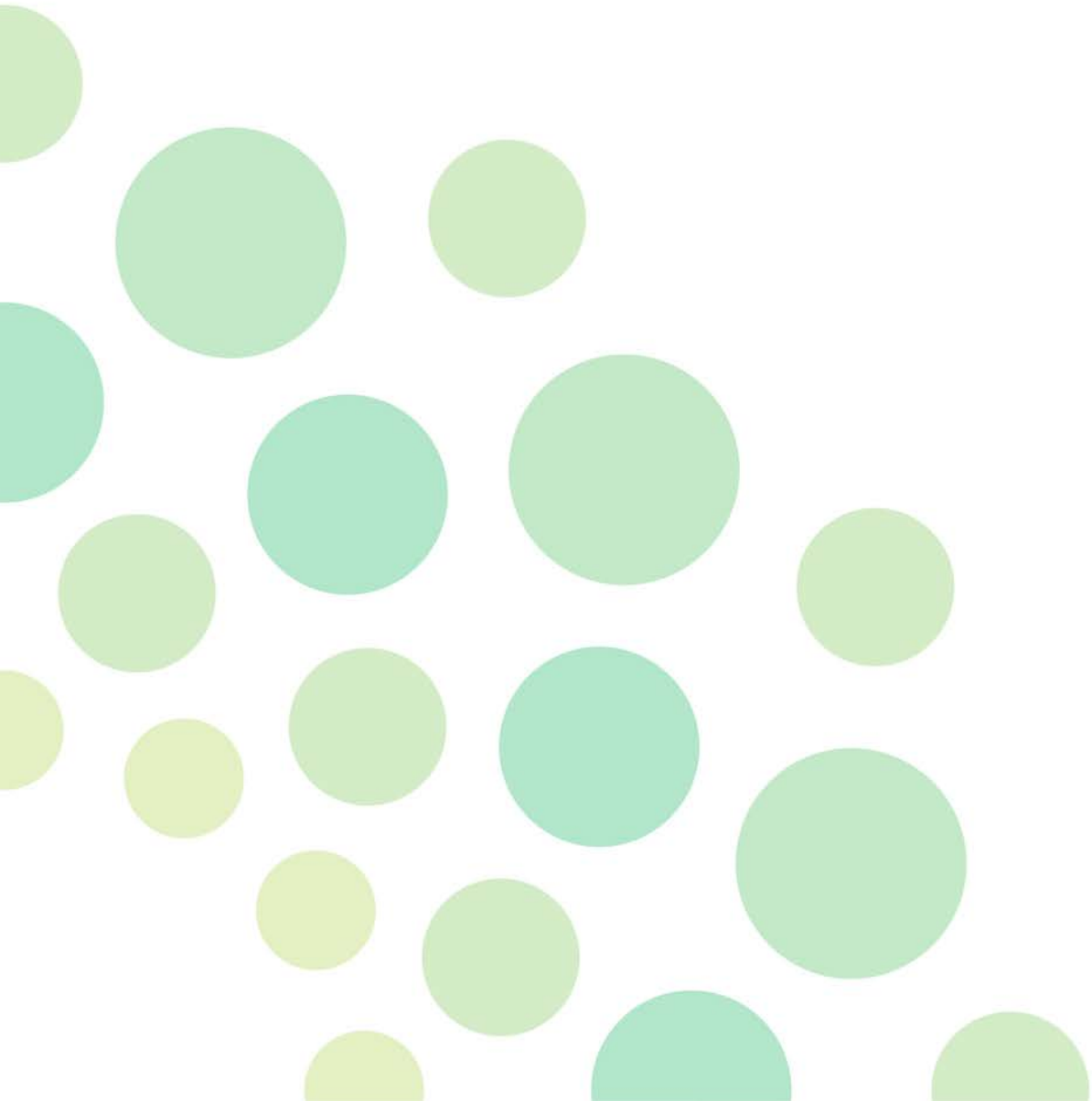
GBMA
Generic and Biosimilar Medicines Association

Making Medicines Affordable

A Pre-Budget Submission

January 2017



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.

