



## National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010

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### Contents

Re-introduction of the Bill.....	2
Purpose .....	2
Background .....	3
Statutory price reductions .....	4
Price disclosure .....	5
Committee consideration .....	7
Position of significant interest groups and political parties .....	7
Dispute resolution .....	8
Key provisions .....	9
Price reductions .....	9
Price disclosure .....	10
Under co-payment data .....	10
Special arrangements .....	11
Concluding comments .....	12

## National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010

**Date introduced:** 29 September 2010

**House:** House of Representatives

**Portfolio:** Health and Ageing

**Commencement:** Sections 1 to 3: Royal Assent

Schedule 1: 1 February 2011

Schedules 2, 3, 4, 6 and 7: 1 December 2010

Schedule 5: 1 April 2012

**Links:** The links to the Bill, its [Explanatory Memorandum and second reading speech](#) can be found on the Bills page, 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/>.

### Re-introduction of the Bill

The National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 (the Bill) was first introduced into the 42<sup>nd</sup> Parliament and lapsed on the proroguing of Parliament in July 2010.

The Bill was re-introduced in the first week of the 43<sup>rd</sup> Parliament with minor amendments. These amendments changed the implementation date of the price disclosure arrangements (from 1 October to 1 December) and the date used to determine the drugs eligible for a statutory price reduction (30 September to 11 October).

### Purpose

The purpose of the Bill is to amend the *National Health Act 1953* (the Act), so as to:

- introduce a number of statutory price reductions to medicines listed on Formulary 2 (F2) of the Pharmaceutical Benefits Scheme (PBS)
- extend price disclosure arrangements to all drugs listed on F2 from December 2011
- enable the Government to collect data about PBS medicines dispensed at a price lower than the co-payment ('under co-payment'), and
- empower the Minister to make arrangements for the supply of pharmaceutical benefits under section 100 special arrangements.

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## Background

The Federal Government and Medicines Australia (MA)<sup>1</sup> signed a Memorandum of Understanding (MOU) in May 2010. The details of the MOU were announced as part of the 2010–11 Budget and the MOU is expected to deliver savings to Government of \$1.9 billion over the next five years. These savings are largely to be achieved through the imposition of price cuts across F2 and the extension of price disclosure arrangements to all products listed on F2.<sup>2</sup> Other features of the MOU include improved access to information held by the Government by MA; a commitment from the Government that no new Therapeutic Groups<sup>3</sup> will be formed; and an undertaking that the Government will not introduce any measure that favours the prescribing or dispensing of generic medicines. A more extensive analysis of the MOU has been published as part of the [Budget Review 2010–11](#).<sup>4</sup>

The Bill addresses three matters contained in the MOU: statutory price reductions, price disclosure and under co-payment data. These are largely technical amendments and relate to matters such as PBS pricing and the calculation of price reductions as a result of statutory price reductions or price disclosure. It also contains amendments to streamline the way drugs are listed for supply under section 100 arrangements and enables the revised Intravenous Chemotherapy Supply Program announced in the 2010-11 Budget to be implemented.

The proposed legislative amendments, while mandating price cuts, do little to re-engineer the generics medicines market in Australia. Commentators anticipate that the Australian Government is therefore likely to continue to pay high prices for generic medicines.<sup>5</sup> The MOU also prevents the Government from introducing any additional price cuts or new policy proposals beyond those agreed, further limiting the capacity of the Government to garner savings from the anticipated market entry of generic versions of several big ticket PBS medicines over the next five years. However discussion of these matters is beyond the scope of the Bills Digest.

As the new arrangements for revised Intravenous Chemotherapy Supply Program were subject to much stakeholder consultation and negotiation, the discussion of this issue in this Bills Digest is limited to the pricing arrangements required for the MOU to take effect.

