



National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2008

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Contents

Purpose	2
Background	3
The PBS	3
Basis of policy commitment	4
Committee consideration	5
Position of significant interest groups	5
Financial implications	5
Main provisions	5
Schedule 1 – Co-marketed brands	5
Comment	7
Schedule 2 – Supply of pharmaceutical benefits to government officers working outside Australia	7
Comment	8
Schedule 3 – Couples living apart	9
Comment	9
Schedule 4 – Miscellaneous	9
Concluding comments	10

National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2008

Date introduced: 29 May 2008

House: House of Representatives

Portfolio: Health and Ageing

Commencement: Schedule 1, 3 and 4 - on Royal Assent
Schedule 2 - the day after Royal Assent

Links: The [relevant links](#) to the Bill, Explanatory Memorandum and second reading speech can be accessed via BillsNet, which is at <http://www.aph.gov.au/bills/>. When Bills have been passed they can be found at ComLaw, which is at <http://www.comlaw.gov.au/>.

Purpose

The National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2008 (the Bill) aims to:

- widen the criteria used to determine that brands of pharmaceutical items may be co-marketed, and also to allow the Minister to determine that co-marketed brands stop being co-marketed
- enable those otherwise eligible to access the Pharmaceutical Benefits Scheme (the PBS), to do so while working outside Australia as officers of the Commonwealth, or of a State or Territory (and also for their accompanying spouses and dependent children)
- provide legally married and de facto couples living apart due to illness or infirmity the same access to PBS safety net arrangements as couples living together
- remove provisions for the gazettal of determinations made in relation to pharmaceutical benefits that may be prescribed by participating dental practitioners and authorised optometrists, and
- make minor technical amendments aimed at improving the operation of the PBS.

These changes will be achieved through relevant amendments to Part VII of the *National Health Act 1953* (the Act).

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Background

The PBS

The PBS is a Commonwealth Government program that has operated for approximately 60 years.¹ It aims to provide Australian residents² with affordable access to a range of medicines, whereby the Commonwealth Government subsidises the costs of those medicines.³ Consumers get the benefit of this subsidy when getting prescriptions for medicine filled under the PBS at pharmacies.⁴

Australia has Reciprocal Health Care Agreements with certain other countries, such as the United Kingdom, Ireland, New Zealand, Malta, Italy and Sweden. People from those countries who visit Australia can also access the PBS.⁵

From 1 January 2008, a general patient pays up to \$31.30 and a recipient of a pension or benefit with a concession card pays \$5.00 for most medicines listed with the PBS.⁶ These payments are called 'patient co-payments', which are revised annually in line with the Consumer Price Index.⁷

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1. See Department of Health and Ageing, 'About the PBS', <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-aboutus.htm-copy2>, accessed on 3 June 2008. The PBS operates under Part VII of the Act, as well as the *National Health (Pharmaceutical Benefits) Regulations 1960* made under the Act.
 2. As to the meaning of 'Australian resident', see *Health Insurance Act 1973* section 3 (all references to 'Australian resident' in the *National Health Act 1953* cross refer to section 3 of the *Health Insurance Act 1973*).
 3. For more information about the Commonwealth Government subsidies of medicines, see Department of Health and Ageing, 'The Real Cost of Medicines', http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-real_cost.htm, accessed on 3 June 2008.
 4. Department of Health and Ageing, 'About the PBS', op. cit.
 5. Department of Health and Ageing, 'About the PBS – how it works for you?', <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-how.htm-copy2>, accessed on 3 June 2008.
 6. Department of Health and Ageing, 'About the PBS – how much should I pay?', <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-howmuch.htm-copy2>, accessed on 3 June 2008.
 7. *ibid.*

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Commonwealth Government expenditure on the PBS for 2008-09 is expected to be \$8,908, with a projected increase to \$9,247 in 2009-10.⁸

For comprehensive historical information on the PBS, see the Bills Digest for the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007.⁹

Basis of policy commitment

The Bill was introduced into the House of Representatives by the Hon. Nicola Roxon MP, Minister for Health and Ageing, on 29 May 2008.