MAKING MEDICINES AFFORDABLE

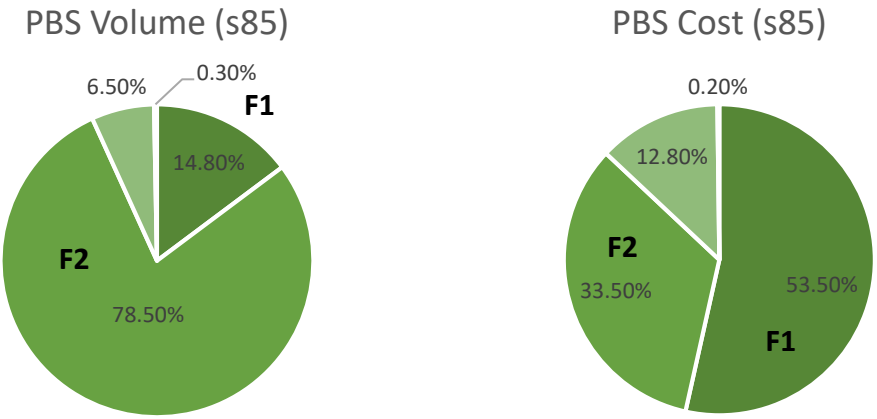
With an ageing population and pressure on the healthcare budget, there has never been a more important time to make medicines affordable.

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

Generic medicines have been a frontline instrument for providing affordable medicines through the PBS, and it is the generic medicines industry that has borne the brunt of pricing reform in recent years as the Australian Government has sought to make the PBS affordable.

Generic medicines are excellent value for money, providing everyday medicines for everyday Australians. The pie graphs below show that generic medicines (in the PBS F2 formulary) account for 78.5% of the volume of PBS medicines for only 33.5% of PBS expenditure.

Figure 1 - Volume and Cost of F2 medicines as a percentage of total PBS medicines dispensed through community pharmacy [1]



Eight out of every ten Australian patients who have a prescription filled at their local pharmacy will be dispensed a medicine from the F2 formulary.

It is important to note that the original brand medicine moves from F1 to F2 upon the listing of the first generic competitor. Data obtained by GBMA from the Department of Health in 2016 shows on average, a 'true generic' (as opposed to the original brand in F2) is dispensed only 60% of the time an F2 medicine is dispensed. This means 40% of prescriptions are being filled with the original brand, even though more affordable generic alternatives are available.

There remains an untapped potential for generic medicine substitution.

Policies to encourage substituting an original brand with a generic will result in direct PBS savings without any loss of benefit for the patient.

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.

The *sustainability initiative* in the 2015 Strategic Agreement between the Australian Government and GBMA acknowledges the important role of the generic medicines industry, and seeks to support its viability for the future. The fact is, without a thriving

[1] Source: Department of Health "Expenditure and prescriptions for 12 months to 30 June 2016." http://www.pbs.gov.au/statistics/expenditure-prescriptions/2015-2016/expenditure-prescriptions-report-2015-16.pdf

generic medicines industry, supply interruptions are inevitable and PBS expenditure will rise as patients are switched to more expensive, patent protected medicines.

RECOMMENDATIONS

GBMA makes the following pre-Budget recommendations in relation to expenditure through the PBS:

Recommendation 1:	Introduce measures to increase the use of generic and biosimilar medicines.
Recommendation 2:	Reform elements of Australia's pharmaceutical intellectual property system to support market entry for affordable generic and biosimilar medicines.

RECOMMENDATION 1

Increasing the use of generic and biosimilar medicines will reduce the cost of health care and deliver the same health outcomes for Australian patients.

A 2017 report from the OECD, *Tackling Wasteful Spending on Health*[2] outlines several strategies to reduce healthcare expenditure, particularly on pharmaceuticals.

Across OECD countries, on average one in every five dollars spent on health is spent on purchasing pharmaceuticals. Therefore ensuring the best health outcome for every government dollar is crucial in reducing ineffective government spending.

Substituting original brand medicines with lower cost, therapeutically equivalent generic medicines offers significant savings to the PBS through price disclosure. Therefore, measures that encourage the increased use of generic medicines support efficient PBS expenditure and reduce wasteful spending.

The OECD report states that polices encouraging the uptake of generic medicines can be grouped into two main categories:

1. policies that aim to support generic medicine market entry and market development; and
2. policies that steer physicians, pharmacists, and patients towards generic medicines.

GBMA supports the implementation of policies in both categories.

GBMA recommends support for the generic medicine market through reform to Australia's intellectual property system as outlined later in this submission. (Recommendation 2)

[2] OECD (2017), *Tackling Wasteful Spending on Health*, OECD Publishing, Paris. http://dx.doi.org/10.1787/9789264266414-en

GBMA recommends physicians should be encouraged to prescribe generic medicines, pharmacists should be encouraged to dispense generic medicines and patients should be encouraged to choose generic medicines.

