



Therapeutic Goods Amendment (Medical Devices and Other Measures) Bill 2008

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Therapeutic Goods Amendment (Medical Devices and Other Measures) Bill 2008

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House: Senate

Portfolio: Health and Ageing

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

Schedules 1, 2, and 5-7 – the day after Royal Assent

Schedule 3 – a single day to be fixed by Proclamation, or six months after Royal Assent, whichever is the earlier.

Schedule 4 – 1 July 2009.

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 (Medical Devices and Other Measures) Bill 2008 (the Bill) seeks to amend the *Therapeutic Goods Act 1989* (the Act) to:

- align the regulatory framework for medical devices with that of prescription medicines in instances of national emergency
- put into effect several regulatory changes that were due to be incorporated in legislation underpinning the now disbanded Australia New Zealand Therapeutic Products Authority (ANZTPA), and
- improve transparency of TGA processes.¹

Background

The Therapeutic Goods Administration (TGA) is the principal regulator of therapeutic goods in Australia. Before a product can be marketed in Australia it must be registered in

1. Explanatory Memorandum, Therapeutic Goods Amendment (Medical Devices and Other Measures) Bill 2008, pp. 1-2.

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the Australian Register of Therapeutic Goods (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 unnecessary regulatory burden.

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.²

In part, the proposed amendments reflect much of what was agreed in the context of the ANZTPA. Before ANZTPA was disbanded in 2007, the TGA undertook a significant consultation process and many of the proposed changes were agreed upon by stakeholders and Government.

Information about the proposed regulatory reform program was announced in July/August 2008. The TGA conducted a series of consultations for each sector; prescription medicines, complementary medicines, over-the-counter medicines and medical devices. The information presented at these sessions was made [publicly available](#) with extensive material about the regulatory reform process. It was noted by the TGA that these consultation sessions were intended to provide an opportunity to discuss how the proposed reforms might be implemented and were not intended to re-open discussion.³

The TGA has described implementation of the reform agenda as ‘an opportunity to reduce regulatory burden across all sectors at the same time.’⁴ Reducing regulatory burden was also noted by the Parliamentary Secretary during the consultation sessions.⁵ The changes to the ‘fit and proper person’ test (for the purposes of holding a manufacturing licence or medical device conformity assessment certificate) and the additional pharmacopoeias to be used as TGA standards were noted in the consultation process and have been reflected in the legislation.

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2. See Therapeutic Goods Administration, ‘Australian therapeutic products legislation’, <http://www.tga.gov.au/legis/index.htm>, accessed 29 January 2009.
 3. Refer to Therapeutic Goods Administration, ‘Consultation on regulatory reforms for therapeutic goods’, www.tga.gov.au/regreform/cons0807.htm, accessed 28 January 2009.
 4. Refer to Therapeutic Goods Administration, ‘Reform of legislation and regulatory framework’, in *TGA News*, issue 57, November 2008, www.tga.gov.au/docs/html/tganews/news57/tganews57.htm, accessed 28 January 2009.
 5. Therapeutic Goods Administration, ‘Consultation on regulatory reforms for therapeutic goods’, *op. cit.*

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Key issues

As the Explanatory Memorandum is quite comprehensive, this section of the Digest simply seeks to summarise the key issues raised by the Bill. The Main Provisions section of the Digest provides more detailed analysis of some of the amendments proposed in the Bill.

The proposed changes in the Bill are:

- changes to the ‘fit and proper person’ test in relation to the grant of manufacturing licences and conformity assessment certificates
- inclusion of the United States Pharmacopeia and European Pharmacopeia as default standards for therapeutic goods
- increased access to information for the public and other regulatory agencies, including more information on the ARTG and the minutes and deliberations of expert advisory committees, and
- clarification of the limits and restrictions that apply to advertisements.

The proposed amendments in the Bill would also enable the Government to stockpile and supply medical devices in situations of medical emergency without having to satisfy certain requirements usually related to the regulatory approval by the TGA. Perhaps the most contentious aspect of this legislation is that these exemptions are not subject to parliamentary disallowance. This provision has also been extended to pharmaceuticals.

The amendments to the Bill seek to balance the objectives of the Act while reducing regulatory burden. Overall, the amendments are not contentious but there are some amendments that warrant further consideration by the Parliament, such as the exemptions for medical devices and associated accountability processes.

