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Growth in expenditure on high cost drugs in Australia

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Social Policy Section

Executive summary

- Despite an overall slowing of growth in expenditure on the Pharmaceutical Benefits Scheme (PBS), the section 100 (s 100) program is showing rapid rates of growth.
- The s 100 program provides pharmaceuticals to those living in isolated areas and for the treatment of complex conditions that require specialist monitoring.
- A number of programs make up the s 100 program. Those with high growth rates include:
 - Expenditure on the Efficient Funding of Chemotherapy is the fastest growing s 100 program with an average annual growth rate of 62.61% from 2009–10 to 2013–14.
 - The Highly Specialised Drugs Program grew at a rate of 6.38% for the same period.
- Although not part of the PBS, the Life Saving Drugs Programme provides access to a limited number of expensive drugs for rare diseases. This programme grew at a rate of 12.68% from 2009–10 to 2013–14.
- The s 100 and LSDP programs provide access to high cost drugs to treat a range of diseases including cancers, HIV/AIDS, Alzheimer's diseases and a number of rare and life threatening conditions. Patients are protected from the true cost of these drugs.
- Given predictions about the increasing rates of diseases such as cancer and Alzheimer's disease, it is likely that expenditure on these medicines is likely to continue to rise as more people require treatment. As a general rule, new drugs are usually more expensive than existing treatments.
- One of the objectives of the National Medicines Policy is timely access to medicines that Australians need, and at cost the community and individuals can afford. Examination of the expenditure on high cost drugs is warranted to ensure that this policy objective is met.

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Introduction

The Pharmaceutical Benefits Scheme (PBS) is one of the defining features of the Australian health care system. The Government subsidises the cost of a wide range of prescription medications to all Australian residents (who hold a Medicare card). Consumers pay a set price (currently \$36.90 for general patients and \$6.00 for concession card holders) and are protected from high costs by safety net arrangements. The majority of medicines on the PBS are dispensed through community pharmacies, but some medications are only available through hospitals.

Governments of all persuasions have kept a close watch on growth in the Pharmaceutical Benefits Scheme (PBS). In the ten years between 1994–95 and 2004–05, the cost of the PBS grew by nearly 13% each year.¹ Growth has slowed since then but nevertheless, the average annual growth rate on the PBS from 2005–06 to 2013–14 has been around 4.86%.² More recently, expenditure has slowed; the Parliamentary Budget Office predicts that in the medium term it will level out at 0.3% per annum.³ The Government expects that growth will average around 4–5% per annum in the longer term.⁴ The slowing of growth in PBS expenditure has been attributed, in part, to the impact of various pricing policies and changes to the co-payment and safety net arrangements introduced in 2005.⁵

Section 85 (s 85) of the *National Health Act 1953* (the *NH Act*) deals with medicines that are mainly dispensed through community pharmacies, such as those medicines often prescribed by general practitioners (GPs). Medicines provided under s 85 include commonly used drugs, such as those used for the treatment of high blood pressure, high cholesterol, infections, diabetes, asthma, depression and mental health conditions. The majority of expenditure on the PBS is provided under s 85 of the Act.

Despite the trend towards contraction in growth of PBS spending overall, there are a number of PBS programs which are showing above average rates of growth. Most notably, the Efficient Funding of Chemotherapy (Chemotherapy) program had an average annual growth rate of 62.61% from 2009–10 to 2013–14.⁶ Further, the Highly Specialised Drug Program (HSDP) grew at an annual rate of 6.38% over the same period.⁷ This increase was noted in a recent report of trends and drivers of growth in the PBS by the Department of Health and by Medicines Australia.⁸ The report suggested that expenditure in these programs was largely unaffected by the changes to co-payment introduced in 2005.⁹

Both of these programs are part of what is known as the Section 100 (s 100) program. This part of the *NH Act* gives the Minister power to make special arrangements for the provision of medicines for people with special circumstances, for example, people living in isolated areas or those receiving treatment for complex conditions.

For a drug to be listed on the PBS it must be clinically and cost effective. However, some drugs used in the treatment of rare diseases do not meet both these criteria. While these medicines may be clinically effective, they are prohibitively expensive and rarely cost effective. The Life Saving Drugs Program (LSDP) provides financial assistance to patients who require expensive and ‘life saving’ drugs not listed on the PBS.¹⁰ Ten products which treat seven rare and life threatening diseases are available through this program. Patients, who must meet strict eligibility guidelines, are reviewed every six months.

