



## Therapeutic Goods Amendment (2009 Measures No. 1) Bill 2009

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## Therapeutic Goods Amendment (2009 Measures No. 1) Bill 2009

**Date introduced:** 19 March 2009

**House:** House of Representatives

**Portfolio:** Health and Ageing

**Commencement:** Sections 1 to 3 and all other provisions not listed in item 2 – on Royal Assent

Schedules 1, 3, and 6-7 (Part 1) – the day after Royal Assent

Schedules 2, 5 and 7 (Part 2) – a single day to be fixed by Proclamation, or six months after Royal Assent, whichever is the earlier.

Schedule 4 – 1 July 2011.

**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. 1) Bill 2009 (the Bill) seeks to amend the *Therapeutic Goods Act 1989* (the Act) to:<sup>1</sup>

- allow registered or listed goods on the Australian Register of Therapeutic Goods (the Register)<sup>2</sup> to be suspended in certain circumstances
- amend manufacturing licences to be issued for single sites only, unless specifically exempted
- amend monitoring powers so as to allow the taking of samples of any therapeutic goods, as well as anything relating to the therapeutic goods on manufacturing premises, and to allow the taking of any still or moving image or any recording

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1. Explanatory Memorandum, Therapeutic Goods Amendment (2009 Measures No. 1) Bill 2009, p. 1.
  2. The Register is also referred to as ARTG. For information about the Register, see Therapeutic Goods Administration, 'Medicines regulation and the TGA – Australian Register of Therapeutic Goods (ARTG)', <http://www.tga.gov.au/docs/html/medregs.htm#artg>, accessed 1 May 2009.

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- amend arrangements for regulating homeopathic and anthroposophic medicines<sup>3</sup>
- enable the making of lists of permissible and prohibited ingredients in listed medicines
- clarify arrangements for the setting of conditions on registered and listed goods, and
- make technical corrections to references to certain legislative instruments to reflect changes in terminology.

These amendments are part of a package of amendments to the Act announced by the Government in 2008.<sup>4</sup>

This Digest will particularly focus on the proposed changes to the regulation of complementary medicines, which involves a substantive change.

## Background

### General

The Therapeutic Goods Administration (TGA), an agency of the Commonwealth Department of Health and Ageing (DoHA), is the principal regulator of therapeutic goods in Australia. Before a product can be marketed<sup>5</sup> in Australia, it must be registered in the Register. 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 unnecessary regulatory burden.<sup>6</sup>

The Act and the *Therapeutic Goods Administration Regulation 1990* (the Regulations) are the primary means by which therapeutic goods and medical devices are regulated in Australia.<sup>7</sup>

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3. Also referred to as complementary medicines in this Digest.
  4. See Therapeutic Goods Administration, 'Regulatory Reform', <http://www.tga.gov.au/regreform/index.htm>, accessed 1 May 2009.
  5. In the context of therapeutic goods, the term 'marketed' refers to promotional activities in selling and distributing therapeutic goods and, in some instances, includes 'advertising'.
  6. For further information about the TGA, see Therapeutic Goods Administration, 'What the TGA does', <http://www.tga.gov.au/about/tga.htm>, accessed 1 May 2009.
  7. For further information about instruments regulating therapeutic goods in Australia, see Therapeutic Goods Administration, 'Australian therapeutic products legislation', <http://www.tga.gov.au/legis/index.htm>, accessed 29 January 2009.

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The objects of the Act are to provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The TGA is responsible for administering the provisions of the Act.

### Complementary medicines

A complementary medicine is a therapeutic good consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and a traditional use. Traditional use means use of the designated active ingredient that is well documented, or otherwise established, according to the accumulated experience of many traditional healthcare practitioners over an extended period; and accords with well-established procedures of preparation, application and dosage.<sup>8</sup>

As previously mentioned, complementary medicines must be registered on the Register before they can be marketed in Australia. The [Australian regulatory guidelines for complementary medicines](#)<sup>9</sup> outlines the regulatory process of complementary medicines, of which there are five phases:

- pre-assessment (brief review of application by TGA i.e. to ensure that key data has been provided)
- evaluation and peer review
- consideration by the Complementary Medicines Evaluation Committee<sup>10</sup> and a recommendation is made to the TGA
- decision by a delegate of the Secretary of DoHA, and
- implementation (if successful).

