



Therapeutic Goods Amendment Bill 2005

Luke Buckmaster
Social Policy Section

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Therapeutic Goods Amendment Bill 2005

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House: House of Representatives

Portfolio: Health and Ageing

Commencement: Sections 1 to 3 and anything else not otherwise specified commence on the Bill receiving Royal Assent; Schedule 1, items 1 to 117 commences on the 28th day after the day after receiving Royal Assent; Schedule 1, item 118 (retrospectively) on 27 November 2003; and Schedule 1, item 158 on 4 October 2007.

Purpose

This Bill proposes to introduce a range of new sanctions and enforcement options under the *Therapeutic Goods Act 1989* (the Act). This is intended to secure better compliance with the regulatory standards for therapeutic goods contained in the Act.

Background

What are therapeutic goods?

A ‘therapeutic good’ can be broadly defined as ‘a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use’.¹ The term therapeutic good therefore can encompass a range of goods including medicines (prescription, over the counter and complementary), medical devices and blood, tissues and cells.

Regulation of therapeutic goods in Australia

Therapeutic goods are regulated under the Act. The purpose of the Act is to ensure the quality, safety, efficacy (where appropriate) and timely availability of therapeutic goods.² Regulatory arrangements for therapeutic goods under the Act are the responsibility of the Therapeutic Goods Administration (TGA), a unit of the Department of Health and Ageing.³

All therapeutic goods sold in Australia must be included on the Australian Register of Therapeutic Goods (ARTG). The TGA is responsible for administering the provisions of the Act and maintaining the ARTG.

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TGA and 'Risk management'

Therapeutic goods on the ARTG are regulated according to a 'risk management' approach. This means that the evaluated risk associated with a particular medicine or medicinal ingredient determines the type of assessment process used by the TGA. The concept of risk is based on an assessment of the 'potential of a product to do harm to those it is intended to help, or to others (such as children) who may come into contact with it—regardless of whether the harm results from following or disregarding the directions for use'.⁴

Higher risk therapeutic goods (Registered medicines), such as those used to treat serious conditions, or which need to be used under a doctor's supervision, are subject to a high level of scrutiny and evaluation by TGA to determine their quality, safety and efficacy. **Lower risk** therapeutic goods (Listed medicines) are assessed by the TGA for quality and safety *but not* efficacy. That is, the TGA does not evaluate Listed medicines prior to supply to determine whether they are effective. However, manufacturers/distributors are legally required to hold information that substantiates therapeutic claims made in relation to a particular Listed medicine and to provide this to the TGA for evaluation should a concern arise.⁵

According to the TGA, the risk-management approach is designed to 'ensure public health and safety, while at the same time freeing industry from any unnecessary regulatory burden and minimising the cost of medicines regulation'. The TGA also states that as part of this approach, it has developed a 'constructive partnership with industry', that contributes to the 'continued viability of industry by creating confidence in, and acceptance of, Australian therapeutic goods, both at home and overseas'.⁶

Regulation of complementary medicines in Australia

The regulation of complementary medicines in Australia has been particularly controversial since the Pan Pharmaceuticals recall in 2003 (see discussion below). As noted above, the TGA is responsible for regulation of complementary medicines in Australia. Types of complementary medicine regulated by the TGA include herbal medicines, vitamin and mineral supplements, other nutritional supplements, traditional medicines such as Ayurvedic (traditional Indian) medicines and traditional Chinese medicines, homoeopathic medicines, and aromatherapy oils (where they make therapeutic claims).⁷

The Australian system of regulation makes no clear distinction between complementary medicines and other medicines. Rather, complementary medicines are regulated according to the same 'risk management' approach that governs regulation of all other medicines listed on the ARTG. Most complementary medicines in the ARTG are considered to be low risk and hence are Listed medicines.⁸

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Overview of events since the Pan recall

Pan recall

On 28 April 2003, the TGA suspended the licence of Australia's largest manufacturer of complementary medicines, Pan Pharmaceuticals, to manufacture therapeutic products, following a series of quality and safety breaches by the company. This situation arose following problems earlier in 2003 with a Pan Pharmaceuticals anti-travel sickness tablet, *Travacalm*, which led to 'potentially life threatening adverse reactions' for more than 60 people.⁹

According to the TGA, subsequent audits of the company revealed 'serious deficiencies in the company's manufacturing and quality control procedures, including systematic and deliberate manipulation of quality control test data'.¹⁰ In response to these findings, the TGA suspended the company's licence with an immediate effect and ordered the recall of all products manufactured by Pan.

