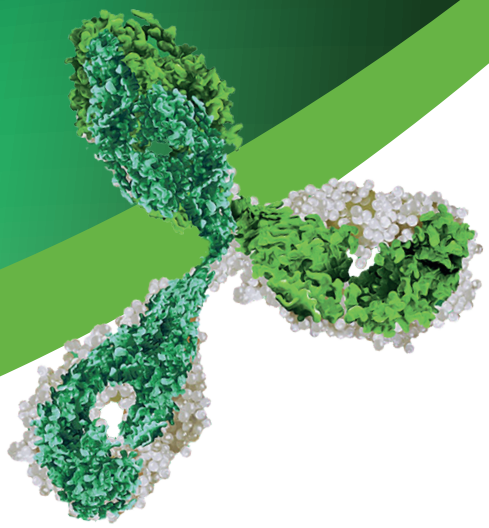
BIOSIMILAR MEDICINES IN AUSTRALIA



FACTSHEET

Health Economics and Sustainability of the PBS

Key points covered in this document

1. Achieving better health outcomes for all Australians through the appropriate use of medicines
2. A competitive market supports the sustainability of the PBS
3. Rising cost pressure on the PBS to continue to fund new, life-changing medicines

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Creating a competitive biological medicine market

Biosimilar medicines have the potential to generate substantial cost savings for the Australian healthcare system through increased market competition, statutory price reductions and price disclosure.[1] In the 2018/19 Budget, the Government estimated that the increased use of generic and biosimilar medicines would lead to a reduction in costs of $335.8 million over five years from 2017.[2]

On receipt of a submission from a biosimilar manufacturer, the **Pharmaceutical Benefits Advisory Committee (PBAC)** may recommend subsidisation for additional therapeutic indications based on reduced costs of existing biological medicines, leading to **greater access to existing biological medicines.**[1,3]

The Government has implemented the following **biosimilar uptake drivers** to increase the use of biosimilar medicines and generate greater market competition:

- Encouraging prescribing of biosimilar medicines for treatment naïve patients.
- Streamlined authority for a simpler and faster approval process for biosimilar medicines versus written authority for reference biological medicines.[3]

Biosimilar medicines have been used worldwide since 2006. They are now used in over 60 countries. **Lower costs and increased access to medicines have been demonstrated internationally.**[4] Following approval in Europe, the arrival of biological medicines for filgrastim triggered a 44% increase in patient access across European nations between 2006 and 2013.[4] By 2020, the use of biosimilar medicines is expected to result in savings of up to €33.4 billion in eight (8) European countries.[4]

Healthcare professional awareness and confidence in biosimilar medicines is vital for increasing their uptake. Initiatives that facilitate their uptake will encourage a competitive biological-medicine market environment.

The High Cost of Biological Medicines

While they have been shown to be cost effective in order to attain public reimbursement, biological medicines nevertheless account for a large proportion of the medicines budget. In 2017-2018, **seven of the ten most expensive Pharmaceutical Benefits Scheme (PBS) medicines were biological medicines**, costing the PBS over $1.5 billion (Table 1).[5]

Table 1. Top 10 PBS Drugs by Highest Government Cost, 2017-18

Rank	Drug name	PBS-subsidised prescriptions	Government cost
1	SOFOSBUVIR + VELPATASVIR	31,047	$695,021,028
2	**ADALIMUMAB**	228,048	**$320,374,082**
3	**AFLIBERCEPT**	239,284	**$304,212,258**
4	LEDIPASVIR + SOFOSBUVIR	10,976	$244,606,914
5	**NIVOLUMAB**	41,839	**$208,068,092**
6	SOFOSBUVIR	10,439	$204,285,271
7	**RANIBIZUMAB**	160,133	**$200,472,514**
8	**DENOSUMAB**	648,197	**$182,104,888**
9	**TRASTUZUMAB**	55,782	**$169,401,131**
10	**INSULIN GLARGINE**	389,177	**$145,203,345**

Adapted from PBS. *Table 5(a): Top 50 PBS Drugs (Generic Name) Sorted by Highest Government Cost, 2017-18.*

BACKGROUND INFORMATION

PBS Access and Sustainability

With rapid developments in expensive modern therapies, it can be difficult to meet the community's expectations regarding subsidised access to all available treatments. Both the effectiveness and cost-effectiveness of treatments need to be considered in making decisions about subsidisation.[6]

New medicines can only be listed on the PBS if they receive a positive PBAC recommendation. The PBAC considers the safety, efficacy and the cost-effectiveness of all medicines when making a recommendation.[7]

The **PBS Access and Sustainability Package,** announced in May 2015, included several initiatives to support access to medicines through the PBS while keeping it sustainable, including pricing reforms, changes to the price disclosure arrangements, and the Biosimilar Awareness Initiative.[8]

A competitive market supports the sustainability of the PBS

Formulary 1 (F1) includes medicines protected by patent (single listed brand). Drugs listed on F1 are subject to statutory price reductions on the fifth, tenth, and fifteenth year anniversary of the date that the drug was listed on the PBS.