An assessment is made on the quality of the product, especially the active ingredients and its excipients.<sup>11</sup> The manufacturing process and level of Good Manufacturing Process

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8. For further information on complementary medicines, see Therapeutic Goods Administration, 'Australian regulatory guidelines for complementary medicines', Part 1, <http://www.tga.gov.au/docs/html/argcm.htm>, accessed 1 May 2009.

9. *ibid.*

10. For information about the Complementary Medicines Evaluation Committee, see Therapeutic Goods Administration, 'Complementary Medicines Evaluation Committee (CMEC)', <http://www.tga.gov.au/docs/html/cmec/cmec.htm>, accessed 1 May 2009.

11. Excipient ingredients are substances used to aid the manufacture of therapeutically active substances into dosage forms suitable for administration to consumers: see Therapeutic Goods Administration, 'Australian regulatory guidelines for complementary medicines', Part 1, Section 6, paragraph 6.2.3.2, p. 38, <http://www.tga.gov.au/docs/html/argcm.htm>, accessed 4 May 2009.

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(GMP), as well as details of quality control processes to ensure consistency, are also assessed by the TGA.

The sponsor is obliged to provide evidence of efficacy, which is reviewed by the TGA. This is a paper based assessment only and the TGA does not conduct any testing of complementary medicines. The safety of the product may be established by reliance on published data or with reference to existing literature. *In vitro* studies are not required. The therapeutic claims of the product are also reviewed to ensure that there is sufficient supporting evidence.

## Basis of policy commitment

### General

As mentioned above, the Government has commenced a reform agenda to update and streamline the existing regulatory framework for all therapeutic goods in Australia. These reforms largely reflect the wide range of regulatory reforms that were developed and consulted on as part of the legislation associated with the proposed [Australia New Zealand Therapeutic Products Authority \(ANZTA\)](#), which was abandoned in 2007.<sup>12</sup>

### Complementary medicines

In general, the Government expects that the proposed amendments will improve the efficiency of the operation of the TGA and strengthen the regulatory framework for complementary medicines.<sup>13</sup> The proposed amendments also reflect recommendations that were made in the 2003 Report to the Parliamentary Secretary to the Minister for Health and Ageing, the Hon. Trish Worth MP, by the Expert Committee on Complementary Medicines in the Health System (the Report)<sup>14</sup> regarding the regulation of homoeopathic

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12. For further information about the regulatory reform of therapeutic goods, see Therapeutic Goods Administration, 'Regulatory reform', <http://www.tga.gov.au/regreform/index.htm>, accessed 1 May 2009. 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 and it is noted that the Therapeutic Goods Amendment (2009 Measures No. 2) Bill may be introduced sometime during in the parliamentary winter sittings.
  13. See *ibid.* and Explanatory Memorandum, *op. cit.*, p. 2.
  14. Expert Committee on Complementary Medicines in the Health System, 'Complementary Medicines in the Health System', *Report to the Parliamentary Secretary to the Minister for Health and Ageing*, September 2003, <http://www.tga.gov.au/DOCS/pdf/cmreport.pdf>, accessed 1 May 2009.

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medicines and related remedies. The Report was in response to the Pan Pharmaceuticals recall in 2003.<sup>15</sup>

In short, recommendation 2.1.8 of the Report recommended that homeopathic and related remedies that make therapeutic claims should be regulated to ensure that they meet appropriate standards of safety and quality.<sup>16</sup> The Report noted that the definition of homeopathic preparation should be amended to reflect only preparations that are made with ingredients consistent with homeopathic principles and practices.<sup>17</sup>

Prior to the legislation being tabled in Parliament, the TGA conducted a series of public consultation sessions which outlined the reform directions and proposed legislative amendments.<sup>18</sup> It was noted that the proposed legislative amendments would provide clarification on the appropriate standard for homeopathic and anthroposphic preparations and make administrative changes. These have been reflected in **Schedule 4**.

