Chapter 1

Introduction and overview of the Bill

1.1 On 16 June 2015, the Senate referred the provisions of the National Health Amendment (Pharmaceutical Benefits) Bill 2015 (the bill) to the Senate Economics Legislation Committee (the committee) for inquiry and report by 23 June 2015.[1]

1.2 The bill amends the *National Health Act 1953* (the Act) to:

- reform pricing arrangements to reduce the cost of some Pharmaceutical Benefits Scheme (PBS) medicines;
- allow pharmacists to discount the co-payment for PBS medicines;
- extend the sunset provisions for pharmacy location rules until 2020;
- revise membership arrangements for the Pharmaceutical Benefits Advisory Committee (PBAC); and
- support the intended operation of the Act through a number of technical changes, including amendments relating to PBS listing for bioequivalent and biosimilar medicines and treating brands as Schedule equivalent.

1.3 The measures contained in the bill are part of a broader PBS Access and Sustainability Package. According to the Minister for Health, the Hon Susan Ley MP, the package will deliver net savings to the budget of more than $3.7 billion over five years.[2]

1.4 This chapter summarises the bill's key components, the consultation process involved in the development of its measures, and its financial implications.

Conduct of the inquiry

1.5 The committee advertised the inquiry on its website and wrote directly to a range of individuals and organisations inviting written submissions. The committee received 23 submissions, which are listed at Appendix 1.

1.6 The committee also held a public hearing in Canberra on 18 June 2015. The names of witnesses who appeared at the hearing are at Appendix 2.

1.7 The committee would like to acknowledge and convey its appreciation to those organisations and individuals who, within a very short timeframe, provided a submission to this inquiry and appeared at its public hearing.

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1 *Journals of the Senate*, 2013-15, No. 96, 16 June 2015, p. 2659.

2 *House of Representatives Hansard*, 27 May 2015, p. 6.

Key components of the bill

1.8 The bill contains three schedules:

- Schedule 1 contains measures commencing the day after Royal Assent, including a five per cent reduction for F1 (patented) medicines, further tightening of price disclosure arrangements to close the combination drug loophole and remove the originator brand from price calculations, and the extension of sunset provisions for pharmacy location rules until 30 June 2020.
- Schedule 2 contains amendments commencing on 1 November 2015, which allow the Minister to determine that brands of medicines (including biosimilars) are equivalent for the purpose of substitution by a pharmacist.
- Schedule 3 contains amendments commencing on 1 January 2016, including allowing pharmacists to discount a patient's co-payment by up to $1.

1.9 The key components of the package are outlined below.

PBS pricing reform

F1 medicines: one-off five per cent reduction

1.10 Under section 85AB of the Act, most PBS listed drugs are assigned to one of two formularies: F1 for single brand drugs, which are generally still under patent; and F2 for drugs that have multiple brands listed on the PBS, which will typically include the originator brand and generic brands. Current price disclosure arrangements (which are explained further below) apply to all F2 drugs, unless they are exempt.

1.11 The bill provides for a statutory one-off five per cent price reduction in the approved ex-manufacturer drug price for F1 drugs that have been listed on the PBS for more than five years.[3]

Removal of originator brand from price disclosure calculations

1.12 Price disclosure arrangements were first introduced in 2007 and are used to help contain PBS costs. The arrangements require suppliers of certain PBS listed brands of medicines to disclose information to the Department of Health relating to the sale price of their medicines. In turn, the government uses this information to better align the price it pays under the PBS to the price at which medicines are supplied in the market.[4]

1.13 According to Ms Ley, price disclosure:

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3 Parliamentary Library, *Bills Digest No. 121, 2014–15, National Health Amendment (Pharmaceutical Benefits) Bill 2015*, 16 June 2015, p. 9.

4 Department of Health, *Pharmaceutical Benefits Scheme Price Disclosure Arrangements: Procedural and Operational Guidelines*, Version 5 (July 2014), pp. 7–8.

> …is important to the PBS as it allows market forces to play a part in the PBS, in a way that would not otherwise occur for subsidised prices. It makes medicines cheaper not only for government, but also for consumers.[5]

1.14 The bill would facilitate further savings from price disclosure by removing originator brands of drugs from calculations of the weighted average disclosed price (WADP) after three years on the F2 formulary. Because originator brands generally maintain higher market prices than their generic competitors, the current approach tends to have the effect of holding the WADP up and reducing the size of any reduction in price.[6]

Flow-on reductions to drugs in F2 combination items

1.15 The bill will also change flow-on pricing rules to enable price disclosure reductions to be proportionately flow on from single-molecule medicines to combination items.

