



## Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009

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## Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009

**Date introduced:** 24 June 2009

**House:** House of Representatives

**Portfolio:** Health and Ageing

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

Schedule 1: 1 July 2010

Schedules 2 and 3 (Part 1): day after Royal Assent

Schedule 3 (Part 2): whichever is the earlier of: on a day to be fixed by Proclamation or six months after Royal Assent

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

### Purpose

The Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009 (the Bill) contains amendments proposed as part of a series of bills amending the *Therapeutic Goods Act 1989* (the Act) to ensure the safety and effectiveness of therapeutic goods in Australia, as well as reducing the regulatory burdens on the therapeutic goods industry.<sup>1</sup>

The Bill, in particular, proposes to:

- change arrangements for the scheduling of medicines and poisons so that there would be separate scheduling of medicines and poisons
- enable the Secretary of the Department of Health and Ageing (DoHA) to declare the purpose for which particular kinds of medical devices cannot be included in the Australian Register of Therapeutic Goods (ARTG)
- extend the circumstances when consultation with, and advice sought from, the Gene Technology Regulator can take place, regarding applications for listing or registration of therapeutic goods, to those goods that either are or contain genetically modified organisms
- extending advertising offence provisions to anyone, not only sponsors, who inappropriately advertises therapeutic goods

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1. M Butler, 'Second Reading Speech: Therapeutic Goods Amendment (2009 Measures No.2) Bill 2009, House of Representatives, *Debates*, 25 June 2008, p. 6973.

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- amend provisions regarding the delegation of the Secretary's powers, and
- enable the Minister to specify advisory statements to be included on labels of particular medicines.<sup>2</sup>

## Background

### General

The Act and the *Therapeutic Goods Administration Regulations 1990* (the Regulations) are the primary means by which therapeutic goods, medical devices and poisons are regulated in Australia.<sup>3</sup>

The Therapeutic Goods Administration (TGA) is the principal regulator of therapeutic goods in Australia and is responsible for administering the provisions of the Act.<sup>4</sup>

Before a product can be marketed in Australia it must be registered on the ARTG. For therapeutic goods such as medicines and medical devices, the TGA makes an assessment of the quality, safety and efficacy of the product. The TGA also has a post-marketing surveillance role and monitors adverse reactions to therapeutic goods. It operates on principles of risk management, balancing the maintenance of public health and safety with reducing regulatory burden.

### Regulatory reforms

The proposed amendments in this Bill reflect the Government's regulatory reform program that was outlined by the TGA in 2008. The regulatory reform program largely reflects what was agreed as part of the establishment of the Australia New Zealand Therapeutic Products Authority (ANZTPA), which has subsequently not been proceeded with.<sup>5</sup>

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2. Explanatory Memorandum, Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009, p. 1. Note that all references to 'Secretary' in this Digest are references to the Secretary of the Department of Health and Ageing.
  3. See Therapeutic Goods Administration, *Australian therapeutic products legislation*, viewed 4 August 2009, <http://www.tga.gov.au/legis/index.htm>
  4. For information about the TGA's role, see Therapeutic Goods Administration, *What the TGA does*, viewed 4 August 2009, <http://www.tga.gov.au/about/tga.htm>
  5. For further information about the regulatory reform of therapeutic goods, see Therapeutic Goods Administration, 'Regulatory reform', viewed 5 August 2009, <http://www.tga.gov.au/regreform/index.htm>

In particular, as part of this reform package, the Therapeutic Goods Amendment (Medical Devices and Other Measures) Bill 2008 had been introduced into the Senate on 3 December 2008, which received Royal Assent on 17 June 2009; and the Therapeutic Goods

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The proposed changes to the scheduling arrangements for medicines and chemicals reflect one of the key recommendations made by the Council of Australian Governments (COAG) Review of Drugs, Poisons and Controlled Substances completed by Ms Rhonda Galbally in 2001 (the Galbally Review).<sup>6</sup> The Galbally Review recommended that there be separate committees to provide advice on the scheduling arrangements for medicines and chemicals.<sup>7</sup>

