



## Therapeutic Goods Legislation Amendment (Annual Charges) Bill 2008

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## Therapeutic Goods Legislation Amendment (Annual Charges) Bill 2008

**Date introduced:** 18 June 2008

**House:** House of Representatives

**Portfolio:** Health and Ageing

**Commencement:** The formal provisions commence on Royal Assent. Schedule 1 commences on a date to be fixed by Proclamation, or six months and one day after Royal Assent, whichever occurs first.

**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 Bill amends the *Therapeutic Goods Act 1989* (Cth) (the Therapeutic Goods Act) and the *Therapeutic Goods (Charges) Act 1989* (Cth) (the Charges Act) in relation to the imposition and collection of annual charges (and exemption from paying a charge).

### Background

The Therapeutic Goods Administration (TGA) ‘carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances’.<sup>1</sup> Particularly, the TGA is responsible for maintaining the Australian Register of Therapeutic Goods (the Register) ‘for the purpose of compiling information in relation to, and providing for evaluation of, therapeutic goods for use in humans’.<sup>2</sup> According to the TGA’s website:

[The Register] is a computer database of therapeutic goods. Therapeutic goods are divided broadly into two classes: medicines and medical devices. Unless exempt, medicines must be entered as either ‘registered’ or ‘listed’ medicines and medical

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1. Therapeutic Goods Administration, ‘What the TGA does’, <http://www.tga.gov.au/about/tga.htm> (accessed on 23 June 2008).
  2. Therapeutic Goods Act, subsection 9A(1).

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devices must be ‘included’ before they may be supplied in or exported from Australia.<sup>3</sup>

The Register includes details about product names and formulations, and the sponsor and manufacturer of the product. As at 23 May 2008, there were approximately 54 000 products on the Register.<sup>4</sup>

Under the Therapeutic Goods Act, an ‘annual registration charge, annual listing charge or annual charge for inclusion’ in the Register is payable by ‘the person in relation to whom the therapeutic goods concerned are registered, listed or included in the Register’ (subsection 43(1)). In addition, an ‘annual licensing charge’ is payable by ‘the holder of the licence to which the charge relates’ (subsection 43(2))—usually a manufacturer.

The annual charges for the registration, listing or licensing of therapeutic goods are set out in regulation 3 of the Therapeutic Goods (Charges) Regulations 1990 (Cth).

The time for the payment of such charges is set out in section 44 of the Therapeutic Goods Act. Currently, the annual charge is payable on the anniversary of the registration, listing or inclusion in the Register of the relevant therapeutic goods, unless the Secretary to the Department of Health and Ageing specifies another day in a notice in writing to the person responsible for paying the charge. The Therapeutic Goods Act currently makes no provision for exemption from paying a charge under that Act.

A charge that is not a fee for service is considered to be a tax, and section 55 of the Constitution provides (in part) that ‘[l]aws imposing taxation shall deal only with the imposition of taxation, and any provision therein dealing with any other matter shall be of no effect’. The purpose of the Charges Act (as revealed by the long title) is therefore ‘to impose an annual charge on the registration, listing and inclusion in the Register of therapeutic goods, and on the licensing of manufacturers of therapeutic goods’. Subsection 5(3) of the Charges Act states that the regulations may exempt from the payment of such charges (but not licensing charges) ‘persons whose turnover of those goods or devices is of low volume and low value’. It provides:

- (3) The regulations shall provide that annual charges in respect of the registration or listing of therapeutic goods, or the inclusion of kinds of medical devices in the Register under Chapter 4 of the *Therapeutic Goods Act 1989*, are not payable by persons whose turnover of those goods or devices is of low volume and low value.

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3. Therapeutic Goods Administration, ‘Australian register of therapeutic goods (ARTG)’, <http://www.tga.gov.au/docs/html/artg.htm> (accessed on 23 June 2008).
  4. *ibid.*

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The phrases 'low volume' and 'low value' are not defined in the Charges Act. However, regulation 5 of the Therapeutic Goods (Charges) Regulations 1990 deals with turnover of low volume and low value. Subregulation 5(1) states:

A person who has turnover, or expects to have turnover, of particular registered or listed therapeutic goods, or kinds of medical devices that are included in the Register under Chapter 4 of the *Therapeutic Goods Act 1989*, may apply to the Secretary for a declaration that the turnover is of low volume and low value.

