



## National Health Amendment (Immunisation Program) Bill 2005

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## National Health Amendment (Immunisation Program) Bill 2005

**Date Introduced:** 14 September 2005

**House:** House of Representatives

**Portfolio:** Health and Ageing

**Commencement:** Sections 1, 2 and 3 commence on Royal Assent. Schedule 1, Parts 1 and 2 commence either on a date to be fixed by Proclamation or six months after Royal Assent, whichever is the earlier.

### Purpose

The purpose of the Bill is to amend the *National Health Act 1953* to give the Pharmaceutical Benefits Advisory Committee (PBAC) responsibility for advising the government on the funding of vaccines under the National Immunisation Program.

### Background

#### Schedule 1—Amendment of *National Health Act 1953*

Since 1997 advice on funding for vaccines under the National Immunisation Program has been provided to the government by the Australian Technical Advisory Group on Immunisation (ATAGI). The Bill proposes to amend the National Health Act to make PBAC responsible for providing this advice, thus absolving ATAGI of this responsibility.

#### The National Immunisation Program

The National Immunisation Program is a joint Commonwealth and state/territory government program which provides free vaccines for major vaccine preventable diseases, such as diphtheria, tetanus, whooping cough, polio, measles, mumps, rubella, and Hepatitis B.<sup>1</sup>

Commonwealth funding for vaccines under the National Immunisation Program is provided through grants from the Commonwealth to the states and territories.<sup>2</sup> The states and territories then provide the vaccines free of charge to providers to administer to the community.<sup>3</sup>

#### The Australian Technical Advisory Group on Immunisation

In 1997 the government established ATAGI to advise and make recommendations on the technical and scientific elements of the National Immunisation Program, and on funding and policy issues.<sup>4</sup> ATAGI's membership includes doctors, immunisation experts, other medical professionals, a consumer representative and a representative from the Department of Health and Ageing.<sup>5</sup>

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Since 1997, ATAGI recommendations have informed the development and implementation of changes to the Australian Standard Vaccination Schedule (which includes a list of all vaccines considered by the National Health and Medical Research Council (NHMRC) to be ‘best practice’) and the National Immunisation Program.<sup>6</sup>

In the 2005–06 Budget, the government announced that the funding advisory functions of ATAGI—that is, the role of providing advice to the Minister on which vaccines should be included in the National Immunisation Program—would be transferred to the Pharmaceutical Benefits Advisory Committee (PBAC). PBAC is the body which advises the government on pharmaceuticals to be listed on the Pharmaceutical Benefits Scheme (PBS).<sup>7</sup>

### **The Pharmaceutical Benefits Advisory Committee**

PBAC is a statutory body established under the *National Health Act 1953* which advises the government on which drugs and medicinal preparations should be made available as pharmaceutical benefits on the PBS. No new drug can be made available on the PBS without a recommendation from PBAC.<sup>8</sup> In considering whether to recommend the inclusion of a new drug or medicine on the PBS, PBAC considers the drug or medicine’s clinical effectiveness, safety and cost-effectiveness (value for money) compared to alternative treatments.<sup>9</sup> PBAC’s membership includes doctors, other health professionals and a consumer representative.<sup>10</sup>

The government argues that PBAC is the logical choice for the role of providing funding advice on vaccines, since ‘PBAC has developed a reputation as a world leader in the rigorous application of evidence-based assessment in developing funding recommendations’.<sup>11</sup> Further, according to Health Parliamentary Secretary Christopher Pyne’s second reading speech, the PBAC process ‘is being copied by other countries around the world. It is only reasonable that we apply it to Government expenditure on vaccines here in Australia’.<sup>12</sup>

### **Basis of policy commitment**

As noted above, the Bill will implement the decision announced in the 2005–06 Budget to transfer the funding advisory functions of ATAGI to PBAC. The government’s rationale for the changes is that they are needed to ‘strengthen cost-effectiveness evaluations of vaccines, and streamline the process for considering vaccines funded under the National Immunisation Program and the Pharmaceutical Benefits Scheme’.<sup>13</sup>

According to the Explanatory Memorandum, the ‘intention of the Bill is to ensure that the vaccine funding advisory arrangements place emphasis on cost-effectiveness assessment, and to provide a transparent and robust framework for evaluating vaccines and making decisions on whether to publicly fund them’.<sup>14</sup> The government argues that this will be achieved by utilising the well-established, rigorous decision-making processes of the Pharmaceutical Benefits Advisory Committee (PBAC) for vaccine funding

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recommendations'.<sup>15</sup> The Australian Technical Advisory Group on Immunisation will continue to provide clinical advice on vaccines to the Health Minister (and in fact will receive increased funding to do so) but will no longer advise on vaccine funding under the National Immunisation Program.<sup>16</sup>