The final report of the Galbally Review was given to the Australian Health Ministers Conference (AHMC) in January 2001. The Working Party of the Australian Health Ministers' Advisory Council (the Working Party) prepared a response to the recommendations made in that report in April 2003, taking into account matters such as the proposed establishment of the Australia New Zealand Therapeutic Products Authority (ANZTPA). While the Working Party recommended that those recommendations be implemented in the 'trans-Tasman context',<sup>8</sup> implementation of recommendation 7 of the Galbally Review report was delayed following the decision to postpone the ANZTPA project in July 2007.<sup>9</sup>

The National Co-ordinating Committee on Therapeutic Goods (NCCTG), originally charged with the task of overseeing the implementation of the Galbally Review recommendations, is now looking to implement the remaining recommendations in an Australia-only context.<sup>10</sup>

It is noted that in its most recent review on chemicals and plastics regulation in 2008, the Productivity Commission (PC) recommended that recommendations relating to the scheduling of chemicals be implemented as soon as feasible.<sup>11</sup>

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Amendment (2009 Measures No. 1) Bill 2009 was introduced into Parliament on 19 March 2009, which is still before the Senate.

6. R Galbally, *National competition review of drugs, poisons and controlled substances legislation*, Final report, Part A, December 2000, p. 39.
7. R Galbally, *National competition review of drugs, poisons and controlled substances legislation*, Recommendation 7, p. 44.
8. See Therapeutic Goods Administration, *Review of drugs, poisons and controlled substances legislation*, viewed 5 August 2009, <http://www.tga.gov.au/docs/html/rdpdf.htm>
9. For historical information about the postponement of the ANZTPA project, see Australia New Zealand Therapeutic Products Authority, *Postponement of the ANZTPA establishment project*, viewed 7 August 2009, <http://www.anztpa.org/>
10. For further information about the NCCTG, see Therapeutic Goods Administration, *National Co-ordinating Committee on Therapeutic Goods (NCCTG)*, viewed 5 August 2009, <http://www.tga.gov.au/docs/html/ncctg.htm>
11. As to the PC's recommendation, see Productivity Commission, *Chemicals and plastics regulation*, Productivity Commission Research Report, July 2008, pp. XLIII, 93.

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In Australia, products that can be harmful (for example, when not used correctly) are grouped together in ‘Schedules’. These Schedules form the Poisons Standard. Each State and Territory has laws governing the supply, availability and oversight of use to ensure safe and effective use.<sup>12</sup> Each Schedule has different requirements, for example, medicines listed on Schedule 2 can only be sold in pharmacies.

Another proposed amendment seeks to ensure greater public safety, in that consideration will also be given to the intended use of a medical device to be listed on the ARTG, so that devices are used for the purpose for which they were intended and not unduly pose a risk to patients. These measures are designed to protect consumers and the broader public health. For example, the self-testing of diseases such as HIV can have serious implications for individuals as there is the possibility of a false positive or a false negative and there is no pre or post counselling. Furthermore, there is no incentive for an individual to notify appropriate health authorities of the results, if positive.

Proposed amendments also seek to ensure uniformity of consumer warnings to be included on medicines. These are general statements such as ‘If symptoms persist beyond 5 days consult a doctor’, designed to provide general advice. The intention of these amendments is to promote consistent information and understanding among consumers.<sup>13</sup>

## Committee consideration

The Bill has been referred to the Senate Community Affairs Legislation Committee (the Committee) for inquiry and report by 7 August 2009.<sup>14</sup>

## Stakeholder positions

Stakeholder commentary has largely been restricted to submissions and public hearings made to the Committee’s inquiry.

In general, although there was broad support for the intent of the Bill, stakeholders raised concerns about issues such as accountability, the consultation process and the lack of detail regarding implementation, particularly with respect to cost recovery. Concern was also raised about the legality of the TGA having responsibility for the regulation of chemicals.<sup>15</sup> In response to the various claims and concerns raised by stakeholders, the

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12. M Butler, op. cit.