Changes to the ‘fit and proper person’ test

Conditions on manufacturing licences would now be linked with the ‘fit and proper person’ test. There would be provision in the legislation to empower the Secretary⁶ to require a licence holder to provide information for the purposes of deciding whether to suspend a licence under the ‘fit and proper person’ test. A manufacturing licence can be revoked if the ‘fit and proper person’ test is not met.

6. ‘Secretary’ means the Secretary to the Department of Health and Ageing: *Therapeutic Goods Administration Act 1989* section 3.

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According to the TGA, the proposed changes to the 'fit and proper person' test are designed to improve objectivity and administrative processes.⁷

Further detail and references to proposed provisions are provided in the Main Provisions section.

Additional default standard

Currently the default standard for submissions to the TGA is the British Pharmacopeia. This is a collection of standards for UK medicinal standards and is considered the official source of UK pharmaceutical standards.⁸ It details the mandatory standards for active substances, excipients and formulated preparations.⁹ The addition of the European and United States Pharmacopoeias as default standards would potentially give the pharmaceutical industry greater flexibility. Sponsors would have to observe all aspects of a given standard.¹⁰

Another amendment of potential benefit to the pharmaceutical industry would be the change in the 'effective date' in the publication of all pharmacopoeias. This means that a manufacturer would be able to adopt the relevant pharmacopoeia at the same time that it comes into effect in that country. Currently, manufacturers of therapeutic goods have to wait for determination and gazettal by the Minister.¹¹

It is not unusual for regulators to accept other standards as part of regulatory process. For example, the FDA accepts the use of alternative pharmacopoeias in limited circumstances.¹² The addition of the United States Pharmacopeia and European Pharmacopeia reflects the growing trend towards harmonisation of global pharmaceutical

7. See Therapeutic Goods Administration, 'Consultation on regulatory reforms July/August 2008 - Regulatory reform common to all product sectors', <http://www.tga.gov.au/regreform/common.htm>, accessed 28 January 2009.

8. Refer to British Pharmacopeia 2009, 'About BP 2009' available at: <http://www.pharmacopoeia.co.uk/2009/about.htm>, accessed on 2 February 2009.

9. *ibid.*

10. Explanatory Memorandum, *op cit*, pp. 17-18 and see Therapeutic Goods Administration, 'Consultation on regulatory reforms July/August 2008 - Regulatory reform common to all product sectors', <http://www.tga.gov.au/regreform/common.htm>, accessed 28 January 2009.

11. See *Therapeutic Goods Administration Act 1989* section 11.

12. Food and Drug Administration, 'Manual of Policies and Procedures: Acceptability of Standards from Alternative Compendia', <http://www.fda.gov/cder/mapp/5310.7R.pdf>, accessed 29 January 09.

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regulation. The TGA has a range of agreements with countries such as Canada, Europe, Singapore, Switzerland and the United States.¹³

Further detail and references to proposed provisions are provided in the Main Provisions section.

Improved information and transparency

According to the Government, Schedule 5 is designed to give greater transparency to information on the ARTG and the deliberations of Committees that provide advice to the TGA.¹⁴ However, it is clearly stated in the Explanatory Memorandum that these measures are not designed to provide full inspection to the ARTG.¹⁵ It is anticipated that greater access to the ARTG will be through the TGA website.

Improved transparency of Committee deliberations would benefit consumers and other stakeholder groups. The challenge for the TGA will be to ensure the timeliness of the release of information.

There are also provisions in the Schedule about the release of information by the Secretary to specific bodies such as regulatory agencies. References such as 'Director-General' and 'head' would be removed to allow for greater information sharing between regulatory agencies. These proposed provisions would be particularly important during times when there is a need for rapid sharing of information such as national emergency, pandemics and emerging disease patterns.

Further detail and references to proposed provisions are provided in the Main Provisions section.

Advertising

Currently, direct to consumer advertising of prescription medication is not permitted in Australia. Advertising for some therapeutic goods is permitted but this requires pre-approval.¹⁶ Schedule 6 is intended to clarify what advertisements require pre-approval and the relevant sanctions. It should be noted that this part of the Act does not apply to advertisements directed towards the medical profession.¹⁷

13. As to these Agreements, see Therapeutic Goods Administration, 'International Agreements', <http://www.tga.gov.au/international/index.htm>, accessed 29 January 2009

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

15. *ibid.*, p. 20.