This decision had a significant impact on Pan (which went into voluntary administration) and other players in the complementary medicines sector, particularly smaller companies that contracted operations out to Pan and suffered financially as a result of the recall. As a result, some in the complementary medicines sector complained that the TGA had 'over-reacted' or been 'heavy handed' in its response to the problems with Pan.¹¹

Expert Committee on Complementary Medicines

As a response to the Pan recall, in May 2003 the Government established the Expert Committee on Complementary Medicines to examine complementary medicines and their use in the health care system.¹² The Committee reported in October 2003 and made a number of recommendations, including that quality standards for all ingredients used in complementary medicines be made legally enforceable, that the evidence required to be held by companies (sponsors) to substantiate claims be subject to much more rigorous assessment and that penalties be increased for companies that refuse to provide the TGA with information to back up these claims.¹³ The Government agreed to implement this and most of the Committee's other recommendations when it publicly responded to the Committee's report in March 2005.¹⁴

Changes to the Act

The Government made a number of changes to the Act in October 2003 in response to the Pan recall. These changes were made to tighten up the regulatory requirements relating to compliance with standards and to enable manufacturers of therapeutic goods to be more readily identifiable.¹⁵ The effect of the 2003 amendments to the Act was a greater focus on manufacturing standards—with complementary medicines manufacturers now required to have all the evidence necessary to prove efficacy (if any was claimed) at immediate notice if requested by the TGA.¹⁶

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Australian National Audit Office report

In December 2004, the Australian National Audit Office (ANAO) released an audit report into Regulation of Non-Prescription Medicinal Products by the TGA. This report was critical of the level of consistency, transparency and accountability in TGA systems, procedures and resource management used in regulating non-prescription medicines.¹⁷ In relation to the Pan case, the ANAO found that ‘the TGA’s views that all its decisions in this case were appropriate have not been supported by a thorough and independent assessment of whether these actions were optimal, or whether they hold lessons for the future’.¹⁸

Underlying the 26 recommendations from the ANAO, were requirements that the TGA improve its data management, documentation and administrative procedures. The Department of Health and Ageing agreed to implement each of the ANAO’s recommendations.¹⁹

Basis of policy commitment

Through the amendments in this Bill, the Government is seeking to provide the TGA with new enforcement options in order to ensure compliance with regulatory requirements for therapeutic goods including product and manufacturing standards. The Parliamentary Secretary to the Minister for Health and Ageing (the Parliamentary Secretary), Christopher Pyne, argues that these new enforcement options are necessary because of ‘deficiencies’ in the range of enforcement measures available to the TGA:

Existing options for dealing with breaches of regulatory requirements are restricted to either criminal prosecution or administrative sanctions such as withdrawing the sponsor’s or manufacturer’s right to continue marketing or manufacturing therapeutic goods. Resort to either of these options may not, in some circumstances, be appropriate or achieve the optimal regulatory outcome, given the time and resources taken to prosecute offenders and the possible need to maintain supply of products to the public because of their essential nature or the lack of available substitute products.²⁰

The sanctions contained in the Bill are to be applied to existing conduct regulated under the Act. In other words, no *new* offences are created by the Bill. Rather, the amendments in the Bill are intended to extend the range of enforcement measures open to the TGA and thus enable it to take ‘timely, appropriate and effective action’ in ensuring compliance by therapeutic goods manufacturers with regulatory standards.²¹

The enforcement options introduced in the Bill are set out in detail in the Explanatory Memorandum. In summary, these are:

Tiered offence regime

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Introduction of an offences regime that seeks to better tailor penalties for criminal conduct under the Act, so that more serious offences will result in stronger criminal sanctions (e.g. **Item 14, Section 19B**).

Alternative verdicts

Allows for the possibility of alternative verdicts for various tiered offences—meaning that a jury may convict a person of a lesser offence if they acquit a person of an offence with an aggravating element but are satisfied that the person is guilty of a lesser offence relating to the same conduct (**Item 14, Section 53A**).

Pre-disclosure notices

Creates a requirement for defendants to provide a pre-disclosure notice (prior to a committal or hearing) of evidence in support of a defence to an offence related to dealings with unapproved goods (**Item 14, Section 19C**).

Civil penalty regime

Introduces a civil penalty regime for breaches of the Act—this is expected to be more effective in deterring and preventing non-compliance with regulatory requirements by body corporates (the bulk of those entities regulated by the TGA) (**Item 129, Chapter 5A, Section 42Y, 42YA, 42YB, 42YC, 42YD, 42YE**).

