The Senate

Economics Legislation Committee

National Health Amendment (Pharmaceutical Benefits) Bill 2015 [Provisions]

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Senate Economics Legislation Committee

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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:
>
> - 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.
>
> 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.

Chapter 2

Views on the bill

2.1 As noted in the previous chapter, the bill contains technical amendments intended to support the intended operation of the Act, including amendments relating to the PBS listing of bioequivalent and biosimilar drugs. These amendments were the key focus of a majority of submissions received by the committee, and the primary matter discussed in the committee's public hearing on 18 June 2015.[1]

Views on measures in the bill other than substitution of biosimilars

2.2 The majority of the evidence received by committee related to biosimilar medicines. However, some submitters also expressed concerns about measures in the bill relating to discounting patient co-payments, pharmacy location rules and pricing policy changes.

Allowing pharmacists to discount the co-payment for PBS medicines

2.3 Overall, the Pharmacy Guild of Australia supported the bill, noting that funding that the government had agreed to invest in professional community pharmacy services as part of the new five-year Sixth Community Pharmacy Agreement (6CPA), is contingent on the passage of the bill. However, it did not support the proposal to allow approved pharmacists to discount PBS patient co-payments which, in its view, was a matter for the Government and the Parliament. It stated:

> The Guild has expressed its concern that discounting of co-payments undermines the fundamental principle of universal access to the PBS across Australia and will commoditise medicine supply without providing any net annual benefit to the most needy and chronically ill patients who reach the PBS safety net.[2]

2.4 Ms Josephine Root, Consumers Health Forum, welcomed the introduction of the $1 dollar co-payment for PBS medications. However, she noted:

> While we know that no consumer will be worse off, and the majority of people who are able to get the discount will be better off, we are concerned that not everybody will benefit equally and we are particularly concerned that there will be a widening gap between urban and rural Australians as

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1 In addition to witnesses and submissions referenced below, other submissions expressing concern about pharmacy-level substitution of biosimilars included: Mr Stephen Murby, *Submission 3*; the Australasian College of Dermatologists, *Submission 7*; Arthritis Australia, *Submission 9*; name withheld, *Submission 12*; Dr George Alex, *Submission 13*; Hospira Inc., *Submission 14*; and Mrs Katherine Stewart, *Submission 17*.

2 Pharmacy Guild of Australia, *Submission 16*, p. [2].

> there is less competition amongst pharmacies in rural areas and so little or no incentive for the community pharmacy to offer the discount.[3]

2.5 The Department of Health submitted that the co-payment was intended to increase competition between pharmacies. With regards to rural and remote areas, it noted that 'just because there is only one pharmacy in a town does not mean it will not offer discounts on patient co-payments'.[4]

Extending the sunset provisions for pharmacy location rules

2.6 The Pharmacy Guild of Australia noted that the bill will enable the continuation of the pharmacy location rules through to 30 June 2020, as part of the 6CPA. It outlined the benefits of the pharmacy location rules:

> During 2014 an independent, national geo-spatial analysis was conducted which found that pharmacies are in almost every case more accessible than the other three essential service studied (supermarkets, banking and medical centres). For example, 87 per cent of Australians live within 2.5km of at least one pharmacy, compared to 80 per cent for medical centres. The location rules do this while continuing to allow for a highly competitive market in which new pharmacies are approved where there is a community need. Indeed, the number of approved pharmacies has increased by 368 (7.2%) between June 2010 and June 2014, which is in line with population growth.[5]

2.7 Similarly, the Department of Health noted that the pharmacy location rules have been important to the supply of medicine, in particular for rural and remote regions of Australia. It noted that 'rural communities, in particular, have benefited from the 2011 location rules changes, with the population to pharmacy ratio in rural areas improving significantly'.[6]

2.8 Ms Root, Consumers Health Forum, expressed concern that the extension of the sunset provisions for pharmacy location rules until 30 June 2020 would protect existing owners from competition. She stated:

> We believe that opening up the sector to competition would be a benefit to consumers. We also believe there are alternative measures that could be put in place to sustain community pharmacies in areas where viability is at risk. Evidence from overseas strongly suggests that competition could lead to

3 Ms Josephine Root, Policy Manager, Consumers Health Forum of Australia, *Proof Committee Hansard*, 18 June 2015, p. 3.

4 Department of Health, *Submission 10*, p. 7.

5 Pharmacy Guild of Australia, *Submission 16*, p. 2.

6 Department of Health, *Submission 10*, p. 8.

better provision of patient services in areas such as after-hour services and a wider range of professional services.[7]