1.16 As the Parliamentary Library's Bills Digest explains:

> A combination product contains more than one active drug. The initial approved price for combination products on the PBS is usually based on the sum of the prices of the individual component drugs. As previously discussed [in the Bills Digest], a single brand combination product is not included on F1 or F2, but rather is set out in the administrative Combination Drug List (CDL). Price changes to one or more component drugs are generally 'flowed on' to the price of the combination drug on the CDL. However, if a second brand of the combination product is PBS listed, the original and competitor combination products move to F2, and component drug price changes are no longer flowed on to the combination products.[7]

1.17 Ms Ley explained the purpose of the change in her second reading speech:

> At present, there is a loophole in the price disclosure framework. It has allowed some companies to avoid flow-on price reductions of component medicines by listing a second brand of their own combination drug. Under the current policy, combination items in F2 have price adjustments only if there is a price disclosure reduction due to direct competition between brands of that item. It has resulted in an inconsistency between the pricing of component medicines and the combination item, providing companies with a revenue windfall at the expense of government. This practice has already cost the government, that is, taxpayers, some $250 million.

5 *House of Representatives Hansard*, 27 May 2015, p. 7.

6 *House of Representatives Hansard*, 27 May 2015, p. 7.

7 Parliamentary Library, *Bills Digest No. 121, 2014–15, National Health Amendment (Pharmaceutical Benefits) Bill 2015*, 16 June 2015, p. 10.

> This change will address the anomaly by ensuring appropriate price reductions are applied to combination items on the PBS and ensuring that the PBS pays the right amount for the same drug treatment.[8]

Allowing pharmacists to discount the co-payment for PBS medicines

1.18 Currently, patients make a co-payment of $6.10 (for concession card holders) or up to $37.70 (for general patients) for PBS medicines, until they reach their safety net for that year. The bill would allow pharmacists to discount a patient's co-payment by up to $1.

1.19 While pharmacists cannot recover the allowable discount from the Commonwealth, the measure is expected to deliver savings to the budget because it will increase the time (but not the out-of-pocket costs) for concessional patients to reach their safety net threshold for the year (after which they receive PBS medicines at no cost). As more than 80 per cent of concessional patients do not reach the safety net threshold, any discounts provided would represent a direct saving to them.[9]

1.20 Ms Ley argued that the measure would increase competition between pharmacies and benefit patients by reducing out-of-pocket costs. She further explained that the measure would address a current inequity in the system:

> General patients—that is, non-concessional patients—already access over 70 million scripts per year for less than the patient co-payment amount of $37.70 and those prices are discounted by pharmacists based on market competition. The final price paid by the general patient can be counted towards their safety net.
>
> But concessional patients cannot benefit from these practices, as all PBS prescriptions are priced above the concessional co-payment amount of $6.10 because we, the government, pay pharmacy a dispensing fee of $6.76 plus mark-ups. To offer a concessional patient a medicine such as amoxicillin at the discounted price of $5.90 that could be offered to a general patient, the payment would not count towards their safety net. Alternatively, they must pay the higher price of the concessional co-payment in order to register the payment towards their safety net. This is not a fair outcome.[10]

Extending the sunset provisions for pharmacy location rules

1.21 Pharmacy location rules, as set out in the Fifth Community Pharmacy Agreement (5CPA; an agreement between the Commonwealth and the Pharmacy Guild of Australia under the Act), place restrictions on where pharmacies can be

8 *House of Representatives Hansard*, 27 May 2015, p. 8.

9 *House of Representatives Hansard*, 27 May 2015, p. 9.

10 *House of Representatives Hansard*, 27 May 2015, p. 9.

located. For instance, they prevent new pharmacies opening within a certain distance of existing pharmacies, or the opening of pharmacies within supermarkets.

1.22 The 6CPA provides for an independent review of the pharmacy location rules, but also agrees to extend the rules in their current form until 30 June 2020. The bill implements the agreement in 6CPA regarding pharmacy location rules (although not the review).[11]

Membership arrangements for the PBAC

1.23 The bill would increase the size of PBAC from 17 to 21 members and establish a new position of deputy chairperson. The changes also provide for industry to be one of the professional groups from which members can be nominated, and provide for broader engagement between PBAC and consumer groups.[12]

Biosimilars

1.24 As noted above, the bill contains a number of technical amendments, including to support the intended operation of the Act in relation to recognising biosimilar medicines for the purposes of the application of statutory price reductions.[13]

1.25 In April 2015, the PBAC provided advice to the Minister regarding the reimbursement of biosimilar medicines on the PBS. It advised that:

> …biosimilar products would be "a" flagged, and therefore suitable for substitution at the pharmacy level, where the data are supportive of this conclusion. The PBAC considered that this would be the Committee's default position.
>
> The PBAC advised that the following would be relevant considerations in establishing that a biosimilar product could be "a" flagged with the originator product:
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> - Absence of data to suggest significant differences in clinical effectiveness or safety compared with the originator product;
> - Absence of identified populations where the risks of using the biosimilar product are disproportionately high;
> - Availability of data to support switching between the originator product and the biosimilar product;
> - Availability of data for treatment-naïve patients initiating on the biosimilar product;

11 *House of Representatives Hansard*, 27 May 2015, p. 8.

12 *House of Representatives Hansard*, 27 May 2015, p. 11.

13 Department of Health, *Submission 10*, p. 4.

- Whether the Therapeutic Goods Administration has deemed a product to be biosimilar with the originator product.