13. M Butler, op. cit.

14. Details of the inquiry are at: Senate Community Affairs Legislation Committee, *Inquiry into the Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009*, viewed 31 July 2009, [http://www.aph.gov.au/senate/committee/clac\\_ctte/therapeutic\\_goods\\_09/index.htm](http://www.aph.gov.au/senate/committee/clac_ctte/therapeutic_goods_09/index.htm)

15. See ACCORD, Submission to the Inquiry into the Therapeutic Goods Administration (2009 Measures No.2) Bill 2009, *Inquiry into the Therapeutic Goods Administration (2009 Measures No. 2)*, July 2009, viewed 25 July 2009,

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TGA argued that the legislation had the support of the state and territory governments, and was the best model for national approach to medicines and poisons scheduling. The TGA did not consider the concerns about the legality of the legislation to be valid.<sup>16</sup> This particular issue is further explored elsewhere in the Digest.

It is noted that the Tasmanian, West Australian and Northern Territory governments have all made submissions to the Inquiry, indicating their support for the legislation as it currently stands.

This section of the Digest will focus on the main issues raised during the public hearings and in the submissions.

### Consultation process

One of the dominant themes of the public hearing and the submissions was the consultation process. The Australian Self Medication Industry (ASMI) suggested that they were not consulted in a ‘meaningful way’.<sup>17</sup> Similarly, in the hearing, ACCORD suggested that the consultation process has been ‘poor’.<sup>18</sup> The Complementary Healthcare Council (CHC) suggested that as the amendments were first developed in the context of the ANZTPA, further consultation is required for them to be implemented in the Australian only context.<sup>19</sup>

In response, the TGA tabled a detailed account of the consultation process. It noted that consultation began in 1996 with the Industry Commission (now PC) Report on the Pharmaceutical Industry. Extensive consultation was also part of the Galbally Review in

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[http://www.aph.gov.au/Senate/committee/clac\\_ctte/therapeutic\\_goods\\_09/submissions/sub04.pdf](http://www.aph.gov.au/Senate/committee/clac_ctte/therapeutic_goods_09/submissions/sub04.pdf)

16. See C Maskell-Knight, Transcript of public hearing, Senate Committee on Community Affairs, *Inquiry into the Therapeutic Goods Administration (2009 Measures No. 2)*, 8 July 2009, viewed 25 July, <http://www.aph.gov.au/hansard/senate/commttee/S12244.pdf>
17. Australian Self Medication Industry (ASMI), Submission to the Inquiry into the Therapeutic Goods Administration (2009 Measures No.2) Bill 2009, *Inquiry into the Therapeutic Goods Administration (2009 Measures No. 2)*, July 2009, p. ii, viewed 25 July 2009, [http://www.aph.gov.au/Senate/committee/clac\\_ctte/therapeutic\\_goods\\_09/submissions/sub01.pdf](http://www.aph.gov.au/Senate/committee/clac_ctte/therapeutic_goods_09/submissions/sub01.pdf)
18. ACCORD, Submission to the Inquiry into the Therapeutic Goods Administration (2009 Measures No.2) Bill 2009, op. cit. For further information about ACCORD, see ACCORD, *About ACCORD*, viewed 7 August 2009, <http://www.accord.asn.au/about>
19. Complementary Healthcare Council (CHC), Submission to the Inquiry into the Therapeutic Goods Administration (2009 Measures No.2) Bill 2009, *Inquiry into the Therapeutic Goods Administration (2009 Measures No. 2)*, July 2009, viewed 25 July 2009, [http://www.aph.gov.au/Senate/committee/clac\\_ctte/therapeutic\\_goods\\_09/submissions/sub06.pdf](http://www.aph.gov.au/Senate/committee/clac_ctte/therapeutic_goods_09/submissions/sub06.pdf)

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2001.<sup>20</sup> There was further stakeholder consultation on the proposed scheduling models in 2005 and the consultation on the final model in 2006. The proposed arrangements for scheduling under ANZTPA were released for public consultation in June 2007. As part of the development of the PC's report on Chemicals and Plastics Regulation in 2008, there was further consultation with industry.<sup>21</sup> This Report also recommended that separate arrangements for scheduling should be implemented as soon as is feasible. The recommendations of the PC's Report were adopted by the Council of Australian Governments (COAG) in 2008. The most recent consultation on the proposed arrangements (as reflected in the proposed amendments) occurred in April-May 2009.

It appears that the proposed amendments do not differ materially from what has already been generally agreed to by Commonwealth, state and territory governments, for some time. Perhaps some of the concerns raised by industry about the lack of consultation relate to the substance of the amendments and their preference for an alternative approach.