2.9 In its submission, the Consumers Health Forum noted that the National Commission of Audit, the Australian National Audit Office's review of the Fifth Community Pharmacy Agreement, the Competition Policy Review by Professor Ian Harper, and the Productivity Commission research paper, *Efficiency in Health*, had independently concluded that the existing pharmacy location rules were anti-competitive and did not benefit consumers.[8]

2.10 The Department of Health acknowledged that several reviews had recommended the need to consider a comprehensive review of government regulations, including rules relating to the location of pharmacies, which are claimed to protect Australian pharmacies from competition. It advised the committee that the government and pharmacy sector have agreed to a review of both remuneration and regulation, including location rules.[9] As part of the 6CPA, the Commonwealth will appoint a panel of three independent reviewers to conduct a comprehensive review of pharmacy remuneration and regulation. The agreement states that the Minister will determine the terms of reference for the comprehensive review after consultation with the Pharmacy Guild of Australia Guild.[10]

2.11 The Consumers Health Forum indicated that it welcomed the independent review of location rules and other aspects of the 6CPA. However, Ms Root expressed concern that the Pharmacy Guild of Australia would be the only party to be consulted on the scope of the review and urged the committee to recommend that consultation over the terms of reference of the review should include a broader group of stakeholders.[11]

PBS pricing reform

2.12 The Consumers Health Forum noted that the legislative changes relating to the one-off 5 per cent price reduction to F1 medicines after five years and the changes to price disclosure will lower the cost of popular medicines, and bring prices more in line with the international market. However, it raised concerns that pharmacies may not pass on the savings to consumers. In its view, the evaluation of the implications of

7 Ms Josephine Root, Policy Manager, Consumers Health Forum of Australia, *Proof Committee Hansard*, 18 June 2015, p. 3.

8 Consumers Health Forum of Australia, *Submission 8*, p. 5.

9 Department of Health, *Submission 10*, p. 8.

10 Department of Health, *Sixth Community Pharmacy Agreement*, May 2015, p. 20.

11 Ms Josephine Root, Policy Manager, Consumers Health Forum of Australia, *Proof Committee Hansard*, 18 June 2015, p. 3.

this policy for general consumer out-of-pocket costs should be included in the scope of the comprehensive review outlined in the 6CPA.[12]

Committee comment

2.13 The committee draws the government's attention to concerns raised by the Consumers Health Forum about the need for broad stakeholder consultation when determining the scope of the comprehensive review of pharmacy remuneration and regulation.

Pharmacy level substitution of biosimilars

2.14 As noted in the previous chapter, the Department of Health informed the committee that the proposed amendments '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. It explained:

> Currently the PBAC provides this advice under its general advice power in section 101(3) of the Act, and the decision regarding schedule equivalence is made by Department. In practice these changes will result in minimal changes to the 'a flagging' process.
>
> …
>
> When making a decision on schedule equivalence the Minister must consider any PBAC advice and may consider advice provided by the TGA on matters it considers in performing its roles and functions. It is not required, or intended, that the PBAC provides advice on each occasion that the Minister considers whether to determine if two brands of pharmaceutical items are schedule equivalent. This is consistent with current practice where PBAC advice is not sought regarding the listing of most generics.[13]

2.15 This proposed amendment gave rise to significant concern across a range of interested entities. For example Mr Tim James, Medicines Australia informed the committee that industry's primary concern was with this issue of substitution of biosimilar medicines at the pharmacy level—a concern shared by patients and healthcare professionals alike.[14]

2.16 A common argument made by many witnesses was that while they supported the greater use of biosimilars in Australia, they had concerns about pharmacy-level substitution of biologic medicines with biosimilars. The Australian Rheumatology Association (ARA) told the committee:

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12 Consumers Health Forum of Australia, *Submission 8*, p. 4.

13 *Submission 10*, p. 10.