Thus, the new vaccine funding advisory structure is designed to consolidate strengths in existing processes and structures: according to information provided by the Department of Health and Ageing during Senate Estimates hearings in June 2005, by relieving ATAGI of any role in advising on funding of vaccines, the new arrangements will allow ATAGI to 'do what it really does best, which is to make clinical recommendations about the use of vaccines'.<sup>17</sup> Likewise, transferring the responsibility for providing advice on funding and cost-effectiveness to PBAC is designed to draw on PBAC's expertise in this area. According to the Secretary of the Department of Health, Jane Halton:

The reality is that cost-benefit analysis is actually a highly specialised activity. ATAGI has done a fantastic job over the last however many years, but the volume of work and the level of technical expertise that is required in respect of vaccines and analysis has become infinitely more complicated in the last few years. Really, that is what the PBAC does par excellence. I think the government's decision is a reflection of what is a new world in this area. So giving that part of the job to the group who have actually demonstrated expertise is a fairly logical conclusion.<sup>18</sup>

### Issues raised by the proposed changes

While there is sound logic in making PBAC responsible for advising on vaccine funding and cost-effectiveness, immunisation experts have raised questions about how effective the 'streamlined' process will be, particularly as little detail has yet been provided about exactly how the new advisory structure will work.<sup>19</sup>

Questions may also be raised about the government's claim that transferring the role of providing advice on vaccine funding from ATAGI to PBAC will improve the transparency of the funding advisory process.<sup>20</sup> While PBAC is recognised as having pioneered the use of cost-benefit analysis in deliberations on recommending pharmaceuticals for subsidy (as the government points out), questions have been raised in the past about the *transparency* of PBAC's processes, as there is no public disclosure of the evidence considered in its decision-making process (according to PBAC, this is because legal issues usually prevent disclosure).<sup>21</sup>

The government also announced during the 2005 Budget that PBAC would be moved towards operating on a cost-recovery basis from July 2007—that is, pharmaceutical companies will have to pay to have their submissions for new drugs to be listed on the PBS to be considered by PBAC.<sup>22</sup> At this stage, it is unclear how advice on vaccines will be provided under PBAC's cost-recovery arrangements (that is, whether vaccine manufacturers will be subject to the same fee-paying arrangements as other pharmaceutical companies or if special arrangements for consideration of vaccines will be

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made). Some commentators have expressed concern about the impact of the move towards cost recovery on PBAC's capacity to perform its functions independently.<sup>23</sup> It is worth noting in this context that a similar body, the Therapeutic Goods Administration (TGA)—which regulates medicines, medical devices, and other chemicals—has operated on a cost recovery basis for some time now, and this arrangement has been subject to criticism. For example, according to the former president of the Australian Medical Association, Dr Bill Glasson, cost-recovery 'jeopardises both the transparency and legitimacy of TGA processes'.<sup>24</sup> Thus, another potential concern raised by the changes proposed in this Bill is the impact of PBAC's move towards cost-recovery on the rigour and independence of its advisory processes in the future.

### **Position of significant interest groups/press commentary**

Since their announcement on budget night, the changes proposed by the National Health Amendment (Immunisation Program) Bill have proven to be controversial: the former Chairman of the Australian Technical Advisory Group on Immunisation recently resigned from the position, reportedly in response to the changes and a lack of consultation about them.<sup>25</sup> Further, as noted above, immunisation experts have expressed scepticism about whether the changes will achieve their stated goals.<sup>26</sup>

Further, some critics of the proposed changes have argued that the transfer of funding advisory functions from ATAGI to PBAC is motivated more by political reasons than a desire to strengthen and streamline the advisory process. For example, Labor health spokeswoman Julia Gillard argues that the decision to remove the role of advising on vaccine funding from ATAGI is 'political payback pure and simple', following a difference of opinion between the government and the Advisory Group on funding of pneumococcal vaccine.<sup>27</sup> In 2002 ATAGI recommended that the vaccine for pneumococcal disease be included on the Australian Standard Vaccination Schedule. The government initially decided not to include the pneumococcal vaccine in the National Immunisation Program (later citing a worldwide shortage in vaccine supply as the reason for its decision).<sup>28</sup> In June 2004, after the issue of funding for pneumococcal vaccine had been the subject of considerable media and political attention,<sup>29</sup> the government announced that the pneumococcal vaccine would be funded through the National Immunisation Program.<sup>30</sup> Labor argues that ATAGI's recommendation that the pneumococcal vaccine be funded created a politically embarrassing situation for the government, and it is now being stripped of its funding advisory role as a consequence.