The PBAC considered that where a biosimilar product could not be "a" flagged at the time of PBS listing, data should be collected to support "a" flagging at a later point.[14]

1.26 Schedule 1 of the bill provides (*inter alia*) that biosimilar medicines will be listed as having the same drug as their reference biologic medicine (that is, of the listed brand). The Explanatory Memorandum explains:

> Bioequivalent or biosimilar medicines are intended to share the same drug with the medicine to which they are a match. The proposed amendment supports the intended operation of the PBS since 2007 Act amendments introduced statutory price reduction.[15]

1.27 Schedule 2 of the bill provides (*inter alia*) for the Minister to determine that a brand of a pharmaceutical item is to be treated as equivalent to one or more other brands of pharmaceutical items. It further provides that the Minister must have regard to any advice given by the PBAC in doing so. The Explanatory Memorandum explains:

> Considerations which will be relevant for the Minister when considering whether to determine that a brand is to be treated as equivalent for the purposes of paragraph 103(2A)(b) include any advice from the PBAC and any information provided by the Therapeutic Goods Administration (TGA) on matters it considers in undertaking its roles and functions. Under the Therapeutic Goods Act 1989, the TGA considers submissions from sponsors in support of bioequivalence or biosimilarity between products. Submissions from sponsors providing evidence of TGA outcomes can also be relevant to PBS listing processes.[16]

1.28 The above mentioned amendments to schedule 2 are not specific to biosimilars, but rather relate to all medicines. In its submission, the Department of Health explained that the technical amendments in the bill regarding schedule equivalence (that is, 'a' flagging) have been designed to reflect the Department's current practice and legal framework in which decisions regarding schedule equivalence can be made. It explained:

> The Commonwealth was put on notice in *Servier Laboratories (Aust.) Pty Ltd v Commonwealth of Australia [2009] FCA 31*, (a case on 'a' flagging perindopril erbumine and perindopril arginine) that the provisions in the Act regarding schedule equivalence required clarification. Specifically Justice Gray noted '….there is some difficulty determining exactly what

14 Pharmaceutical Benefits Advisory Committee, *Recommendation made by the PBAC—April 2015 PBAC Special Meeting*, http://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2015-04/2015-04-biosimilars.pdf.

15 Explanatory Memorandum, p. 7.

16 Explanatory Memorandum, pp. 17–18.

> power the Department was exercising when making the representations about equivalence'.
>
> To avoid future uncertainty regarding the legislative basis for decisions relating to schedule equivalence, the Government has taken this opportunity to set out a clear framework in the Act, which is intended to provide certainty for all stakeholders.
>
> The amendments in the Bill expressly provide both the Minister with a decision-making power regarding Schedule equivalence and the PBAC with a specific function to provide advice to the Minister on Schedule equivalence.
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> Currently the PBAC provides this advice under its general advice power in section 101(3) of the Act, and the decision regarding Scheduled equivalence is made by Department. In practice these changes will result in minimal changes to the 'a flagging' process.[17]

1.29 While the changes at schedule 2 are not specific to biosimilars, concerns were expressed by a number of witnesses that the amendments at schedules 1 and 2 in effect allow biosimilars to be treated in the same way as generic medicines. These concerns are outlined in the next chapter.

Consultation

1.30 The Department of Health advised the committee that the government had worked closely over the past five months with the Pharmacy Guild of Australia, the Generic Medicines Industry Association, the Consumers Health Forum of Australia, Medicines Australia and more than 20 other stakeholders to 'develop the package of measures that will ensure ongoing access to innovative medicines through a sustainable PBS'.[18]

1.31 According to Ms Ley, the PBS Access and Sustainability Package was developed through a process in which:

> Inputs and ideas were canvassed from all sectors, about all sectors. Meetings ranged from a roundtable, to group discussions, to one-on-one meetings.[19]

Financial Implications

1.32 According to the Explanatory Memorandum, the broader PBS Access and Sustainability Package will deliver net savings to the budget of more than $3.7 billion over five years.[20] As this figure relates to the broader package, it includes savings and

17 Department of Health, *Submission 10*, p. 10.

18 Department of Health, *Submission 10*, p. 3.

19 *House of Representatives Hansard*, 27 May 2015, p. 6

20 Explanatory Memorandum, p. 3.

expenditure not included in the bill. The Explanatory Memorandum did not provide a breakdown of the savings and expenditure for each of the measures in bill. However, the Department of Health's submission does provide a breakdown of savings measures in the broader package.[21]

Scope and structure of this report

1.33 This report comprises two chapters. The following chapter considers the issues raised by key stakeholders in submissions. Submissions received by the committee commented on measures in the bill relating to biosimilar medicines, pricing policy changes, discounting patient co-payments and pharmacy location rules. As the committee has been asked to examine the provisions of the bill, this report does not examine issues raised by submitters relating to the broader PBS Access and Sustainability Package which are not included in the bill.

1.34 The committee's overall conclusion can be found at the end of the next chapter.

21 Department of Health, *Submission 10*, p. 16.