### Cost recovery arrangements

The majority of stakeholders raised concerns about the implementation of cost recovery arrangements.<sup>22</sup> ASMI noted that it was not possible to comment in 'significant detail' as the proposed arrangements have not been made available.<sup>23</sup> The ACCORD submission also raised questions about how the proposed cost recovery arrangements would work. The submission from the TGA to the Senate Committee notes that costs of scheduling will be fully cost recovered from the industry but no detail is provided.<sup>24</sup>

### Appropriateness of TGA to regulate chemicals

Both ACCORD and the CHC raise questions about the appropriateness of the TGA to regulate chemicals. While supportive of the intent to separate medicines and scheduling arrangements, CHC questioned whether the TGA was the most appropriate body to administer the Advisory Committee on Chemicals Scheduling as the role of the TGA was

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20. The Galbally Review noted that industry was 'generally in favour' of separating medicines and poisons scheduling. See Department of Health and Ageing, Submission to the Inquiry into the Therapeutic Goods Administration (2009 Measures No. 2) Bill 2009, *Inquiry into the Therapeutic Goods Administration (2009 Measures No. 2)*, July 2009, p. 16, viewed 25 July 2009,

[http://www.aph.gov.au/Senate/committee/clac\\_ctte/therapeutic\\_goods\\_09/submissions/sub02.pdf](http://www.aph.gov.au/Senate/committee/clac_ctte/therapeutic_goods_09/submissions/sub02.pdf)

21. Productivity Commission, op. cit.

22. See, for example, submissions by ASMI, ACCORD and CHC, op. cit.

23. ASMI submission, op. cit., p. 2.

24. DoHA submission, op. cit., p. 5.

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to assess and monitor therapeutic goods.<sup>25</sup> It suggested that a more appropriate body would be the Department of Health and Ageing, Office of Chemical Safety and Environmental Health.<sup>26</sup> ACCORD also argued that the primary role of the TGA was to regulate therapeutic goods, not chemicals.<sup>27</sup>

In response, the TGA noted that the agreed AHMC model does not support two committees under different Acts.<sup>28</sup> It was also argued that having two separate Acts amending the one Poisons Standard would not be a useful way to proceed.<sup>29</sup> Further, the TGA noted that the states and territories have indicated strong support for a single scheduling standard to allow for appropriate reference to their respective legislation and that ACCORD had previously been advised of this.<sup>30</sup>

### Constitutional issues

As noted previously, ACCORD argued, during the hearings and in its written submission, that the TGA did not have the constitutional power to regulate chemicals. On request from the Committee, ACCORD submitted the legal opinion which formed the basis of its argument. The main arguments can be summarised as follows:

- there are inherent weaknesses in the constitutional underpinnings of the Act and these will be further highlighted by extending the scope of the TGA to chemical regulation
  - the Australian Constitution does not give the Commonwealth Parliament power to make laws with respect to chemicals<sup>31</sup>
- establishment of the Advisory Committee on Chemical Scheduling and empowering the Secretary may not be constitutionally valid, especially in light of the reasons articulated in *Pape v Commissioner of Taxation*, particularly the following:

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25. CHC submission, op. cit., p. 3.

26. CHC submission, op. cit., p. 3.

27. ACCORD submission, op. cit., p. 7.

28. DoHA submission, op. cit., p. 6.

29. C Maskell-Knight (Principal adviser, TGA), Transcript of public hearing, Senate Committee on Community Affairs, *Inquiry into the Therapeutic Goods Administration (2009 Measures No. 2)*, 8 July 2009, p. CA 31, viewed 25 July, <http://www.aph.gov.au/hansard/senate/commtee/S12244.pdf>

30. DoHA submission, op. cit., pp. 6–7.

31. ACCORD, Supplementary Submission to the Inquiry into the Therapeutic Goods Administration (2009 Measures No. 2) Bill 2009, *Inquiry into the Therapeutic Goods Administration (2009 Measures No. 2)*, July 2009, Attachment 1, p. 1, viewed 23 July 2009, [http://www.aph.gov.au/Senate/committee/clac\\_ctte/therapeutic\\_goods\\_09/submissions/sub04a.pdf](http://www.aph.gov.au/Senate/committee/clac_ctte/therapeutic_goods_09/submissions/sub04a.pdf)