### **ALP/Australian Democrat/Greens policy position/commitments**

As noted above, the Opposition has accused the government of stripping back the powers of ATAGI as 'political payback' for having embarrassed the government over pneumococcal vaccine funding. Neither the Australian Democrats nor the Greens have commented publicly on the proposed changes.

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## Financial impact

PBAC will receive \$7.8 million in additional funding over the next four years to expand its current role to include providing advice on funding vaccines, as shown in table 1.

Table 1: Additional funding to PBAC for immunisation advisory role<sup>31</sup>

2005–06 (\$m)	2006–07 (\$m)	2007–08 (\$m)	2008–09 (\$m)	Total (\$m)
1.7	2.0	2.0	2.0	7.8

As noted above, the Government also announced during the Budget that ATAGI would receive additional funding (\$5 million over 4 years) to ‘strengthen its ongoing role in providing evidence-based clinical advice on the medical administration of vaccines’.<sup>32</sup>

## Main Provisions

### Schedule 1—Amendment of *National Health Act 1953*

The following amendments proposed by the Bill relate to the *National Health Act 1953*.

**Items 1 and 2** insert new definitions of ‘vaccine’ and ‘designated vaccine’ into subsection 4(1) of the Act. ‘Designated vaccines’ will be defined as those vaccines which the Minister ‘may provide, or arrange for the provision of’ (through the National Immunisation Program) (as defined by proposed new subsection 9B(2))

**Item 3** repeals the existing section 9B of the Act and inserts a new section 9B, under which the Minister may provide or arrange for the provision of designated vaccines. The proposed new section specifies that the Minister cannot determine that a particular vaccine is a designated vaccine unless PBAC has made a recommendation to this effect. The new section will specify that the Minister cannot revoke or amend a determination that a particular vaccine will be a designated vaccine unless PBAC has made a recommendation to this effect. The new section will require that any advice provided by PBAC to this effect will have to be tabled in both Houses of Parliament. The new section also specifies that the vaccine-related powers conferred on the Minister by the *Quarantine Act 1908* are not limited by the new section 9B.

**Item 4** inserts new subsections in section 101 of the Act expanding the powers of PBAC to provide advice to the Minister on vaccines for the purposes of proposed new section 9B. Proposed new subsection 4C specifies that PBAC must consider the cost-effectiveness of vaccines in deciding whether to recommend that a vaccine be a designated vaccine, and proposed new subsection 4D specifies that PBAC cannot recommend a vaccine that is more expensive than an alternative vaccine be a designated vaccine ‘unless the PBAC is satisfied that the more expensive vaccine provides significant improvement in efficacy or

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reduction of toxicity over the alternative vaccine'.<sup>33</sup> Proposed new subsection 4F allows for the PBAC to recommend that designated vaccines only be provided in certain circumstances (for example, to people in certain age groups).

**Item 5** amends subsection 101A(1)(b) to require PBAC to establish a sub-committee to assist PBAC in its vaccine funding advisory role if directed to do so by the Minister.

**Items 6 and 7** amend subsection 100A(2) to increase the membership of the PBAC by two, and to make the role of PBAC Chairperson a full-time role (this is to account for the expected increase in PBAC's workload as a result of its expanded role). **Item 8** amends subsection 100A(6) of the Act to clarify that members of PBAC other than the Chairperson are part-time office-holders, and **item 9** makes transitional arrangements for the move to the PBAC Chairperson becoming a full-time position.

## Concluding Comments

As noted above, there appear to be sound reasons for moving the role of providing vaccine funding advice from ATAGI to PBAC. However, for the various reasons canvassed in the Background section above the measures proposed by this Bill are likely to attract some controversy.

## Endnotes

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1. Immunise Australia website, see [http://immunise.health.gov.au/nip/nip\\_final.pdf](http://immunise.health.gov.au/nip/nip_final.pdf) (accessed 9 October 2005).
  2. *Budget Paper No. 3—Federal Financial Relations 2004–05*, p. 44.
  3. Christopher Pyne, Parliamentary Secretary to the Minister for Health and Ageing, 'National Health Amendment (Immunisation Program) Bill 2005', House of Representatives, *Debates*, 14 September 2005, p. 3.
  4. Department of Health and Ageing website, see <http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/health-publth-strateg-immunis-termfofr.htm> and <http://www.seniors.gov.au/internet/wcms/Publishing.nsf/Content/cda-pubs-cdi-2003-cdi2702-hm-cdi2702o.htm> (accessed 9 October 2005).
  5. Department of Health and Ageing website, see <http://www.seniors.gov.au/internet/wcms/Publishing.nsf/Content/cda-pubs-cdi-2003-cdi2702-hm-cdi2702o.htm> (accessed 9 October 2005).