16. *ibid.*, p. 22.

17. *Therapeutic Goods Administration Act 1989* subsection 42AA(1).

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The Bill proposes that false or misleading representation (express or implied) would not be permitted under the Act.¹⁸

Further detail and references to proposed provisions are provided in the Main Provisions section.

Exemptions for medical devices

In normal circumstances, therapeutic goods such as prescription medicines; over-the-counter medicines; and medical devices must be listed on the ARTG before they can be marketed in Australia.¹⁹ The Bill contains provisions for medical devices to be stockpiled and supplied in emergency situations without having to satisfy certain requirements under the Act for approval by the TGA. These are similar to existing provisions for therapeutic goods that been in place since 2002 and are also intended to be used in situations of national emergency, such as bioterrorism or the emergence of a highly contagious disease.

Further detail and references to proposed provisions are provided in the Main Provisions section.

Main provisions

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

- medical devices
- emergency exemptions in relation to therapeutic goods that are not medical devices
- ‘fit and proper person’ test
- additional default standards
- information disclosure, and
- advertising.

Medical devices

Item 2 of Schedule 1 of the Bill proposes to **insert new Part 4-6A** into **Chapter 4** of the Act, containing provisions that would exempt certain medical devices from requirements under Chapter 4 of the Act (Medical Devices), so as to allow those medical devices to be stockpiled to deal with actual or possible emergencies.

18. See **proposed section 42DKB** in **item 9** of **Schedule 6** of the Bill.

19. See, for example, *Therapeutic Goods Administration Act 1989* section 9A; *Therapeutic Goods Administration Regulation 1990* Part 2C, Schedules 3 and 4.

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Under **proposed subsection 41GS(1)**, the Minister would have the discretionary power to make a written exemption from the following requirements:

- essential principles or requirements of medical devices as set out in the regulations (section 41CA)
- requirements relating to the obligations of manufacturers of medical devices in relation to conformity assessment procedures, as well as medical devices classifications, as set out in the regulations (sections 41DA and 41DB)
- conformity assessment certificates (Part 4-4), and
- including medical devices in the Australian Register of Therapeutic Goods (Part 4-5).

However, **proposed subsection 41GS(2)** would limit the use of that discretion, whereby the Minister could only exercise that discretion if he or she is satisfied that it would be in the national interest for the exemption to be made to deal with:

- a possible threat to public health that may be caused by a possible future emergency, or
- an actual threat to public health caused by an emergency that has in fact occurred.

Such an exemption would not be a legislative instrument²⁰ under **proposed subsection 41GS(6)**.

However, under **proposed section 41GV**, if the Minister does make such an exemption, the Minister would have to take reasonable steps to give a copy of either the exemption or the variation/revocation thereof, to each person who imports, manufactures, supplies or exports the relevant medical devices.

In addition, there are notification and tabling requirements under **proposed section 41GW**.

The exemption would be subject to particular conditions set out in **proposed section 41GT** and would be able to be varied or revoked under **proposed section 41GU**.

Item 35 of Schedule 1 of the Bill proposes to **insert new Division 3A** into Part 4-11 of Chapter 4 of the Act. Division 3A would contain provisions dealing with offences and civil penalties related to the proposed exemptions.

Proposed offences include:

- criminal offences for breaching a condition of an exemption (**proposed section 41MNB**)

20. As to what are legislative instruments, see *Legislative Instruments Act 2003* sections 5-9.

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- civil penalties for:
 - breaching a condition of an exemption (**proposed section 41MNC**), and
 - making misrepresentations about medical devices (**proposed section 41MND**).

Criminal penalties

Where the breach of a condition of an exemption is likely to cause serious risk to public health, the maximum penalty is five years imprisonment and/or 2000 penalty units (\$220 000).²¹ Where it is a corporation that is found guilty of an offence, the pecuniary penalty can be up to five times that applying to an individual,²² hence in this case, the potential penalty for a corporation would be \$1.1 million.