The overarching policy framework for the provision of medicines in Australia is the National Medicines Policy.¹¹ One of the objectives of this policy is ‘timely access at a cost the community and individual can afford’. This has meant that drugs which are expensive and typically unaffordable for most Australians have been available

1. Department of Health (DoH), [‘About the PBS: managing the cost of the scheme’](#), PBS pages, accessed 26 August 2014.
2. See Table 2. Calculations based on [PBS expenditure and prescriptions reports](#) between June 2005 and June 2014, Table 1(a).
3. Parliamentary Budget Office, [Projections of government spending over the medium term](#), Report 02/2014, Canberra, 2014, p. 34, accessed 25 September 2014.
4. Senate Community Affairs Legislation Committee, [Official committee Hansard](#), 22 October 2014, p. 85, accessed 4 November 2014.
5. Department of Health and Ageing (DoHA) and Medicines Australia (MA), [Trends in and drivers of Pharmaceutical Benefits Scheme expenditure report](#), Report for the Access to Medicines Working Group, May 2013, p. 10, 17, accessed 26 August 2014.
6. See Table 1. Calculations based on [‘Table 12: PBS Other—summary of direct payments and advances’](#). ‘Expenditure and prescriptions twelve months to 30 June 2013’, op. cit., p. 17 and [‘Table 15: PBS Other—summary of direct payments and advances’](#), ‘Expenditure and prescriptions twelve months to 30 June 2014’, op. cit., p. 20, accessed 5 November 2014.
7. Ibid.
8. DoHA and MA, [Trends in and drivers of Pharmaceutical Benefits Scheme expenditure report](#), op. cit., p. 14–15.
9. Ibid., p. 14.
10. DoHA, [Annual report 2012–13](#), Volume 1, p. 67, accessed 26 August 2014.
11. DoH, [National medicines policy](#), accessed 6 November 2014.

through the PBS and/or the LSDP. As an example, the cost of one of the drugs used in the treatment of pancreatic and breast cancer ranges from \$1306.56 to \$2618.04 per 100mg vial.¹² There is limited publicly available information about the costs of medicines listed on the LSDP, but the 2011–12 Budget papers noted that the combined cost of two drugs listed on the LSDP over five years was estimated to be around \$4.2 billion.¹³ The cost to Government of products listed under s 100 is publicly available through the *Schedule of Pharmaceutical Benefits*, which is published online.¹⁴

Although there is no definition of what constitutes a ‘high cost’ drug in Australia, for the purposes of this paper, high cost drugs have been defined as are those funded through the s 100 program and LSDP. The paper provides an overview of the expenditure of high cost drugs in Australia and examines the average annual growth of these programs.¹⁵ The outlook for expenditure on high cost medicines and possible policy responses is also considered.

Section 100

Section 100 of the Act provides that the Minister:

...may make special arrangements for, or in relation to, providing that an adequate supply of pharmaceutical benefits will be available to persons:

- (a) who are living in isolated areas; or
- (b) who are receiving treatment in circumstances in which pharmaceutical benefits (other than those to which subsection (1A) applies) are inadequate for that treatment; or
- (c) if the pharmaceutical benefits covered by the arrangements can be more conveniently or efficiently supplied under the arrangements.¹⁶

A number of programs are funded under s 100. These include:

- Highly Specialised Drug Program
- Efficient Funding of Chemotherapy
- Botulinum Toxin Program
- Growth Hormone Programme
- IVF/GIFT program
- Opiate Dependence Treatment Program¹⁷

The largest s 100 program is the HSDP. This funds high cost drugs for the treatment of complex conditions that require hospital specialist management or continuing specialist monitoring. These include HIV/AIDS, hepatitis, cancers, severe and chronic arthritis, osteoporosis and organ transplants (including the long term use of immunosuppressive agents). These medicines are only available under the clinical management of hospital-based specialists with local management by GPs. The majority of expenditure on the HSDP occurs in public

12. DoH, Section 100 – items available under special arrangement, ‘[Paclitaxel nanoparticle albumin bound](#)’, PBS website, accessed 19 November 2014. The price differs according to the type of cancer being treated.

13. Australian Government, *Budget measures: budget paper no. 2: 2011–12*, p. 221. The addition of Soliris (eculizumab) was estimated to cost \$135.9 million over five years. Although the alternative arrangements for the supply of Fabrazyme (agalsidase beta) delivered a saving to Government, they were estimated to cost \$4.2 million over five years.

14. DoH, ‘[Section 100 – items available under special arrangement](#)’, PBS website, accessed 19 November 2014. Note that the cost to Government is the DPMQ price.

15. Note that medicines available under s85 are not considered in this paper.

16. [National Health Act 1953](#), Part VII, Pharmaceutical benefits, Division 5, section 100, accessed 2 September 2014.

17. DoH, ‘[Section 100 – items available under special arrangement](#)’, PBS pages, accessed 2 September 2014. Note that the Botulinum Toxin Program is for non-cosmetic use and IVF/GIFT refers to In Vitro Fertilisation (IVF) and Gamete Intra Fallopiian Transfer (GIFT).

hospitals.¹⁸ HSDP prescriptions are supplied through hospital and community pharmacies. Patients are required to pay a contribution to the supply of each highly specialised drug.¹⁹

Overview of S 100 expenditure

Average annual growth of s 100 programs since 2005–06 has been 13.39%.²⁰ More recently, from 2009–10 to 2013–14, average annual growth has been 13.48%.²¹

During that time, the highest rate of growth occurred in the Chemotherapy program, at 62.61%.²² From 2011–12 to 2012–13, expenditure on this program more than doubled, from \$222.5 million to \$478.9 million. Recently, however, it has slowed.²³ It is outside the scope of this paper to speculate on the reasons for this growth but possible explanations include the listing of newer, more expensive drugs with associated high uptake by clinicians, changing patterns to the diagnosis and treatment of disease and consumer expectations and preferences. Remuneration to pharmacists for the dispensing of chemotherapy drugs also contributes to overall expenditure.