14 Mr Tim James, Chief Executive Officer, *Proof Committee Hansard*, 18 June 2015, p. 2.

> We think that treatment decisions need to be made by the treating doctor and an informed patient. New patients may be started on a biosimilar drug or on an originator drug, but this is a clinical decision that needs to be made by the specialist. If switching at the pharmacy is permitted, what happens if something goes wrong? How will the pharmacovigilance be managed? If people are being swapped from month to month, from prescription to prescription without their doctor knowing, how will it be possible to know which agent is to blame if there is a problem? There are certainly precedents for this having happened in the past. Do we want to take the risk of such unforeseen problems and, if so, who bears this risk?[15]

2.17 Similarly, Medicines Australia told the committee that its members (who made up the majority of biosimilars companies) supported the 'effective, safe and successful entry of biosimilars into the Australian market'. However, it did not believe the proposed arrangements for substitution at the pharmacy level would achieve this.[16] Mr James explained further:

> Medicines Australia does support clinician-led substitution of biosimilar medicines, and Medicines Australia would support pharmacy level substitution only based on a transparent decision-making process, supported by appropriate evidence not absence of evidence to the contrary. On biosimilars, and across our healthcare system, notions of safety first, of do no harm and of putting into practice the precautionary principle should always come first.[17]

2.18 Consumers Health Forum welcomed the introduction of biosimilars into the Australian market and the additional price competition it anticipated this would bring. However, it too expressed strong concerns about the safety implications of pharmacy-level substitution:

> This is a premature move in our opinion, given the paucity of evidence on the safety of switching patients from a biologic to a biosimilar. We have had a number of representations from very concerned consumer groups for people who have taken a long time to get onto a biologic and are worried that they will then have to switch to a biosimilar and they are not sure what the effect on them will be. We believe that any switching should be only done with the informed consent of the consumer and the prescribing doctor. We know this is a complex issue, but the key point is there is not sufficient evidence of the safety of switching patients. Any move to do so would lead to an unnecessary and unacceptable increased risk of adverse outcomes for Australian patients.[18]

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15 Dr Mona Marabani, President, Australian Rheumatology Association, *Proof Committee Hansard*, 18 June 2015, p. 2.

16 Mr Tim James, Chief Executive Officer, Medicines Australia, *Proof Committee Hansard*, 18 June 2015, p. 2.

17 *Proof Committee Hansard*, 18 June 2015, p. 2.

18 Ms Josephine Root, Policy Manager, Consumers Health Forum of Australia, *Proof Committee Hansard*, 18 June 2015, p. 3.

2.19 Consumers Health Forum stressed the need for more consultation on the issue, and suggested that the proposed changes would put Australia out of step with the rest of the world.[19]

2.20 The Generic Medicines Industry Association acknowledged that 'biosimilars must go through rigorous assessment by the Therapeutic Goods Administration, and it is only after they have passed that rigorous assessment that they are made available to Australian patients'.[20] However, it also noted that the issue at stake was not whether biosimilars were being adequately assessed for quality, safety and efficacy, but rather whether they would be adequately assessed as safe and effective for substitution.[21]

Biosimilars are not generic biologicals

2.21 A number of witnesses, including the ARA and Medicines Australia, expressed concern that the bill would in effect allow biosimilars to be treated in the same way as generic medications. These witnesses stressed that biosimilars should not be regarded as generic biological medications.[22] As the ARA put it:

> Biologic medications are extremely complex molecules grown using living organisms and it is virtually impossible to replicate them exactly. Minor variations in the manufacturing process can have a major impact on efficacy and patient safety. Consequently it cannot be assumed that a biosimilar can be used interchangeably with its biologic reference product.[23]

2.22 The Alliance for Safe Biologic Medicines explained why this difference between biosimilars and chemical medicines was a relevant safety concern in terms of patient responses:

> Unlike chemical medicines, the greater size, complexity and sensitivity of biologics means that they cannot be copied exactly. A reverse-engineered biosimilar medicine from a different cell line designed to mimic the therapeutic properties of its reference biologic medicine can only ever be 'similar' to that product, never the same. Even seemingly minor production differences can produce unexpected effects, including unwanted immune responses that may harm rather than heal. We know that patient responses can vary with chemical medications and expect the same to be true with biologic ones. However, given the chronicity and seriousness of the

19 Ms Josephine Root, Policy Manager, Consumers Health Forum of Australia, *Proof Committee Hansard*, 18 June 2015, p. 7.

20 Mrs Belinda Wood, Chief Executive Officer, Generic Medicines Industry Association, *Proof Committee Hansard*, 18 June 2015, p. 4.

21 Mrs Belinda Wood, Chief Executive Officer, Generic Medicines Industry Association, *Proof Committee Hansard*, 18 June 2015, p. 8.

22 Mr Tim James, Chief Executive Officer, Medicines Australia, *Proof Committee Hansard*, 18 June 2015, p. 8; Dr Mona Marabani, President, Australian Rheumatology Association, *Proof Committee Hansard*, 18 June 2015, p. 2.

