



Australian Government
Department of Health

Biosimilar
MEDICINES

Biosimilar Medicines

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Coalition of National Nursing & Midwifery Organisations

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Biosimilar
MEDICINES

National Medicines Policy

**Access to
medicines**

**Quality,
safety and
efficacy of
medicines**

**Quality Use
of Medicines**

**A
responsible
and viable
medicines
industry in
Australia**



Overview

- What are biosimilars?
- Why are they important?
- How are they approved for use and subsidy in Australia?
- Important facts about biosimilars
- Biosimilar Awareness Initiative



What are biosimilar medicines?



Biological and biosimilar medicines come from living cells

Biosimilar medicines are **highly similar**

The effects are the same



Biological Medicine	Reference Biological Brand (sponsor)	Biosimilar Brands (sponsor)	Treats / Class of Medicine	Date of First PBS listed Biosimilar Brand
Epoetin lambda	Eporex® brand of epoetin alfa (Janssen-Cilag)	Novicrit® (Novartis)	Anaemia	01/08/2010 (pre-dated current PBAC approach to advice on 'a' flagging)
Filgrastim	Neupogen® (Amgen)	Nivestim® (Pfizer) Tevagrastim® (Teva Pharma Australia) Zarzio® (Sandoz)	Blood cell support - cancer treatments	01/04/2011 (pre-dated current PBAC approach to advice on 'a' flagging)
Infliximab	Remicade® (Janssen Cilag) 'a' flagged	Inflectra® (Pfizer) 'a' flagged	(bDMARD) Biological disease modifying antirheumatic drugs	01/12/2015
Follitropin alfa	Gonal-F® (Merck Serono Australia)	Bemfola® (Finox Biotech Australia)	Fertility treatment support	01/08/2016
Etanercept	Enbrel® (Pfizer) 'a' flagged	Brenzys® (Merck Sharp & Dohme) 'a' flagged	(bDMARD) Biological disease modifying antirheumatic drugs	01/04/2017



Why are they important?

Improved access for
more patients



More brand options



Savings are reinvested
to improve health care





Regulatory Approval

Therapeutic Goods Administration

How are they regulated?





