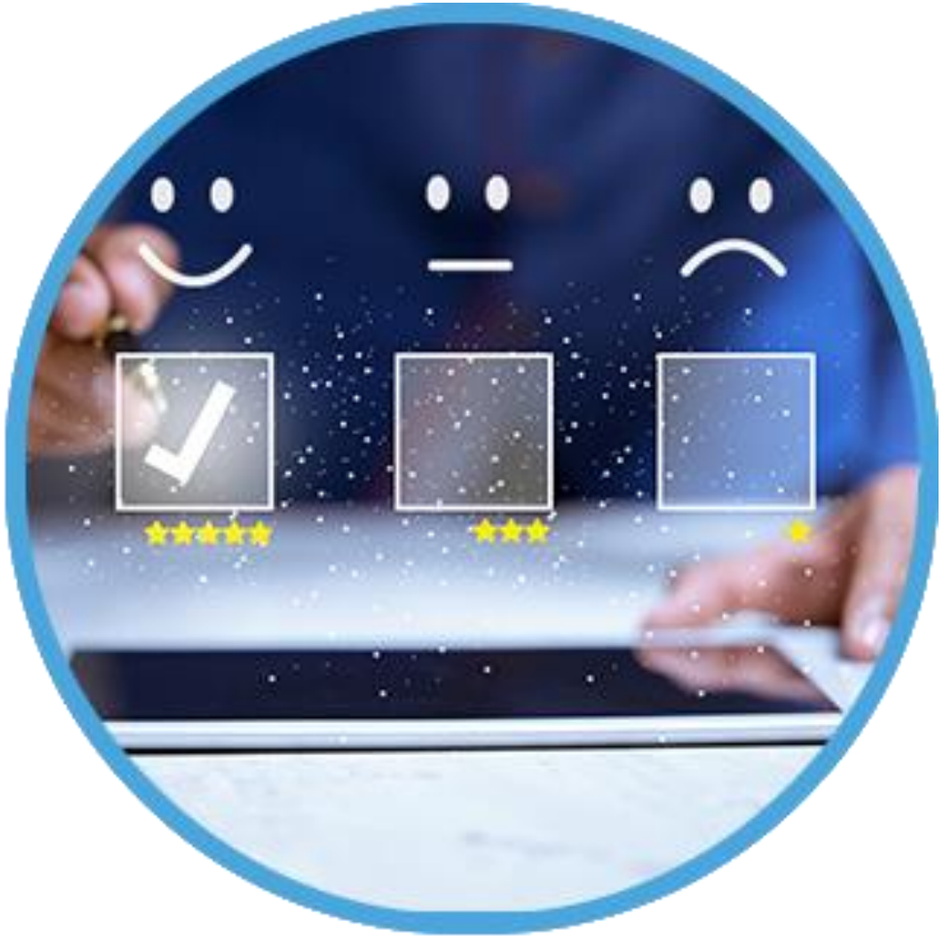
Questions

Tell us what you think…



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Introducing Arthritis Connections

6 p.m. ET

Newly launched program

Arthritis Connections

Bringing together people living with arthritis

Join us for:

- Q & A with registered dietitian Kim Arrey
- Smaller virtual discussion groups to engage, connect and learn from others in a supportive environment

Register at: **Visit arthritis.ca/connections or click the link in your email inbox**

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