23 Australian Rheumatology Association, *Submission 5*, p. 1.

> diseases these medications are designed to treat, we believe there is less margin for error and recommend a slower and more conservative approach to substitution until more is known about these medications.[24]

2.23 It might be noted that PBAC itself has stated that biosimilar drugs are not to patented originator biologic drugs what generic drugs are to originator synthetic molecule drugs, in the sense that biosimilar drugs can never be exactly the same the drugs on which they are based. As the PBAC put it in a statement released on 18 June 2015:

> The difference between biosimilar drugs and generic drugs is that generic drugs are usually exactly the same as the original patented medicine. Because of both the complex nature of biologics and the way they are made, even though biosimilar drugs act in the same way as the original patented biologic, they may not be exactly the same. However we would not recommending them as substitutable with each other unless the PBAC is sure of their equal safety and effectiveness.[25]

Roles of the PBAC and TGA in assessing substitutability of biosimilars

2.24 As noted above, Generic Medicines Industry Association made clear that all biosimilars must go through rigorous assessment by the TGA, before they are made available to Australian patients'.[26] Even so, concerns were expressed by a number of witnesses regarding the role given to the PBAC in advising the Minister as to whether a biosimilar should be listed as substitutable for its reference product. It was observed by some that responsibility for assessing the quality, safety and efficacy of drugs is the responsibility of the TGA. While the PBAC has some capability in this regard, unlike the TGA its primary remit is to evaluate products for cost-effectiveness and reimbursement. CreakyJoints Australia suggested that the changes would in effect mean Australia was shifting the onus for assessing medicine safety from a safety regulator (the TGA) to a funding authority (the PBAC).[27] For its part, Medicines Australia told the committee:

> We believe there has been an unfair tilt away from the role of the Therapeutic Goods Administration. Its primary role is to assess quality, safety and efficacy. The PBAC does that to some extent as well—or safety and efficacy—but their primary remit is cost-effectiveness. We believe, because of the significant potential safety considerations, that the role of the Therapeutic Goods Administration should not be usurped and that the

24 Alliance for Safe Biologic Medicines, *Submission 2*, pp. 1–2.

25 Pharmaceutical Benefits Advisory Committee, statement, 'Safety of biosimilar medicines', 18 June 2015, p. 1.

26 Mrs Belinda Wood, Chief Executive Officer, Generic Medicines Industry Association, *Proof Committee Hansard*, 18 June 2015, p. 4.

27 CreakyJoints Australia, *Submission 6*, p. 3.

> primary advice should be from that organisation in terms of determining the suitability of substitution.[28]

2.25 Highlighting the TGA's fundamental role in monitoring and evaluating the safety and evidence of the medicines that Australians rely on daily, Medicines Australia formed the view:

> The Government's policy diminishes the TGA's role in safeguarding the health of Australians and raises concerns regarding the quality of decision making and ultimately patient safety.[29]

2.26 It argued that because of its fundamental role, the TGA must therefore be 'a critical source of advice on whether pharmacy level substitution of a particular medicine is appropriate, and the monitoring of post-market safety'.[30] In essence, Medicines Australia submitted that:

> The TGA is the appropriate body to be the primary source of advice on whether the higher standard of substitutability has been established and Medicines Australia is concerned that the present proposal fails to recognise and support this critical role for the TGA.[31]

2.27 The International Federation of Pharmaceutical Manufacturers & Associations noted that the TGA has 'adopted a robust science based approach for the approval of biosimilars which is aligned with the requirements of the WHO, European Medicines Agency and US Food and Drug Administration.[32] It argued that while the PBAC has the authority to make recommendations on substitution:

> …the TGA is appropriately positioned to evaluate the scientific evidence and determine the suitability of biosimilars and should remain the independent advisor to the Government in all matters of medicines' regulation and approval.[33]

2.28 Similarly, the ARA argued that:

> …it is critical that decisions regarding safety and efficacy of all medicines, including biologics and biosimilars, should rest with the TGA. Therefore, we think the bill needs to be amended to reflect this.[34]

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28 Dr Krishan Thiru, Member Company Representative, Medicines Australia, *Proof Committee Hansard*, 18 June 2015, p. 7.

29 *Submission 22*, p. 3.

30 *Submission 22*, p. 6.

31 *Submission 22*, p. 8.

32 *Submission 21*, p. 1.

33 *Submission 21*, p. 4.

34 Dr Mona Marabani, President, Australian Rheumatology Association, *Proof Committee Hansard*, 18 June 2015, p. 2. Also see Australian Rheumatology Association, *Submission 5*, p. 1.