## Committee consideration

On 19 March 2009, the Senate Selection of Bills Committee resolved that the Bill not be referred to committees.<sup>19</sup>

## Position of significant stakeholders

### Complementary medicines

The Complementary Healthcare Council (CHC) of Australia has long supported the existing regulatory framework for complementary medicines, arguing that that it is ‘world

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15. In 2003, the TGA initiated the largest recall in Australia and more than 1600 complementary medicines were withdrawn from the Australian marketplace. The recall was in response to the failure of Pan Pharmaceuticals to maintain appropriate manufacturing and quality control standards.
  16. Expert Committee on Complementary Medicines in the Health System, op. cit., p. 18.
  17. *ibid.*
  18. See Therapeutic Goods Administration, ‘Consultation on regulatory reforms for therapeutic goods’, <http://www.tga.gov.au/regreform/cons0807.htm>, accessed 1 May 2009.
  19. Senate Selection of Bills Committee, *Report*, No. 4, 2009, p. 4, [http://www.aph.gov.au/senate/committee/selectionbills\\_ctte/reports/2009/rep0409.pdf](http://www.aph.gov.au/senate/committee/selectionbills_ctte/reports/2009/rep0409.pdf), accessed 7 May 2009.

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class'.<sup>20</sup> Although there has been no specific commentary on the proposed amendments, the CHC has previously argued against calls for a stronger regulatory framework for complementary medicines.<sup>21</sup>

When the ANZTPA formally disbanded, the CHC expressed disappointment that the joint regulatory agency was not being established but advocated that many of the proposed changes to the regulatory framework for complementary medicines should be implemented.<sup>22</sup> This is consistent with the public consultation documents released by the TGA indicating widespread stakeholder support for many of the changes to be implemented in the context of ANZTPA.

The Australian Self Medication Industry (ASMI) has also expressed support for the complementary medicine regulatory framework as it currently stands.<sup>23</sup> Like the CHC, ASMI supported the proposed changes that were due to be implemented in the context of ANZTPA for complementary medicines to still go ahead.<sup>24</sup>

Although there has been no explicit statement of support for the proposed amendments, it could be inferred that there is general support from stakeholders as the legislation largely reflects what had previously been agreed to in the context of ANZTPA.<sup>25</sup>

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20. Complementary Healthcare Council of Australia, 'NPS survey into complementary medicines draws limited conclusions', *media release*, 21 November 2008, <http://www.chc.org.au/News/MediaRelease/>, accessed 1 May 2009.
  21. Complementary Healthcare Council of Australia, 'Complementary medicine regulations protect consumers', *media release*, 3 June 2008, <http://www.chc.org.au/News/MediaRelease/>, accessed 1 May 2009.
  22. Complementary Healthcare Council of Australia, 'Trans tasman harmonisation', *media release*, 24 July 2007, <http://www.chc.org.au/News/MediaRelease/>, accessed 1 May 2009.
  23. Australian Self Medication Industry, 'Tightening of controls over complementary medicines not warranted', *media release*, 30 March 2008, <http://www.asmi.com.au/documents/media-releases/Tightening%20of%20Complementary%20Controls.pdf>, accessed 1 May 2009.
  24. Australian Self Medication Industry, 'Future of healthcare regulation in Australia should not be derailed by Trans Tasman differences', *media release*, 31 July 2007, <http://www.asmi.com.au/documents/media-releases/Trans%20Tasman%20Jul07.pdf>, accessed 1 May 2009.
  25. For a critique of existing regulation of complementary medicine and discussion of general proposals for reform, see K. Harvey, 'A review of proposals to reform complementary medicines', *Australian Health Review*, May 2009, vol. 33, no. 2, pp. 279-287.

