

Understanding biological & biosimilar medicines

Frequently Asked Questions

Q. What is a biological medicine?

A. Biological medicines, including biosimilars, are derived or manufactured from a living biological system. They include hormones (e.g. insulin), enzymes (to speed up chemical reactions), blood factors (to regulate clotting), antibodies (to support the immune system), vaccines and advanced therapies (such as cell, gene and tissue therapy products).

Biological medicines are among many of today's most important medicines. By 2020, it is predicted that seven of the top ten medicines worldwide will be biological.*

Q. What is a biosimilar medicine?

A. A biosimilar is a biological medicine that is developed to be similar to an approved biological medicine (the 'originator' biological medicine) and can only be marketed after the patent and data exclusivity period has expired. As its name suggests, a biosimilar is not an exact copy of its originator biological medicine due to its complex molecular structure and unique manufacturing process. Manufacturers of biosimilars are required to demonstrate that there are no clinically meaningful differences between the biosimilar and originator biological medicine in terms of safety, quality and efficacy.*

Q. What is a small molecule medicine?

A. Small molecule medicines are made by combining certain chemicals in a defined series of chemical reactions. Because these molecules are smaller and involve fewer process steps than biological medicines, they are easier to duplicate. This kind of medicine is often taken orally, most often as a pill.

Generic medicines: A medicine that contains an exact copy of the active pharmaceutical ingredient of the small molecule originator medicine.

Biological medicines: Biological medicines, including biosimilars, that have been developed in living organisms.

Originator medicines: The original medicine on which a biosimilar or generic drug bases its application for marketing authorisation.

Q. How are biological medicines different?

A. There are several key differences between biological and small molecule medicines:

- **Molecular structure** – biological medicines are much larger and more complex than small molecule medicines.
- **Development and manufacture** – biological medicines have complex manufacturing processes that must be tightly controlled to provide a consistent product.
- **Immunogenicity** – due to their size and complexity, biological medicines have the potential to induce unwanted or unexpected immune reactions.
- **Administration** – most biological medicines, including biosimilars, must be administered by injection or infusion.
- **Transport and storage** – biological medicines generally degrade quickly if subject to high temperatures. Therefore, biological medicines, including biosimilars, usually need to be stored in a refrigerator.

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