



*Generic Medicines Industry
Association Pty Ltd*

Making Medicines Affordable

**A submission to the
Senate Select Committee on Health**

September 2014

1. Introduction

The Generic Medicines Industry Association (GMiA) and our members welcome the opportunity to make this submission to the Senate Select Committee on Health. We understand the Committee will inquire into and report on health policy, administration and expenditure. Within the broad scope offered by the Terms of Reference, this submission will focus on a key area of government expenditure, the Pharmaceutical Benefits Scheme (PBS). The PBS is an important area of government expenditure, and is a world-class system that benefits every Australian.

2. About GMiA

GMiA is the national association representing companies that manufacture, supply and export generic medicines. GMiA represents all major generic medicine suppliers in Australia and more than 90% of all generic medicines dispensed in Australia. Members of GMiA ensure all Australians are offered the highest quality generic medicines whilst providing affordable health outcomes that benefit all Australians. Members of GMiA take seriously their role in the responsible provision of generic medicines in Australia.

The generic 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 \$400 million.

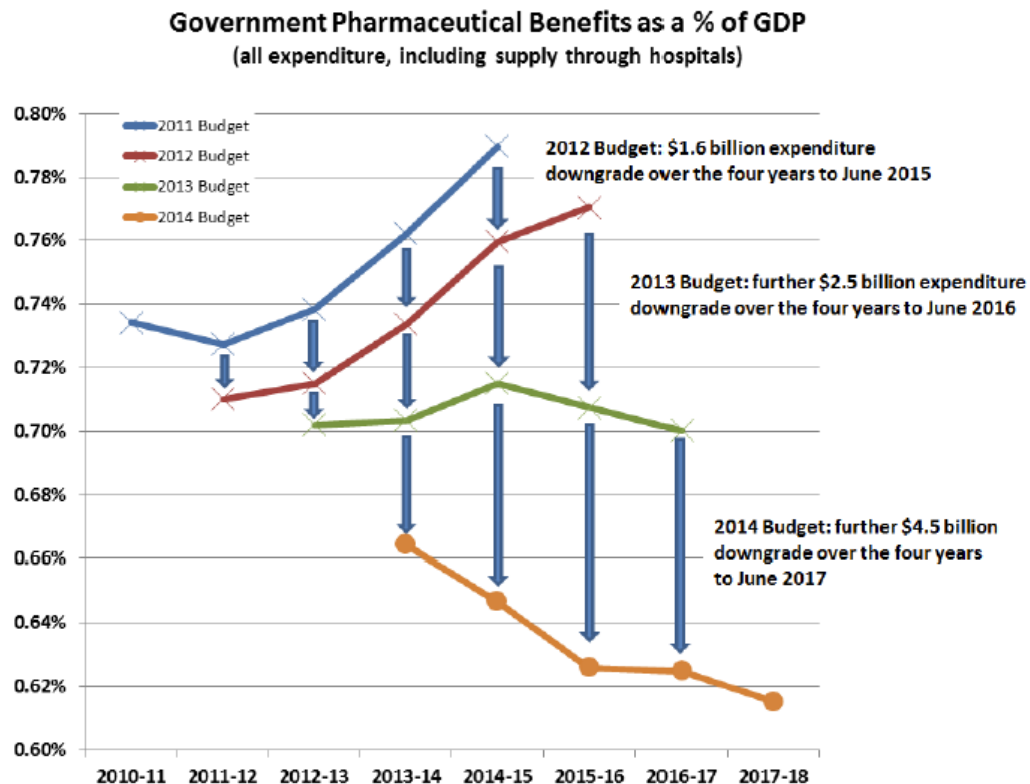
3. Evidence shows the PBS is sustainable

PBS reforms in 2007, 2010 and 2013 continue to deliver significant savings to the government that are greater than expected. The quantum of these savings demonstrates that the PBS is sustainable and further pricing reform is not required.

The 2014 Federal Budget revealed that the PBS will cost \$4.5 billion less from 2013-14 to 2016-17 than was expected in last year's Budget. While \$0.7 billion of this was attributed to increases in co-payments and safety net thresholds to be introduced from January 2015, the remaining \$3.8 billion is a windfall benefit from existing reform and lower than expected growth.

As shown below, these latest forward estimates show that PBS expenditure as a percentage of Gross Domestic Product (GDP) is expected to decline to less than 0.62% by 2017-18.¹

¹ Medicines Partnership of Australia. PBS Scorecard, May 2014.



In addition, a recent report from the Australian Institute of Health and Welfare (AIHW)² confirms that the expenditure on the PBS is in decline. Whilst total health expenditure rose to \$147.4 billion in 2012/13, as a proportion of total government health expenditure, PBS expenditure has fallen from 8.3% to 7.2%.

These greater than expected savings have been delivered as a result of price disclosure – a policy that reduces the price of generic medicines over time. Importantly, price disclosure applies only to the F2 formulary of the PBS and is where all generic medicines are listed. The PBS savings therefore have been delivered by generic medicines through price competition.

It is in this context of delivered savings that recommendations made in the 2014 National Commission of Audit report to overhaul the PBS are not required, must not be implemented and would only destroy the Australian generic medicines industry and jeopardise access to essential medicines for patients.

² Australian Institute of Health and Welfare 2014. Health expenditure Australia 2012–13. Health and welfare expenditure seriesno.52. Cat. No.. HWE 61. Canberra: AIHW

4. Policy change is needed to increase generic medicine utilisation

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. GMiA 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.