International practice

2.29 A number of submitters informed the committee that the proposed amendment on biosimilars was not consistent with international practice. Indeed, Medicines Australia argued that the legislative enablement of PBAC policy on biosimilar substitution:

> …puts Australia out of step with the rest of the world. In effect, biosimilars can be deemed substitutable at the pharmacy level unless evidence is provided to establish otherwise.

2.30 Dr Thiru, Medicines Australia, informed the committee that:

> …in all jurisdictions around the world that we are aware, the regulatory authority is the organisation that is commenting on substitutability, not the reimbursement organisation. In Europe, we are not aware of any country that is permitting multiple substitutions on existing patients from one biologic.[35]

2.31 According to Dr Thiru, in France new patients are able to start on the biosimilar agent, but existing patients are not. It is driven by the prescriber.[36]

2.32 The International Federation of Pharmaceutical Manufacturers & Associations supported this contention. It informed the committee that the proposal 'may put Australia out of step with the rest of the world which has taken a more considered approach to the issues of substitution of biosimilars and patient safety'.[37] It stated:

> Without exception, countries to which Australia would normally be compared in respect to pharmaceutical policy have uniformly declared that generics-style substitution of biosimilars is inappropriate—a position formalized in either law or policy and sometimes both. Instead, these countries have emphasized in their regulatory, clinical and health technology assessment guidance that such decisions to switch a given patient's therapy should be made with the involvement of the treating physician.[38]

2.33 The Biotechnology Industry Organization similarly agreed with the view that the policies contemplated by the proposed amendment 'run contrary to sound scientific policy and medical practice and are thus inconsistent with the global best practice of other advanced economies'.[39]

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35 *Proof Committee Hansard,* 18 June 2015, p. 9.

36 *Proof Committee Hansard,* 18 June 2015, p. 9.

37 *Submission 21*, p. 1.

38 *Submission 21*, p. 2.

39 *Submission 15*, p. 1.

Safety concerns about the 'default position' of the PBAC on biosimilars

2.34 As noted in the previous chapter, the PBAC has advised that its default position will be that biosimilar products would be 'a' flagged and therefore suitable for substitution at the pharmacy level where the data is supportive of this position. The data it would have regard to would include the absence of any data suggesting substitution suggesting differences in the efficacy or safety of the biosimilar from the originator, and the availability of data to support substitution.[40]

2.35 A number of witnesses argued that substitution should require data demonstrating safety and efficacy, rather than simply an absence of adverse data. For instance, Medicines Australia expressed concern that the default position of the PBAC will be that is that if there is no evidence that substitution is unsafe then it would recommend substitution. It suggested that the default position should instead be that until evidence of safety was provided, substitution should not be permitted.[41]

2.36 Some witnesses also noted the lack of evidence regarding not only switching of biosimilars, but switching back-and-forth between two or more biologics. For example, the Alliance for Safe Biologic Medicines submitted that it opposed:

> ...pharmacy-level substitution of biosimilars until these medicines have been sufficiently evaluated for safety and efficacy, including repeated switching between products—whether it be between the reference biologic and a biosimilar or between two biosimilars.[42]

2.37 Similarly, the Biotechnology Industry Organization suggested that while it did not question the overall safety or efficacy of biosimilars:

> …the effects of repeatedly alternating among two or more similar biological medicines have not - to the best of our knowledge - been fully evaluated by the Australian regulator. This is an important consideration from product safety and efficacy due to the molecular size, complexity and subsequent propensity of biologics to generate unwanted immune reactions.[43]

2.38 Dr Paul Kubler from the ARA also emphasised the lack of evidence about the effects of switching at the pharmacy level:

> There have been a few comments about the scientific evidence behind switching. Firstly, if you were to talk about flagging it allow for multi-substitutions to occur at pharmacy level. So, in simple terms, switching just

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40 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.