Infringement notices

Introduces infringement notices (on-the-spot fines) for strict liability offences and breaches of civil penalty provisions where the readily assessable elements of the breach can be identified (**Item 129, Chapter 5A, Section 42YJ, 42YK**).

Enforceable undertakings

Enables the TGA to accept court enforceable undertakings to either remedy breaches of regulatory requirements or to not engage in future conduct that would breach regulatory requirements in lieu of taking legal or administrative action (**Item 129, Chapter 5A, Section 42YL**).

Extended geographical jurisdiction

Provides for certain offences to extend to conduct by an Australian resident, citizen or body corporate outside Australia where there is an equivalent offence in the laws of the relevant overseas jurisdiction (**Item 6, Section 5A**).

Extension of body corporate liability

Extends of the liability of a body corporate to executive officers who are directly involved in the day-to-day management of the company, if the body corporate commits and offence or contravenes a civil penalty provision under the Act (**Item 145, Sections 54B, 54C**).

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Warrant mechanism and search warrant powers

Introduces a new warrant mechanism for the purposes of enabling investigations to take place in relation to civil penalty contraventions and extends the power under search warrants to allow for the securing of additional evidence (eg. **Items 131, 132**).

Release of information

Allows for the public release of information about decisions made under the Act or Regulations, and release, to Australian and overseas regulatory agencies, of information relating to an breach or alleged breach of the Act or Regulations involving therapeutic goods (**Item 155**).

In addition to the new enforcement options listed above, the Bill also proposes to make three minor amendments to the Act (see the Explanatory Memorandum for further details).

Position of significant interest groups/press commentary

While there has been little media coverage of the Bill since it was introduced into the Parliament, media reports prior to its introduction suggest that some in the therapeutic goods industry (including manufacturers of pharmaceuticals, complementary medicines and medical devices) will possibly have concerns about certain aspects of this Bill. Commenting on a draft copy of the Bill made available to industry, the Director of the Complementary Healthcare Council (CHC), Tony Lewis, said that the complementary medicines industry is ‘not at all happy’ with many aspects of the Bill²² and therapeutic goods industry executives are reported to have criticised the Bill as potentially damaging to the industry.²³ The chief executive of the Medical Industry Association of Australia (MIAA), the representative body for the medical devices sector, Brian Vale, has described the Bill as like taking a ‘sledgehammer to a walnut’.²⁴

The main concerns raised by industry are summarised below. Note that, according to media reports, despite the above criticisms, some in the therapeutic goods sector such as MA and Medicines Australia are supportive of other aspects of the Bill (though, these aspects are not specified).²⁵

Insufficient consultation

The MIAA’s Brian Vale has stated that ‘there’s been no early discussion over where the TGA wants to get with the bill ... the bill was constructed before it got to industry. It was effectively presented as virtually a fait accompli’.²⁶ This has been disputed by the Parliamentary Secretary, Mr Pyne, who has said that ‘the industry has had at least four or five meetings with the Department of Health’.²⁷

Discretionary powers

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Organisations such as Medicines Australia (MA) and the Australian Self-Medication Industry (ASMI) have both expressed concern about the level of discretionary power the TGA appears to have under the Bill. According to one media report, MA has complained that ‘it is not particularly clear ... precisely how the regulator will decide when to pursue a criminal penalty ... There seems to be a degree of discretion available to the TGA, which is not good regulatory practice’.²⁸

Release of information

According to one media report, therapeutic goods industry executives regard the provisions to allow the public release of information about decisions made under the Act or Regulations as being of concern. This is because it is thought that, under the penalty system proposed in the Bill, some manufacturers, regardless of whether they are innocent or guilty, may choose to accept a fine in order to avoid the expense of contesting proceedings. In such an instance, it has been argued, it would be unfair for information about the case in question to be made publicly available.²⁹

Infringement notices

According to one media report, complementary medicines manufacturers have expressed concern about lack of understanding of how infringement notices will operate in practice. There has also been further concern that once an infringement notice is issued, there will not be any independent avenue for arbitration outside the TGA.³⁰

Impact on smaller companies

The CHC’s Tony Lewis has argued that the new fines proposed in the Bill are potentially damaging to the complementary medicines industry, in particular: ‘we believe that our part of the industry is different to the drug industry because in the main it’s made up of small and medium-sized businesses and the potential fines would be extremely damaging to most businesses ... The issue is we haven’t seen the guidelines as to how the fines would be applied. What kind of fine would be applied to someone when the size of the lettering on the [pill jar] is wrong? We don’t know’.³¹

Analysis of measure

As noted above, the TGA’s risk-management approach is designed to strike a balance between ensuring public health and safety, while avoiding unnecessary administrative and financial costs to industry through excessive regulation.