The previous Government announced a PBS reform package in November 2006.¹⁰ According to the Government at the time, the aim of the reforms was:

to protect patients from higher out of pocket costs, get better value from market competition among brands of generic (off-patent) medicines and recognise the importance of world-class life-enhancing drugs to patients.

The fundamentals of the PBS will not change. Patients will continue to meet only the standard co-payments and in some cases will also pay less. The main changes will be in the way that the Government prices medicines that are operating in a competitive market. These medicines will take a series of price drops, and eventually will move to a system where the price they are actually being sold in the market will reflect the price that the Government pays.¹¹

Ultimately, the previous Government had sought to ensure the economic sustainability of the PBS, which had been a particular source of concern for several Governments.¹² In the Health and Ageing portfolio, as in other portfolios, costs of programs and improving access to those programs are competing objectives.

The current Bill proposes further amendments, the aims of which are consistent with the stated aims of that reform package (please refer to the 'Purpose' section of the Digest above).

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8. Australian Government, 'Expenses and Net Capital Investments', *Budget Paper No. 1: Budget Strategy and Outlook 2008-09*, p. 6–17.
 9. Luke Buckmaster and Diane Spooner, '[National Health Amendment \(Pharmaceutical Benefits Scheme\) Bill 2007](#)', *Bills Digest*, no. 169, Parliamentary Library, Canberra, 2006-07, pp. 3–6.
 10. See the Hon. Tony Abbott, Minister for Health and Ageing, 'PBS Reform', *media release*, Canberra, 16 November 2006.
 11. *ibid.* See also [National Health Amendment \(Pharmaceutical Benefits Scheme\) Act 2007](#).
 12. See Luke Buckmaster and Diane Spooner, *op. cit.*, pp 3–6.

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Committee consideration

The Bill has been reviewed by the Senate Standing Committee for the Scrutiny of Bills (the Committee) but the Committee did not comment on it.¹³

Position of significant interest groups

At the time of writing, the position of significant interest groups is not known.

There is no information in the Explanatory Memorandum nor in the Second Reading Speech for the Bill on whether the Government has consulted with significant interest groups regarding the proposed amendments in the Bill.

Financial implications

The Government states that amendments proposed in Schedules 1 and 4 have no financial implications.¹⁴

However, the Government states that the expected financial implications for Schedules 2 and 3 are approximately as follows:

- Schedule 2 (pharmaceutical benefits to government officers working outside Australia) – annual cost of \$0.3 million, and
- Schedule 3 (pharmaceutical benefits extending to couples who live apart due to illness or infirmity) – annual cost of \$1.1 million.¹⁵

Main provisions

Schedule 1 – Co-marketed brands

Items 1-5 propose to **amend section 84AE** of the Act, in an effort to expand the criteria used in determining whether brands of pharmaceutical items are co-marketed.¹⁶

13. Senate Standing Committee for the Scrutiny of Bills, *Alert Digest*, no. 4, Senate, Canberra, 4 June 2008, p. 58.

14. Explanatory Memorandum, 'National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2008', p. 3.

15. *ibid.*

16. *ibid.*, pp. 1, 4–5. As to the meaning of co-marketed brands, see *National Health Act 1953* subsection 84AE(2).

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Generally, section 84AE of the Act allows two or more brands of a pharmaceutical item to be treated as the same brand if:

- the regulations prescribe the brands as being co-marketed brands of that item, or
- the Minister determines that the brands are co-marketed brands of that item if the brands satisfy certain criteria pursuant to subsection 84AE(3).

Item 1 proposes to **substitute paragraphs 84AE(2)(a) and (b)** of the Act, with respect to the meaning of ‘co-marketed brands’.

Under **proposed subsection 84AE(3B)** in **item 5 of Schedule 1** of the Bill (see below), the Minister would have discretionary power to determine that all brands that are prescribed by the regulations as being co-marketed brands of a pharmaceutical item, cease being so if certain factors are satisfied.