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1. Medicines Australia represents the 'innovative medicines sector' in Australia. See '[About Us](#)' on the Medicines Australia [website](#).
  2. Formulary 2 (F2) was established under the PBS Reforms implemented in 2007. F2 contains products with multiple brands including generic medicines.
  3. Therapeutic groups are defined groups of drugs which have similar safety, efficacy and health outcomes. The prices for all medicines in a group are based on the lowest priced drug. There are seven therapeutic groups.
  4. R de Boer, Pharmaceuticals and pharmacy, *Budget Review 2010–11*, Parliamentary Library, Canberra, 2010, viewed 6 October 2010, <http://www.aph.gov.au/library/pubs/rp/BudgetReview2010-11/HealthPharmaceuticals.htm>
  5. P Clarke, 'Drug deal costing billions: Medicines Australia', *The Australian*, 15 May 2010, viewed 12 October 2010, <http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22media%2Fpressclp%2F4TPW6%22>

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## Statutory price reductions

The 12.5 per cent price reduction policy was introduced by the Howard Government in 2005. This policy was designed to ensure that the Government achieved price reductions when generic medicines were listed on the PBS. In short, when the first new brand (generic) of medicine was listed on the PBS, a mandatory 12.5 per cent reduction for all medicines was applied to all medicines in the reference group. This usually occurred around the time of patent expiry. Once a group received a 12.5 per cent cut, further reductions would not be made when other brands were listed. This was expected to generate savings of about \$800 million over four years to Government.

Under the PBS Reform arrangements announced in 2007, the 12.5 per cent reduction policy applied to products listed on Formulary 2 (F2), where relevant.<sup>6</sup> There was a 'flow-on' effect as the reduction applied to all brands, forms and strengths of that drug, and to drugs that are interchangeable with that medicine (that were listed on F2).

The 2007 PBS Reform arrangements also contained one-off statutory price reductions. F2 was divided into two separate formularies Formulary 2A (F2A) and Formulary 2T (F2T) with separate pricing arrangements. Staged price cuts of 2 per cent per annum for three years were applied to F2A products from 2008. A one-off 25 per cent price cut was applied to products on F2T but for some products this was phased over the life of the patent.

The proposed amendments introduce two further statutory price reductions. All medicines on F2 will experience a price reduction of two to five per cent on 1 February 2011.<sup>7</sup> The price reduction reflects the level of discounting that has been operating in the market—products on F2A will be subject to a two per cent reduction and products on F2T will receive a five per cent reduction. From 1 February 2011, the 12.5 per cent reduction will be increased to 16 per cent when the first new brand enters the market.

By international comparisons, this price reduction is relatively low. For example, the Netherlands introduced a mandatory price reduction in 2008, which halved the price of medicines at the time of patent expiry.<sup>8</sup> Provinces such as Alberta and Ontario in Canada have recently introduced price cuts for generic medicines of up to 56 per cent (45 per cent for brands already listed on the market)<sup>9</sup> and 25 per cent<sup>10</sup> respectively. Both of these provinces had relatively high pricing for generic medicines.

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6. Department of Health and Ageing (DoHA), *Pharmaceutical Benefits Scheme (PBS) reform*, media release, 2 February 2007, viewed 12 October 2010, [http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs\\_reform\\_02feb07.htm](http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs_reform_02feb07.htm)
  7. N Roxon (Minister for Health and Ageing), 'Second reading speech: National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010', House of Representatives, *Debates*, 29 September 2010, p. 5.
  8. P Clarke, 'Drug deal costing billions: Medicines Australia', *The Australian*, 15 May 2010, viewed 12 October 2010, <http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22media%2Fpressclp%2F4TPW6%22>
  9. Alberta Health and Wellness, *Alberta Pharmaceutical Strategy*, fact sheet, January 2010, viewed 6 October 2010, <http://www.health.alberta.ca/documents/Pharma-Strategy-2-Generic-Drugs.pdf>
  10. Ontario Ministry of Health and Long-term Care, *Reforming Ontario's Drug System*, media release, 7 April 2010, viewed 6 October 2010, <http://news.ontario.ca/mohltc/en/2010/04/expanding-access-to-affordable-drugs.html>.

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The Government did not provide any information about the rationale for selecting the 16 per cent reduction.