Where there is no likelihood of serious risk to public health, the penalty is proposed to be four years imprisonment and/or 240 penalty units (\$26 400).²³

Note, however, that in both the above instances, it is proposed that strict liability²⁴ would apply to the fact that the device is of a kind covered by the exemption in **proposed section 41GS**.²⁵

Where the offence is a strict liability offence, the penalty is proposed to be 60 penalty units (\$660).²⁶

Note that the Bill only refers to ‘penalty’ not ‘maximum penalty’. This conforms with the amendments proposed in Chapter 7 of the Bill and it is noted that the aim of these proposed amendments is to conform with subsection 4B(3A) of the *Crimes Act 1914*.²⁷

It is also noted that these penalties generally conform to similar penalties in the Act.²⁸

21. **Proposed subsection 41MNB(1) in item 35 of Schedule 1** of the Bill. Note that one penalty unit is \$110: *Crimes Act 1914* section 4AA.

22. *ibid.*, subsection 4AB(3).

23. **Proposed subsection 41MNB(3) in item 35 of Schedule 1** of the Bill.

24. Strict liability means that there is no need to prove fault (in other words, intention, knowledge, recklessness or negligence): see Attorney-General’s Department, *Guide to Framing Commonwealth Offences*, p. 24.

[http://www.ag.gov.au/www/agd/rwpattach.nsf/VAP/\(454DFAFE2D6830FB1D0597823A67B5D6\)~A+Guide+to+Framing+Commonwealth+Offences+Civil+Penalites+%E2%80%A6.pdf/\\$file/A+Guide+to+Framing+Commonwealth+Offences+Civil+Penalites+%E2%80%A6.pdf](http://www.ag.gov.au/www/agd/rwpattach.nsf/VAP/(454DFAFE2D6830FB1D0597823A67B5D6)~A+Guide+to+Framing+Commonwealth+Offences+Civil+Penalites+%E2%80%A6.pdf/$file/A+Guide+to+Framing+Commonwealth+Offences+Civil+Penalites+%E2%80%A6.pdf), accessed 13 January 2009.

25. **Proposed subsections 41MNB(2) and (4) in item 35 of Schedule 1** of the Bill.

26. **Proposed subsection 41MNB(5) in item 35 of Schedule 1** of the Bill.

27. Explanatory Memorandum, *op. cit.*, p. 24.

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Civil penalties

The maximum civil penalties are:

- 5000 penalty units or \$550 000 for individuals, and
- 50 000 penalty units or \$5 500 000 for corporations.

It is also noted that, as with the penalties proposed for criminal offences, these penalties generally conform to similar penalties in the Act.²⁹

Emergency exemptions in relation to therapeutic goods that are not medical devices

Item 1 of Schedule 2 of the Bill proposes to **amend section 18A** of the Act by **inserting new subsections (9A) and (9B)**.

Section 18A provides for emergency exemptions in relation to therapeutic goods.

The proposed amendments would have the effect that:

- an exemption under subsection 18A(1) would not be a legislative instrument,³⁰ and
- if the Minister makes an exemption under subsection 18A(1), the Minister must take all reasonable steps to inform any person or class of persons who import, manufacture, supply or export the therapeutic goods to which section 18A applies, by giving each person a copy of the exemption, or the variation/revocation thereof.

These proposed amendments are similar to **proposed sections 41GS and 41GV** above.

Fit and proper person test

The proposed amendments to the test applied in determining whether a person is a 'fit and proper person' in relation to grants of manufacturers' licences and conformity assessment certificates seek to narrow its scope and make it consistent with similar tests in other legislation.³¹

Items 2-6 of Schedule 3 of the Bill propose to **amend section 38** of the Act.

28. See, for example, *Therapeutic Goods Act 1989* subsections 20(2A)-(2D), 22(7AB)-(7AE).

29. See, for example, *Therapeutic Goods Act 1989* sections 22AA-22B. See also Therapeutic Goods Administration, 'Remedial actions for medical devices' (draft), December 2008, pp. 7-9, <http://www.tga.gov.au/devices/argmd-drrem.pdf>, accessed 20 January 2009.

30. As to what are legislative instruments, see *Legislative Instruments Act 2003* sections 5-9.

31. See Explanatory Memorandum, op. cit., p. 2.

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In particular, **item 2** proposes to **replace paragraphs 38(1)(g)-(i)** of the Act with **new paragraphs 38(1)(g) and (h)**.

Subsection 38(1) generally provides that the Secretary must grant a manufacturing licence unless the Secretary is satisfied of several matters, which include:

(g) the applicant is not a fit and proper person to hold a licence; or

(h) a person who is participating in, or is likely to participate in, managing the applicant's affairs is not a fit and proper person to participate in the management of the affairs of a holder of a licence; or

(i) a person who has, or is likely to have, effective control over the applicant is not a fit and proper person to have effective control over a holder of a licence.