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6. Department of Health and Ageing website, see <http://www.seniors.gov.au/internet/wcms/publishing.nsf/Content/cda-pubs-cdi-2003-cdi2702-htm-cdi2702o.htm> (accessed 9 October 2005).
7. *Budget paper No. 2—Budget Measures 2005–06*, p. 198.
8. Department of Health and Ageing website, see <http://www.seniors.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-listing-committee.htm#pbac> (accessed 9 October 2005).
9. Department of Health and Ageing, see [http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-list\\_on\\_pbac.htm](http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-list_on_pbac.htm) (accessed 10 October 2005).
10. Department of Health and Ageing, see <http://www.seniors.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-listing-pbacmembership.htm> (accessed 10 October 2005).
11. Pyne, op. cit.
12. *ibid.*
13. *Budget paper No. 2—Budget Measures 2005–06*, p. 198.
14. Explanatory Memorandum, p. 1.
15. *ibid.*
16. Tony Abbott, Minister for Health and Ageing, ‘Health Budget Fact Sheet 4—Protecting the nation against health threats’, *Media release*, 10 May 2005, see <http://parlinfoweb.parl.net/parlinfo/Repository1/Media/pressrel/JGAG60.pdf> (accessed 10 October 2005); B. Nogrady, ‘Government defends vaccine approval process restructure’, *Australian Doctor*, 17 June 2005, p. 2.
17. Community Affairs Legislation Committee, Budget estimates hearings, 2 June 2005.
18. *ibid.*
19. Nogrady, ‘Government defends vaccine approval process restructure’, op. cit.; B. Nogrady, ‘Vax group head quits after restructure’, *Australian Doctor*, 17 June 2005, p. 2.
20. Abbott, ‘Health Budget Fact Sheet 4—Protecting the nation against health threats’, op. cit.
21. M. Howe, ‘All change at the PBAC’, *Australian Doctor*, 23 March 2001, p. 33; K. Harvey, ‘Free trade and the cost of medicines’, *Access*, vol. 6, no. 3, May–June 2004, pp. 19–24.
22. Tony Abbott, Minister for Health and Ageing, ‘Health Budget Fact Sheet 3: Pharmaceutical Benefits Scheme: to be reinforced’, *Media release*, 10 May 2005, see <http://parlinfoweb.parl.net/parlinfo/Repository1/Media/pressrel/JGAG60.pdf> (accessed 10 October 2005).
23. See, for example, T. Faunce, Submission to Productivity Commission Inquiry Impact of Advances in Medical Technology on Healthcare Expenditure in Australia, 1 July 2005, see [http://www.pc.gov.au/study/medicaltechnology/subs/\\_Toc519695877](http://www.pc.gov.au/study/medicaltechnology/subs/_Toc519695877) (accessed 10 October 2005).

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24. Bill Glasson, 'Speech to Harvard Health Australia, The American Club, Sydney, 16 September 2004', *Media Release*, Australian Medical Association, 16 September 2004.
25. Nogrady, '[Vax group head quits after restructure](#)', op. cit.
26. *ibid.*; Nogrady, '[Government defends vaccine approval process restructure](#)', op. cit.
27. Julia Gillard, Shadow Minister for Health, Transcript—Doorstop Interview, Parliament House, Canberra, 11 May 2005, see <http://parlinfoweb.parl.net/parlinfo/Repository1/Media/pressrel/TSZF60.pdf> (accessed 10 October 2005). See also Julia Gillard, Shadow Minister for Health, 'The 2005-06 Howard Government Health Budget—Taking a Scalpel to Health', Address to the Brighton Branch of the ALP, 14 May 2005, see <http://parlinfoweb.parl.net/parlinfo/Repository1/Media/pressrel/LD1G60.pdf> (accessed 10 October 2005).
28. D. Wroe, 'Newborns to get free vaccinations', *The Age*, 14 May 2005, p. 5.
29. See, for example, M. King, 'Children are dying but Howard refuses to help', *Courier-Mail*, 13 April 2004, p. 13; L. Gooch, 'Australia 'dropped the ball' on vaccine', *The Age*, 14 May 2005, p. 5; J. Frenkel, 'Political games with children', *Herald-Sun*, 11 May 2004, p. 19.
30. Tony Abbott, Minister for Health and Ageing, Transcript: Announcement of the Pneumococcal Vaccination Program, Doorstop Interview, 11 June 2004, see <http://parlinfoweb.parl.net/parlinfo/Repository1/Media/pressrel/OOYC60.pdf> (accessed 10 October 2005).
31. Explanatory Memorandum, p. 2.
32. Abbott, 'Health Budget Fact Sheet 4—Protecting the nation against health threats', op. cit.
33. Explanatory Memorandum, pp. 4–5.

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