Australian Government
Department of Health

Biosimilar
MEDICINES

Biosimilar Medicines

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Coalition of National Nursing & Midwifery Organisations

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National Medicines Policy

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

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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	Eprex® 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

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Why are they important?

Improved access for more patients

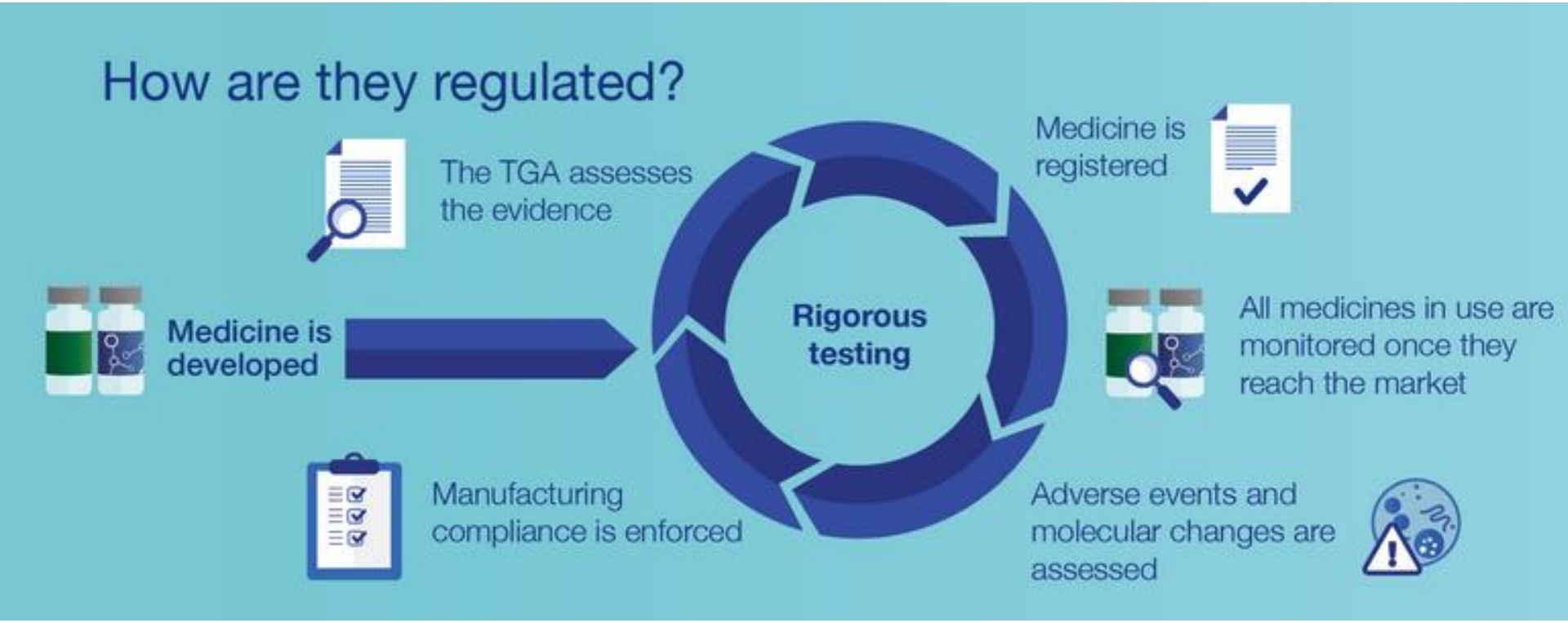
More brand options

Better health care

Savings are reinvested to improve health care

Regulatory Approval

Therapeutic Goods Administration



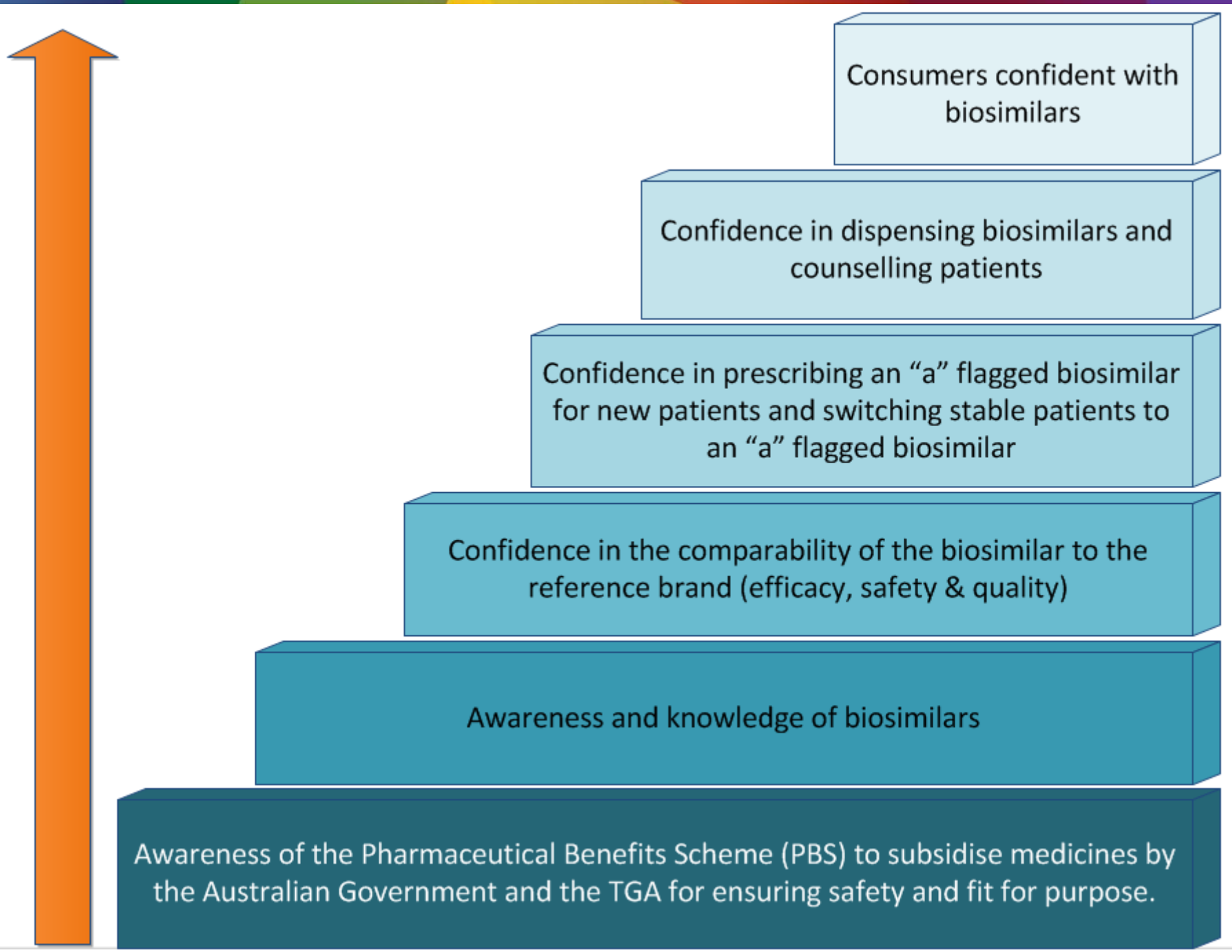
Decision to Subsidise

