



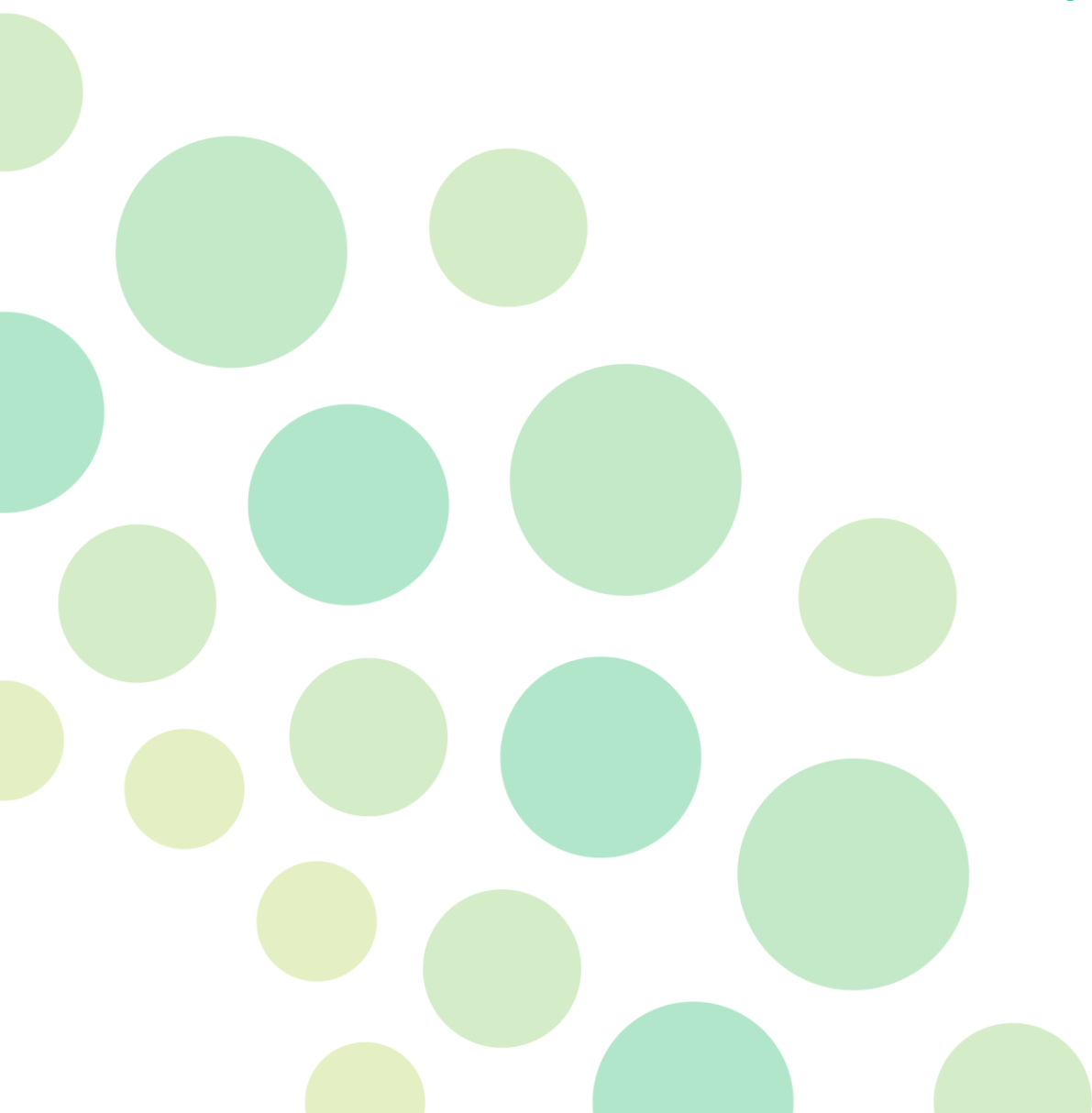
GBMA

Generic and Biosimilar
Medicines Association

Making Medicines Affordable

A Pre-Budget Submission

February 2016



INTRODUCTION

The Generic and Biosimilar Medicines Association (GBMA) welcomes the opportunity to provide this pre-Budget submission to the Treasurer. We understand that in difficult economic times, it is essential to ensure taxpayers are receiving value for money from every dollar spent by the Australian Government.