The effect of the proposed amendment in **item 1** is that the Minister’s discretionary power proposed in **item 5** may in fact override the regulations that prescribe brands as being co-marketed brands of a pharmaceutical item.

According to the Government, this proposed amendment would allow for greater flexibility in accommodating the necessary changes to be made when new brands of medicines are listed on the PBS.¹⁷

Items 2-4 propose to **amend subsection 84AE(3)** by **replacing paragraph 84AE(3)(c); inserting new paragraphs 84AE(3)(d) and (e); and repealing subsection 84AE(3)note** in the Act.

Subsection 84AE(3) of the Act provides for ministerial determination with respect to co-marketed brands of pharmaceutical items.

In particular, the proposed amendments in **items 2-4** specify that co-marketed brands could be co-marketed brands of more than one pharmaceutical item with the same drug as long as all of the pharmaceutical items have exactly the same co-marketed brands.

Item 5 proposes to **insert new subsections 84AE(3A) and (3B)** into the Act.

Proposed subsection 84AE(3A) would give the Minister discretionary power to vary or revoke a determination made pursuant to subsection 84AE(3) that two or more brands of a pharmaceutical item are co-marketed brands if certain criteria are satisfied. This power to

17. See Nicola Roxon, Minister for Health and Ageing, ‘Second Reading Speech: National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2008’, House of Representatives, *Hansard*, 29 May 2008, p. 72.

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revoke or vary such determinations would be made by legislative instrument.¹⁸ The criteria for revoking or varying such determinations reflect recognition that situations change over time and in some cases, co-marketed brands may no longer meet the criteria listed in **proposed paragraphs 84AE(3)(c)-(e)** of the Act (as discussed above).

Proposed subsection 84AE(3B) would give the Minister discretionary power to determine that co-marketed brands prescribed as such by the regulations cease to be co-marketed brands if certain criteria are satisfied. Again, this proposed provision reflects recognition that situations change over time and in some cases, co-marketed brands may no longer meet the criteria listed in **proposed paragraphs 84AE(3)(c)-(e)** of the Act. Under this proposed amendment, the Minister's determination could override the regulations (see also **item 1** above).

Item 6 proposes that amendments proposed in **Schedule 1** above would apply prospectively, in relation to ministerial determinations made:

- on or after the date of Royal Assent, and
- in relation to brands that, before or after that date, are listed or co-marketed brands of a pharmaceutical item.

Comment

It would be helpful to know what are the Government's and the pharmaceutical industry's opinions regarding the impact (if any) of the proposed co-marketing amendments on the pharmaceutical industry.

Schedule 2 – Supply of pharmaceutical benefits to government officers working outside Australia

Items 1-15 propose to amend provisions in the Act relating to pharmaceutical benefits entitlements and export restrictions on pharmaceutical items.

As stated in the Explanatory Memorandum,¹⁹ the proposed amendments in Schedule 2 of the Bill would enable people already entitled to pharmaceutical benefits in Australia, to access those benefits while working overseas as Commonwealth, State or Territory officers (government officers) as defined. The proposed amendments would also enable the accompanying spouses and dependant children of those government officers to access pharmaceutical benefits.

18. As to disallowance of legislative instruments, see *Legislative Instruments Act 2003* sections 42, 44.

19. Explanatory Memorandum, op. cit., pp. 1–2.

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Comment

Notably, ‘spouse’ is defined in section 84B of the Act as:

- (a) a person who is legally married to, and is not living, on a permanent basis, separately and apart from, that person; and
- (b) a de facto spouse of that person.

‘De facto spouse’ is defined in section 4 of the Act as:

a person who is living with another person of the opposite sex on a *bona fide* domestic basis although not legally married to that other person.

Therefore, by definition, the proposed amendments would not apply to same sex couples.

However, it is noted that the Government’s [2007 National Platform](#) states that it:

supports legislative and administrative action by all Australian governments to eliminate discrimination, including systemic discrimination, on the grounds of race, colour, sex, religion, age, sexuality, gender identity, disability, genetic makeup, political or other opinion, national or social origin, property, birth or other status.²⁰

...