Changes to the remuneration of chemotherapy drugs administered by infusion or injection came into effect on 1 December 2011. These were designed to achieve ‘greater efficiency’ by reducing wastage and delivering savings to Government.²⁴ Previously, approved suppliers or pharmacies were paid according to the number of vials of a s 100 drug used, rather than the amount of drug actually dispensed (for example, a patient requires 30ml but the drug is only available in 20ml vials). Now, payment is for the combination of vials that most cost efficiently comprise the required patient dose.²⁵ Patients only pay the PBS co-payment on the original prescription and are not charged for repeats.²⁶

The new chemotherapy remuneration arrangements have only been in place for two years, so it is premature to assess their effectiveness. A recent review of the funding arrangements for chemotherapy services did not attempt to comment on whether wastage had been reduced or if the predicted savings to Government had been achieved (\$85.2 million over five years).²⁷

Average annual growth in the HSDP has been around 6.38% from 2009–10 to 2013–14.²⁸ A longer time series shows an average annual growth rate of 10.63% (2005–06 to 2013–14).²⁹ Other s 100 programs showing strong rates of growth from 2009–10 to 2013–14 include the Opiate Dependence Treatment Program (9.28%), Botulinum Toxin Program (including Dysport) (10.81%) and the Continuing Medication Program which assists people who are homeless and require assistance with accessing PBS medications (18.92%) (listed as ‘Other’ in Table 1).³⁰

18. DoHA and MA, [Trends in and drivers of Pharmaceutical Benefits Scheme expenditure report](#), op. cit., p. 40.

19. This varies according to where the drug is dispensed. For example, the contribution rate for general patients who receive these drugs as outpatients in public hospitals is \$29.50 (effective 1 January 2014). For further information see DoH, [‘What are the current fees and charges’](#), PBS pages, accessed 22 September 2014.

20. See Table 2.

21. See Table 1. A separate calculation was made for 2009–10 to 2013–14 as there were revisions to the data. See note accompanying Table 1.

22. See Table 1.

23. A number of expensive drugs were listed on the PBS during this time. See, for example, T Plibersek (Minister for Health and Ageing), [Statement from Tanya Plibersek on listing of PBS Drugs](#), media release, 23 June 2013, accessed 23 September 2014 and P Dutton (Minister for Health and Minister for Sport), [New medicines available through the PBS](#), media release, 28 October 2013, accessed 23 September 2014.

24. DoH, [‘Revised arrangements for the efficient funding of chemotherapy drugs and streamlined authority data capture’](#), PBS pages, accessed 2 September 2014.

25. Ibid. Note that remuneration to pharmacists contributes to the overall cost of the PBS.

26. Ibid.

27. DoH, [‘Report to the Minister for Health: review of the funding arrangements for chemotherapy services’](#), DoH, October 2013, accessed 19 November 2014. This measure was announced as part of the 2010–11 Budget, see Australian Government, [Budget measures: budget paper no. 2: 2010–11](#), p. 253, accessed 22 September 2014.

28. See Table 1.

29. See Table 2.

30. As advised by DoH via email on 28 August 2014. The Continuing Medication Program assists people who are homeless and require assistance with accessing PBS medications. The PBS co-payment is reimbursed to eligible organisations which purchase PBS medications on behalf of their clients. Sixteen organisations across Australia have been approved to provide this service. For further detail, see Australian Healthcare Associates, [Final report: review of the existing supply and reimbursement arrangements for drugs listed under S100 of the National Health Act 1953](#), February 2010, pp 113–114, accessed 22 September 2014.

The Botulinum Toxin Program subsidises the full cost of botulinum toxin to eligible patients, in specific circumstances, for the treatment of cerebral palsy, stroke, chronic migraine and urinary incontinence, see Department of Human Services, [Botulinum Toxin program](#), Medicare pages, accessed 15 December 2014.

Table 1 shows the average annual growth rates of PBS programs not funded by s 85 (standard medications) from 2009–10 to 2013–14. This time series was chosen as the revisions have been made to previously published data and may not be directly comparable to earlier years.³¹ For the purposes of this paper, only expenditure on the HSDP and total expenditure on s 100 is considered in detail. If predictions about future incidence and prevalence of diseases such as Alzheimer’s disease and cancer are correct, these programs will continue to show strong rates of growth. For example, the Australian Institute of Health and Welfare (AIHW) predicts that the incidence of cancer will increase by 40% in the period from 2007 to 2020.³² Many of the drugs used in the treatment of cancer are part of the s 100 program.