Australia's National Medicines Policy aims to improve health outcomes for all Australians, focusing especially on people's access to, and wise use of, medicines.

Importantly, the National Medicines Policy is based on central objectives including:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford; and
- maintaining a responsible and viable medicines industry.

This submission will focus on a key area of government expenditure, the Pharmaceutical Benefits Scheme (PBS), making recommendations that support the objectives of the National Medicines Policy highlighted above.

RECOMMENDATIONS

With an ageing population and pressure on the healthcare budget, there has never been a more important time to make medicines affordable.

It is vital to ensure Australian patients have ongoing and reliable access to affordable medicines. This means Australia needs to support the industry that supplies these medicines.

Generic medicines have been a frontline instrument for providing affordable medicines through the PBS. The generic medicines industry has therefore borne much of the brunt of pricing reform in recent years as the Australian Government has sought to make the PBS affordable.

With this in mind, GBMA makes the following pre-Budget recommendations in relation to expenditure through the PBS:

Recommendation 1: Honour the commitments made in the 2015 Strategic Agreement between the Australian Government and GBMA.

Recommendation 2: Commit to no further PBS reform in the 2016/17 Budget.

Recommendation 3: Introduce measures to increase the use of affordable generic and biosimilar medicines.

RECOMMENDATION 1: HONOUR THE COMMITMENTS MADE IN THE 2015 STRATEGIC AGREEMENT BETWEEN THE AUSTRALIAN GOVERNMENT AND GBMA.

In 2015, GBMA (formerly GMiA) signed a Strategic Agreement with the Australian Government to support the ongoing supply of affordable generic and biosimilar medicines in Australia and deliver a five year period of certainty for the industry that provides them.

The Agreement recognises the essential role of generic medicines and biosimilars in delivering affordable healthcare through the PBS. It also recognises the significant savings that continue to be delivered by generic medicines and biosimilars, first by providing competition and then through price disclosure.

The Agreement makes a number of commitments, including that no further price-related changes will be made to the F2 formulary, and that the Department of Health and GBMA will work collaboratively to identify, and resolve quickly, any unintended consequences of budget savings particularly where they may impact on the reliable supply of vital, affordable medicines for Australian patients.

In the 2016 Budget, GBMA is seeking a commitment from the government to honour the commitments made in the Strategic Agreement.

- **Commit to no further price-related changes to F2 formulary**

The greatest impact on PBS affordability has been driven by the price disclosure policy which reduces over time the cost of medicines in the F2 formulary.

The F2 formulary of the PBS is a 'multi-brand formulary'. It contains original brand medicines with expired patents, along with their competing generic brands. Therefore, it is generic medicines that underpin affordability first by introducing competition and then through price disclosure.