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- a key consideration in this case was the limitations on the executive power of the Commonwealth.<sup>32</sup>

## Parliamentary scrutiny and accountability

The legal opinion put forward in the ACCORD supplementary submission also criticises the lack of parliamentary scrutiny of provisions in the regulations to which the proposed amendments will give effect. That legal opinion suggests that it is ‘generally undesirable’ for Parliament to delegate the substance of the law to regulations.<sup>33</sup>

It is noted that one of the issues of concern to the Senate Standing Committee for the Scrutiny of Bills is the inappropriate delegation of legislative power, such as determination of important matters in regulations.<sup>34</sup>

The lack of detail about the regulations and wording of legislative instruments was also criticised by ASMI and CHC. ASMI had specific concerns about the constitution of the expert committee; merits and judicial review; arrangements for delegated legislative instruments (**item 11** – section 52A(2), **item 2** – section 52E(2)); and directions from AHMAC or its sub-committees.<sup>35</sup> It is important to note that the recommendations of an expert committee are not binding on the Secretary and that it is possible for alternate views not listed in the legislative framework to be taken into account when making decisions about scheduling.

## Commentary

### General

In essence, many of the issues raised by stakeholders reflect different approaches to regulation. For example, the TGA argues for a consensual approach in partnership with the states and territories; whereas ACCORD and, to a lesser extent—ASMI and CHF, suggest a more rigorous approach with greater Commonwealth involvement and control. The TGA has cited the support of the states and territories as justification for its approach, but questions about the best approach to poisons scheduling remain open.

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32. ACCORD, Supplementary Submission, p. 2. See also *Pape v Commissioner of Taxation* [2009] HCA 23; (2009) 257 ALR 1.

33. ACCORD, Supplementary Submission, p. 4.

34. One of the Terms of Reference of the Senate Standing Committee on the Scrutiny of Bills is to examine all bills that come before Parliament and report to the Senate whether any bill inappropriately delegates legislative power: see Senate Standing Committee on the Scrutiny of Bills, *Senate Scrutiny of Bills Committee*, viewed 7 August 2009, <http://www.aph.gov.au/senate/committee/scrutiny/cominfo.htm>

35. ASMI submission, op. cit., pp. 3–4.

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In its review of chemicals and plastics regulation, the PC advocated for the implementation of AHMAC arrangements with a strong intergovernmental agreement and that each state and territory should have uniform frameworks by adopting template legislation.<sup>36</sup> In addition, the PC recommended implementation of the proposed reforms to separate the poisons and medicines scheduling processes and that the Secretary should be the decision maker.<sup>37</sup> The PC further recommended that the arrangements be reviewed after two years to ensure consistency of decision making and determine the impact on industry. State and territory governments were recommended to adopt all poison scheduling decisions under the new arrangements by reference and to adopt a consistent framework through either a template or model approach.<sup>38</sup>

The proposed amendments do not fully address the issues raised by the PC. There is insufficient information available to make an assessment of the proposed amendments vis a vis the recommendations of the PC. Despite this, it would appear that there would be significant benefits in adopting a nationally consistent approach with identical legislative framework in each state and territory.

### **Constitutional validity of poisons scheduling**

It is widely accepted that the Commonwealth has little actual power to make laws relating to poisons/chemicals.<sup>39</sup>

Commonwealth's power to make laws in relation to poisons under the Act is generally limited, under subsection 6(1) of the Act to:

- (a) things done by corporations; and
- (b) things done by natural persons or corporations in so far as those things are done:
  - (i) in the course of, or in preparation for, trade or commerce between Australia and a place outside Australia, among the States, between a State and a Territory or between 2 Territories; or
  - (ii) under a law of the Commonwealth relating to the provision of pharmaceutical or repatriation benefits; or
  - (iii) in relation to the Commonwealth or in relation to an authority of the Commonwealth.

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36. Productivity Commission, *op. cit.*, pp. 99–104.

