Australian Government
Department of Health

# Biosimilar medicines: the basics

INFORMATION FOR
## CONSUMERS AND CARERS

# Improving access to life-changing medicines

## What are biological and biosimilar medicines?

Biological medicines contain substances that are made by living cells or organisms. A biosimilar medicine is a highly similar version of a reference biological medicine, which is the first brand to market.

Biological medicines are not referred to as generic medicines. This is because the processes that produce biological medicines are naturally variable. No two batches of a biological medicine are ever exactly the same (even from the same manufacturer).

Biosimilar medicines are used to treat the same diseases, in the same way, as the reference biological medicines. Biosimilar medicines have been tested and shown to be as safe and effective as the reference biological medicines.

## Who uses them and who chooses?

Biological medicines are used to treat serious diseases and chronic conditions such as cancers, diabetes, severe psoriasis, rheumatoid arthritis, Crohn's disease, ulcerative colitis, multiple sclerosis and kidney disease.

It is up to you and your doctor to choose which biological medicine to use. You should discuss with your doctor which medicine is right for you.

Your doctor may decide whether to prescribe a particular brand of medicine. If they do not make this choice, your pharmacist might offer you the choice of brands. However, your doctor can tick a box on the script to say that substitution by the pharmacist is not permitted, if they think you should only take a particular brand.

## Why are biosimilar medicines important?

The use of biosimilar medicines can improve health care for Australians.

Biosimilar medicines encourage market competition, which makes medicines more affordable. Because most medicines in Australia are subsidised, lower prices allow the government to subsidise more medicines or spend more on other areas of health care.

Biosimilar medicines give patients access to more brand options and can reduce the risk of medicine shortages.

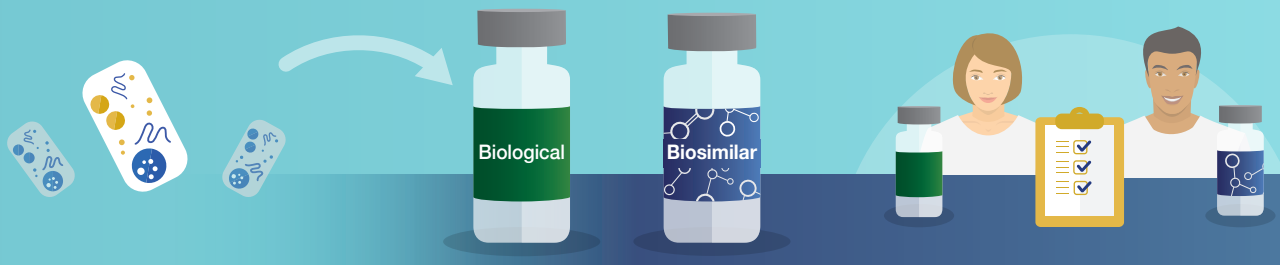
## How are biosimilar medicines assessed and regulated?

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

The system addresses every step in medicine production and use:

- Before any medicine is registered and allowed onto the market, it undergoes rigorous testing and evaluation.
- Medicine manufacturers must comply with standards that ensure product safety, quality and consistency.
- The TGA monitors the safety of all medicines used in Australia. If there is a risk to patients from any medicine, the TGA takes action to address the risk.

# What are biosimilar medicines?




Biological and biosimilar medicines come from living cells

Biosimilar medicines are **highly similar**

**The effects are the same**

# Who uses them?

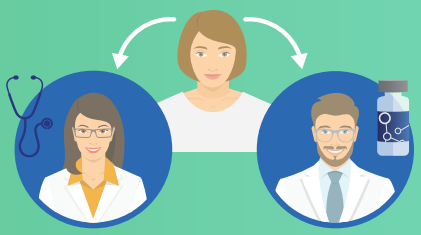
Biological medicines provide **important new ways to treat many serious and chronic conditions**

**Arthritis**

**Cancer**

**Intestinal diseases**

**Diabetes**



Talk with your doctor or pharmacist about choosing biosimilar medicines

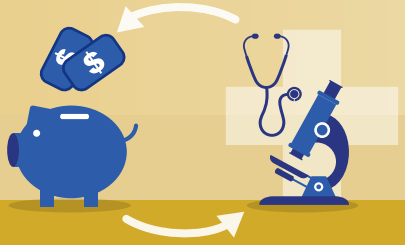
# Why are they important?

**Improved access for more patients**

More brand options

**Better health care**

**Savings are reinvested to improve health care**



# How are they regulated?

**Medicine is developed**

TGA assesses the evidence

**Rigorous testing**

Medicine is registered

All medicines in use are monitored once they reach the market

Manufacturing compliance is enforced

Adverse events and molecular changes are assessed

# Commonly asked questions about biosimilar medicines

## Q. Will I have the same health outcome no matter which brand is used?

A. Yes. Since biosimilar medicines have been assessed to be as safe and effective as the reference biological brand, they also provide the same health outcomes. Research has found no difference in health outcomes between patients who switched to biosimilar medicines and those who remained on the reference brand.

## Q. How long have biosimilar medicines been used?

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.

## Q. Will taking a biosimilar medicine affect my access to PBS subsidised treatment?

A. No. If you change from a reference biological medicine to the biosimilar medicine or vice versa, it is considered to be the same ongoing treatment because these medicines have been assessed to be equally safe and effective.

## 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.

# Where can I find more information?

You can refer to detailed information for consumers on the Biosimilar Awareness Initiative webpage at www.health.gov.au/biosimilars.

You can also discuss any further questions you have about biosimilar medicines with your health care provider.

## Information available from the Therapeutic Goods Administration

- Consumer Medicines Information leaflets: www.tga.gov.au/consumer-medicines-information-cmi
- How to report a side effect of a medicine: www.tga.gov.au/report-side-effect-medicine

Provided by:

**www.health.gov.au/biosimilars**

All information in this publication is correct as at March 2017

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