Decision to Subsidise

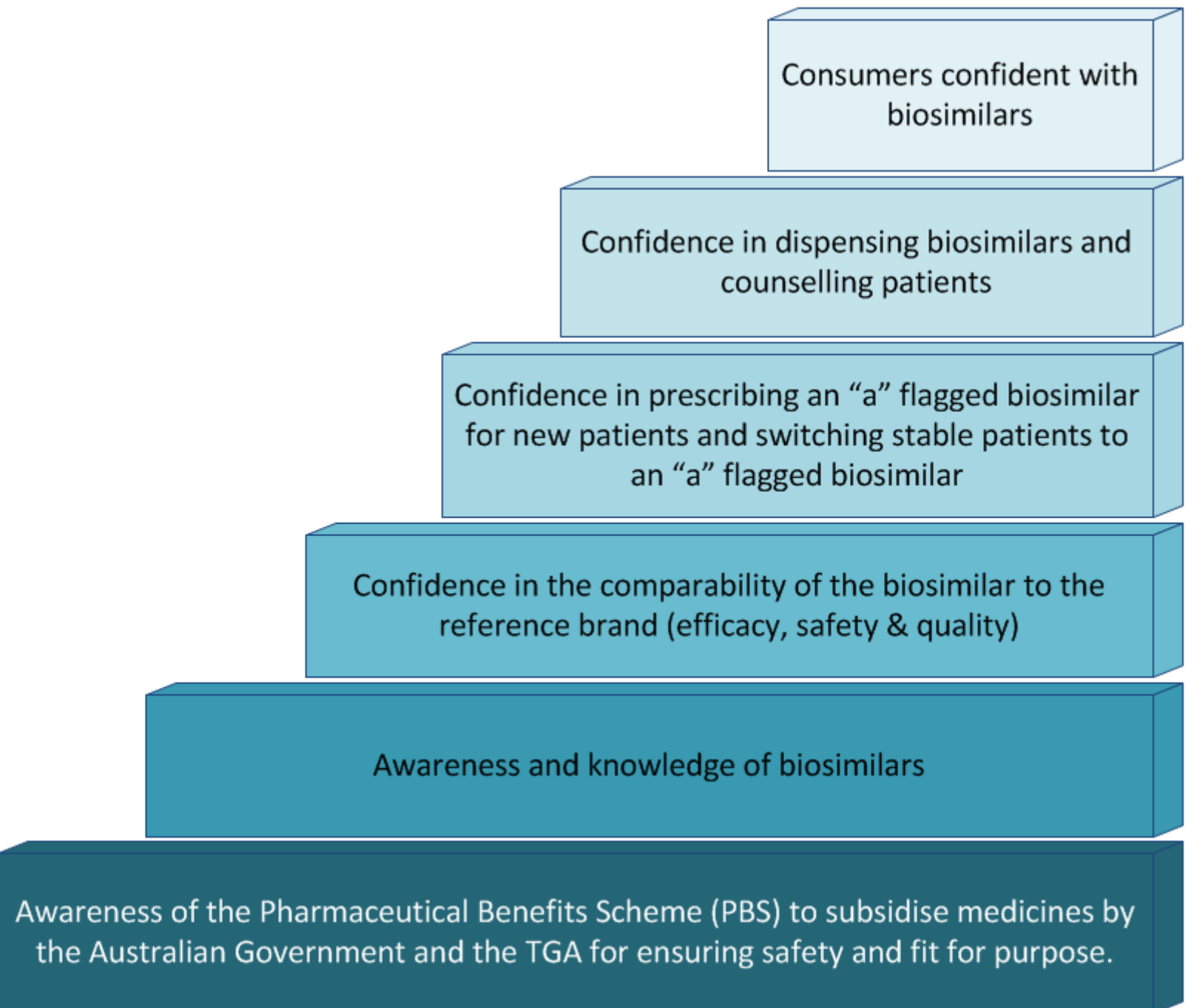
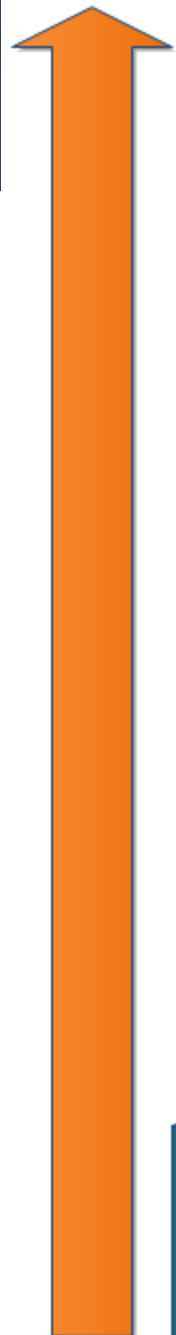
Pharmaceutical Benefits Advisory Committee (PBAC)

- TGA approval is mandatory
- Recommendations to the Minister for Health
- Recommendation and decision on pharmacist substitution is on a case by case basis
- Decisions on PBS listing – Minister for Health/delegate



Important facts

- Extrapolation of indications
- Switching
- Immunogenicity
- Pharmacovigilance





Biosimilar MEDICINES

The Department of Health

Ministers | For Consumers | For Health Professionals | About | Media Centre | Programs & Campaigns | Resources | Ageing & Aged Care

Home | Programs & Campaigns | Programs & Initiatives | Biosimilar Awareness Initiative

Biosimilar Awareness Initiative

The Initiative was announced in May 2015 as part of the Pharmaceutical Benefits Scheme Access and Sustainability Package. The aim of the Initiative is to support awareness of, and confidence in, the use of biosimilar medicines for healthcare professionals and consumers.

Page last updated: 14 December 2016

AT A GLANCE

A biosimilar medicine is highly similar to a 'reference biological medicine'. The reference biological medicine is the first brand to market. Biological and biosimilar medicines are made from one or more active substances that come from living cells.

Biological and biosimilar medicines are used to treat serious diseases such as cancers, diabetes, inflammatory digestive disorders and arthritis.