37. Productivity Commission, *op. cit.*, Recommendation 5.1, p. 104

38. Productivity Commission, *op. cit.*, Recommendation 5.1, p. 105

39. See Productivity Commission, *op. cit.*, p. 31; C Maskell-Knight (Principal adviser, TGA), Transcript of public hearing, *op. cit.*

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In effect, the regulation of poisons/chemicals in Australia is multi-jurisdictional and achieved by a national co-ordinated approach, with the Commonwealth involved in policy, as well as legislating on frameworks and national standards; and the states and territories directly regulating the use of such substances within their own jurisdictions.

It is worth noting that, as the PC has stated in its report, chemical regulation in Australia:

has traditionally been organised around distinct end uses. Thus separate regimes are in place for industrial chemicals, agricultural chemicals and veterinary medicines, pharmaceutical and therapeutic goods, and food. Similar institutional arrangements apply in other countries. Merging some or all of these regimes, just to harmonise chemical regulation, could compromise the purpose of these different streams of regulation. For example, chemical contamination of food is an important public health issue, but it is only one among many relevant regulatory issues concerning food, and hence is best considered through that particular regulatory lens.<sup>40</sup>

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is grafted onto, generic regulatory frameworks that govern public health, occupational health and safety (OHS), transport safety, agriculture, the environment and national security. Chemicals regulation is a means to an end; it manages the risks that chemicals might pose to the achievement of broad social and economic objectives — such as achieving a safe workplace, safe disposal of waste, or achieving effective and efficient transport — but it is managing only one source of risk. Thus while there are genuine reasons for regulating chemicals at various stages of their lifecycle, chemical regulation is not of itself a strong unifying influence in an institutional sense.<sup>41</sup>

Hence, there is a variety of regulatory frameworks relating to the use of chemical and poisons.<sup>42</sup>

It is also important to note that, currently, although the National Drugs and Poisons Schedule Committee (NDPSC) makes national scheduling and regulatory decisions in relation to poisons:

Poisons scheduling and controls set at the national level have little legal authority in Commonwealth law, but play an important role in advising state and territory governments on how poisons should be scheduled and regulated within their jurisdictions. State and territory governments maintain full control over the

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40. Productivity Commission, op. cit., pp. 31–32.

41. Productivity Commission, op. cit., p. 32.

42. For examples of the myriad of regulatory frameworks relating to chemical use, see Productivity Commission, op. cit., pp. 137–168 (chemicals in the workplace), 169–197 (transport) and 199–228 (agricultural and veterinary chemical products).

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manufacture, sale and use of poisons in their jurisdictions, and there is no obligation on them to adopt NDPSC recommendations.<sup>43</sup>

The Bill does not propose an entirely new area of poisons/chemicals regulation by the Commonwealth. It simply proposes to rearrange existing scheduling arrangements.

In addition, as Mr Maskell-Knight, Principal Adviser, TGA, pointed out during the Committee's Inquiry:

there seems to be a misconception that because something is in the Therapeutic Goods Act it means the Therapeutic Goods Administration is going to be solely responsible for it. That is not so. The act confers power on the secretary of the department; the Therapeutic Goods Administration is a division within the department. We are the secretary's arms and legs in relation to medicines. The proposal is not that we suddenly become the secretary's arms and legs in relation to chemicals. The idea is that the Office of Chemical Safety and Environmental Health will continue to support the secretary in that role. The secretary can delegate their scheduling decision-making powers to any officer within the department. The expectation is the medicine scheduling power will be devolved to the TGA and the chemical scheduling power will be devolved to the office of chemical safety. The intention is to have a common secretariat for the advisory committees within the TGA. The reason for that is to facilitate exchange of information between the two committees and also, frankly, it will be cheaper for the industry if we have one committee rather than two.<sup>44</sup>

It may also be worth pointing out that Schedule 1 of the Bill does not contain any enforcement provisions. The Advisory Committee on Chemicals Scheduling may 'make recommendations' and 'provide advice' to the Secretary in relation to matters such as the classification and scheduling of chemicals; other changes to the Poisons Standard; and restrictions to be imposed with respect to particular substances (see **item 8 - proposed section 52C**). The Secretary must simply 'have regard to' such recommendations and advice (see **item 12 - proposed section 52E**).

The actual enforcement of the Poisons Standard is undertaken by states and territories.