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## Financial implications

The Government states that the amendments proposed in the Bill will not have any financial impact on the Commonwealth, and will have, at most, a low impact on the therapeutic goods industry.<sup>26</sup>

## Main provisions

**Schedules 1 to 7** of the Bill propose amendments in relation to matters including:

- suspension of registered and listed goods from the Register
- manufacturing licenses
- monitoring powers
- homeopathic and anthroposophic medicines
- therapeutic goods ingredients, and
- miscellaneous amendments, including conditions on therapeutic goods.

### Suspension of registered and listed goods from ARTG

The Act already allows for medical devices to be suspended from the Register in certain circumstances, including where it is considered that remedial action can be taken to address the grounds of suspension. However, this is not the case with respect to therapeutic goods. Amendments in **Schedule 1** of the Bill seek to address this anomaly. Examples of such proposed amendments are as follows.

**Item 2 of Schedule 1** of the Bill proposes to insert **new sections 29D-29G** into Part 3.2 of Chapter 3 of the Act (registration and listing of therapeutic goods).

Under **proposed subsection 29D(1)**, the Secretary<sup>27</sup> would have a discretionary power to suspend the registration or listing of therapeutic goods if satisfied that:

- either:
  - if the goods remain on the Register, there is a potential risk of death, serious illness or serious injury, and

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26. Explanatory Memorandum, op. cit., p. 2. As there does not appear to be a Regulation Impact Statement (RIS), it is possible that the Bill has received a RIS exemption from the Office of Best Practice Regulation (the OBPR).

27. ‘Secretary’ means the Secretary to the Department of Health and Ageing: *Therapeutic Goods Administration Act 1989* section 3. However, the Secretary may authorise certain persons to exercise powers under the provisions of the Act: *ibid.*, section 7A.

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- within the suspension period, the person concerned is likely to be able to take the necessary action to ensure, if the therapeutic goods were to remain on the Register, those goods would not cause a potential risk of death, serious illness or serious injury, or
- it is likely that there are grounds for cancelling the registration or listing of the goods in particular circumstances.<sup>28</sup>

Where it is likely that there are grounds for cancelling the registration or listing of the goods in particular circumstances under **proposed paragraph 29D(1)(b)**, **proposed subsection 29D(2)** would require the Secretary to provide written notice to the person in relation to whom the therapeutic goods are included in the Register, of the Secretary's intention to suspend and reasons for doing so, as well as to afford that person a reasonable opportunity to make submissions in relation to the proposed suspension of goods.

Under **proposed subsection 29D(3)**, the Secretary must not make any final decision about suspension of goods until he or she has considered any such submissions.

Under **proposed subsection 29D(4)**, a notice of suspension must specify the period of suspension, which must not exceed six months.

**Proposed section 29E** provides for when any suspension would become effective and extension of suspensions.

Notably, under **proposed paragraph 29E(1)(a)**, if the suspension is necessary to prevent a potential risk of death, serious illness or serious injury, suspension takes effect on the day on which notice is given to the person. In any other case, under **proposed paragraph 29E(1)(b)**, suspension becomes effective on a day that is 20 days or later after the notice is given to the person, as specified in the notice itself.

A suspension is effective until the Secretary revokes it under **proposed section 29F** (**proposed paragraph 29E(2)(a)**) or at the expiration of either:

- the specified period of suspension under **proposed subsection 29D(4)**, or
- the specified period (if any) for which suspension is extended under **proposed subsection 29E(3)** (**proposed paragraph 29E(2)(b)**).

Suspensions may, by written notice to the person concerned, be extended for a period of not more than six months (**proposed subsection 29E(3)**) or revoked (**proposed section 29F**).

Under **proposed subsection 29F(1)**, if the Secretary is satisfied that:

- the ground(s) upon which the registration or listing of the therapeutic goods were suspended no longer apply, and
- there are no other grounds upon which to suspend the registration or listing of those goods,

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28. See *ibid.*, paragraphs 30(1)(da)-(f), subsections 30(1A), 30(1C) and 30(2).

