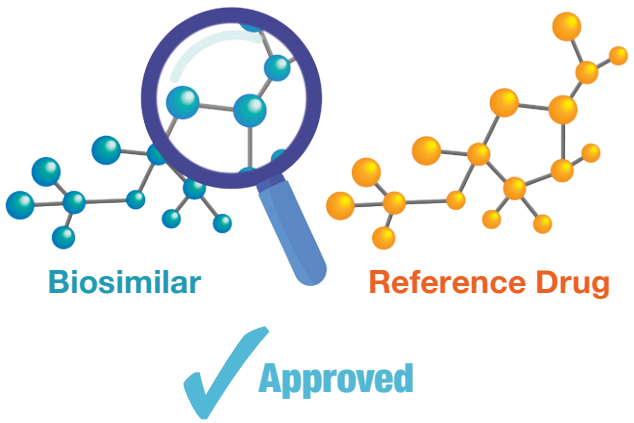
Frequently Asked Questions

1. **Compared with the originators, will biosimilars induce more adverse drug reactions?**

   Each biologic has its own risk to trigger an immune response in the body, such as allergic symptoms. Currently, there is no evidence suggesting a higher risk of adverse drug reactions with biosimilars than with the originators. Besides, immunogenicity would be rigorously investigated in humans before the biosimilars can be approved. Therefore, the safety profile of biosimilars is ensured.

2. **Are biosimilars unregistered products?**

   No. All medicines, including biosimilars, must go through a stringent regulatory process in order to be approved for public use. Currently, the World Health Organization (WHO), the European Union (EU), the United States and Hong Kong have developed individual guidelines for biosimilars. Registration of biosimilars requires information including clinical and non-clinical data, quality studies, and risk management plans. This ensures the medicines are up to standard in terms of quality, efficacy, and safety.



3. **Is it safe for me to switch to a biosimilar if I started using the originator first?**

   All biologics, including biosimilars, could cause immune reactions in the body. Currently, there is no evidence showing biosimilars would cause more immune reactions as compared to the originators. When a patient has started treatment on the originator, doctor will consider whether it is clinically justifiable to switch to a biosimilar by assessing the potential risks, and discuss with the patient on the appropriateness of the switch. If you experience any adverse drug reactions, you should report them to your healthcare professionals.

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Biosimilars

藥劑職系及服務統籌委員會
COC-Grade (Pharmaceutical Services)

醫院管理局
HOSPITAL AUTHORITY

What Are Biologics

In contrast to conventional medicines that are chemically synthesised through simple steps of reaction and are easily replicated, biologics are made or extracted from living cells and synthesised through complex biotechnological processes. Due to the complexity and variance in each cells, there would be differences in the make-up of each biologic.

What are Biosimilars

Unlike generic medicines, which are exact chemical copies of the branded drugs, biosimilars are not identical to the originator (also known as the reference product). However, the two are highly comparable in structure, and hence biosimilars have high similarity in terms of efficacy, safety, and quality profile as the originator. In other words, any differences between the originator and a biosimilar are not considered clinically significant.

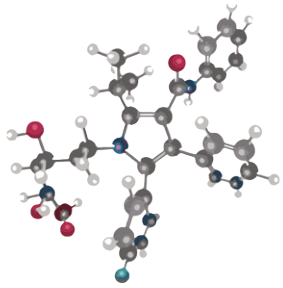
Biosimilars have high similarity with the originator. Doctors will exercise their professional judgement to prescribe the originator product or biosimilar product. Patients are encouraged to discuss with their doctors on their treatment.

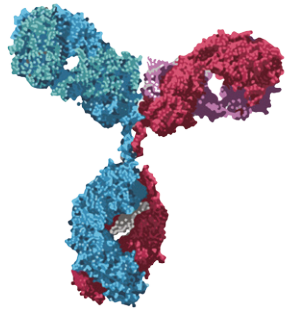
Why are there Biosimilars

Similar to generic medicines, biosimilars could only be manufactured after expiration of the originator's patent and product approval by local health regulatory authorities to ensure that they meet all the safety and quality standards.

Biosimilars can help drive down the prices of biologics by introducing competition and making medications more accessible to patients, especially those who previously cannot afford biologics. Also, the availability of lower-cost biosimilars could help improve the utilisation of public healthcare resources.

In recent years, the expiring patents of many biologics have led to the emergence of various biosimilars with relatively lower- priced treatment options for patients. With more drug companies willing to invest in the production of biosimilars, it is anticipated that there will be more biosimilars available in the market.





	Small Molecule Drugs	Biologics
Molecular size / Weight	Small; Low molecular weight	Very Large; High molecular weight
Structure	Simple	Complex
Manufacturing	Chemical synthesis; exact copies can be reproduced	Synthesised from living cells; identical copies cannot be reproduced
Examples	Aspirin, Paracetamol	Insulins, monoclonal antibodies