The introduction of biosimilar medicines encourages competition in our Australian market. This will lead to a reduction in the cost of medicines, resulting in savings to the health care system.

These lower prices improve affordability of, and access to new treatments for seriously ill patients.

Biosimilar medicines are tested in Australia. They are checked for safety and to confirm they provide the same health outcomes as the reference biological medicine.

PROGRAMS & INITIATIVES

- Biosimilar Awareness Initiative
- Information for consumers
- Information for health care professionals
- Abbreviations and definitions
- Research
- Reference Group
- Casemix
- Folate
- Food Regulation System
- Living Organ Donation

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About your biosimilar medicine

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Biosimilar medicines: the basics

INFORMATION FOR HEALTH CARE PROFESSIONALS

- What are biological and biosimilar medicines?
- How are biosimilar medicines developed?
- How is the safety of biosimilar medicines monitored (pharmacovigilance)?
- Is there a difference in health outcomes between the biosimilar medicine and the reference medicine?
- Who chooses whether the biosimilar medicine is used?
- Where can I find more information?

What are biological medicines?

Biological medicines, including live or more active substances that are organisms.

These medicines are used to treat cancers, diabetes, rheumatoid arthritis, multiple sclerosis and influenza as antibodies and Crohn's disease.

Biosimilar medicines are highly similar to an already registered biological medicine. This is because the biological systems used to make the resulting product are also biological medicines, including live cells.

For a biosimilar medicine to be approved, it must be proven to be as safe and effective as the reference medicine, and of critical quality attributes for the function of the molecule.

Biosimilar medicines that are approved have not been assessed to have no clinical and to be therapeutically equivalent biological medicines.

Biosimilar medicines are expected to be more affordable.

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Biosimilar medicines: the basics

INFORMATION FOR CONSUMERS AND CARERS

- What are biological and biosimilar medicines?
- Who uses them and who chooses?
- Why are biosimilar medicines important?
- How are biosimilar medicines assessed and regulated?
- Commonly asked questions about biosimilar medicines.
- Where can I find more information?

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Biosimilar Medicines

Factsheet for Consumers and Carers

Biosimilar etanercept on the Pharmaceutical Benefits Scheme

Listing of etanercept (Enbryo®) on the PBS from 1 April 2017

Enbryo® is a new brand of the Pharmaceutical Benefits Scheme (PBS) medicine etanercept. It is a biosimilar to the reference biological medicine Enbrel® (etanercept) which has been on the PBS since 1999. Enbryo® is a biosimilar to Enbrel® and has been approved for use on the PBS. It is a biosimilar to Enbrel® and has been approved for use on the PBS. It is a biosimilar to Enbrel® and has been approved for use on the PBS.

What is a biosimilar medicine?

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What is etanercept?

Etanercept is a biological medicine that is used to treat a range of inflammatory arthritis, including rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, chronic plaque psoriasis and plaque psoriasis. It is also used to treat Crohn's disease and ulcerative colitis.

What is a biological medicine?

A biological medicine is made from one or more active substances that come from living cells or organisms. Biological medicines are used to treat serious diseases such as cancers, diabetes, inflammatory digestive disorders and arthritis.

Community Pharmacy Dispensing & PBS brand substitution

Enbryo® is the first biosimilar medicine to be approved for use on the PBS. It is a biosimilar to Enbrel® and has been approved for use on the PBS. It is a biosimilar to Enbrel® and has been approved for use on the PBS.

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What is etanercept used for?

Etanercept is used on the PBS to treat severe active rheumatoid arthritis, ankylosing spondylitis, psoriasis, psoriatic arthritis, chronic plaque psoriasis, juvenile idiopathic arthritis, chronic plaque psoriasis and plaque psoriasis. It is also used to treat Crohn's disease and ulcerative colitis.

What is a biological medicine?

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Community Pharmacy Dispensing

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Further information

The Initiative webpage includes a comprehensive literature review and the information materials mentioned in this presentation:

www.health.gov.au/biosimilars

Other information:

- www.tga.gov.au/publication/evaluation-biosimilars

For any further questions - National Medicines Policy section

nmp@health.gov.au



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