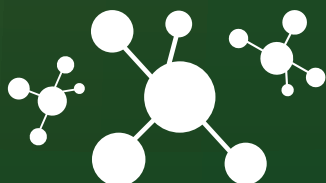


BIOSIMILAR MEDICINES

INFORMATION FOR CONSUMERS AND CARERS

This brochure has been designed to answer common questions about biosimilar medicines.



Biological medicines are medicines made by living cells or organisms. They are usually made of proteins that are naturally produced in the human body.



Biological medicines treat illnesses such as cancer, diabetes, severe psoriasis, rheumatoid arthritis, inflammatory bowel disease, multiple sclerosis and kidney disease. They have helped **improve life for thousands of Australians**.



A **biosimilar medicine** is a highly similar version of an original brand of a biological medicine, marketed by a different manufacturer once the patent on the original brand expires.



Biosimilar brands of biological medicines are **thoroughly tested to show that they are just as safe and effective as the original** biological brands before they are approved by Australian regulators.



It is up to you and your doctor to choose which biological medicine is right for you.

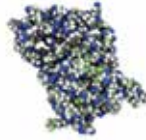
What are biological and biosimilar medicines?

Biological medicines

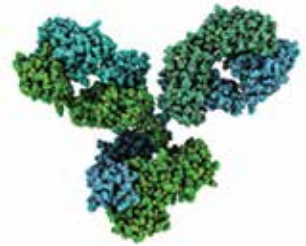
Biological medicines are large complex molecules that are made by living cells or organisms. They are usually made of large proteins that are naturally produced in the human body.



Aspirin (example of a non-biological medicine)



Simple biological medicine



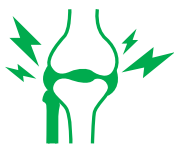
Complex biological medicine

When a biological medicine is given to a patient, it functions like a protein that occurs naturally in the body, resolving symptoms and preventing or slowing the progression of the disease.

Biological medicines have helped to improve the lives of thousands of Australians living with conditions such as cancer, diabetes, severe psoriasis, rheumatoid arthritis, Crohn's disease, ulcerative colitis, multiple sclerosis and kidney disease.



Cancers



Arthritis



Psoriasis



Inflammatory digestive disorders



Growth disorders



Diabetes

Biosimilar medicines

A biosimilar medicine is a highly similar version of an original brand of a biological medicine, brought to market once the patent on the original brand expires.

Unlike a generic medicine, which has an identical ingredient to the original brand, the reason these medicines are known as biosimilar medicines is because biological medicines are large molecules made from living cells, and so the processes that produce them are naturally variable. This means that no two batches are ever exactly the same – not even from the same manufacturer.

Biosimilar brands of biological medicines are used to treat the same diseases, in the same way and have been thoroughly evaluated by the Therapeutic Goods Administration (TGA) in Australia to show that they are just as safe and effective as the original brands of biological medicines.

Experience with biosimilar medicines

Biosimilar medicines have been available in Europe since 2006 and are now used by over 60 countries around the world – world wide there are over 700 million treatment days of clinical experience with biosimilar medicines.

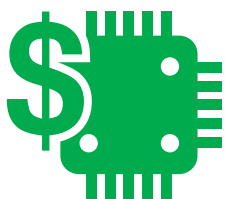
In Australia, biosimilar medicines have been used safely since 2010.

Regulation of biological and biosimilar medicines in Australia

Australia has a strong regulatory system that ensures the **safety, efficacy and quality of all medicines, including biological medicines**. The regulatory system is managed by the Therapeutic Goods Administration (TGA), which is part of the Australian Government Department of Health.

The TGA regulates every step involved in the production and use of medicine in Australia:

- Before any medicine, including a biosimilar medicine, is registered and allowed on the market, it must undergo thorough testing and evaluation
- All medicine manufacturers must comply with strict standards that ensure product safety, quality and consistency; and
- The TGA monitors the safety of all medicines, including biosimilar medicines, used in Australia. If there is a risk to Australians from any medicine, the TGA takes action to address this risk



Development of biosimilar medicines requires significant investment and state-of-the-art technologies

Benefits of biosimilar medicines

The Australian Pharmaceutical Benefits Scheme (PBS) subsidises medicines to make them more affordable to patients. This means life-saving medicines – including biological medicines which can cost hundreds or even thousands of dollars per treatment – only cost \$40.30; or \$6.50 if you have a concession card. The Australian Government pays the remaining cost.

Biosimilar medicines have the potential to generate substantial cost-savings for the Australian healthcare system. When a biosimilar medicine becomes available in Australia, it encourages market competition between manufacturers, which in turn, can make these high-cost medicines more affordable for the Australian Government to subsidise. As most medicines in Australia are subsidised through the Pharmaceutical Benefits Scheme (PBS), these lower prices allow the Government to use the cost-savings to subsidise more medicines or spend more on other areas of healthcare.