## Price disclosure

The original rationale for price disclosure arrangements was to ensure that the Government reaped the savings from generic medicines that were being offered to pharmacists through discounting. Products listed on F2 were required to disclose the 'actual market price' as a condition of listing. The actual market price is the price at which the drug sold to wholesalers and/or pharmacists, which may be less than the price paid by Government.

Implementation, to date, has been fraught with both administrative complexity and legal challenge and very few products have been subject to discounts as result of price disclosure arrangements.<sup>11</sup> The extension of price disclosure arrangements to all brands on F2 (currently over 1600)<sup>12</sup> will be a significant challenge for Government. In a submission to the Senate Inquiry on Consumer Access to Pharmaceutical Benefits, the Department of Health outlined various difficulties associated with implementation of price disclosure and delays in price reductions, including legal challenge, administrative error and complexities of administration.<sup>13</sup> It also noted that these concerns had been addressed and that appropriate protocols and procedures had been developed and implemented to ensure consistency and accuracy of decision making.<sup>14</sup> It remains to be seen whether the new procedures and protocols will have the intended effect.

Schedule 4 of the Bill sets out the details of calculations for the price disclosure arrangements and mandates the minimum average of 23 per cent price reduction for the first round of price disclosure starting on 1 December 2010. It is important to note that, in practice, there is a significant delay between notification of price reduction and the date that it will take effect. For example, the price reductions that will be calculated from the price disclosure cycle commencing on 1 December 2010 will not take effect until 1 April 2012.<sup>15</sup> Given the inherent dynamic nature of markets, it is unlikely that the price disclosed in December 2010 will be an accurate reflection of the market price in April 2012, almost two years after the price was disclosed.

The Government expects that this reduction of at least 23 per cent will represent a 'very large saving' to the PBS.<sup>16</sup> While this cannot be disputed, it remains to be seen whether the savings will continue in the long term. The United Kingdom (UK) introduced a series of price cuts in 2005 and an evaluation in 2007 suggested that the effects of the price cut are reduced over time and it is not

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11. Department of Health and Ageing, *The impact of PBS reform: report to the Parliament on the National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007*, Commonwealth of Australia, Canberra, February 2010, viewed 12 October 2010, <http://dpl/Books/2010/ImpactPBSReform.pdf>

12. N Roxon (Minister for Health and Ageing), op. cit., p. 4

13. Department of Health and Ageing (DoHA). Submission to the Senate Committee References Committee, *Inquiry into consumer access to pharmaceutical benefits*, March 2010, viewed 6 October 2010, [http://www.aph.gov.au/Senate/committee/clac\\_ctte/consumer\\_access\\_pharm\\_benefits/submissions/sub27.pdf](http://www.aph.gov.au/Senate/committee/clac_ctte/consumer_access_pharm_benefits/submissions/sub27.pdf)

14. Ibid.

15. N Roxon (Minister for Health and Ageing), op. cit., p. 4.

16. Ibid.

clear whether the savings are temporary or long term.<sup>17</sup> It also noted that arbitrary price cuts may unfairly penalise drugs, which are already cost-effective or have already been subject to discounting.<sup>18</sup> The impact of further cuts to already low priced drugs was noted in submissions to the Senate Inquiry into Consumer Access to Pharmaceutical Benefits.<sup>19</sup>

From the introduction of PBS reform until December 2009, a total of 38 drugs were subject to price disclosure.<sup>20</sup> Of these, only six have been subject to price reduction.<sup>21</sup> For the products that were subject to reduction, the range of price reduction was considerable from 14.57 per cent to 71.80 per cent.<sup>22</sup> The Generic Medicines Industry Association (GMiA) estimates that this has generated savings of \$30 million per annum.<sup>23</sup> In the context of an almost \$8.5 billion dollar program (per annum), questions could be asked about the benefits of the policy for government, taxpayers and the industry.