41 Dr Krishan Thiru, Member Company Representative, Medicines Australia, *Proof Committee Hansard*, 18 June 2015, p. 10.

42 Alliance for Safe Biologic Medicines, *Submission 2*, p. 1.

43 Biotechnology Industry Organization, *Submission 15*, p. 2.

> means transitioning from the original five biologic drugs to the reference problem. But interchangeability goes further than that. Interchangeability refers to switching back and forth between the original and the biosimilar. The evidence for the first biologic about to be approved, which is infliximab, is that they have only done a single substitution, at one year of therapy; they have not done multiple substitutions. In total, 227 patients have been followed for one year after a single switch. The evidence base was it did not create any additional safety concerns for up to one year after a single switch. But there is no evidence regarding multiple switches.[44]

2.39 Medicines Australia indicated that it did support clinician-led substitution of biosimilars. However, it would only support pharmacy-level substitution 'based on a transparent decision-making process, supported by appropriate evidence not absence of evidence to the contrary'.[45]

Need to monitor and report issues relating to substitution of biosimilars

2.40 Some witnesses, such as the Gastroenterological Society of Australia, pointed to the need for pharmaco-surveillance and a robust pharmacovigilance framework to 'monitor and report outcomes and any adverse effects associated with biologic/biosimilar therapy'.[46]

2.41 The International Cancer Advocacy Network, meanwhile, suggested that in the instance substitution of biosimilars was considered safe and substitution occurred, the pharmacist should be required to notify the physician (and thus the patient).[47]

Potential effects on compassionate supply arrangements

2.42 Some submitters raised questions about the effect of the proposed arrangements on compassionate access arrangements that companies supplying originator biological medicines sometimes provide to patients. The Gastroenterological Society of Australia explained:

> The current fixed prescribing rules for dose intervals of biologics do not allow for the clinical reality that many patients require dose escalation to maintain clinical remission. This is not achievable under the current PBS schedule and the pharmaceutical companies that supply these originator biological medicines have been giving compassionate supply in order for clinicians to be able to provide increased doses and recapture clinical response and remission. With the introduction of biosimilars, and if they are considered substitutable, it is not known if the biosimilar pharmaceutical

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44 Dr Paul Kubler, Member, Australian Rheumatology Association, *Proof Committee Hansard*, 18 June 2015, pp. 8–9.

45 Mr Tim James, Chief Executive Officer, Medicines Australia, *Proof Committee Hansard*, 18 June 2015, p. 3.

46 Gastroenterological Society of Australia, *Submission 1*, p. 2.

47 International Cancer Advocacy Network (ICAN), *Submission 4*, p. 2.

> companies will offer a similar compassionate access program. Also, there are significant concerns that if substitution of the originator and biosimilar product occur without the prescriber's control, then the potential legal ramifications of providing compassionate access to additional biologic drug where the actual prior source of the biologic agent is not known, may prevent these companies from continuing to offer this compassionate program. This will result in a significant proportion of patients losing response to this therapeutic class with many facing surgery and impaired quality of life.[48]

PBAC responses to concerns regarding pharmacy-level biosimilar substitution

2.43 In a statement issued on 18 June 2015, the PBAC outlined the process by which it would recommend listing a biosimilar treatment to allow substitution by a doctor or pharmacist:

> According to PBAC guidelines, if the biosimilar is approved by the Therapeutic Goods Administration as a safe and equally effective treatment compared to another drug, the PBAC will then consider listing the biosimilar drug on the PBS.
>
> During this assessment process, the PBAC will also consider whether the biosimilar drug should be listed to allow substitution by a doctor or pharmacist. This will be done on a case by case basis.[49]

2.44 According to PBAC, the changes will help to make biologic drugs more affordable for patients:

> It is important that pharmaceutical companies earn a fair return on their investment in new drugs, which is what the patent period ensures. However, as with the introduction of generic drugs in the past, many expensive, high-use biologic drugs are coming off patent in the next five to 10 years in Australia and this presents an opportunity for other companies to produce these biologics which may make the drugs more affordable.[50]

Legislative or administrative solution

2.45 Mrs Wood wanted to make clear that the proposed amendment was a technical one that:

> …does not legislate that there will be a free-for-all substitution. It actually provides the mechanism for the PBAC should they determine down the

48 Gastroenterological Society of Australia, *Submission 1*, pp. 2–3.

49 Pharmaceutical Benefits Advisory Committee, statement, 'Safety of biosimilar medicines', 18 June 2015, p. 1.

50 Pharmaceutical Benefits Advisory Committee, statement, 'Safety of biosimilar medicines', 18 June 2015, p. 1.

> track that there is evidence to support substitution. The technical amendment provides that mechanism for them.[51]

2.46 Mr David Quilty, Pharmacy Guild of Australia, explained further that the proposed amendment:

> …actually provides a head of power for the minister where the minister can decide that there is equivalence based on the advice of the PBAC, but there has to be a determination. This simply provides that head of power. Nothing would change expressly as a result of this legislation.[52]