The table below provides an overview of policies implemented in OECD countries to incentivise the main stakeholders towards the use of generic medicines.

Table 1 – Policy tools to promote use of generic medicines in OECD countries

	Prescription in INN			Generic drug substitution			Incentives to prescribe/dispense/ purchase generics		
	Not allowed	Allowed	Mandatory	Not allowed	Allowed	Mandatory	Incentives for pharmacists	Incentives for patients	Incentives for physicians
Australia		X			X		F	F	-
Austria	X			X			-	NF	NF
Belgium		X		X			NF	F	F&NF
Canada[1]		X[1]	X[1]		X[1]	X[1]	F[1]	F[1]	[1]
Chile			X[2]		X		-	F	NF[2]
Czech Republic		X			X		..	F	F
Denmark		X				X	NF	F	NF
Estonia		X				X	-	NF	NF
Finland		X				X	NF	F	NF
France			X		X		F	F	NF&F
Germany		X				X	NF	F	F
Greece		X			X		-	F	NF
Hungary		X			X		NF	F	F
Iceland					X		..	F	..
Ireland		X			X		NF	F	NF
Italy		X				X	NF	F	NF
Japan		X			X		F	F	[3]
Korea		X			X		F	F	..
Luxembourg		X		X			..	NF&F	NF
Mexico			X		X			F	NF
Netherlands		X			X		F	F	..
New Zealand		X			X[4]		F	F	NF
Norway		X			X		F	F	NF
Poland		X			X		NF	F	-
Portugal			X		X		N	NF&F	N
Slovak Republic		X				X	NF	F	NF
Slovenia			X		X		NF	NF	NF&F
Spain		X				X	NF&F[5]	NF&F	NF&F[5]
Sweden		X				X	NF&F	F	NF
Switzerland		X			X		F	F	-
Turkey		X			X		..	F	-
United Kingdom		X			X		F	-	NF
United States[6]							F[6]	F[6]	-

Note: F=financial incentive; NF=non-financial incentive; ..=information not available. For pharmacists, this table only considers incentives provided by drug coverage schemes. Market incentives (such as rebates from manufacturers, vertical integration, etc) are not reported. Source: OECD Report: Tackling Wasteful Spending on Health, Chapter 4. Reducing ineffective health care spending on pharmaceuticals.

Future savings will come from increased use of biosimilars.

Biological medicines are created by biologic processes, as distinct from chemically synthesised medicines. A biosimilar is a biological medicine that is comparable in quality, safety, and efficacy to the reference biological medicine.

Like the savings generated by generic medicine competition, 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.

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.

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 2015 Strategic Agreement between the Australian Government and GBMA, this financial commitment is essentially driving the volume uptake of these medicines and the resulting PBS savings.

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.

Some policies to increase uptake of generic medicines can also be applied to biosimilars.

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.

RECOMMENDATION 2: IMPLEMENT SENSIBLE INTELLECTUAL PROPERTY REFORM

Using the patent system to delay market entry for generic and biosimilar medicines only benefits the patent holder and imposes unnecessary costs on consumers, the PBS and taxpayers.

Over the last three years, there have been two reports to government that make recommendations to reform Australia's intellectual property system for pharmaceuticals – the Pharmaceutical Patents Review (2013)[3] and the Productivity Commission Report into Intellectual Property Arrangements (2016)[4].

Australia can no longer ignore expert reports that recommend reform to pharmaceutical intellectual property.

The most recent Productivity Report into Intellectual Property Arrangements concludes that Australia's patent system grants exclusivity too readily, allowing a proliferation of low-quality patents, frustrating follow–on innovators and stymieing competition.

In addition, to raise patent quality, the Australian Government should increase the degree of invention required to receive a patent; abolish the failed innovation patents scheme; reconfigure costly extensions of term for pharmaceutical patents; reduce the scope of strategic behaviour (evergreening); and allow manufacture for export.

The OECD report cited earlier states policies to increase availability of generic and biosimilar medicines can reduce ineffective spending on pharmaceuticals. Therefore, removing intellectual property barriers to generic and biosimilar market entry in Australia will improve the efficiency of health care spending and support long-term PBS sustainability.

GBMA supports implementation of the Productivity Commission recommendations that deliver sensible reform to support generic and biosimilar medicine market entry, acknowledge the importance of genuine innovation, and do not contravene Australia's obligations to international trade agreements.

[3] https://www.ipaustralia.gov.au/sites/g/files/net856/f/2013-05-27_ppr_final_report.pdf

[4] http://www.pc.gov.au/inquiries/completed/intellectual-property/report

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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