Proposed new paragraph 38(1)(g) provides that the Secretary must be satisfied that, within the 10 year period immediately before the licence application, at least one of the following persons:

- the licence applicant
- a manager making, or participating in making, decisions affecting all or a substantial part of the applicant's affairs, and
- if the applicant is a body corporate, someone who is a major interest holder, in other words, a person who is either:
 - in the position to cast or control the casting of, more than a fifth of the maximum number of votes that might be cast at the body corporate's general meeting, or
 - holds more than a fifth of the body corporate's issued share capital (excluding what does not carry a right to participate beyond a specified amount in distribution of profits or capital),³²

had:

- been convicted of an offence either against the Act or corresponding State law; or against a Commonwealth, State or Territory law involving fraud or dishonesty
- been ordered to pay a pecuniary penalty for contravening a civil penalty provision either of the Act or corresponding State law; or of a Commonwealth, State or Territory law involving fraud or dishonesty
- breached a condition of a manufacturing licence³³

32. See **proposed item 1** of **Schedule 3** of the Bill.

33. As for the meaning of 'manufacturing licence', see *Therapeutic Goods Act 1989* subsection 38(1B). The Bill does not propose to change this meaning.

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- had a manufacturing licence revoked or suspended, or
- been a manager or major interest holder of the body corporate at the time that the above offence, contravention, breach or suspension/revocation occurred in relation to the body corporate.

In addition, **proposed new paragraph 38(1)(h)** would enable other circumstances to be prescribed by regulations, which could influence the Secretary's determination.

Currently, subsection 38(1A) provides for what the Secretary must consider in determining whether the person meets the 'fit and proper person' test above.

Item 3 of Schedule 3 proposes to **amend subsection 38(1A)** by replacing the existing provisions with a reference to section 19B of the *Crimes Act 1914* or corresponding State or Territory law dealing with the finding that a person has committed an offence and acting on that finding, without recording a conviction.

Other items in Schedule 3 of the Bill propose similar amendments to other provisions in the Act. Examples are as follows.

Section 41 (items 9-11)

Currently, paragraphs 41(1)(a)-(cd) give the Secretary discretion to suspend or revoke a manufacturing licence in specific circumstances, generally involving commission of offences, orders being made against the licensee and associated persons, and such persons not being considered to be fit and proper persons.

Subsection 41(1A) currently sets out what the Secretary must consider in relation to the 'fit and proper person' test.

Section 41EC (items 13-14)

It is necessary that the medical device, or the manufacturing processes used to make that device, conforms to legislative requirements. Conformity assessment of a medical device, which is the responsibility of the manufacturer of that device,³⁴ is an examination of the evidence that is generated, and procedures that are undertaken, by the manufacturer, in deciding whether a medical device is safe and performs as it should.³⁵

34. As to the manufacturers' responsibilities in relation to conformity assessment procedures, see Therapeutic Goods Administration, 'Conformity assessment overview' (draft), November 2008, p. 6, <http://www.tga.gov.au/devices/argmd-drca.pdf>, accessed 20 January 2009.

35. See *ibid.* As to the meaning of 'conformity assessment procedures', see also *ibid.*

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Section 41EC currently deals with how applications for conformity assessment certificates³⁶ are considered. A conformity assessment certificate is one issued under existing section 41EE.³⁷

Under existing section 41EA, the regulations may prescribe the kinds of:

- manufacturers of medical devices, or
- medical devices,

in relation to whom conformity assessment certificates must be issued before applications for the kind of:

- medical devices manufactured by those manufacturers, or
- medical devices,

are included in the Register.

The form of and procedures relating to applications are provided for in existing section 41EB.

Currently, **paragraphs 41EC(3)(a)-(c)** set out factors involving the ‘fit and proper person’ test, which the Secretary must consider when deciding whether to issue such certificates. **Items 13-14** propose amendments to those paragraphs, which are similar to amendments proposed in **items 2-3** of **Schedule 3**.

Section 41ET (items 18-19)

In addition, **items 18-19** propose similar amendments to **paragraphs 41ET(1)(e)-(g)** and **subsection 41ET(1A)**. Those provisions currently set out in what circumstances the Secretary may revoke a conformity assessment certificate and considerations of the ‘fit and proper person’ test.