The Government is limited in the savings that can be achieved through price disclosure. Under the current [Pharmaceutical Benefits Scheme Price Disclosure Arrangements: Procedural and Operational Guidelines](#), products subject to price disclosure arrangements are removed from the therapeutic group and any price reduction does not 'flow-on' to all products in this group.<sup>24</sup> Under previous reference pricing arrangements, any price reduction was applied to all drugs in that group. Leaving aside the principle of equal government subsidy for equal health outcome, which has previously governed the entire operation of the PBS (the principle still operates, albeit in limited circumstances), the Government is unable to fully capitalise on the savings that might be achieved through price reduction as the price cut applies to one product, rather than all products in the entire group.

International experience suggests that price disclosure arrangements are notoriously challenging to implement and often circumvented.<sup>25</sup> Questions have also been asked about the effectiveness of

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17. Office of Fair Trading (OFT). *The Pharmaceutical Price Regulation Scheme: an OFT market study*. Office of Fair Trading, United Kingdom, viewed 6 October 2010, [http://www.offt.gov.uk/shared\\_offt/reports/comp\\_policy/oft885.pdf](http://www.offt.gov.uk/shared_offt/reports/comp_policy/oft885.pdf)

18. Ibid.

19. Generic Medicines Industry Association (GMiA), Submission to the Senate Committee References Committee, *Inquiry into consumer access to pharmaceutical benefits*, March 2010, viewed 6 October 2010, [http://www.aph.gov.au/Senate/committee/clac\\_ctte/consumer\\_access\\_pharm\\_benefits/submissions/sub16.pdf](http://www.aph.gov.au/Senate/committee/clac_ctte/consumer_access_pharm_benefits/submissions/sub16.pdf)

20. Department of Health and Ageing, *The impact of PBS reform*, op. cit., p. 37.

21. Ibid.

22. Ibid., p. 37.

23. GMiA, op. cit., p. 16.

24. Department of Health and Ageing, *Pharmaceutical benefits scheme price disclosure arrangements: procedural and operational guidelines*, Department of Health and Ageing, July 2007, p. 48, viewed 12 October 2010, [http://www.pbs.gov.au/files/industry/Pricing\\_Matters/Price\\_Disclosure/PBS%20Price%20Disclosure%20Procedural%20and%20Operational%20Guidelines.pdf](http://www.pbs.gov.au/files/industry/Pricing_Matters/Price_Disclosure/PBS%20Price%20Disclosure%20Procedural%20and%20Operational%20Guidelines.pdf)

25. See, for example, S Kwon, 'Pharmaceutical reform and physician strikes in Korea: separation of drug prescribing and dispensing', *Social Science and Medicine*, vol. 57, 2003, pp. 529-38.

price disclosure in a market that is not fully competitive.<sup>26</sup> Concerns have also been raised about the complexity of the policy and the lack of transparency due to the commercial in confidence nature of the data that is provided.<sup>27</sup> Furthermore, price disclosure is considered to ‘fail the test of efficient regulation’ with high compliance costs.<sup>28</sup>

## Committee consideration

As previously noted, this Bill was first introduced into the 42<sup>nd</sup> Parliament. That Bill had been referred to the Senate Community Affairs Legislation Committee (the Committee) for inquiry and report by 26 August 2010. However, the Committee decided to discontinue the inquiry following the dissolution of the 42<sup>nd</sup> Parliament on 19 July 2010.<sup>29</sup>

This Bill had also been reviewed by the Senate Scrutiny of Bills Committee and no comment was made.<sup>30</sup>

Upon re-introduction of the current Bill, it was referred to the Committee for inquiry and report on 16 November 2010.<sup>31</sup>

## Position of significant interest groups and political parties

There are mixed views among stakeholders.