Formulary 2 (F2) includes medicines subject to competition (multiple brands available).[9]

When the first competitor brand becomes available (Figure 1, Step 1), the originator brand moves from F1 to F2, undergoes a statutory 25% price reduction (Step 2) and is subject to Price Disclosure (Step 3).[10]

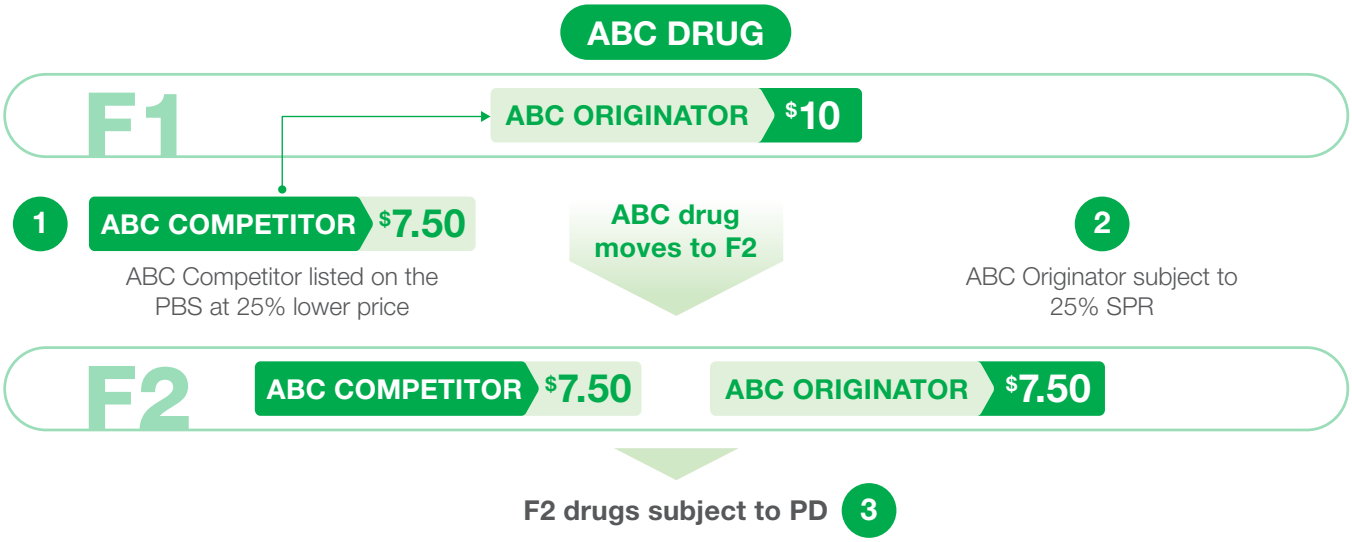


Figure 1. Transition of brands through the PBS. Adapted from Australian Government - Department of Health. *PBS Pricing Forum*, December 2018.[10]

PD, price disclosure; **PBS,** Pharmaceutical Benefits Scheme; **SPR,** statutory price reduction.

Price disclosure helps to ensure the subsidy for PBS medicines **reflects the average price** in the market. All medicines* listed on the F2 formulary are subject to price disclosure whereby all manufacturers of affected products must disclose sales volume and revenue data every six months to the Price Disclosure Data Administrator (PDDA). The PDDA calculates weighted averages for disclosed prices and compares them to the current PBS ex-manufacturer price for brands of each pharmaceutical item. If a price difference of 10% or more is found (or 30% or more for medicines that have been subject to price disclosure for 42 months or more), then a price reduction will occur on the next price reduction day (reduction days occur on 1 April and 1 October each year).[11]

*Some exemptions apply.

Price disclosure in action

Infliximab became subject to price disclosure following the listing of a biosimilar competitor on 1 December 2015. This has led to price reductions each cycle since (Table 2):[12–14]

Infliximab price disclosure reductions for October 2017, 2018 & 2019 cycles

	Average price (April)	Weighted average percentage difference between in-market price and PBS list price	Reduced price (October)
2017	$574.85	11.73%	$507.42
2018	$507.42	11.59%	$448.61
2019	$448.61	28.51%	$320.71

Price refers to the approved ex-manufacturer price (AEMP).