2.47 Making this same point, Mrs Felicity McNeil, Department of Health, indicated:

> …with or without this amendment the practice of the PBAC determining whether any drug—a generic or a biosimilar—should be recognised for A-flagging would continue. The decision of the PBAC to make a recommendation as to whether a generic or a biosimilar should be A-flagged would continue.[53]

2.48 The Department explained that the concerns expressed by stakeholders essentially related to a matter of administrative practice as distinct from a legislative issue. That is, the legislation made it possible for the Minister to make a decision about the pharmacy-level substitutability of a biosimilar, and for the PBAC to provide advice on such matters, but it by no means mandated listing of biosimilars as substitutable. Mr Andrew Stuart noted the important distinction between the legislation and administrative practice. He informed the committee:

> The legislation makes something possible but certainly does not mandate it, so I would say that, if you are contemplating amendments to the legislation, be very careful about making something impossible which most of the stakeholders wish to be possible under the right and controlled conditions. The debate is about what the right and controlled conditions are, and I would say that is an administrative matter, not a legislative matter.[54]

2.49 In this regard, Mr Stuart also emphasised that the power already existed and the amendment was intended to put it beyond doubt following a legal case. He went on to explain:

> The legislation actually does not, in respect of A-flagging or substitution, distinguish between small molecules and biosimilars. It covers both

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51 Mrs Belinda Wood, Chief Executive Officer, Generic Medicines Industry Association, *Proof Committee Hansard*, 18 June 2015, p. 10.

52 Mr David Quilty, Executive Director, Pharmacy Guild of Australia , *Proof Committee Hansard*, 18 June 2015, p. 10.

53 *Proof Committee Hansard*, 18 June 2015, p. 12.

54 Mr Andrew Stuart, Deputy Secretary, Department of Health, *Proof Committee Hansard*, 18 June 2015, p. 12.

> eventualities and you will not find the word 'biosimilars' in the legislation in association with those issues.[55]

2.50 Mr James indicated that Medicines Australia had been working with the government to understand its intent and to understand very recent announcements, including by the PBAC, in relation to this particular area of practice. Importantly he noted that Medicines Australia was seeking to work through this in such a way that it might deliver an outcome that was non-legislative. Medicines Australia, however, were yet to find 'an entirely satisfactory, comfortable position as far as a resolution of this fundamental question of patient safety is concerned'.[56] He stated further:

> The solution may be a policy based solution. It may not necessarily bring about a change to the legislation.[57]

2.51 Medicines Australia principal concern was with the process—'what is the evidence base, the decision-making process, the mechanism, by which that substitution is going to be assured to be safe and in the interests of patients'.[58] It recommend that the government undertake broad and transparent public consultation across all stakeholders, including industry, clinicians and patient organisations, with the aim of producing informed guidance on how and under what circumstances 'a' flagging of biosimilar medicines can occur. It believed that this suggested approach would provide comfort to all stakeholders.[59]

Patient's choice

2.52 The Department further explained that if a biosimilar was deemed suitable for pharmacy-level substitution, the ultimate choice on whether to receive it would sill rest with the patient:

> There have been concerns raised here today that because the PBAC may be of a mind to recommend substitution of a biosimilar that would somehow compel a patient to use that biosimilar. The same processes that we have for allowing clinicians to make that decision—that is, that brand substitution is not permitted—would apply to the choice of the consumer not to have that biosimilar dispensed to them. Those policy parameters are still in place just as they are for generics.[60]

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55 *Proof Committee Hansard*, 18 June 2015, p. 14.

56 *Proof Committee Hansard*, 18 June 2015, p. 5.

57 *Proof Committee Hansard*, 18 June 2015, p. 5.

58 *Proof Committee Hansard*, 18 June 2015, p. 6.

59 *Submission 22*, p. 1.

60 Mrs Felicity McNeill, First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health, *Proof Committee Hansard*, 18 June 2015, p. 16.

2.53 The Department added that the government had set aside $20 million in funding for an education program to help ensure health consumers were able to make informed choices about the use of biosimilars.[61]

2.54 In its 18 June statement, the PBAC also explained that, as with generics, patients would retain the final choice as to which version of the drug they receive. Moreover, a clinician would 'still have the ability to indicate a biologic drug is not to be substituted for a biosimilar for their patient if they do not consider it appropriate in that particular case'. To do so, the clinician would simply tick a box indicating that brand substitution is permitted, a process 'already familiar to clinicians as it is the current process for generic versions of synthetic molecule drugs'.[62]

2.55 Asked the monitoring of adverse effects from pharmacy-level substitution of biosimilars, the Department responded:

> Adverse events are already supposed to be reported to the TGA in respect of any medicine, not just if it is a biosimilar but any generic or any individual molecule, whether it has brand competition or not. The patients and clinicians avail themselves of those areas.[63]

Conclusion

2.56 The committee notes the concerns registered by the great majority of submissions on the provisions dealing with the substitution of biosimilars at the pharmacy level. The committee understands, however, that their concerns may best be addressed through the actual administrative process that produces the advice to the Minister rather than legislation. Consequently, the committee is recommending that such concerns be resolved through improved administrative processes.