It is noted that the ‘fit and proper person’ test set out in these proposed provisions are generally consistent with tests used in other regulatory regimes.³⁸

Importantly, **items 12** and **22** of Schedule 3 propose to **insert new section 41AA**, as well as **subsections 41ET(4)** and **41JA(3)** respectively into the Act, which would provide for

36. As to the meaning of ‘conformity assessment certificates’, see *ibid.*, p. 2.

37. *Therapeutic Goods Act 1989* section 3.

38. See, for example, *Customs Act 1901* section 67H; *Education Services for Overseas Students Act 2000* subsections 9(6)-(6A); APRA, *Prudential Standard LPS 520 – Fit and Proper*, January 2008; ASIC, ‘External Administration – Liquidator Registration’, *Regulatory Guide 186*, RG186.21-RG 186.24.

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spent convictions protections. These protections are part of a Spent Convictions Scheme (the Scheme), that subject to certain exclusions, aim to protect against discrimination based on certain previous convictions, once a particular period of time has passed without the person in question re-offending.³⁹

Additional default standards

Schedule 4 of the Bill contains proposals to amend existing provisions in the Act in relation to default standards.

Certain proposed amendments, such as **items 2, 5, 8-9, 11, 13-14, 16-19**, simply delete references to ‘animal(s)’ or ‘British Pharmacopeia (Veterinary)’, which reflect that the Act does not regulate therapeutic goods for veterinary use.

Other proposed amendments relate to amending the definitions of ‘standard’, ‘British Pharmacopeia’, ‘European Pharmacopeia’ and United States Pharmacopeia-National Formulary, to include the European Pharmacopeia and United States Pharmacopeia-National Formulary as alternative default standards to which therapeutic goods must conform, in addition to the existing default standard—the British Pharmacopeia.

Item 15 proposes to **replace existing section 13** of the Act with a **new section 13**. This proposed amendment generally reflects the use of additional default standards and the non-application of the Act to therapeutic products for veterinary purposes.

Information disclosure

Items 4-8 of **Schedule 5** of the Bill propose to **amend subsections 61(3) and (4); as well as paragraphs 61(2)(a), 61(2)(b), 61(3A)(a) and 61(4A)(a)-(ba)** of the Act, to the effect that the Secretary would be able to release information to the organisation rather than simply to the person in the position of ‘head’ or ‘Director-General’ of that organisation. The aim is to reduce administrative difficulties in giving information to another regulatory body when the head of that body cannot be contacted.⁴⁰

In addition, **items 13 and 14** of **Schedule 5** of the Bill propose to **insert new subsections 61(5AA), 61(5AB), 61(5C) and 61(5D)** into the Act, with the effect that the Secretary would be able to release therapeutic goods information of a kind specified by legislative instrument, either to a person, body or authority also specified by legislative instrument that the Secretary would be able to make or to the public.

39. For information about the Scheme, see Australian Federal Police, ‘Spent Conviction Scheme’, http://www.afp.gov.au/services/operational/criminal_history_checks/spent_convictions_scheme.html, accessed 15 January 2009.

40. Explanatory Memorandum, op. cit., p. 20.

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Advertising

The Act and Regulations regulate the advertising of therapeutic goods⁴¹ and Schedule 6 of the Bill proposes amendments to the Act relating to such advertising.

The proposed amendments basically restructure Divisions 1-3 of Part 5-1 of the Act dealing with advertisements.

However, it is noted that **item 9 of Schedule 6** of the Bill proposes to **insert new subsection 42DKB(2)** into the Act, whereby a notice under **proposed new subsection 42DKB(1)** prohibiting the publication or broadcasting of an advertisement containing a false or misleading representation, would not be a legislative instrument.⁴²

Comments

While it may be argued that overall, the proposed amendments are not contentious, the following proposed amendments warrant further consideration by the Parliament.

First, the Bill proposes that certain notices would not be legislative instruments.⁴³ If such notices are not legislative instruments, they would not be tabled in Parliament and not be subject to parliamentary scrutiny and disallowance.

According to the Government, the reason why it proposes that notices of exemption allowing medical devices and therapeutic goods to be stockpiled in case of future possible or current actual national emergencies is because the contents of the stockpile should be classified as 'confidential' to protect it from potential bioterrorists using it to plan attacks for diseases or other agents for which Australia is not prepared.⁴⁴ The question remains, however, that notwithstanding national security, what systems will be implemented to ensure accountability in relation to such major decisions?