Table 1: expenditure by year ending June 2010, 2011, 2012, 2013 and 2014 for selected PBS programs not funded by s 85 (\$ millions)

	2009–10 \$ m	2010–11 \$ m	2011–12 \$ m	2012–13 \$ m	2013–14 \$ m	Average annual growth (%)
Highly specialised drugs	858.5	946.7	939.6	1,013.30	1,099.50	6.38
Safety net card issue fees	8.5	8.9	9.1	9.6	10	4.15
Drs Bag items	15	15.6	13.4	15.3	19.1	6.23
Opiate Dependence Treatment Program	33.1	36.9	39.7	42.6	47.2	9.28
Special Authority Program	81.7	77.3	78.2	83.1	96.6	4.28
Chemotherapy	83.8	94.8	222.5	478.9	585.9	62.61
Aboriginal health services (GST exclusive)	38.1	43	48.6	41.3	43.1	3.13
Botulinum Toxin Program (including Dysport)	12.8	13.6	14.8	16.3	19.3	10.81
Paraplegic and Quadriplegic Program	0.5	0.6	0.6	0.5	0.5	0.00
In vitro fertilisation	75	70.7	79.2	82.9	85.5	3.33
Human growth hormones	25.3	27.4	27.9	28.6	26.9	1.54
Other	0.1	0.1	0.1	0.2	0.2	18.92
Total	1,232.40	1,335.50	1,473.70	1,812.60	2,033.90	13.34
Total s 100	1,208,914,172	1,379,163,153	1,703,306,489	1,787,690,086	2,004,744,608	13.48

Note 1: HSD and Chemotherapy data for 2012–13 may not be comparable to previously published data due to changes in data collection procedures and drug allocation processes. Where there have been changes, data for previous years have also been revised to present a consistent time series. The revised data reflects current definitions of Section 100 programs as published on pbs.gov.au.

Note 2: Expenditure figures refer to payments made through Department of Human Services and directly from the Department of Health.

Note 3: Total Section 100 is the combined total of expenditure on the Highly specialised drugs, Chemotherapy, Botulinum, Human growth hormones, IVF/GIFT programs and the Opiate dependence treatment program.

Source: [Table 12: PBS Other - Summary of direct payments and advances, Department of Health, PBS expenditure and prescriptions twelve months to 30 June 2009 to 2014](#)

Notwithstanding any caveats about the revisions to the data from 2009–10 to 2013–14, a longer time series shows sustained growth in the HSDP and total expenditure on s 100 programs. When compared against growth in the overall PBS, it is clear that these programs are growing at a much higher rate than s 85 expenditure. See Graph 1. Table 2 shows the average annual growth rates for selected PBS programs for the same period.

31. DoH, ‘[PBS expenditure and prescriptions to 30 June 2013](#)’, op. cit., p. 17. PBS website, accessed 4 September 2014.

32. Australian Institute of Health and Welfare (AIHW), [Cancer incidence projections: Australia, 2011–2020](#), Cancer series no. 66, AIHW, Canberra, 2012, p. viii, accessed 22 September 2014.

Graph 1: average annual growth rates (%) for selected PBS programs from 2005–06 to 2012–13

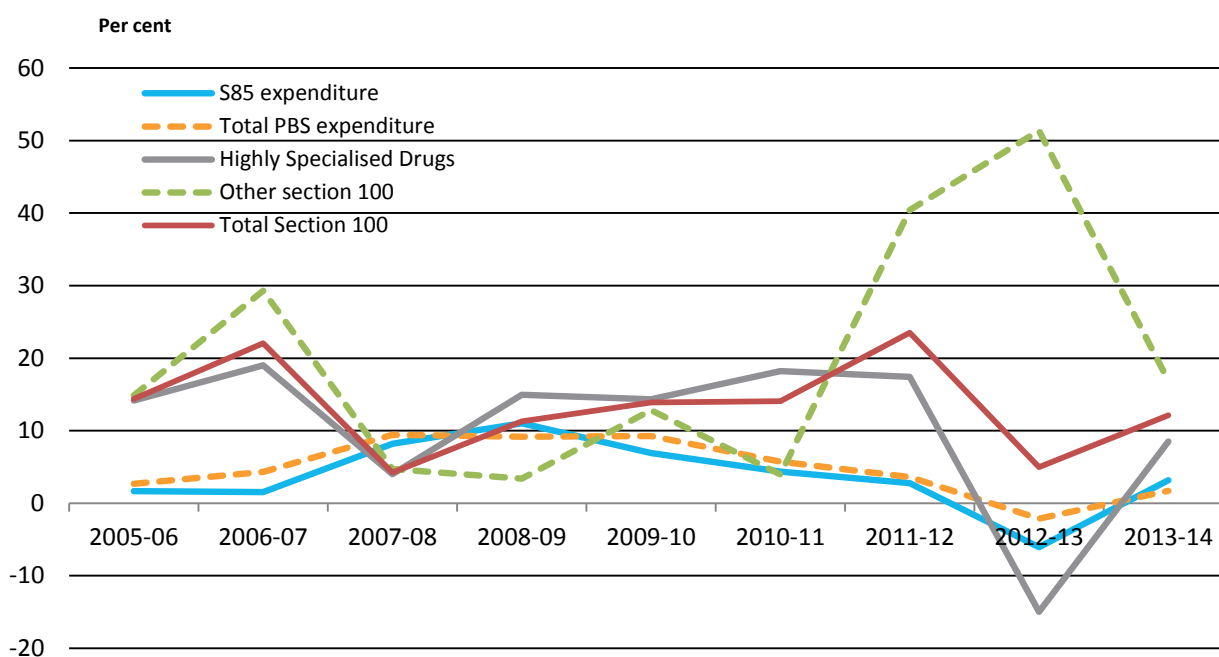


Table 2: average annual growth rates (%) for selected PBS programs from 2005–06 to 2013–14