In explaining the need for the new, more flexible range of enforcement options contained in this Bill, the Government has sought to emphasise that this measure is in line with the need to maintain this balance. Currently, in the instance of a company (such as Pan) that fails to comply with regulatory requirements, the TGA is restricted in its options to either criminal prosecution or administrative sanctions such as withdrawal of a manufacturing licence. In contrast, the new enforcement options proposed in this Bill are seen as

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affording the TGA with the flexibility necessary to achieve a more optimal regulatory outcome—that is one capable of striking a balance between the health and safety needs of consumers (including their need to have access to therapeutic products) and the viability of industry.³²

The purported benefits of this greater flexibility are encapsulated in the Parliamentary Secretary's comments that:

With the new measures the TGA will be better placed to deter a company's continuing breaches of regulatory requirements before they become so serious that administrative action has to be taken that could put the company out of business.

Deterring non-compliance by industry as a whole is important in protecting consumers but it also creates a fairer environment for all players as law-abiding sponsors and manufacturers are not unfairly disadvantaged by their non-compliant competitors. Increased compliance also leads to greater credibility and attractiveness of marketed products.³³

As such, the Government sees the measures in this Bill as promoting optimal outcomes for all players in the therapeutic goods sector.

On the other hand, concerns raised by some in the therapeutic goods industry (discussed above) suggest that there are some areas in which the flexibility for the TGA arising from the new enforcement options might possibly be detrimental to the viability of industry—particularly small-to-medium sized players such as the majority of those in the complementary medicines sector.

As can be seen above, particular concerns have been raised in the therapeutic goods sector in relation to such aspects of the Bill as:

- the level of discretionary power afforded the TGA and uncertainty about how this power will be applied in particular circumstances;
- the potentially unfair and detrimental impact of allowing the TGA to publicly release information about actions taken or decisions made under the Act or Regulations;
- the potential impact of fines proposed in the Bill on small and medium-sized businesses, including those in, what many in the sector argue, is the lower-risk complementary medicines sector;
- in the case of the proposed infringement notices, the absence of independent arbitration processes.

Concerns such as these suggest that, for some in the therapeutic goods sector, the measures proposed in this Bill shift the balance of risk away from ensuring the viability of the industry (or, at least, the viability of the industry in its current, relatively diverse form) and hence away from good regulatory practice. As outlined above, this is a particular concern within the complementary medicines sector.

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The extent to which the new enforcement powers under this Bill might possibly diminish the viability of the therapeutic goods industry (or sections of it) is difficult to evaluate until they begin to be applied by the TGA. Nevertheless, it appears that some in the industry are concerned that these measures have been proposed without sufficient consultation and leave them open to the possibility of arbitrary action.

Main Provisions

Schedule 1 to the Bill provides for amendments to the *Therapeutic Goods Act 1989* to

- implement the new enforcement options for the TGA outlined above; and
- make minor amendments to advertising requirements, an amendment to correct a technical omission to a section of the Act and an amendment to include an instrument of exemption in the list of certificates that the Secretary may issue as evidence of certain matters

These provisions are described in detail in the Explanatory Memorandum to the Bill.

Endnotes

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- 1 [Regulation of therapeutic goods in Australia](#), Therapeutic Goods Administration website (accessed 29 August 2005). ‘Therapeutic use’ refers to use in or in connection with: preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; influencing inhibiting or modifying a physiological process; testing the susceptibility of persons to a disease or ailment; influencing, controlling or preventing conception; testing for pregnancy; or replacement or modification of parts of the anatomy.
 - 2 [Medicines Regulation and the TGA](#), Therapeutic Goods Administration, Department of Health and Ageing, September 2004, p. 1.
 - 3 This responsibility is exercised in cooperation with State and Territory Governments and industry. There are five main processes used by the TGA in regulating therapeutic goods: pre-market evaluation and approval; development, maintenance and monitoring of the systems for listing medicines; licensing of manufacturers; post-market monitoring; and assessment of medicines for export.
 - 4 [Medicines Regulation and the TGA](#), op. cit., p. 4.
 - 5 *ibid.*, p. 4.
 - 6 *ibid.*, p. 1.
 - 7 Expert Committee on Complementary Medicines in the Health System, [Complementary medicines in the Australian health system](#), report to the Parliamentary Secretary to the Minister for Health and Ageing, October 2003, p. 43.