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the Secretary *must* revoke the suspension by written notice to the person concerned.

However, under **proposed subsection 29F(2)**, if the person concerned applies in writing or at the Secretary's own initiative, the Secretary *may* revoke the suspension.

If, after the person concerned makes an application for the suspension to be revoked, the Secretary decides not to do so, the Secretary *must* provide the person with written notice of that decision and the reasons for it (**proposed subsection 29F(4)**).

It is noted that, in relation to decisions to suspend and to revoke suspension, there are requirements for publication of particulars of those decisions in the *Government Gazette*<sup>29</sup> (**proposed subsections 29D(5)** and **29F(3)**).

It is noted that the Secretary's decisions made under those proposed amendments would be reviewable by the Minister at first instance and that the Minister's decision would be reviewable by the Administrative Appeals Tribunal (the AAT) under section 60 of the Act.

### Manufacturing licences

The Act requires a person who manufactures therapeutic goods (not medical devices) to hold a manufacturing licence, subject to certain exceptions.<sup>30</sup> The TGA may currently issue such a licence authorising the manufacture of therapeutic goods at more than one premise.<sup>31</sup> Amendments proposed in **Schedule 2** seek to ensure that a manufacturing licence only applies to one site, unless otherwise allowed in guidelines that the Secretary determines. Examples of such proposed amendments are as follows.

**Item 5 of Schedule 2** of the Bill proposes to **insert new subsections 37(1A)** and **37(1B)** into the Act.

Under **proposed subsection 37(1A)**, a manufacturing licence application must generally relate to only one manufacturing site.<sup>32</sup>

However, **proposed subsection 37(1B)** provides that if, after considering guidelines that would be developed under **proposed section 38A**,<sup>33</sup> an applicant believes that a licence could be granted covering two or more manufacturing sites, that applicant may identify

29. See Attorney-General's Department, *Government Gazettes*, <http://www.ag.gov.au/govgazette>, accessed 28 April 2009.

30. See *Therapeutic Goods Administration Act 1989* Chapter 3 Part 3-3; *Therapeutic Goods Regulations 1990* regulation 18, Schedule 8.

31. See current definition of 'manufacturing premises': *Therapeutic Goods Administration Act 1989* section 3.

32. As to the proposed meaning of 'manufacturing site', see Therapeutic Goods Amendment (2009 Measures No. 1) Bill 2009 Schedule 2 item 2.

33. *ibid.*, Schedule 2 item 12.

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those sites in the manufacturing licence application and state his or her reasons for doing so.

**Item 11 of Schedule 2** of the Bill proposes to insert **new subsections 38(2A) and 38(2B)** into the Act. Section 38 of the Act sets out certain matters for the Secretary's consideration when deciding whether to grant a manufacturing licence.

Under **proposed subsection 38(2A)**, the Secretary *must* consider the guidelines that would be developed under **proposed section 38A**<sup>34</sup> when granting manufacturing licences.

Under **proposed subsection 38(2B)**, the Secretary *must*, in the licence itself, authorise the specific licence holder to carry out particular steps in the manufacture of specified therapeutic goods at each manufacturing site covered by the licence.

**Item 12 of Schedule 2** of the Bill proposes to insert **new sections 38A and 38B** into the Act.

**Proposed section 38A** provides that the Secretary *must* make guidelines that set out when a licence may cover two or more sites and that such guidelines be made by legislative instrument.

**Proposed section 38B** provides for converting old licences covering two or more sites into new licences that comply with the proposed requirements by revoking the old licence and granting new licences that together cover all of the sites under the old licence. There would be no charges for the new licences issued (**proposed subsection 38B(10)**). Notably, decisions to revoke the old licence would not be subject to review under section 60 of the Act (**proposed subsection 38B(11)**). However, this is not expected to be problematic as the new licences would cover all sites under the old licence and no proprietary rights would be extinguished.