The Generic Medicines Industry Association (GMiA) opposes price disclosure, whereas Medicines Australia (MA) supports the policy.<sup>32</sup> GMiA has argued that price disclosure is incompatible with Government principles of equal subsidy for equal health outcome and that the policy places a significant administrative burden on both sponsors and Government, notwithstanding the administrative and conceptual complexity.<sup>33</sup> By contrast, MA has been positive about the MOU and the proposed legislative amendments suggesting that the government would benefit from more

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26. Senate Community Affairs Reference Committee, ‘Reference: Consumer access to pharmaceutical benefits’, *Committee Hansard*, 7 May 2010, pp. CA 56-7, viewed 6 October 2010, <http://www.aph.gov.au/hansard/senate/commtee/S12998.pdf>

27. *Ibid.*, p. CA 51.

28. *Ibid.*

29. Senate Community Affairs Committee, *Final Report: National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010*, viewed 6 October 2010, [http://www.aph.gov.au/senate/committee/clac\\_ctte/nat\\_hlth\\_pbs\\_10/report/index.htm](http://www.aph.gov.au/senate/committee/clac_ctte/nat_hlth_pbs_10/report/index.htm)

30. Senate Scrutiny of Bills Committee, *Alert Digest*, no. 6 of 2010, 16 June 2010, viewed 6 October 2010, <http://www.aph.gov.au/senate/committee/scrutiny/alerts/2010/d06.pdf>

31. Australia, Senate, *Hansard*, 30 September 2010, pp. 103 and 105.

32. See, for example, Medicines Australia (MA), Submission to the Senate Committee References Committee, *Inquiry into consumer access to pharmaceutical benefits*, 13 April 2010, viewed 6 October 2010, [http://www.aph.gov.au/Senate/committee/clac\\_ctte/consumer\\_access\\_pharm\\_benefits/submissions/sub29.pdf](http://www.aph.gov.au/Senate/committee/clac_ctte/consumer_access_pharm_benefits/submissions/sub29.pdf) and GMiA, *op. cit.*

33. GMiA, *op. cit.*, p. 16.

efficient pricing of pharmaceuticals on the PBS.<sup>34</sup> It also welcomed the 'greater certainty' that the MOU and the price disclosure arrangements provided.<sup>35</sup>

In general terms, the Pharmacy Guild welcomed the MOU suggesting that it provided 'greater certainty', noting that the anticipated savings from the MOU were taken into account in the Fifth Community Pharmacy Agreement that was negotiated (and announced) around the same time.<sup>36</sup> The Consumers Health Forum of Australia has commented broadly on PBS Reform and suggested that consumers have not been disadvantaged as a result.<sup>37</sup>

During the election campaign, the Opposition signalled its commitment to the MOU and that the Coalition had no plans for further reform of the PBS beyond the MOU.<sup>38</sup> The re-introduction of the legislation to the Parliament was met with support from Medicines Australia.<sup>39</sup> The position of the minor parties and Independents was not clear at the time of writing.

## Dispute resolution

In giving evidence to a previous Senate inquiry into Consumer access to pharmaceutical benefits, MA observed the absence of a formal price disclosure dispute resolution and audit process.<sup>40</sup> This does not appear to be addressed in the legislation.

The Department of Health and Ageing (DoHA) has noted that there are 'appropriate protocols and procedures are in place for all steps and stages of the price disclosure process' but formal dispute resolution mechanisms were not specified.<sup>41</sup> The most recent [Pharmaceutical Benefits Scheme Price Disclosure Arrangements: Procedural and Operational Guidelines](#) (July 2007) does not contain any provision for dispute resolution. The audit requirements contained in the guidelines are directed towards the 'responsible person' (usually the pharmaceutical manufacturer). The [Impact of PBS](#)

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34. Medicines Australia, op cit.