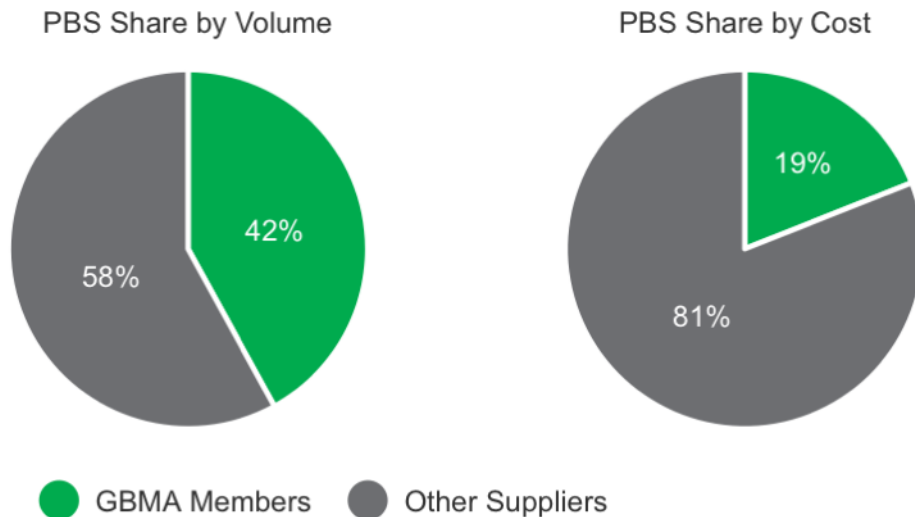
- **Commit to the *sustainability initiative* to support industry**

The generic medicines industry has borne much of the brunt of pricing reform in recent years as the Australian Government has sought to make the PBS affordable, and generic medicines have been a frontline instrument for driving affordability.

Figure 1 shows that GBMA members supply nearly of the volume of PBS medicines dispensed through community pharmacies for only 19% of PBS expenditure. This clearly demonstrates that generic medicines are excellent value for money.

It also demonstrates that a small number of companies are responsible for supplying a significant volume of the medicines Australian patients rely on. Viability of these suppliers is vital in ensuring the ongoing, reliable supply of affordable medicines.

Figure 1: Volume and Cost of GBMA-supplied generic medicines as a % of total PBS medicines dispensed through community pharmacy ¹



The *sustainability initiative* in the Agreement acknowledges the important role of the generic medicines industry, and seeks to support its viability for the future. The fact is, without a thriving generic medicines industry, supply interruptions are inevitable and PBS expenditure will rise as patients are switched to more expensive, patent protected medicines.

- **Commit to the \$20 million biosimilars awareness campaign**

Biological medicines are created by biologic processes, as distinct from medicines that are chemically synthesised, and are used to treat a range of conditions from cancer and diabetes to arthritis and auto-immune diseases. They are expensive, are being increasingly prescribed by doctors and therefore are now the fastest growing segment of PBS expenditure.

When relevant patents have expired, biological medicines can also be marketed by companies other than the company that originally marketed the product. This novel subclass of biological medicines is most commonly known as ‘biosimilars’. A biosimilar is a biological medicine that is comparable in quality, safety, and efficacy to the reference biological medicine.

Biosimilars provide a unique opportunity to help manage the growing costs of biological medicines on the PBS. They offer therapeutically equivalent and more cost-effective alternatives to existing, high-cost biological medicines. This means that savings can be made, or more patients can be treated within the same budget.

¹ Source: Department of Health “Expenditure and prescriptions for 12 months to 30 June 2014.” <http://www.pbs.gov.au/statistics/2013-2014-files/expenditure-and-prescriptions-12-months-to-30-june-2014.pdf>

The government is investing \$20 million over 2015-18 for activities designed to improve awareness and confidence in biosimilar medicines, for health professionals and consumers. Included in the Agreement with GBMA, this financial commitment is essential driving the volume uptake of these medicines and the resulting PBS savings.

RECOMMENDATION 2: NO FURTHER PBS REFORM IN 2016/17 BUDGET

Spending on the PBS represents excellent value for money.

PBS reforms in 2007, 2010, 2013 and more recently the 2015 PBS Access and Sustainability Package (PASP) continue to deliver significant savings to the government that are well beyond the original projections, at around \$25 billion to 2017.

The quantum of these savings demonstrates that the PBS is affordable. Further savings measures are not required nor justified, and will only jeopardise access to essential medicines for patients.

Several factors demonstrate that the PBS trend is towards declining expenditure and support the recommendation for no further PBS reform.

