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Biologics and Biosimilars
FAQs for Health Care Professionals

- **What are biologic drugs?**
  - Biologic drugs, commonly referred to as "Biologics," are made using living organisms or their cells.
  - When compared to chemically produced drugs, biologics consist of larger and more complex molecules.
  - The first version of a biologic drug to be produced is called the **reference** or **originator** biologic.

- **What are biosimilar?**
  - Biosimilars are highly similar versions of originator biologic drugs. They are marketed when the patent expires on the originator biologic drug.
  - Because of the high degree of similarity, there are no expected clinically meaningful differences in efficacy and safety between a biosimilar and its reference biologic drug.

- **Are biosimilars the same as generics?**
  - No. A generic drug is a simpler molecule and can copy exactly the original brand name medication.
  - Biologic drugs are made from live cells and are more complex than traditional drugs. Biosimilar drugs are highly similar to their reference biologic. The biosimilar will work in the same way as the reference biologic.
  - Each batch of a biologic drug can have minor variations from the first biologic that was made. These minor changes can happen with each batch of a reference biologic and with the biosimilar copies, but do not change the effect or safety of the drug.

- **How are Biosimilars Regulated in Canada?**
  - Biosimilars are regulated as new drugs under the *Food and Drugs Act* and the *Food and Drug Regulations*
    - Biosimilars must meet the same regulatory standards as other biologic drugs and are only authorized after a scientific evaluation by Health Canada
  - Biosimilar manufacturers must:
    - demonstrate the quality of the drug
    - perform extensive comparative studies to the reference biologic drug that demonstrate high similarity in structure, function, safety and efficacy

- **Are biosimilars safe and effective compared to the originator biologic drug?**
  - Yes. Biosimilars have been used in Canada for over 10 years and in many other countries including the United States, Australia, the United Kingdom and in the European Union for more than 15 years. Regulators have not identified any relevant differences in the type, severity, or frequency of side effects between biosimilars and their respective biological originators.

- **How can I determine if a product is a biosimilar?**
  - Health Canada requires that the manufacturer of a biosimilar drug include a statement in the product monograph indicating that the product is a biosimilar to the reference or originator biologic**.** This statement can be found immediately above "PART 1: HEALTH PROFESSIONAL INFORMATION" within a Canadian drug product monograph.

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- **Does switching to a biosimilar impact patient outcomes?**
  - Health Canada indicates that patients and health care providers can be confident that biosimilars are effective and safe for each of their authorized indications, and that no differences in efficacy and safety are expected following a change in routine use between an originator biologic and its biosimilar in an authorized indication.
  - The safety and efficacy of switching to biosimilars is supported by a large body of international evidence. There are many research studies which show little to no clinical differences between biosimilars and their originators, either when used with new patients, or for patients switching to a biosimilar.

- **Are biosimilars less costly than originator biologics?**
  - Yes. Biosimilar drugs cost less since the foundation of research and development has already been completed by the manufacturer of the originator biologic.
  - The originator biologic drug is protected by a patent for several years, which allows its manufacturer to recoup research and development costs. Once the patent expires, other manufacturers can produce and market biosimilars at a lower cost.

Examples of Originator Biologics and Biosimilars*

Molecule	Originator	Biosimilars			
Adalimumab	Humira®	Abrilada® Amgevita™	Hadlima® Hulio®	Hyrimoz® Idacio®	Simlandi™ Yuflyma™
Bevacizumab	Avastin®	Aybintio® Abevmy®	Bambevi®	Mvasi®	Zirabev®
Enoxaparin	Lovenox®	Elonox®	Inclunox®	Noromby®	Redesca®
Etanercept	Enbrel®	Brenzys®	Elrezi®		
Filgrastim	Neupogen®	Grastofil®	Nivestym™		
Infliximab	Remicade®	Inflectra®	Renflexis™		
Insulin aspart	NovoRapid®	Kirsty®	Trurapi®		
Insulin glargine	Lantus®	Basaglar®	Semglee®		
Insulin lispro	Humalog®	Admelog®			
Rituximab	Rituxan®	Riabni®	Riximyo®	Ruxience™	Truxima™
Trastuzumab	Herceptin®	Herzuma®	Kanjinti®	Ogivri®	Trazimera®

*** For details on formulary coverage, please refer to the PEI Pharmacare and Health PEI Oncology formularies.**