

Key Facts You Need to Know about Generic Medicines in Australia

The Pharmaceutical Benefits Scheme (PBS) is central to the delivery of medicines to all Australians.

The generic medicines sector is an essential part of the PBS providing affordable access to high quality medicines to all Australians irrespective of where they live or their income level.

Structural reforms have delivered significant savings to the PBS BUT changes have cut too deep and will cost Australians more in the long term.

1. Generic medicines are an equivalent choice

- Generic medicines deliver the same effect in the body and health benefit as the original brand.
- Generic medicines meet the same strict government regulatory standards as the original brand.

2. Medicine prices fall when a generic medicine enters the market

- When the first generic medicine equivalent enters the market there is an automatic statutory 16% price reduction. This generates immediate and significant savings to the PBS and the Australian public.
- Generic medicines drive ongoing price reductions via the price disclosure policy, generating further significant savings.

3. Generic medicines have delivered greater PBS savings than expected

- During 2007 – 2017, savings to the PBS are reliably forecast to be \$18 billion, well in excess of the Government forecasts of \$4.9 billion.
- A total of \$4 billion in savings has been realised since 2010. This is twice the original forecasted four year savings of \$1.9 billion.

4. These unplanned PBS savings put at risk a viable generic medicines industry jeopardising patient access to medicines

- Manufacturers are paid less than \$2.00 for many essential medicines listed on the PBS. Today 200 products are supplied at below cost on the PBS risking continued supply to patients.
- In 2012, a year of unprecedented generic medicines launches, the Australian generic medicines sector experienced zero growth. Negative growth is expected for the Australian generic medicines sector in 2013 and beyond. This is due to the current price disclosure policy.

5. A policy that encourages generic medicines dispensing will drive greater PBS savings

- There are 100 million prescriptions dispensed for generic medicines each year in Australia, but by world benchmarks, the figure should be 180 million. If this target was achieved there would be significant savings to the PBS.

6. The Australian government overpays for medicines if invalid patents are not challenged

- Potentially invalid patents are costing the PBS hundreds of millions of dollars. There are more than 20 medicines with patents under active challenge at present.
- A successful challenge to an invalid pharmaceutical patent means an earlier PBS-listing of the generic medicine generating significant savings to government and taxpayers.
 - i. Generic market entry of the medicine clopidogrel (a commonly prescribed life-saving medicine that thins the blood and prevents stroke) was delayed by the presence of a patent that was found to be invalid and revoked in 2010. If this were to occur today, the lost savings to the PBS attributable to the revoked patent has been estimated to be about **\$644 million**.
 - ii. In the case of the medicines venlafaxine and venlafaxine extended-release (commonly prescribed anti-depressants) the total cost to the PBS attributable to an invalid patent that was revoked has been estimated to be about **\$209 million**.
- Current Australian intellectual property law is unbalanced. It rewards originators for defending potentially invalid patents and does not appropriately reward parties that successfully challenge these patents. This imbalance is the subject of the Pharmaceutical Patents Review Report completed in 2013 and the report should be publicly tabled.
- Patent challenges are expensive, costing in excess of \$5 million dollars generally taking five or more years to complete. An unviable generic medicines industry can not challenge potentially invalid patents.

7. Biosimilar medicines offer a solution to the increasing cost of biological medicines

- Biological medicines are of high cost to the PBS and are being increasingly prescribed. Today, three of the top ten highest cost PBS-listed medicines are biological medicines and this will grow to six by 2016.
- A biosimilar medicine is a version of an already registered biological medicine that can drive significant savings to the PBS, given the right policy environment.
- The current PBS system does not enable the quick and efficient listing of biosimilar medicines. Without an efficient biosimilar medicine listing process, government, taxpayers and consumers will continue to pay more for PBS medicines.

8. High regulatory and compliance standards act as disincentives in Australia

- The 'red tape burden' and associated additional costs that pharmaceutical companies face in Australia must be acknowledged and addressed.

A viable generic medicines industry means affordable high quality medicines for patients, savings to government and jobs for Australians.

- The generic medicines industry triggers national growth through manufacturing, productivity, innovation, exports, high-value goods and services and jobs.
- Generic medicines companies in Australia export goods valued at \$390 million a year, in addition to supplying medicines manufactured in Australia to the PBS.
- The generic medicines sector in Australia employs 2800 Australians and more than 60% have tertiary qualifications.
- A viable generic medicines industry in Australia is critical to the Federal Government's aim of ensuring an affordable PBS and this value-add industry remaining in Australia.