**Item 19 of Schedule 2** of the Bill proposes to **insert new sections 40A and 40B** into the Act.

Under **proposed subsection 40A(1)**, the Secretary has a discretion as to whether to vary a manufacturing site authorisation in relation to a manufacturing licence, at his or her own initiative and by written notice to the licence holder.

Under **proposed paragraph 40A(2)(a)**, if the notice states that the variation is necessary to prevent imminent risk of death, serious illness or serious injury, the variation becomes effective on the day that the notice is given to the licence holder. Otherwise, under **proposed paragraph 40A(2)(b)**, the variation becomes effective on the day specified in the notice but no earlier than 28 days after the notice is given to the licence holder.

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34. *ibid.*

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**Proposed subsection 40B(1)** provides that the licence holder may apply to the Secretary for a variation of the manufacturing licence to cover additional manufacturing sites if the licence holder, after considering guidelines that would be developed under **proposed section 38A**,<sup>35</sup> believes that the licence could cover the additional sites. Such applications are subject to certain requirements provided for under **proposed subsection 40B(2)**. Where such an application is made and accompanied by any prescribed inspection fee, the Secretary *may* vary the licence accordingly by written notice to the licence holder (**proposed subsection 40B(3)**). However, where the Secretary exercises such discretion, he or she *must*, in such notice, vary the licence to authorise the licence holder to carry out particular steps in manufacturing specified therapeutic goods at each additional manufacturing site (**proposed subsection 40B(4)**). Variations would become effective on the day that the notice is given to the notice holder (**proposed subsection 40B(5)**).

It is noted that the Secretary's decisions made under those proposed amendments would also be reviewable by the Minister at first instance and that the Minister's decision would be reviewable by the AAT under section 60 of the Act.

Licence holders may also apply for a variation of a manufacturing site authorisation<sup>36</sup> relating to a manufacturing licence.

In addition, **Schedule 2** contains amendments to the Act providing for transfer of licences where particular circumstances change, such as a change in ownership of the manufacturing operations.

For example, **item 21** of **Schedule 2** of the Bill proposes to **insert new section 41AAA** into the Act, which provides that the *Therapeutic Goods Regulations 1990* (the Regulations) may provide for the transfer of manufacturing licences, including:

- applications for transfer
- application fees
- assessment of applications
- conditions of transfer on licences, and
- review of decisions made under the Regulations.

### Monitoring powers

The Act already contains provisions enabling authorised persons ("TGA inspectors") under the Act to enter and inspect manufacturing premises<sup>37</sup> and to take samples of

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35. *ibid.*

36. As to the proposed meaning of 'manufacturing site authorisation' see *ibid.*, Schedule 2 item 3.

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therapeutic goods while at those premises.<sup>38</sup> The Government states that the current provisions are outdated and inconsistent.<sup>39</sup> Amendments to monitoring powers under the Act are primarily proposed in **Schedule 3** of the Bill and seek to, as their general purpose, make monitoring compliance under the Act more consistent.

In general, while on premises, TGA inspectors would be able to:

- inspect those premises and therapeutic goods/medical devices on those premises, and
- examine, measure, take and conduct tests on and take samples of any therapeutic goods/medical devices on those premises or anything on those premises relating to any therapeutic goods/medical devices.<sup>40</sup>

In addition, while on premises, inspectors would be able to take still or moving images; or recordings, of those premises or anything on those premises.<sup>41</sup> The Act currently refers to taking photographs, including video recordings, as well as making sketches of the premises and anything on the premises.<sup>42</sup>

### Homeopathic and anthroposophic medicines

**Schedule 4** of the Bill contains proposed amendments to improve the regulatory framework for homeopathic and anthroposophic medicines in Australia. Examples of proposed amendments are as follows.

**Item 9 of Schedule 4** of the Bill proposes to **insert new sections 3AA** (homeopathic preparations) and **3AB** (anthroposophic preparations) into the Act.