It is also noted that the following would not be legislative instruments:

-
41. However, the Act and Regulations do not apply to certain advertisements, such as advertisements directed to health professionals (practicing in both traditional and natural medicine), people engaged in wholesale of therapeutic goods, hospital purchasing officers, as well as members of the Australian branch of an organization prescribed under Schedule 1 of the *Therapeutic Goods Regulations 1990: Therapeutic Goods Act 1989* section 42AA. See also Therapeutic Goods Administration, 'Advertising Therapeutic Goods in Australia', <http://www.tga.gov.au/advert/index.htm>, accessed 22 January 2009.
 42. As to what are legislative instruments, see *Legislative Instruments Act 2003* sections 5-9.
 43. As to what are legislative instruments, see *ibid.*
 44. Explanatory Memorandum, *op. cit.*, p. 1.

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- notices prohibiting advertisements containing misleading and false representations (**proposed subsection 42DKB(2) – item 9 Schedule 6**), and
- ministerial orders relating to the non-applicability of standards in particular circumstances (**proposed subsection 13(5) – item 15 Schedule 4**),

thereby also removing such notices from Parliamentary scrutiny and disallowance, raising questions of necessity, as well as transparency and accountability. A possible compromise would be that there should be legislative instruments, which would not be subject to disallowance in accordance with the provisions of section 44 of the *Legislative Instruments Act 2003*.

Second, the proposed amendments would give the Minister discretionary power in relation to certain matters, which include:

- making, varying and revoking exemptions
- specifying persons and bodies to whom therapeutic goods information may be released
- specifying the kind of therapeutic goods information that may be released, and
- determining the applicability of standards in certain circumstances involving therapeutic goods consisting of a mixture of ingredients or a combination of component parts (**proposed subsection 13(5) – item 15 Schedule 4**).

However, the proposed amendments do not specify the parameters underpinning the exercise of that discretion. For example, under **proposed subsection 41GS(2) in item 2 of Schedule 1** of the Bill, references are made to ‘potential threat to public health’ and ‘possible future emergency’ without including an explanation of how, and on what basis, such matters would be determined.

The wording is similar to existing subsection 18A(2) of the Act.

It is also noted that the Regulations do provide for the establishment of various Committees whose roles include providing specialist advice to the Minister about various issues, such as standards. These Committees include:

- Therapeutic Goods Committee (regulation 34),⁴⁵ and
- Medical Device Evaluation Committee (regulation 35).⁴⁶

45. For information about the Therapeutic Goods Committee, see Therapeutic Goods Administration, ‘Therapeutic Goods Committee’, <http://www.tga.gov.au/docs/html/tgc.htm>, accessed 22 January 2009.

46. For information about the Medical Devices Evaluation Committee, see Therapeutic Goods Administration, ‘Medical Devices Evaluation Committee’, <http://www.tga.gov.au/docs/html/mdec/index.htm>, accessed 22 January 2009.

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Presumably, in practice, the Minister would consult these Committees when making decisions proposed under the Bill.

Third, the Bill, itself, does not refer to review mechanisms of decisions made by the Secretary or Minister. While it is noted that both the Act⁴⁷ and the Regulations⁴⁸ do provide for review of decisions, such review is limited to the types of decisions listed in the legislation. It does not appear that existing appeal rights would apply to many of the proposed amendments.

Finally, several important matters would be left to be specified in regulations yet to be made. This makes it difficult to assess the likely impact and effect of the proposed amendments, thereby affecting proper consultation with stakeholders. This is particularly relevant given that the Government has stated that the financial burden of these proposed amendments would be cost-recovered from industry.⁴⁹

Concluding comments

The aims of the amendments proposed in the Bill are not disputed. However, notwithstanding national security requirements for Schedules 1 and 2, the means by which such purposes are to be achieved do raise several concerns.

As there has been little published stakeholder comment about the proposed amendments it is not possible to comment on stakeholder reactions or acceptance of the proposed amendments. The absence of such commentary should not be read as a signal about stakeholder confidence in the operational effects of the proposed changes. Rather, the issues identified in this Digest point to the need for more detailed examination of the practicalities of some of the amendments.

47. See *Therapeutic Goods Act 1989* section 60.

48. See *Therapeutic Goods Regulations 1990* regulations 5M, 48.

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

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