The question of whether the Commonwealth has constitutional power to take on a stronger, more coercive role in relation to the regulation of poisons/chemical use, as advocated by some, remains open. The Bill does not propose such a role for the Commonwealth.

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43. Productivity Commission, *op. cit.*, p. 96.

44. C Maskell-Knight (Principal adviser, TGA), Transcript of public hearing, *op. cit.*

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## Financial implications

The Government states that there will be no financial impact to the Commonwealth as the TGA operates on a cost recovery basis.<sup>45</sup>

## Main provisions

The Bill contains three Schedules, which contain proposed provisions relating to:

- scheduling substances
- precluding medical devices from being included in ARTG where the intended use of the device would pose a health risk, and
- miscellaneous matters, such as consultation between the Secretary and the Gene Technology Regulator.

### Schedule 1

Part 6–3 of the Act currently contains provisions establishing the NDPSC, clarifying the NDPSC's functions and matters relating to the Poisons Standard.<sup>46</sup> Part 6–3 currently provides for the joint scheduling of medicines and poisons by the NDPSC.

Amendments proposed in Schedule 1 seek to separate the scheduling of medicines and substances other than therapeutic goods.

For example, **item 8 of Schedule 1** proposes to **insert new sections 52B–52C** into the Act. **Proposed sections 52B and 52C** establish the advisory committees on medicines and chemical scheduling respectively in similar terms. These committees would replace the NDPSC. Each committee would be constituted by members from each state and territory, as well as the Commonwealth, according to the regulations. Functions of the committees would include:

- subject to certain provisos, make recommendations to the Secretary about classification and scheduling of medicines and chemicals\*
- make recommendations to the Secretary about changes to the Poisons Standard other than the Schedules

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

46. For information about the Poisons Standard, see Comlaw, *Poisons Standard 2008*, viewed 31 July 2009, <http://www.comlaw.gov.au/comlaw/management.nsf/lookupindexpagesbyid/IP200838167?OpenDocument>; Productivity Commission, op. cit., p. 97.

See also Explanatory memorandum, op. cit., p. 4.

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- reconsider such recommendations
- advise the Secretary about restrictions to be imposed in relation to particular substances,\* and
- any other functions prescribed in the regulations.

Note that functions marked with an \* would not apply to substances:

- (in relation to medicines) to the extent that those substances are, or are included in, goods other than therapeutic goods
- (in relation to chemicals) to the extent that those substances are, or are included in, therapeutic goods.

**Item 10** proposes to **replace subsections 52D(2)-(4)** in the Act with **new subsections 52D(2)-(3)**. These amendments would effectively empower the Secretary, not the NDPSC as it occurs now, to amend the current Poisons Standard or prepare a document in place of the current Poisons Standard. The Secretary would do so either on his or her own initiative or following an application under **proposed section 52EAA** (see below).

**Item 12** proposes to **replace section 52E** in the Act with **new sections 52E and 52EAA**. **Proposed section 52E** provides for certain matters that the Secretary must consider when amending or substituting the Poisons Standard, which include:

- the risks and benefits of using the substance
- the purpose and extent of use of the substance
- the toxicity of a substance
- the potential of abuse of the substance, and
- any other matters considered necessary by the Secretary to protect public health.

In addition, when amending the Poisons Standard, the Secretary must:

- comply with specified guidelines, such as those of the Australian Health Ministers' Advisory Council, which are brought to the Secretary's attention, and
- consider any recommendations or advice of either one of the advisory committees on medicines and chemical scheduling.

The Secretary has discretion as to whether to seek advice from one or both of:

- a committee that the Secretary considers appropriate
- any person.

Importantly, the Secretary may consider information other than the above when amending or substituting the Poisons Standard.

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**Proposed section 52EAA** enables a person to apply for amendment of the Poisons Standard and sets out the requirements for such applications.

### Comment

It is noted that ‘poisons’ and ‘chemicals’ have, in general, been referred to almost interchangeably. It has been decided to continue to do so in this Digest.

However, it is noted that the Act itself generally refers to ‘poisons’ and ‘substances’, while the Bill generally refers to substances other than therapeutic goods, ‘chemicals’ in relation to the name of the proposed new committee, and ‘poisons’ in relation to the Poisons Standard.<sup>47</sup>

In the absence of explanation, Parliament may consider seeking clarification of the various terms used and how those terms relate to each other.