1. The Final Budget Outcome 2014-15 demonstrates PBS expenditure was \$10.322 billion, a reduction from the \$10.351 billion spent in 2013-14. It also demonstrated that in the years 2010-2015, the PBS average annual growth rate was negligible, at 0.69%. This is a remarkable reduction from the 7.87% average annual growth rate during the previous five years.
2. The Productivity Commission puts the cost of the PBS per person at a 10 year low, stating that PBS spending per person fell almost 6 per cent in 2014-15 alone.

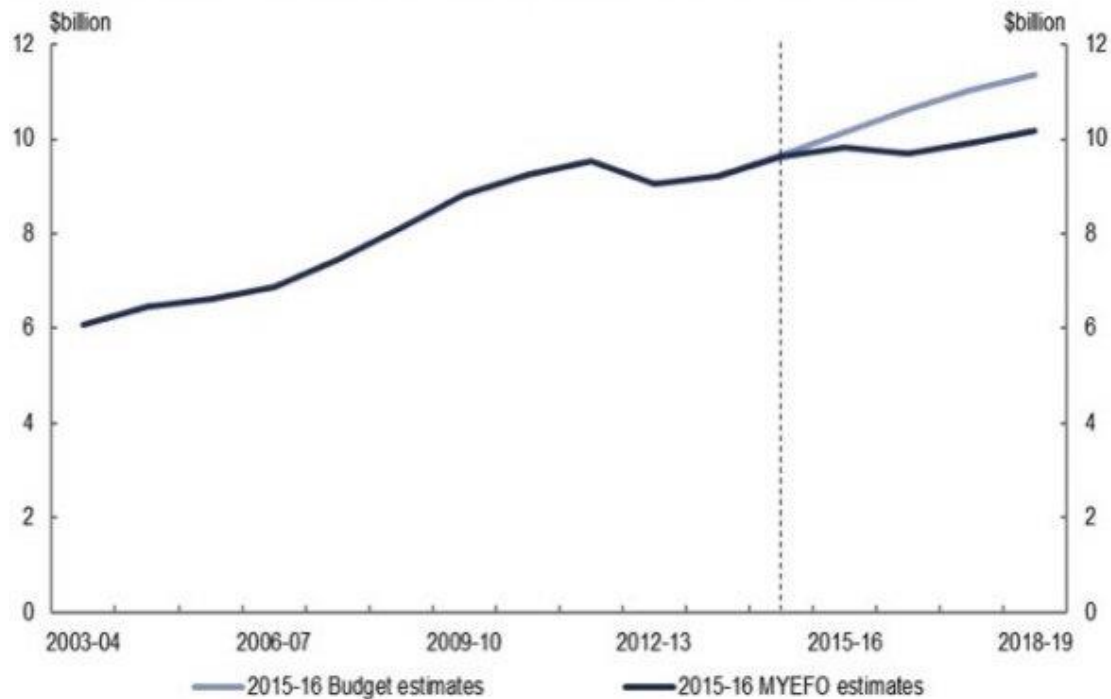
According to the Commission: "Real expenditure on the PBS, which rose relatively steadily from \$6.9 billion (\$337 per person) in 2005-06 to a high of \$7.9 billion (\$350 per person) in 2011-12, decreased to \$7.1 billion (\$299 per person) in 2014-15."²

3. A report by the Parliamentary Budget Office (PBO) in January 2016 shows a \$3.6 billion cut in forecast spending on the PBS over the four years to 2018-19 as shown in Figure 2.

According to the PBO, "Relative to the 2015-16 Budget, policy decisions are expected to decrease spending on the PBS by \$2.0 billion over the four years to 2018-19, largely reflecting the reforms to pricing, access and supply of medicines under the Sixth Community Pharmacy Agreement."