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- 8 *ibid.*, pp. 46–47.
- 9 [National Medicines Regulator Suspends Drug Company's Manufacturing Licence](#), Media Release, Therapeutic Goods Administration, 28 April 2003. See also, Hon Trish Worth MP, [Federal Government to Strengthen Pharmaceutical Laws](#), Media Release, Parliamentary Secretary to the Minister for Health and Ageing, 28 April 2003. .
- 10 *ibid.*
- 11 See, for example: C. Fitzsimmons, '[I was denied justice, says Pan boss](#)', *Australian*, 25 August 2003; '[Pan Recall Questioned After New Test Results](#)', *Canberra Times*, 27 August 2003; R. Robinson, '[The Pan pain](#)', *Herald Sun*, 17 April 2004; E. Hilary, 'Health and freedom at stake', *Acres Australia*, 11:3, 2003-04, p. 29.
- 12 [Expert committee on complementary medicines in the health system](#), Therapeutic Goods Administration website (accessed 30 August 2005).
- 13 Hon. Trish Worth, Parliamentary Secretary to the Minister for Health and Ageing, [Government moves to restore confidence in complementary medicines industry](#), media release, 31 October 2003. See also Expert Committee on Complementary Medicines in the Health System, [Complementary medicines in the Australian health system](#), *op. cit.*
- 14 Hon. Christopher Pyne, Parliamentary Secretary to the Minister for Health and Ageing, [Australian Government supports reform for complementary medicine](#), media release, 9 March 2005. See also Hon. Christopher Pyne, Parliamentary Secretary to the Minister for Health and Ageing, [Government response to the report of the Expert Committee on Complementary Medicines in the Health System](#), Australian Government, March 2005.
- 15 [Therapeutic Goods Amendment \(Regulatory Issues\) Bill 2005—Industry Briefing](#), Therapeutic Goods Administration, March 2005, p. 2.
- 16 D. Cadden, '[Natural withdrawal symptoms](#)', *Sydney Morning Herald*, 3 March 2005.
- 17 L. Allen, '[Regulator rapped after Pan recall](#)', *Australian Financial Review*, 17 December 2004; J. Sexton, '[Drugs watchdog sloppy, audit finds](#)', *Australian*, 17 December 2004.
- 18 Australian National Audit Office, [Regulation of non-prescription medicinal products](#), Audit report No. 18, 2004-05, at para 5.68. The ANAO stated that in the Pan case, 'an expert advisory group advised that there were imminent risks of death, serious illness, or serious injury. These would have been present during the 12-week period that the TGA was auditing and preparing for enforcement action. Such an assessment would also enable the TGA to consider whether, should another risk of serious health consequences emerge in the future, the ongoing exposure of the public to potential risks is appropriately balanced with other considerations'.
- 19 Australian National Audit Office, *op. cit.*
- 20 Hon. Christopher Pyne, Parliamentary Secretary to the Minister for Health and Ageing, [Therapeutic Goods Amendment Bill 2005: Second Reading Speech](#), House of Representatives, *Debates*, 17 August 2005, p. 1.
- 21 *ibid.*

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- 22 L. Allen, '[Vitamin makers build TGA resistance](#)', *Australian Financial Review*, 23 June 2005.
- 23 L. Allen, '[Drug rule breakers face public exposure](#)', *Australian Financial Review*, 8 June 2005.
- 24 L. Allen, '[Drug rule breakers face public exposure](#)', op. cit.
- 25 see, for example, L. Allen, '[Crackdown a bitter pill for drug industry](#)', *Australian Financial Review*, 7 June 2005; L. Allen, '[Vitamin makers build TGA resistance](#)', op. cit.
- 26 *ibid.*
- 27 L. Allen, '[Vitamin makers build TGA resistance](#)', op. cit.
- 28 L. Allen, '[Crackdown a bitter pill for drug industry](#)', op. cit.
- 29 L. Allen, '[Drug rule breakers face public exposure](#)', op. cit.
- 30 L. Allen, '[Vitamin makers build TGA resistance](#)', op. cit.
- 31 *ibid.*
- 32 Hon. Christopher Pyne, Parliamentary Secretary to the Minister for Health and Ageing, [Therapeutic Goods Amendment Bill 2005: Second Reading Speech](#), op. cit., p. 1
- 33 *ibid.*, p. 3.

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