**Proposed subsection 3AA(1)** defines ‘homeopathic preparation’ as one that was manufactured from a ‘mother substance’ using procedures described in a homeopathic pharmacopoeia.<sup>43</sup> Mother substance means:<sup>44</sup>

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37. This includes other premises of persons, under the Act, in relation to whom therapeutic goods are included in the Register: see *Therapeutic Goods Administration Act 1989* subsection 46A(4).
  38. *ibid.*, sections 46A and 48.
  39. Explanatory Memorandum, *op. cit.*, p. 17.
  40. See, for example, Therapeutic Goods Amendment (2009 Measures No. 1) Bill 2009 Schedule 3 items 4, 10, and 12; Schedule 2 item 14.
  41. See, for example, *ibid.*
  42. See, for example, *Therapeutic Goods Administration Act 1989* paragraph 48(1)(c).
  43. As to the proposed meaning of homeopathic pharmacopoeia, see Therapeutic Goods Amendment (2009 Measures No. 1) Bill 2009 Schedule 4 item 4.

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- an animal
- a plant
- an alga
- a fungus
- a micro-organism
- a mineral or mineral compound
- a chemical, or
- something obtained from any of the above.

**Proposed subsections 3AA(3), (4) and (5)** would give the Minister a discretionary power to, by legislative instrument:<sup>45</sup>

- specify that particular publications and/or part thereof are homeopathic pharmacopoeia
- exempt specified monographs in specified homeopathic pharmacopoeia, and
- exempt specified statements in specified monographs in specified homeopathic pharmacopoeia.

**Proposed section 3AB** provides similarly in relation to anthroposophic preparations.

**Item 12 of Schedule 4** of the Bill proposes to **insert new section 13A** into the Act, dealing with homeopathic and anthroposophic standards.

### Ingredients in therapeutic goods

Examples of proposed amendments are as follows.

**Item 3 of Schedule 5** of the Bill proposes to **insert new sections 26BB, 26BC, 26BD, and 26BE** into the Act.

**Proposed subsection 26BB(1)** would give discretionary power to the Minister in making a determination by legislative instrument to specify:

- active ingredients relating to medicine, and
- permitted concentrations and/or total amounts of some or all of those ingredients.

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44. *ibid.*, Schedule 4 item 7.

45. In other words, these actions are open to parliamentary scrutiny. Legislative instruments are available on the Federal Register of Legislative Instruments website, through [www.comlaw.gov.au](http://www.comlaw.gov.au).

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According to **proposed section 26BC**, the Minister may also vary such a determination, also by legislative instrument.

**Proposed section 26BD** would enable a person to apply to the Minister for a variation of the Minister's determination under **proposed section 26BB**. **Proposed section 26BD** also provides for formal requirements of such application; discretion by the Minister in requesting further information from the applicant and in varying the determination following proper application and payment of any prescribed fee.

**Proposed section 26BE** provides for prohibited, as well as limited components and/or ingredients relating to therapeutic goods, as specified by the Minister in a determination made by legislative instrument, which the Minister may vary.

**Item 1 of Schedule 5** of the Bill proposes to insert **new paragraphs 26(1)(ea) and (eb)** into the Act. Under **proposed paragraphs 26(1)(ea) and (eb)**, the Secretary may refuse to list therapeutic goods if the goods contain a component or ingredient that:

- is specified in the determination relating to prohibited components and/or ingredients under **proposed subsection 26BE(1)**, or
- exceeds the permitted concentration or total amount of that component or ingredient under **proposed subsection 26BE(2)**.

**Item 2 of Schedule 5** of the Bill proposes to insert **new paragraphs 26A(2)(ca)-(cd)** into the Act. Under **proposed paragraphs 26A(2)(ca)-(cd)**, a person wishing for certain medicine to be listed, must certify that:

- if a determination under **proposed section 26BB**, in relation to permissible active ingredients, applies to a medicine, that medicine only contains active ingredients specified in that determination
- if a determination under **proposed section 26BB**, in relation to permissible active ingredients, applies to a medicine and that determination also specifies permitted concentrations or total amount of the active ingredient, the active ingredient does not exceed the permitted concentration or total amount
- if a determination under **proposed subsection 26BE(1)**, in relation to prohibited components or ingredients, applies to a medicine, such medicine does not contain a component or ingredient that is specified in that determination, and
- if a determination under **proposed subsection 26BE(2)**, in relation to limited components or ingredients, applies to a medicine and that determination also specifies permitted concentrations or total amount of the component or ingredient, the medicine must not contain the concentration or total amount of the component or ingredient exceeding the permitted levels.