	2005–06	2006–07	2007–08	2008–09	2009–10	2010–11	2011–12	2012–13	2013–14	Average annual growth
S 85 expenditure	1.68	1.52	8.20	11.01	6.91	4.34	2.78	-6.06	3.17	3.73
Total PBS expenditure	2.70	4.30	9.42	9.18	9.28	5.73	3.62	-2.15	1.69	4.86
Highly Specialised Drugs	14.15	19.00	4.01	14.96	14.35	18.22	17.43	-14.97	8.51	10.63
Other section 100	14.87	29.27	4.70	3.37	12.84	3.96	40.43	51.35	16.90	19.74
Total Section 100	14.36	22.04	4.23	11.31	13.90	14.08	23.50	4.95	12.14	13.39

Note 1: S 85 expenditure is on cash accounting basis.

Note 2: Expenditure on HSD and Chemotherapy for 2012–13 may not be directly comparable to previously published data due to changes in data collection procedures and drug allocation processes.

Source: Department of Health, [PBS Expenditure and Prescriptions reports between June 2005 and June 2014](#), Table 1(a), Table 1(b), Table 12.

Expenditure on s 85 is the majority of PBS expenditure, as noted in Table 3 below. However, total expenditure on s 100 and HSDP expenditure as a proportion of the PBS is growing. If growth in these programs continues at the current rates and s 85 expenditure remains relatively stable, expenditure on these programs will account for a greater proportion of PBS expenditure in the future.

Table 3: expenditure by PBS program as a proportion of total PBS expenditure

	2005–06	2006–07	2007–08	2008–09	2009–10	2010–11	2011–12	2012–13	2013–14
Total PBS expenditure	6,163,129,539	6,428,298,644	7,033,815,575	7,679,272,440	8,391,678,245	8,872,667,330	9,193,652,758	8,996,412,527	9,148,527,860
Highly Specialised Drugs	8.56%	9.77%	9.28%	9.78%	10.23%	11.44%	12.96%	11.26%	12.02%
Section 100	12.16%	14.23%	13.56%	13.82%	14.41%	15.54%	18.53%	19.87%	21.91%
S 85 expenditure	87.53%	85.19%	84.25%	85.66%	83.80%	82.70%	82.03%	78.75%	79.89%

Source: Department of Health, [PBS expenditure and prescriptions reports between June 2005 and June 2014](#), Table 1(a), Table 1(b), Table 12.

Life Saving Drugs Programme

The Australian Government provides subsidies for limited range of medicines not eligible for funding under PBS through the LSDP. The LSDP provides funding to cover the costs of very expensive and life-saving drugs for rare and life threatening medical conditions.³³ Ten medicines are funded for seven conditions:

- imigulcerase (Cerezyme), velaglucerase (VPRIV) and miglustat (Zavesca) to treat Gaucher disease
- agalsidase alfa (Replagal) and agalsidase beta (Fabrazyme) for Fabry's disease
- laronidase (Aldurazyme) for Mucopolysaccharidosis (MPS) Type I
- idursulfase (Elaprase) for MPS Type II
- galsulfase (Naglazyme) for MPS Type III
- alglucosidase alfa (Myozyme) for infantile-onset Pompe disease
- eculizumab (Soliris) for Paroxysmal Nocturnal Haemoglobinuria³⁴

Each condition has separate eligibility guidelines and patients must request access to the LSDP. Patients are reviewed every six months to ensure they continue to meet eligibility guidelines.³⁵ In 2013–14, the LSDP assisted 257 patients.³⁶

The LSDP is funded by an annual appropriation item approved by Parliament.³⁷ Table 4 shows the estimated actual expenditure as reported in the Portfolio Budget Statements from 2008–09 to 2013–14.³⁸ The figure for 2014–15 has been included for illustrative purposes and is an estimate only. For the purposes of comparison with other time series used in this paper, the average annual growth rate from 2009–10 to 2013–14 was 12.68%.³⁹ This is above the average annual growth rate of 2.18% for the PBS for the same period.⁴⁰

Table 4: average annual growth of Life Saving Drugs Program (LSDP)

	2008–09	2009–10	2010–11	2011–12	2012–13	2013–14	2014–15	Average annual growth 2009–14
Expenditure (millions)	96,383	77,473	139,473	133,554	154,417	141,504	151,424	
Annual Growth Rate		-19.62%	80.03%	-4.24%	15.62%	-8.36%	7.01%	12.68%

Source: [Department of Health and Ageing Portfolio Budget Statements from 2008–09 to 2013–14](#)

Outlook for expenditure on high cost medicines

The Intergenerational Report 2010 predicted that spending on pharmaceuticals will remain a significant proportion of health spending, rising from \$443.0 real per capita in 2012–13 to \$534.0 real per capita in 2022–23.⁴¹ Similarly, the AIHW has predicted that from 2003 to 2033 expenditure on pharmaceuticals is likely to increase by 163%.⁴² These predictions are based on a projection model first published in a report for the United Nations in 2007.⁴³ The model takes into account changes in health and residential aged care expenditure, disease expenditure data and assumes that new technologies will have a similar impact to currently observed trends.⁴⁴

33. DoH, '[Other supply arrangements outside the PBS](#)', accessed 2 September 2014.

34. DoHA, [Annual Report 2012–13](#), Volume 1, p. 67–8.

35. *Ibid.*, p. 68.