### Schedule 2

Amendments proposed in Schedule 2 of the Act relate to ensuring that medical devices used in ways that threaten public and individual health are not included in ARTG.

**Item 1** proposes to **insert new section 41BEA** into the Act. **Proposed section 41BEA** gives discretionary power to the Secretary to specify, by legislative instrument, purposes for which a medical device of a particular type is not used exclusively.<sup>48</sup>

**Item 2** proposes to **insert new paragraph 41FD(ia)** into the Act, so that a person wishing to apply for a medical device to be included in ARTG must certify that that kind of device is not used exclusively for one or more purposes specified by the Secretary in **proposed section 41BEA** (see above).

**Item 3** proposes to **insert new paragraph 41FF(1A)** into the Act. The effect of this proposed amendment is that, following an application by a person for a medical device to be included in ARTG, the Secretary must not include that kind of medical device in ARTG if the Secretary is satisfied that the particular kind of device will be exclusively used for one or more purposes specified by the Secretary in **proposed section 41BEA** (see above).

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47. The Bill proposes to amend the definition of ‘substance’ in **item 6 of Schedule 1**. The current definition of ‘substance’ is ‘any medicine or poison’: *Therapeutic Goods Act 1989* section 52A.

48. Legislative instruments in these provisions would be open to parliamentary scrutiny and be available on the Federal Register of Legislative Instruments website, through [www.comlaw.gov.au](http://www.comlaw.gov.au).

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## Schedule 3

Schedule 3 contains provisions proposing various amendments relating to matters such as:

- extending advertising offence provisions to anyone, not only sponsors, who inappropriately advertises therapeutic goods
- extending the circumstances when consultation with, and advice sought from, the Gene Technology Regulator can occur, regarding applications for listing or registration of therapeutic goods, to those goods that either are or contain genetically modified organisms
- amending provisions regarding the delegation of the Secretary's powers, and
- enabling the Minister to specify advisory statements to be included on labels of particular medicines.

**Item 2** proposes to **replace subsection 22(5)** of the Act to the effect that it would be an offence for anyone, not just the sponsor, to advertise registered therapeutic goods for an indication that is not one for which the therapeutic goods are included in ARTG.

Note that **item 5** proposes a similar amendment, in relation to medical devices, to **section 41ML** of the Act.

**Item 4** proposes to **replace subsection 30D(1)** of the Act to extend the ability of the Secretary to seek advice from the Gene Technology Regulator about genetically modified organisms, as well as genetically modified products.<sup>49</sup>

**Item 6** proposes to **amend paragraph 57(8)(b)** in the Act, so that the Secretary's powers to make exemptions from requirements in certain circumstances, such as where the medicine is in short supply, may be delegated to any person in a position within the TGA prescribed by the regulations for this purpose, as opposed to just the Director of the Drug Safety and Evaluation Branch of the TGA as is the case now.

**Item 8** proposes to **insert new paragraph 3(5)(ca)** into the Act in relation to advisory statements. **Proposed new paragraph 3(5)(ca)** provides that labels of medicines, included in a class of medicines prescribed by the Regulations for the purposes of this new paragraph, must contain advisory statements specified under **proposed subsection 3(5A)** in relation to medicines (see below).

**Item 9** proposes to **insert new subsections 3(5A) and (5B)** into the Act. **Proposed new subsection 3(5A)** provides that the Minister may specify advisory statements for the purposes of **proposed new paragraph 3(5)(ca)** by legislative instrument. **Proposed new subsection 3(5B)** provides that the Minister may specify different types of advisory

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49. The meaning of 'genetically modified organisms' is the same as in the *Gene Technology Act 2000*: **item 1 Schedule 3**.

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statements for different medicines or classes of medicines for the purposes of **proposed subsection 3(5A)**.

## **Concluding comments**

Many of the stakeholder concerns were expressed in the course of the Committee's Inquiry and largely relate to amendment proposed in Schedule 1 of the Bill. However, it is specifically noted that most of the detail of what is proposed in the Bill will be set out in the Regulations. The lack of detail in the Bill does preclude comprehensive analysis of proposed amendments.

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