35. Ibid

36. Pharmacy Guild of Australia, *Federal Budget and Fifth Agreement deliver certainty*, media release, 11 May 2010, viewed 12 October 2010, [http://www.guild.org.au/uploadedfiles/National/Public/News\\_and\\_Events/Media\\_Release\\_Archive/MR\\_Budget\\_11\\_May10.pdf](http://www.guild.org.au/uploadedfiles/National/Public/News_and_Events/Media_Release_Archive/MR_Budget_11_May10.pdf)

37. Consumers Health Forum of Australia, Submission to the Senate Committee References Committee, *Inquiry into consumer access to pharmaceutical benefits*, March 2010, viewed 6 October 2010, [http://www.aph.gov.au/Senate/committee/clac\\_ctte/consumer\\_access\\_pharm\\_benefits/submissions/sub20.pdf](http://www.aph.gov.au/Senate/committee/clac_ctte/consumer_access_pharm_benefits/submissions/sub20.pdf)

It should be noted that the consumers are largely shielded from the impact of PBS Reform as the co-payment policy was not affected by PBS Reform. It is likely that there will be a greater impact on consumers in the mid to long term future as products will be priced beneath the co-payments and pricing is to be subject to the discretion of pharmacists. This represents a direct transfer of costs borne by government to the consumer.

38. P Dutton (Shadow Minister for Health and Ageing), *Letter to Medicines Australia*, 20 August 2010, viewed 30 September 2010, <http://www.medicinesaustralia.com.au/pages/images/20100826-Medicines-Aust-Letter.pdf>

39. Medicines Australia, *New Parliament should pass PBS savings bill*, media release, 29 September 2010, viewed 29 September 2010, [http://www.medicinesaustralia.com.au/pages/view\\_news.asp?id=209](http://www.medicinesaustralia.com.au/pages/view_news.asp?id=209)

40. Medicines Australia, op. cit., p. 11.

41. DoHA, op. cit., p. 20.

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[Reform Report to Parliament](#) outlined the various strategies that DoHA has undertaken including quality assurance measures, provision of the calculation tool to manufacturers, forming an informal audit and dispute resolution group with industry and engaging KPMG as consultants to develop dispute resolution and audit arrangements.<sup>42</sup>

Despite these measures, it would appear that for the purposes of transparency and natural justice, this should be addressed in the legislative framework.

## Key provisions

### Price reductions

**Schedule 1** contains amendments proposed to the Act in relation to an increase in price reduction from 12.5 per cent to 16 per cent when the first new brand of a PBS medicine is listed. This increase will occur on and after 1 February 2011.

**Schedule 2** contains amendments proposed to the Act relating to one-off 2 per cent, 5 per cent and 25 per cent price reductions to F2.<sup>43</sup> This includes reductions that may occur for new brands of pharmaceutical items having drugs with outstanding staged reductions, as a result on the price cuts proposed under the 2007 Reforms.<sup>44</sup> In these circumstances, the listing of a new brand generally triggers:

- the bringing forward of all outstanding staged reductions for the brand with the outstanding staged reductions, and
- equivalent price reductions in all other brands of pharmaceutical items having the same drug.<sup>45</sup>

**Schedule 3** relates to the merging of Parts A and T of F2 to a single formulary. Proposed amendments would change the date for merger of Parts A and T of F2 from 1 January 2011 to 1 December 2010.

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42. Department of Health and Ageing, *The impact of PBS reform*, op. cit., pp. 38-39.

43. The reference to 'F2' is a reference to Formulary 2, one of two formularies on which pharmaceutical items are listed. F1 contains items that are single brand medicines (only one medicine of its type is listed on the PBS). F2 contains multiple brands and, typically, include medicines that are interchangeable at the patient level and where generic drugs are available: R de Boer, 'Pharmaceuticals and pharmacy', Parliamentary Library, *Budget Review 2010–2011*, May 2010, Canberra, p. 173, viewed 6 October 2010, <http://www.aph.gov.au/library/pubs/RP/2009-10/10rp17.pdf>

44. The new brands of pharmaceutical items may or may not be 'bioequivalent' or 'biosimilar' to existing listed brand: two medicinal products containing the same active substance are considered bioequivalent if they are pharmaceutically equivalent or pharmaceutical alternatives and their bioavailabilities (rate and extent) after administration in the same molar dose lie within acceptable predefined limits—these limits are set to ensure comparable in vivo performance, i.e. similarity in terms of safety and efficacy: see *European Medicines Agency—Committee for medicinal products for human use, Guideline on the investigation of bioequivalence*, 20 January 2010, viewed 6 October 2010, [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2010/01/WC500070039.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/01/WC500070039.pdf)