36. DoH, [Annual Report 2013–14](#), Volume 1, p. 59, accessed 2 September 2014.

37. DoH, [The review of the Life Saving Drugs Program](#), accessed 2 September 2014.

38. Note that the LSDP is currently reported under Program 2.3 in Budget Related Paper 1.10. See Australian Government, [Budget measures: budget related paper no. 1.10: Health portfolio](#), p. 83, accessed 2 September 2014. It has previously been reported under Outcome 3. Prior to 2008–09, expenditure on the LSDP was not disaggregated.

39. See Table 4.

40. See Table 4. Calculation for average annual growth in the PBS from 2009–10 to 2013–14 were based information presented in Table 2.

41. Australian Government, Australia to 2050: future challenges ([Intergenerational report 2010](#)), 2010, p. 54, accessed 5 November 2011.

42. J Goss, '[Projection of Australian health care expenditure by disease, 2003 to 2033](#)', Health and welfare expenditure series no. 36. Cat. no. HWE 43. AIHW, Canberra, 2008, p. 29, accessed 4 September 2014.

43. *Ibid.*, p. 2.

44. *Ibid.*, p. 2.

Of relevance to this paper, expenditure on pharmaceuticals for neurological conditions, Parkinson's disease, dementia and cancer is predicted to grow considerably, as shown below:⁴⁵

Table 5: comparative expenditure on pharmaceuticals per person treated by disease group 2002–03 to 2032–33

Disease group	2002–03	2012–13	2022–23	2032–33	Change 2002–03 to 2032–33
Neurological	298	470	833	1,474	394%
Dementia	40	58	93	157	297%
Parkinson's disease	46	71	127	225	388%
Other neurological	213	341	613	1,092	414%
Cancer	252	354	558	867	244%
Endocrine, nutritional and metabolic	977	1,256	1,720	2,336	139%

Note: spending in 2006–07 dollars

Source: Table adapted from J Goss, '[Projection of Australian health care expenditure by disease, 2003 to 2033](#)', Health and welfare expenditure series no. 36. Australian Institute of Health and Welfare, Canberra, 2008, p. 29, Table 11.

Many of the drugs used to treat these conditions are funded by the s 100 program. As discussed earlier and as shown in Table 2, the average annual growth in government expenditure on s 100 (total) was 13.39% per annum from 2005–06 to 2013–14. This is around three times the rate of average annual growth of total PBS expenditure for the same period. Table 3 highlights that if growth rates remain constant and currently policy parameters remain, s 100 programs will account for a growing proportion of PBS expenditure.

Total government expenditure in 2013–14 on s 100 and LSDP medicines was around two billion—with new additions in 2014.⁴⁶ This is an area of expenditure which warrants closer policy attention, notwithstanding the therapeutic importance of these drugs. Recent analysis of the growth in the PBS concluded that the growth in expenditure of the HSDP was a 'key driver' of PBS expenditure.⁴⁷ Given the AIHW predictions about future expenditure on pharmaceuticals and current rates of growth for high cost drugs, expenditure on high cost drugs is likely to continue to increase. Furthermore, the introduction of generic cancer drugs does not necessarily result in significant savings. They are usually priced comparatively high and are often not widely used as newer treatments are considered to be the 'gold standard'.⁴⁸ As a general rule, new cancer drugs are more expensive than current options.⁴⁹

The Government has recently commenced a review of the LSDP to consider access and equity, value for money and the future administration of the program.⁵⁰ One of the terms of reference for the review is to compare the subsidisation and equity principles of the PBS and LSDP.⁵¹ The review will also consider the 'value for money' of drugs listed on the LSDP by their evaluating treatment outcome (quality of life and cost) as well as identifying new and emerging treatments that may potentially seek subsidisation through the LSDP in the future.⁵² The Department of Health has previously acknowledged that rare diseases are an emerging area of additional expenditure and one for which the Government needs to prepare.⁵³

Possible options

It has been predicted that the current high cost of cancer drugs signals even greater cost for future (cancer) drugs.⁵⁴ Combined with the growing burden of diseases, such as cancer and Alzheimer's disease, this poses a

45. Drugs used in the treatment of these diseases are often listed under s100 arrangements. Table adapted from Goss, op. cit., p. 29, Table 11.

46. See, for example, P Dutton (Minister for Health and Minister for Sport), [New treatment for cancer approved for PBS listing](#), media release, 16 September 2014.

47. Department of Health and Ageing and Medicines Australia, [Trends in and drivers of Pharmaceutical Benefits Scheme expenditure report](#), op. cit., p. 44.