We know that every time a generic 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 medicine are absolutely essential.

Recognising the savings that can be realised through generic medicine utilisation, countries across the OECD including the US and the UK, now have policy levers in place to increase their use of generic medicines. No such policy currently exists in Australia. We therefore need policies that genuinely improve patient access to generic medicines and deliver greater savings while maintaining the right to choose for prescribers, pharmacists and patients.

GMiA recommends policies must be implemented that drive utilisation of more affordable, high quality, safe and efficacious generic medicines thus ensuring the ongoing sustainability of the PBS.

5. Biosimilars can help contain the rising cost of biological medicines

Biological medicines are created by biologic processes, as distinct from medicines that are chemically synthesised.

Biological medicines are used to treat a range of conditions, are being increasingly prescribed by doctors and are therefore a rapidly increasing part of PBS expenditure. IMS report data that in 2013, Australia spent about \$1.3 billion (15% of PBS) on biological medicines, up from about \$748 million in 2009 (see figure 1). A review of Department of Health data shows ten of the top sixteen fastest growing PBS expenditure items, when comparing the 2012 and 2013 financial years, are biological medicines (see figure 2).

Figure 1: Expenditure on biological medicines in Australia (Source: IMS, March 2014)

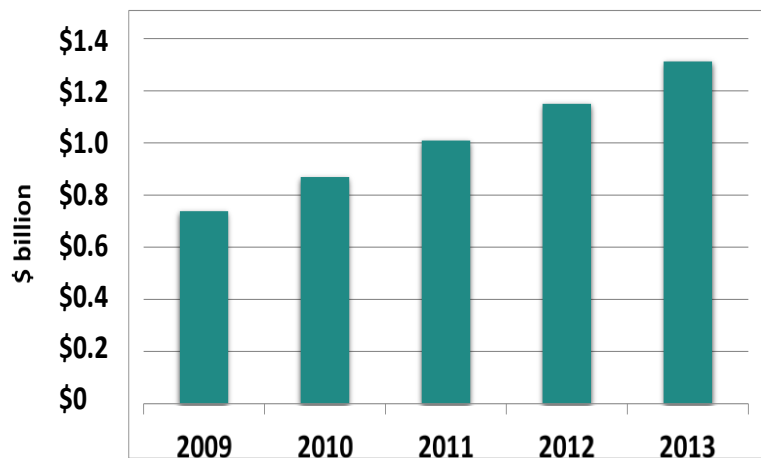


Figure 2: PBS expenditure – Ten of the top sixteen fastest growing PBS expenditure items are biological medicines

Rank	Drug	Year ending Jun 2012				Year ending Jun 2013				Change	
		Volume	Govt Cost \$	Total Cost \$	Ave Price \$	Volume	Govt Cost \$	Total Cost \$	Ave Price \$	Govt Cost \$	%
1	Aflibercept	0	0	0	0.00	30,929	60,508,007	60,851,742	1,967.47	60,508,007	New
2	Fingolimod	14,039	32,182,789	32,494,680	2314.60	34,880	79,919,784	80,719,426	2,314.20	47,736,995	149.33
3	Adalimumab	111,611	198,802,937	201,253,295	1803.17	129,313	229,412,116	232,369,892	1,796.96	30,609,179	15.40
5	Denosumab	26,333	9,043,744	9,326,859	354.19	86,504	31,674,216	32,643,609	377.37	22,630,472	250.23
6	Abatacept	178	308,981	312,234	1754.12	9,751	16,924,588	17,088,608	1,752.50	16,615,608	5377.56
10	Etanercept	72,658	127,752,968	129,177,843	1777.89	78,790	138,332,029	139,930,070	1,775.99	10,579,061	8.28
11	Golimumab	18,283	32,106,980	32,499,814	1777.60	24,099	42,300,533	42,838,720	1,777.61	10,193,553	31.75
14	Nilotinib	1,646	9,076,866	9,102,137	5529.85	3,398	17,644,016	17,707,801	5,211.24	8,567,150	94.38
15	Dasatinib	2,312	12,325,553	12,368,807	5349.83	3,971	20,200,110	20,278,641	5,106.68	7,874,556	63.89
16	Ustekinumab	3,241	20,452,873	20,539,074	6337.26	4,509	28,221,014	28,342,804	6,285.83	7,768,141	37.98

Department of Health, Table 8a, "Expenditure and prescriptions for 12 months to 30 June 2013"
<http://www.pbs.gov.au/statistics/2012-2013-files/expenditure-and-prescriptions-12-months-to-30-06-2013.pdf>

A biosimilar is a biological medicine that is comparable in quality, safety, and efficacy to the reference biological medicine and has been evaluated by the TGA according to their guidelines and other relevant EU guidelines adopted by the TGA.³

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.

³ TGA - <http://www.tga.gov.au/industry/pm-argpm-biosimilars-01.htm>

GMiA recommends government create a separate formulary for biological medicines (F3) that better reflects the competitive dynamics currently in play. A prerequisite for entry into this formulary is that registration has been secured through the TGA's Similar Biological Medicinal Products pathway.

In the future, should regulators and the government determine that biological medicines can be considered substitutable, then subsequent listing within F2 would be practical, given that competitive dynamics similar to chemical generic medicines would then be established.

6. Conclusion

We look forward to working with you to deliver mutually beneficial outcomes and the maintenance of a sustainable PBS, as an important cornerstone of health policy and healthcare expenditure in Australia.