45. Explanatory Memorandum, op. cit., p. 9.

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## Price disclosure

**Schedule 4** contains amendments relating to price disclosure.

Currently, price disclosure may be voluntary or, in some circumstances, mandatory. Price disclosure, previously agreed to in the context of the 2006 reform package, is only applied at the time of listing of a new brand on F2 and therefore is voluntary for existing products.<sup>46</sup>

Manufacturers must disclose the actual price at which medicines are supplied to wholesalers and/or pharmacists; and price reductions occur if there is a difference of more than ten per cent between the weighted average disclosed price and the price paid by the Government.<sup>47</sup> Under current price disclosure arrangements, suppliers provide the price at which the drug is sold to wholesalers and/or pharmacies. DoHA then invites other suppliers of the same medicines to disclose their pricing arrangements. This information is then used to calculate the weighted average price. If the price reduction is less than 10 per cent of the ex-supplier price, the price reduction will not apply. If the reduction is greater than 10 per cent, the weighted average disclosed price will be the subsidised price, rather than the disclosed price.<sup>48</sup>

Amendments proposed in **Schedule 4** mean that price disclosure requirements will apply in relation to all brands of pharmaceutical items that have a drug on F2, except for brands of exempt items.<sup>49</sup>

## Under co-payment data

The Act does not contain provisions relating to co-payments per se.

**Schedule 5** of the Bill contains amendments proposed in relation to under co-payment data that may be obtained, as well as amendments proposed in relation to privacy protection provisions. Under co-payment data refers to all scripts that are dispensed under the PBS but are priced lower than the co-payment (currently \$33.30). This usually affects people without a concession card, as concession card holders are protected by the concessional co-payment (\$5.40).

For example, **items 4–7** of **Schedule 5** propose to amend **section 135AA** in the Act, which relate to privacy guidelines. This means that any use or disclosure of co-payment data by the Government will be done so in accord with the *Privacy Act 1988* and the secrecy provisions of the Act.<sup>50</sup>

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46. As to the meaning of 'F2', see above note 43.

47. R de Boer, op. cit., p. 173.

48. Ibid.

49. See **proposed section 99ADA** (**item 2** of **Schedule 4** of the Bill). An 'exempt item' is an item determined by the Minister to be exempt under section 84AH of the Act.

50. See Explanatory Memorandum, op. cit., p. 34.

## Special arrangements

**Schedule 6** contains amendments proposed in relation to special arrangements under section 100 of the Act.

Section 100 currently relates to special arrangements for providing that an adequate supply of special pharmaceutical products be available to people who are either living in isolated areas or are receiving medical treatment in such circumstances where pharmaceutical benefits:

- cannot be conveniently or efficiently supplied in accordance with Part VII of the Act (other than section 100); or
- are inadequate for that medical treatment.

The listing process for section 100 medicines will be amended so that section 100 medicines will come within the concepts of a *pharmaceutical benefit*, a *pharmaceutical item* and a *listed drug*. The provisions of the Act will then apply to section 100 drugs in the same way that they apply to all other PBS drugs. However, a section 100 arrangement may modify the application of those provisions.<sup>51</sup> For example, under **proposed paragraph 100(1)(b)**, medicines that are not generally available under Part VII of the Act (Pharmaceutical Benefits) may, in particular circumstances, be provided under an arrangement pursuant to section 100 (see **item 12 of Schedule 6**).<sup>52</sup>

In addition, it is noted that Pharmaceutical Benefits Advisory Committee (PBAC)'s role in relation to the listing of drugs will be the same under the amended Act as it currently is—the Minister will not be able to list a drug on the PBS, either as a generally available drug, or a section 100 special arrangement drug, unless PBAC has recommended that it be so listed.