48. M Siddiqui and V Rajkumar, '[The high cost of cancer drugs and what we can do about it](#)', *Mayo Clinic Proceedings*, 87(10), October 2012, pp. 935–943, accessed 24 September 2014.

49. Ibid.

50. Department of Health, [Post market review of the Life Saving Drugs Programme](#), PBS pages, accessed 5 November 2014.

51. Ibid.

52. Ibid.

53. Senate Community Affairs Legislation Committee, [Official committee Hansard](#), op. cit., p. 92.

54. Ibid., p. 93.

significant challenge for the current Government as it attempts to deal with what it has described as ‘unsustainable’ growth in the health care system.⁵⁵ Despite its concerns, the Government has placed an average of 24 new or amended listings on the PBS per month, compared to eight per month which were added under the previous Government.⁵⁶ The continued listing of products of the PBS is perhaps recognition of the necessity of these medicines for the treatment and management of disease.

The Minister for Health determines what is listed on the PBS and LSDP, based on recommendations by the Pharmaceutical Benefits Advisory Committee (PBAC). By law, the PBAC is required to consider the clinical and cost-effectiveness of all medicines recommended for listing on the PBS and a product cannot be listed without a positive recommendation from the PBAC. Recommendations are based on the clinical and cost effectiveness, as well as incremental cost-effectiveness of individual medicines and how they compare with therapeutically similar products. Other considerations for listing that may be considered by the PBAC include equity, rule of rescue, quality use of medicine and risk sharing.⁵⁷ In contrast to drugs listed on the PBS, those on the LSDP must be clinically effective; they are not required to be cost effective.⁵⁸

A measure of costs-effectiveness often used by the PBAC is cost per Quality Adjusted Life Year (QALY)—a measure that ‘combines extension of life and quality of life in a single index that allows comparisons across health interventions’.⁵⁹ The cost per QALY gives a guide to the cost of the medicine necessary to extend a person’s life one year in a good state of health, or for longer period in a reduced state of health.

The PBAC has not set a minimum or maximum QALY figure. A report of an analysis of data included in 125 submissions made to the PBAC between July 2005 and November 2006 found that sponsors included claims of cost per QALY that ranged from less than \$15,000 per QALY to greater than \$200,000 per QALY⁶⁰. Some medicines claiming less than \$15,000 per QALY were accepted and some were rejected, while some claiming more than \$200,000 per QALY were accepted and some rejected. An earlier study of medicines listed between 1994 and 2004 found that the average cost per QALY in submissions for listing was \$46,000.⁶¹

The use of cost per QALY as a cost-effectiveness measure is not without criticism, and the use of cost-effectiveness as a rationing criterion has itself been criticised.⁶² An alternative being discussed is the use of a ‘minimum effectiveness threshold’.⁶³ This would require the health treatments (surgery, behavioural interventions and imaging, as well as medicines) demonstrate they provide some minimum of improvement in health outcomes if funding were to be provided, or existing funding continued. Clinical effectiveness would have to take a range of other factors into consideration.

Another alternative is the ‘value based assessment of health technologies’ currently being implemented by the National Institute for Health and Care Excellence (NICE) in the United Kingdom.⁶⁴ This approach takes into account the burden of illness (measured in QALYs) and the wider societal impact of a condition (that is, the capacity of an individual with the condition to engage with society compared to how those without the condition

55. See, for example, P Dutton, (Minister for Health and Minister for Sport), [Address to CEDA conference](#), speech, 19 February 2014, accessed 25 September 2014. The Minister notes the PBS is a growing component of health expenditure. He also notes that premature death due to bowel cancer and Alzheimer’s disease has increased by 18% and 170%, respectively, over the past 20 years.

56. Senate Community Affairs Legislation Committee, [Official committee Hansard](#), op. cit., p. 86, accessed 4 November 2014. Note that the previous Government delayed the listing of products on the PBS due to high costs. For further information, see R de Boer, [‘Making savings from the PBS – is deferring the listing of medicines the answer?’](#), FlagPost weblog, 4 April 2011, accessed 25 September 2014.

57. Note that these factors are not automatically considered by the PBAC, the sponsor must include these as part of their submission. For further information, see DoH, [PBAC guidelines: section F – options to present additional relevant information](#), accessed 23 September 2014. Rule of rescue applies when the following four factors apply concurrently: no treatment alternative in Australia, the medical condition is severe, progressive and expected to lead to premature death, only applies to a small number of patients and the proposed medicine provides worthwhile clinical improvement. For further information, see DoH, [PBAC guidelines: F.3 – other relevant factors](#), accessed 24 September 2014.

58. Cost effectiveness is unlikely to be achieved as these diseases are rare and the cost of medicines is high.

59. DoH, [PBAC guidelines: appendix 7 – utility valuation of health outcomes](#), accessed 23 September 2014.

60. K Markarounas-Kirchmann, J Stoelwinder, M Kirchmann, [Predicting successful listing of pharmaceuticals on the PBS](#), conference presentation, 6th World Conference on Health Economics, iHEA, Copenhagen, Denmark, 2009, accessed 23 September 2014.