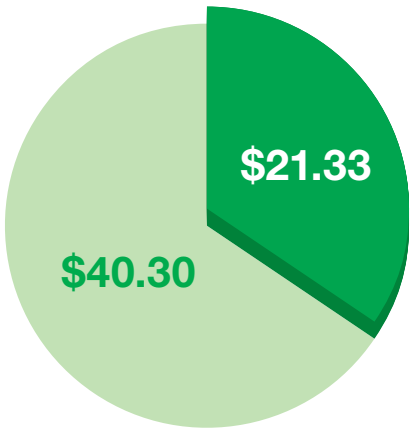
HEALTH ECONOMICS AND THE SUSTAINABILITY OF THE PBS

PBS Pricing Overview

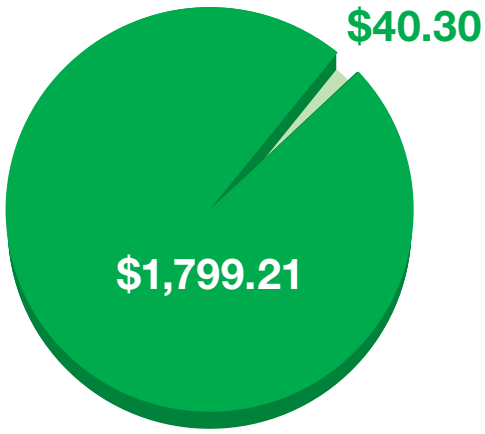
The PBS pays pharmacists the PBS-dispensed price of the medicine, less any patient contribution.[15] Currently, all PBS-subsidised medicines are capped at a maximum cost of $40.30 for general patients, and $6.50 for concessional patients (plus any delivery or after hours fee, brand or therapeutic group premium, or special patient contribution that may be applicable).[16]

Examples of Government subsidies by therapy for general (non-concessional) patients

Asthma & COPD
(fluticasone + salmeterol 250mcg/25mcg inhaler)



Chronic Myeloid Leukaemia
(imatinib 400 mg)



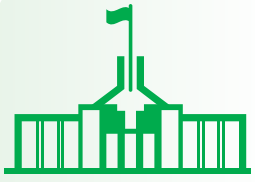
Patient co-payment
Gov't subsidy

Adapted from PBS. *Pharmaceutical Benefits. Fees, patient contributions and safety net thresholds.* 2019.[16]

Cost breakdown for PBS-listed medicines

Patient co-payment (non-concession)

- PBS-dispensed price for medicine (up to $40.30)
- Fee up to $1.23 for recording safety net expenditure
- Optional pharmacy charge of $4.53 or less (total charge cannot exceed $40.30)
- Delivery or after-hours fee, brand or therapeutic group premium, or special patient contribution that may be applicable.



Government subsidy

Any additional cost of medicines exceeding patient co-payments up to the dispensed price

The PBS-dispensed price includes:

- the medicine cost to the pharmacist
- dispensing fees
- an Administration, Handling and Infrastructure fee (AHI fee)
- any other fees the pharmacist is entitled to.[15]

The PBS pricing structure doesn't apply to medicine prices that are less than the general patient contribution.[15]

What fees are pharmacists entitled to?†

Dispensing Fees	
Ready-prepared	$7.39
Dangerous drug fee	$3.11
Extemporaneously-prepared	$9.43
Allowable additional patient charge	$4.53

Administration, Handling and Infrastructure (AHI) Fee	
Medicine cost to pharmacist	**AHI Fee**
< $180	$4.09
$180 to $2,089.71	$4.09 plus 3.5% of the amount by which the price to pharmacists exceeds $180
> $2,089.71	$74.79

Adapted from PBS. Pharmaceutical Benefits. Fees, patient contributions and safety net thresholds. 2019.[16]

†Additional fees dependent on item being dispensed; fee composition per item dispensed will vary.

Working Together for Better Health Outcomes

The National Medicines Policy is based on a partnership with Governments, health educators, health practitioners and other healthcare providers and suppliers, the medicines industry, consumers and the media to **bring about better health outcomes for all Australians,** focussing especially on people's access to, and appropriate use of, medicine.[6]

The PBS represents one of the Government's commitments to achieving this objective. The PBS provides timely, reliable and affordable access to necessary medicines for all Australian residents with a Medicare card.[18]

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