It is also noted that the proposed new mechanism for declaring drugs to be section 100 special arrangements drugs, provides no general power for the Minister to make unilateral declarations. The Minister's power is limited to the situation where PBAC has made a recommendation that the drug be a section 100 special arrangement drug.<sup>53</sup>

Proposed amendments will also enable section 100 special arrangements to be made to ensure supply of pharmaceutical benefits to people who are receiving *treatment*, not just medical treatment as is currently the case. Consequently, section 100 special arrangements will now include other treatments such as dental and optometrical treatment.<sup>54</sup>

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51. Ibid., p. 37.

52. These circumstances are where people receive treatment in circumstances where, in general, the pharmaceutical benefits are inadequate for that treatment.

53. See Explanatory Memorandum, op. cit., p. 39.

54. Ibid., p. 42.

## Concluding comments

Not all generic medicines in Australia are priced at inappropriately high levels and to apply price cuts across the PBS may ‘take a blunt axe where a surgeon’s scalpel’ may be more appropriate.<sup>55</sup> The proposed arrangements may be inappropriately harsh on some products and inappropriately soft on others.<sup>56</sup> Furthermore, the Government does not appear to have a clear policy objective for the pricing and purchasing of generic medicines. The proposed price cuts are likely to deliver some mechanistic savings but it remains to be seen whether the savings will continue in the long term. It is no longer clear whether the Government is purchasing a ‘health outcome’ informed by principles of economic evaluation or is attempting to achieve the lowest price possible for generic medicines. Even so, the proposed statutory price cuts are low by international comparisons.

It appears that alternate models for purchasing generic medicines such as contractual arrangements with multiple suppliers or competitive tendering are not considered to be viable alternatives for Government.<sup>57</sup> Rather, in pursuing the arrangements proposed in the Bill, the Government is creating an additional administrative burden in an already complex scheme. Furthermore, it is not clear whether the burden of administration will outweigh the potential savings.

The provision of under co-payment data is a positive step forward for transparency. For the first time, the Government will have access to comprehensive information about the cost to consumers for under co-payment medicines. Under PBS reforms, the cost of medicines to consumers was expected to reduce as medicines would be priced under the co-payment as a result of price cuts. To date, the average decrease of under co-payment items was \$1.92 and the average increase was \$0.64.<sup>58</sup> It is important to note that under co-payment prescriptions are priced at the discretion of the pharmacist. This represents a transfer of cost for prescription medicines from the Government to consumers—and this may disadvantage some consumers. The Government has been silent on the proposed use of this data, for example, whether the affordability of under co-payment prescriptions and broader issues of access to medicines will be monitored.

The lack of a formal dispute resolution mechanism and audit process in relation to price disclosure could be considered an omission from the legislation. It remains to be seen whether the processes that DoHA has established will be satisfactory for both Government and stakeholders. However, the operation of the price reductions associated with price disclosure should become more transparent under the Bill as these would now be determined by legislative instrument.

As noted earlier, the most contentious aspects of the MOU are not contained in the Bill. The proposed amendments are largely technical in nature and seek to further expand the PBS reforms that were introduced in 2007. There has been mixed commentary from stakeholders about the

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55. L Bufone, ‘High prices for generics in Australia – more competition might help’, *Australian Health Review*, vol. 33, no. 2, pp. 200-214.

56. *Ibid.*

57. See *ibid* for a description of competitive tendering and how this might work in Australia.

58. Department of Health and Ageing, *The impact of PBS reform*, *op. cit.*, p. 10.

reforms, however, there has not been a comprehensive debate about the pricing and purchasing of generic medicines in Australia. It remains to be seen whether the proposed price cuts and reductions as a result of price disclosure will deliver the anticipated \$1.9 billion of savings (over five years) to Government. Implementation, to date, has been a complex and contested process; and is only anticipated to deliver savings of \$103 million (over four years)—considerably less than the predicted savings of \$580 million.<sup>59</sup> The MOU expressly prohibits the Government from pursuing any other policy proposals for generic medicines during the life of the Agreement. Given the difficulties associated with the current arrangements, expansion of price disclosure arrangements and achievement of the proposed savings will be a significant challenge for Government.

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59. Ibid, p. 51