61. A Harris, S Hill, G Chin, JJ Li, E Walkom, [The role of value for money in public insurance coverage decisions for drugs in Australia: a retrospective analysis 1994–2004](#), *Medical Decision Making*, 28(5), 2008, pp 713–722.

62. D Brock, [‘Ethical issues in the use of cost effectiveness analysis for the prioritization of health care resources’](#), in G Khushf, ed, *Handbook of bioethics – taking stock from the field from a philosophical perspective*, Springer, 2004, pp. 353–380, accessed 24 September 2014.

63. A Buyx, D Friedrich, B Schone-Siefert, [‘Rationing by clinical effectiveness’](#), *British Medical Journal*, 342, 5, March 2011, pp. 531–533, accessed 24 September 2014.

64. National Institute for Health and Care Excellence (NICE) is a statutory body which provides national guidance and advice to improve health and social care. See [About us](#), NICE website, accessed 19 November 2014.

participate, also measured in QALYs).⁶⁵ Implementation has not been without controversy, and there has been some dispute about this approach.⁶⁶

There are no easy policy responses to the listing of high cost medicines on the PBS. A number of issues require resolution, such as pricing and access. Broader questions about the balance between access to newer, (usually) more expensive medicines and older, established treatment regimens, also need to be addressed. Expenditure on the PBS remains uncapped and affordability of the PBS is a vexed issue. To date, governments have continued to support the PBS but have implemented various measures to curb growth. Access to high cost drugs is often tightly controlled and based on eligibility criteria

The difference that exists now between LSDP medicines, that have only to show clinical effectiveness, and s 100 programs, that must show cost-effectiveness, is narrowing; for example, on the agenda for the November 2014 PBAC meeting, four drugs and indications were to be considered for s 100 and, if not successful, for inclusion on the LSDP.⁶⁷ With new, possibly more expensive medicines being developed for serious diseases, and the number of people eligible for treatment with these drugs increasing, there is the likelihood of an even faster rate of growth of government expenditure on these medicines than has been experienced in the past.

Concerns have been expressed by consumer patient advocacy groups about the delays in listing high cost drugs (often cancer drugs) on the PBS.⁶⁸ Yet balancing the community's expectations over the sometimes lengthy process of getting value for money through the PBAC, with the desire of individual patients and their clinicians to give 'some hope' of extended life that new, but often unproven medicines promise, is not straightforward.

To lay the ground work for future policy development, a review of the processes for funding high cost medicines is warranted. The review could:

- examine the need for separate programs (such as s 100, HSDP and the LSDP) and the feasibility of developing a single framework with uniform criteria for subsidy and use⁶⁹
- consult with the community, consumer organisations, clinicians and other stakeholder groups to establish what are community views on funding and use of very high cost drugs (and high costs medical interventions) so as to provide the government, politicians and the PBAC with guidance on community values and views and
- consult with the community, consumer organisations, clinicians and other stakeholder groups to establish community views on the criteria for listing high cost drugs on the PBS: use of cost-effectiveness, the rule of rescue, role and interpretation of equity and whether minimum clinical effectiveness thresholds should be included.⁷⁰

It is likely that no matter how successful the proposed consultations are, there will probably always be limits to what the government, acting on behalf of the community, will fund. These questions are inherently difficult to answer due to the intertwined nature of the political and policy aspects of the problem.⁷¹ The issues are complex, debates are rarely objective and governments often have limited policy options.⁷²

Conclusion

Expenditure on high cost drugs on the PBS is rising and, to date, it shows no sign of slowing. The growing incidence of diseases such as cancers and Alzheimer's disease is likely to contribute to increased expenditure as new treatments become available. There has been little community debate about what should be publicly

65. National Institute for Health and Care Excellence: Centre for Health Technology Evaluation, [Value based assessment of health technologies](#), consultation paper, 2013, accessed 25 September 2014.

66. J Rafferty, 'NICE proposes alternative for value based pricing', BMJ Blogs, 25 February 2014, accessed 25 September 2014.

67. Senate Community Affairs Legislation Committee, [Official committee Hansard](#), op. cit., p. 90.

68. See, for example, Consumers Health Forum, 'Australian health care – out of pocket and out of date', *Health Voices*, 12, April 2013, accessed 24 September 2014.

69. As noted previously, one of the terms of reference for the review of the LSDP is to compare the subsidisation and equity principles of the PBS and LSDP.

70. Buyx et al, *Rationing by clinical effectiveness*, op. cit. See footnote 57 for an explanation of 'rule of rescue'.

71. A Boxall, [What are we doing to ensure the sustainability of the health care system?](#), Research paper, 4, 2011–12, Parliamentary Library, Canberra, 2011, accessed 15 December 2014.

72. See, for example, ibid and S Duckett, [Forget the copayment. Seven tips for an affordable, quality health care system](#), The Conversation weblog, 19 August 2014, accessed 15 December 2014.

funded and the price the community, and the government, should (or is willing to) pay. It is not reasonable to expect that governments will fund all the treatments that might be available, but an informed community debate based on a review of the available evidence may enable a consensus to emerge about appropriate access to medicines and the limits to what the community (taxpayer) and individuals can afford.

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