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## Miscellaneous amendments in Schedule 7

Examples of proposed miscellaneous amendments in **Schedule 7** are as follows.

**Item 3 of Part 1 of Schedule 7** of the Bill proposes to **insert new section 7C** into the Act. **Proposed section 7C** would enable the Secretary to use computer programs, under his or her control, when making decisions. It is noted that the proposed section would afford some level of protection when this process is used—if the Secretary substitutes a decision for an initial decision made by using a computer program when the Secretary is satisfied that the initial decision is incorrect, the Secretary can only do so within 60 days of the initial decision being made (**proposed subsection 7C(4)**).

**Item 14 of Part 1 of Schedule 7** of the Bill proposes to **insert new section 30A** into the Act. **Proposed section 30A** would enable the Secretary to revoke any cancellation of the registration or listing of therapeutic goods, which had been requested under paragraph 30(1)(c) of the Act, on subsequent written request by the person who had initially requested such cancellation, as well as on payment of a prescribed application fee. In addition, once a cancellation is revoked, the cancellation is taken to have never occurred. The Government states that this proposed amendment addresses a situation where a person in relation to whom therapeutic goods are listed or registered has mistakenly applied to the Secretary to cancel that registration or listing under existing paragraph 30(1)(c) of the Act. Without **proposed section 30A**, if the person actually wishes to continue the registration or listing, he or she would have to reapply all over again.

**Item 30 of Part 2 of Schedule 7** of the Bill proposes to **replace subsections 28(1) and (2)** of the Act with new **subsections 28(1), (2), (2A) and (2B)** relating to conditions to which the registration or listing of therapeutic goods would be subject. Such conditions would be contained in a determination made by the Minister by legislative instrument and could be imposed on the registration or listing of therapeutic goods by written notice to the person concerned.

**Item 34 of Part 2 of Schedule 7** of the Bill proposes to **insert new paragraphs 28(5)(aa) and (ab)** into the Act, relating to additional conditions to which the registration or listing of therapeutic goods would be subject. Under **proposed paragraphs 28(5)(aa) and (ab)**, these would include conditions relating to:

- prohibition on supplying or exporting these goods after expiry date for the goods, and
- advertising the subject goods for indications<sup>46</sup> only accepted in relation to inclusion of those goods in the Register.

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46. In the area of health care, ‘indications’ often refers to the signs and symptoms indicating the presence, aetiology and treatment of a disease, and in particular relation to the Bill, the purposes for which certain therapeutic goods are approved and used.

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**Item 36** of **Part 2** of **Schedule 7** of the Bill proposes to **insert new subsections 28(5B)** and **(5C)** into the Act, also relating to an additional condition to which the listing of medicine would be subject. Under **proposed subsections 28(5B)** and **(5C)**, the additional condition is that, unless the medicine is exempt under Part 3-3 of the Act, each step of the medicine manufacturing process in Australia must be carried out either by a holder of licence under Part 3-3 of the Act or someone who is exempt under that Part. In addition, each step of that manufacturing process carried out outside of Australia must be certified under subsection 26A(3) or **proposed subsection 28A(2)** (see below) of the Act.

**Item 37** of **Part 2** of **Schedule 7** of the Bill proposes to **insert new section 28A** into the Act, which would provide for the certification by the Secretary that manufacturing steps outside Australia, in relation to a listed medicine, comply with acceptable manufacturing and quality control procedures.

## Concluding comments

Many of the amendments reflect recommendations made to Government in 2003 and are administrative in nature.

It could be considered that these amendments go some way in strengthening the regulatory framework for complementary medicines in Australia and in providing greater protection and information for consumers.

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