² Source: Productivity Commission Report on Government Services 2016 – Volume E: Health
<http://www.pc.gov.au/research/ongoing/report-on-government-services/2016/health/rogs-2016-volumee-health.pdf>

Figure 2: Downward revision of PBS expenditure estimate to 2018-19, comparing Budget with MYEFO estimate, as reported by the Parliamentary Budget Office ³



The 2016 Budget is the first since the negotiation of the Sixth Community Pharmacy Agreement in and the PASP in 2015. Elements of the PASP are still being implemented and the full impact of these reforms will not be realised for some time. GBMA therefore requests no further PBS reform in the 2016 Federal Budget to allow industry to come to terms with the reform measures.

³ Source: 2015-16 Mid-Year Economic and Fiscal Outlook – charts
http://www.apb.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Budget_Office/Chart_packs

RECOMMENDATION 3: INTRODUCE MEASURES TO INCREASE THE USE OF AFFORDABLE GENERIC AND BIOSIMILAR MEDICINES.

Generic and biosimilar medicines offer excellent value for money. Through price disclosure, the cost of generic and biosimilar medicines decreases over time, while the patient health outcome remains the same. Therefore the cost effectiveness of generic medicines increases over time.

The greatest impediment to the rapid reduction of the PBS list price of generic medicines remains the relatively slow uptake of more affordable generic medicines in the Australian market. GBMA recommends sensible policy changes that will increase the utilisation of generic medicines. This will drive further savings to the PBS through the price disclosure mechanism.

Every time a generic or biosimilar medicine is dispensed across the pharmacy counter, the economy benefits from substantial savings through the price disclosure policy.

The price disclosure mechanism results in the continual lowering of the price of generic medicines listed on the PBS, driving savings to the PBS. It is the generic medicine that drives the important savings, not the original brands post loss of market exclusivity.

Given the regulated nature of the pharmaceutical market, policies that provide the physician, pharmacist and patient a reason to choose the generic brand are absolutely essential.

GBMA recommends policies must be implemented that drive utilisation of the more affordable, high quality, safe and efficacious generic medicines while maintaining the right to choose for prescribers, pharmacists and patients, to ensure the ongoing affordability of the PBS.

In order for Australia to realise all the benefits of biosimilars, a competitive market must be supported by government policy that removes barriers to market entry and encourages uptake.

In addition to the \$20 million initiative to drive awareness, it is important that market uptake drivers are implemented to encourage the use of biosimilars as savings can only be realised if biosimilars are prescribed and dispensed to patients. Significant market entry barriers currently exist in the prescribing and dispensing of biosimilars. These market entry barriers need addressing and GBMA recommends the implementation of uptake drivers for biosimilars.

Recognising the cost to manufacture and register a biosimilar is significantly greater than a chemically synthesised generic medicine, it should follow that biosimilars cannot be expected to deliver the same quantum of savings as chemical generic medicines. In addition, any market competition will take time to develop and thus prudence is necessary when seeking savings. Understanding how the competitive market dynamic will work ensures that the natural barriers in existence can be overcome for entrants.

In allowing this, the government can have confidence that medium term savings can accrue from the biosimilars market.

CONCLUSION

GBMA commits this submission to the Treasurer for consideration and we look forward to working with you to deliver mutually beneficial outcomes, the maintenance of an affordable PBS, the ongoing and reliable supply of affordable medicines and the viability of the industry that supplies them.

ABOUT GBMA

GBMA (formerly the Generic Medicines Industry Association, GMiA) is the national association representing companies that manufacture, supply and export generic and biosimilar medicines. GBMA represents all major generic medicine suppliers in Australia and more than 90% of all generic medicines dispensed in Australia. Members of GBMA ensure all Australians are offered the highest quality generic and biosimilar medicines whilst providing affordable health outcomes that benefit all Australians. Members of GBMA take seriously their role in the responsible provision of affordable medicines in Australia as described in the National Medicines Policy.

The generic and biosimilar medicines sector is a high value-add sector delivering significant health and economic benefits to the Australian public.

The availability of generic medicines in this country helps to deliver:

- Timely access to affordable medicines;
- Substantial savings to the PBS;
- Thousands of highly skilled jobs; and
- Domestic manufacturing and annual exports of around \$300 million.



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