Where necessary, Labor will take special measures designed to achieve equality and eliminate the effects of both historic and contemporary discrimination.²¹

In particular, the Government has stated that:

Labor believes that people are entitled to respect, dignity and the opportunity to participate in society and receive the protection of the law regardless of their sexuality or gender identity. Labor supports the enactment of legislation prohibiting discrimination on the grounds of a person's sexuality or gender identity and will audit Commonwealth legislation to amend provisions that unfairly discriminate against any person on the grounds of sexuality or gender identity.²²

The definitions of ‘spouse’ and ‘de facto spouse’ in the Act and the proposed amendments in Schedule 2 of the Bill appear to contradict the Government’s pre-election statements.

20. Australian Labor Party, *National Platform and Constitution 2007*, clause 10, http://www.alp.org.au/download/now/2007_national_platform.pdf, accessed on 5 June 2008.

21. *ibid.*, clause 11.

22. *ibid.*, clause 15.

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Schedule 3 – Couples living apart

Items 1 and 2 propose to **amend section 84B** and **paragraph 87(2)(c)** of the Act relating to safety net concession and pharmaceutical benefits entitlement cards issued to people who are either legally married or are in de facto relationships within the meaning of the Act (see above).

Under the Act, a family can combine certain PBS charges toward a joint safety net threshold and once that threshold is reached, all members of that family benefit from reduced PBS charges for the rest of that calendar year.²³ However, couples who live apart because of illness or infirmity are treated as if they live separately on a permanent basis; they are not considered to be spouses or de facto spouses under the Act and do not benefit from having a family safety net threshold. Consequently, they have to pay more in terms of PBS contributions before they reach their individual safety net thresholds.

The proposed amendments in Schedule 3 of the Bill would allow couples who live apart because of illness or infirmity to continue to be considered as family for the purposes of entitlement to safety net concession and pharmaceutical benefits entitlement cards. In other words, such couples would no longer be considered as living separately on a permanent basis.

Item 3 ‘applies the amended definition of spouse for annual safety net entitlement periods commencing from 1 January of each year from 2009 onwards’.²⁴

Comment

Please refer to the above comments regarding definitions of ‘spouse’ and ‘de facto spouse’ in the Act and exclusion of same sex couples.

Schedule 4 – Miscellaneous

Items 1-3 propose to amend the definitions of ‘combination item has a drug’ and ‘pharmaceutical item has a drug’ in accordance with proposed amendments in Schedule 1 of the Bill relating to co-marketed items.

In addition, **items 4 and 5** propose to **amend subsections 88(1A) and 88(1C)** of the Act.

Subsection 88(1A) and 88(1C) in the Act refer to the Minister’s determinations specifying the pharmaceutical benefits for which participating dental practitioners and authorised optometrists may write prescriptions.

23. Explanatory Memorandum, op. cit., p. 2.

24. *ibid.*, p. 8.

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The proposed amendments would replace the requirement to publish the Minister's determination in the *Government Gazette* with the requirement that the Minister's determination be made by legislative instrument. The Government submits that publication in the *Government Gazette* would be unnecessary because the legislative instruments proposed by these amendments must be registered in the Federal Register of Legislative Instruments (FRLI).²⁵

Item 6 proposes that **items 4** and **5** of **Schedule 4** above would apply prospectively, to determinations made on or after the date of Royal Assent.

Concluding comments

In general, the proposed amendments in this Bill would result in greater access to and affordability of the PBS for people otherwise entitled to use it. The proposed amendments are intended to allow for greater flexibility and efficiency of the PBS.

However, two important issues remain to be addressed:

- what effect, if any, would the proposed co-marketing provisions have on the pharmaceutical industry, and
- the conflict between the Government's pre-election commitment regarding same sex couples and the amendments proposed in the Bill.

25. *ibid.*, p. 3. As to the registration of legislative instruments in the FRLI, see *Legislative Instruments Act 2003* sections 20, 22, 24.

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