Around the world, biosimilar medicines are enhancing competition in the marketplace



In the five largest European markets alone, biosimilar medicines have saved over 2 billion AUD



The potential savings offered by biosimilar medicines could help support the long-term sustainability of the Australian healthcare system

Who chooses which biological or biosimilar medicine to use?

It is up to you and your doctor to choose which biological or biosimilar medicine is right for you.

If more than one brand of your medicine is available and they are considered equivalent on the PBS, the pharmacist can offer you the choice of brand, but only if the doctor has not ticked a box on your prescription to say 'brand substitution not permitted'. Talk to your doctor or pharmacist about biosimilar medicines and if they are right for you.





Commonly asked questions about biosimilar medicines

Q. Will I get the same benefit from a biosimilar medicine?

- A.** Yes. Since biosimilar medicines have been assessed to be as safe and effective as the original biological brand, they also **provide the same health benefits**. Ongoing research on biosimilar medicines continues to find no difference in health outcomes between patients who start or switch to a biosimilar medicine and those who remain on the original brand.
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Q. Are biosimilar medicines safe to use?

- A.** Biosimilar medicines have been used since 2006 when they were introduced in Europe. Their use has steadily increased over time, and they are available in **more than 60 countries** around the world.

Biosimilar medicines have been available in Australia since 2010 and have helped to improve life for thousands of Australians with serious illnesses such as cancer, rheumatoid arthritis, inflammatory bowel disease, severe psoriasis, multiple sclerosis and kidney disease.

Q. Will a biosimilar medicine be the same quality as the original brand?

- A.** Australia has a strong regulatory system that ensures the safety, effectiveness and quality of all medicines. Biosimilar brands of biological medicines are **thoroughly tested** to show that they are just as safe and effective as the original biological brand before they are approved for use in Australia.
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Q. What are the benefits of choosing a biosimilar medicine?

- A.** Using biosimilar medicines has the potential for **substantial cost savings** within the Australian healthcare system. As most medicines in Australia are subsidised through the Pharmaceutical Benefits Scheme (PBS), these lower prices allow the Government to use the cost-savings to subsidise more medicines or spend more on other areas of healthcare.
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Q. Will my medicine look different if I use a biosimilar medicine?

- A.** The appearance of your medicine may change, depending on the particular brand you choose. The way the medicine is used may be different, but the active ingredient does not change. You can discuss how best to use your medicine with your doctor, pharmacist or nurse. Further information is available in the Consumer Medicines Information sheet that comes with your medicine.
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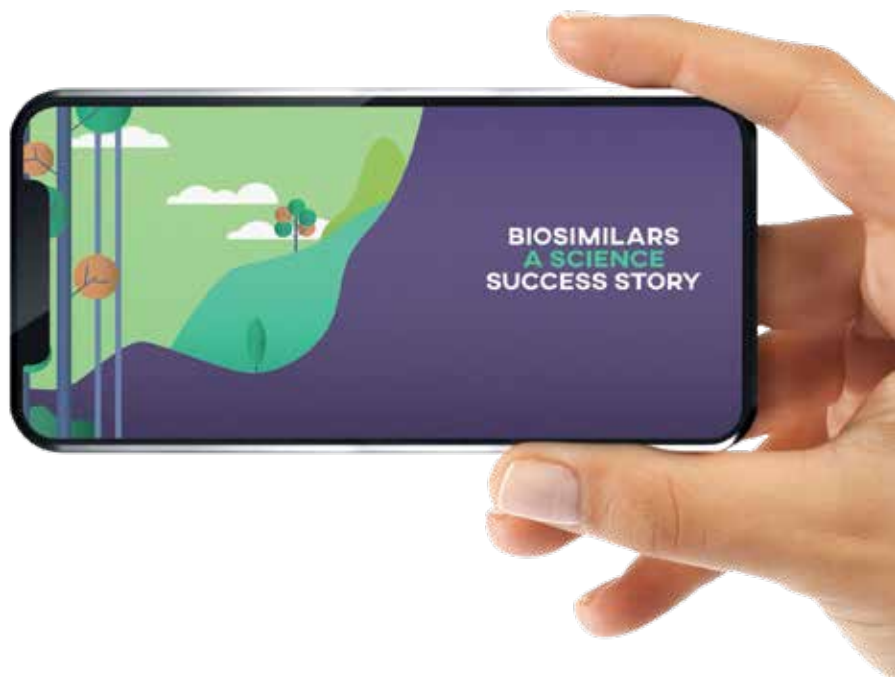
Where to find more information?

Your healthcare team is the best source of information unique to you and for the management of your health.



Further information

You can find more information on biosimilar medicines online at the Biosimilar Hub www.biosimilarhub.com.au



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