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


Consumers confident with biosimilars
Confidence in dispensing biosimilars and counselling patients
Confidence in prescribing an “a” flagged biosimilar for new patients and switching stable patients to an “a” flagged biosimilar
Confidence in the comparability of the biosimilar to the reference brand (efficacy, safety & quality)
Awareness and knowledge of biosimilars
Awareness of the Pharmaceutical Benefits Scheme (PBS) to subsidise medicines by the Australian Government and the TGA for ensuring safety and fit for purpose.

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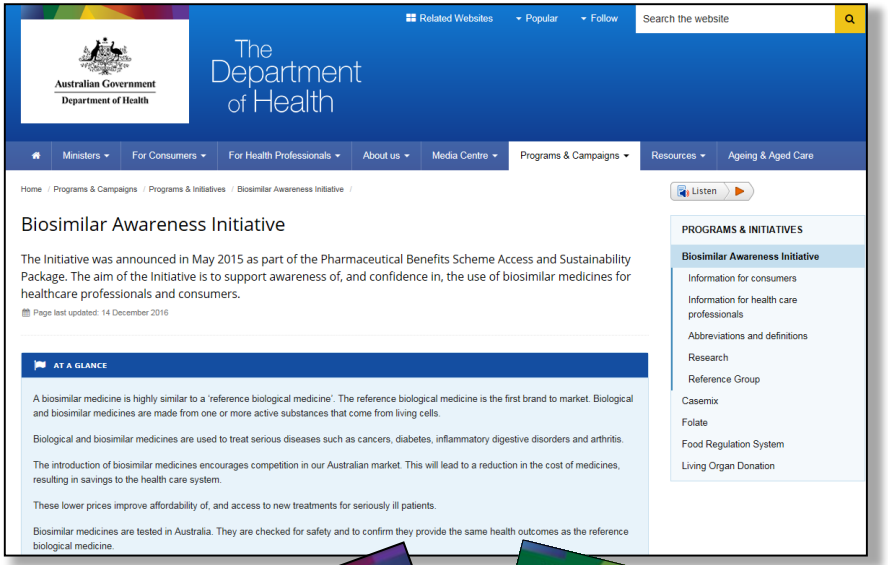

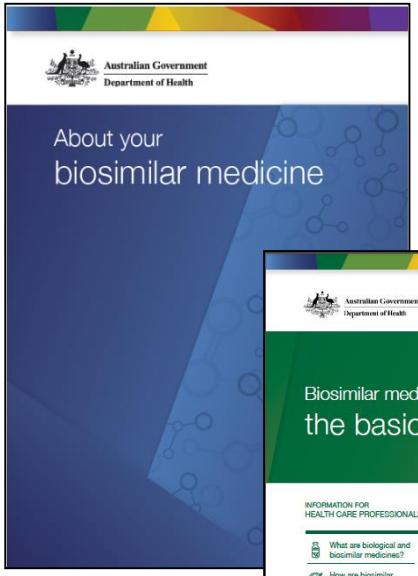

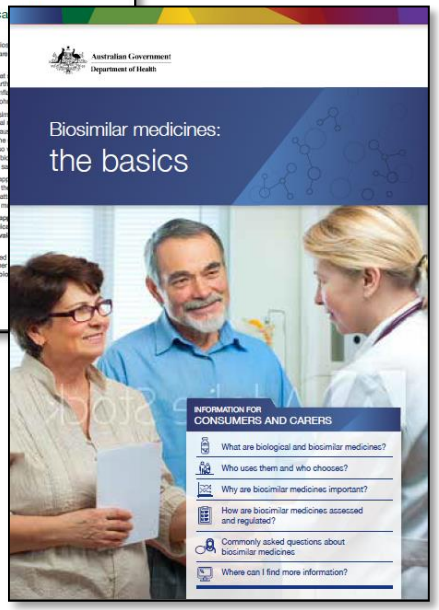

Further information

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

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