

Biological and Biosimilar Medicines

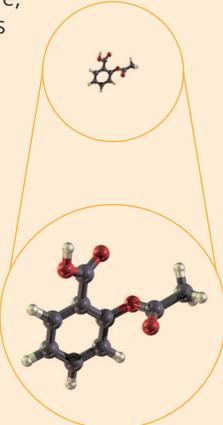
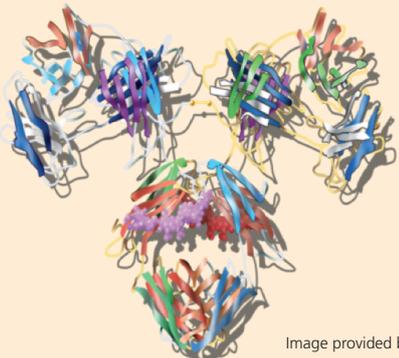
Fact Sheet 2: What are biological and biosimilar medicines?

This Fact Sheet provides an overview of what biological and biosimilar medicines are, what they are used for, how they are different to chemical medicines, and how they are produced.

- **Biological medicines** are large, complex molecules which are made from living organisms. They are different to traditional chemical medicines, which are made from combining simple, small chemical ingredients.
- Biological medicines are made up of proteins that are naturally produced in the human body. These proteins are what treat a patient's condition.
- They are made using **biotechnology techniques**.
- They have revolutionized the prevention, cure and management of diseases such as:
 - cancers
 - diabetes
 - multiple sclerosis
 - heart attacks
 - stroke
 - autoimmune diseases (e.g. rheumatoid arthritis)
 - a number of rare disorders.

What is biotechnology?

- Biotechnology uses scientific and engineering methods to manipulate living organisms, such as bacteria or yeast, in order to produce a product or perform a function.
- It is often associated with the production of medicines, where the genes of a living organism are manipulated so that they produce therapeutic proteins.

Chemical medicine	Biological medicine
<p>Small, simple structure, e.g. aspirin: 21 atoms</p> 	<p>Medium to very large, complex, heterogeneous structure, e.g. monoclonal antibody: >20,000 atoms</p>  <p><small>Image provided by Amgen</small></p>
Made by combining chemical ingredients – easy to reproduce exactly	Made using living cells through biological synthesis – difficult to reproduce exactly
Often stable for long periods of time	Less stable – sensitive to light, heat, denaturation or degradation
Unlikely to cause an immune reaction due to small size	More likely to cause an immune reaction due to size and structure
Can be taken orally in capsule form	Often administered by injection or infusion
Can often be self-administered at home	Often administered at hospital
Usually prescribed by general practitioner or primary care physician	Usually for the treatment of severe diseases and prescribed by specialists

- **Biosimilar medicines** are developed to be highly similar to a biological medicine which has already been approved and made available for patients, once the original patent has expired.
- The biological medicine that has already been approved is often called the **reference product**.
- Once approved, a biosimilar medicine is a **highly similar** version of a biological medicine and has comparable **quality, safety and efficacy**.
- This is shown through a **biosimilar comparability exercise** (see Fact Sheet 3).
- Biosimilar medicines are not generic medicines (identical copies of branded chemical medicines).

Why make biosimilars?

- Biosimilar medicines are developed in order to provide **alternative products**, usually at a **lower cost** than the original biological medicine, i.e. reference product.
- This can provide **more treatment options** for patients and **increase accessibility**.

How are biological and biosimilar medicines produced?

Biological medicines are produced using cells whose genes have been modified to produce a certain protein. This process is much more complex and sensitive than the process to produce a chemical medicine.