2.57 Also, many submitters were of the firm view that the TGA should have a far more substantial role in that advice. In this regard, the committee endorses Medicines Australia's recommendation for a broad and transparent public consultation across all stakeholders, including industry, clinicians and patient organisations, with the aim of producing informed guidance on how and under what circumstances 'a' flagging of biosimilar medicines could occur. The committee agreed with Medicines Australia that such an approach would provide comfort to all stakeholders.[64]

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61 Mrs Felicity McNeill, First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health, *Proof Committee Hansard*, 18 June 2015, p. 16.

62 Pharmaceutical Benefits Advisory Committee, statement, 'Safety of biosimilar medicines', 18 June 2015, p. 2.

63 Mrs Felicity McNeill, First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health, *Proof Committee Hansard*, 18 June 2015, p. 18.

64 *Submission 22*, p. 1.

Recommendation 1

2.58 The committee recommends that the government undertake immediately a broad and transparent public consultation across all stakeholders, including industry, clinicians and patient organisations, with the aim of producing informed guidance on how and under what circumstances 'a' flagging of biosimilar medicines can occur.

Recommendation 2

2.59 The committee recommends further that the government give close and careful consideration to the role of the TGA with a view to ensuring that its role offers reassurance to the industry, clinicians and patient organisations that the safety of patients would not be compromised by the process for determining whether a biosimilar is suitable for substitution at pharmacy level.

Recommendation 3

2.60 Given that the main concerns raised about the provisions of the bill could be addressed by improved processes that do not require legislative changes, the committee recommends that the bill be passed.

2.61 The committee, however, does urge the government to proceed immediately, through recommendations 1 and 2, to resolve concerns about the process allowing biosimilars to be substituted at the pharmacy level.

Senator Sean Edwards

Chair

Appendix 1
Submissions received

Submission Number	Submitter
1	Gastroenterological Society of Australia (GESA)
2	Alliance for Safe Biologic Medicines
3	Mr Stephen Murby • Attachment 1
4	International Cancer Advocacy Network (ICAN)
5	Australian Rheumatology Association (ARA)
6	CreakyJoints Australia
7	Australasian College of Dermatologists
8	Consumers Health Forum of Australia • Attachment 1
9	Arthritis Australia
10	Department of Health
11	Dr Paul Kubler
12	Name Withheld
13	Dr George Alex
14	Hospira Inc.
15	Biotechnology Industry Organization (BIO)
16	The Pharmacy Guild of Australia
17	Mrs Katherine Stewart • Supplementary to submission 17
18	AusBiotech
19	Diabetes Australia
20	Medical Software Industry Association (MSIA)
21	International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
22	Medicines Australia
23	Health Consumers Council (WA) Inc. • Attachment 1

Appendix 2

Public hearings and witnesses

CANBERRA, 18 JUNE 2015

ARMSTRONG, Mr Stephen, Group Executive, Pharmacy Viability, Pharmacy Guild of Australia

CHESWORTH, Mr Peter, Head of Division, Sectoral Growth Policy Division, Department of Industry and Science

HENDERSON, Mr Nick, Acting Assistant Secretary, Pharmaceutical Policy Branch, Pharmaceutical Benefits Division, Department of Health

JAMES, Mr Tim, Chief Executive Officer, Medicines Australia

KUBLER, Dr Paul, Member, Australian Rheumatology Association

MARABANI, Dr Mona, President, Australian Rheumatology Association

MCNEILL, Mrs Felicity, First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health

QUILTY, Mr David, Executive Director, Pharmacy Guild of Australia

ROOT, Ms Josephine, Policy Manager, Consumers Health Forum of Australia

SINCLAIR, Mr Paul, Branch President, NSW Branch, Pharmacy Guild of Australia

STUART, Mr Andrew, Deputy Secretary, Department of Health

THIRU, Dr Krishan, Member Company Representative, Medicines Australia

WOOD, Mrs Belinda, Chief Executive Officer, Generic Medicines Industry Association