Subregulations 5(4) and (5) set out the matters which the Secretary may take into account in determining whether to make a declaration that the turnover is of low volume and low value:

- (4) In considering the application, the Secretary may take into account:
  - (a) the value of the wholesale turnover of the goods in the financial year immediately before the financial year to which the charge relates; or
  - (b) if there was no turnover of those goods in the preceding financial year — the value of the estimated wholesale turnover of the goods in the financial year immediately after the financial year to which the charge relates.
  
- (5) However, the Secretary must make a declaration if the Secretary is satisfied that the charge for registration or listing, or inclusion in the Register under Chapter 4 of the *Therapeutic Goods Act 1989*, that would be payable, if the application was refused, is more than:
  - (a) 6.8% of the value of the wholesale turnover of those goods in the financial year immediately before the financial year to which the charge relates; or
  - (b) if there was no turnover of those goods in that preceding financial year — 6.8% of the value of the estimated wholesale turnover of those goods in the financial year immediately after the financial year to which the charge relates.

### Press commentary

There appears to be no press commentary on the Bill.

### The position of non-government, political parties

At the time of writing, no political party (other than the ALP in introducing the Bill into Parliament) has expressed any position on the Bill.

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## Financial implications

According to the Explanatory Memorandum for the Bill, the amendments ‘will have very low impact on business, individuals or the economy’.<sup>5</sup> This is because the proposed amendments really do no more than alter the dates for payment of annual charges, in circumstances where (a) administrative arrangements that mirror the proposed legislative scheme are already in place, and (b) the charges are already levied but paid at different dates throughout the year. It may be that the Bill will have positive financial implications. The Bill proposes that regulations will provide for greater scrutiny of applications for exemption from liability to pay annual charges, including the ability to recover charges previously the subject of successful, but presumably fraudulent or misleading, applications for exemption. The actual financial implications will thus depend on the extent and efficiency of the TGA’s administrative cost recovery procedures.

## Main provisions

### Amendments to the *Therapeutic Goods Act 1989*

**Item 1 of Schedule 1** repeals current section 44 of the Therapeutic Goods Act, which, as mentioned above, provides that an annual charge is payable on the anniversary of the registration, listing or inclusion in the Register of the relevant therapeutic goods, unless the Secretary to the Department of Health and Ageing specifies another day in a notice in writing to the person responsible for paying the charge.

**Item 1** then inserts **proposed revised section 44**, which provides for the payment of all annual charges on a date to be ‘worked out under the regulations’ or 1 October each year (unless the regulations specify another date).

This change would seem to have obvious benefits for simplifying administrative processes for the TGA. For example, it can issue one large batch of invoices for payment of charges due on 1 October each year (or such other date as may be prescribed in the regulations), rather than issuing numerous invoices throughout the year. The TGA will be in a better position to know what its expected income is for the coming year and when to expect the moneys, and to take appropriate action to recover unpaid moneys in a wholesale, rather than piecemeal, way.

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5. Explanatory Memorandum for the Therapeutic Goods Legislation Amendment (Annual Charges) Bill 2008, p. 2. An electronic copy is available at <http://parlinfoweb.parl.net/parlinfo/Repository/Legis/ems/Linked/18060801.pdf>, accessed on 25 June 2008.

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On the other hand, the current arrangement provides the TGA with year-round cashflow—although admittedly, the flow may be irregular and of varying amounts. It also has the advantage of accounts being issued as a matter of daily (or fortnightly/monthly) routine.

However, presumably the proposed arrangement has emanated from, or been developed in consultation with, the TGA in light of its experience with the current arrangement. It can only be assumed that the TGA is supportive of the proposed arrangement, whatever its advantages or disadvantages may be. Also, according to its website, it seems that the TGA already issues invoices in September, and so it seems that the proposed legislative change simply brings the legislation into line with current administrative practice.<sup>6</sup>

**Item 2 of Schedule 1** inserts **proposed section 44A**, which deals with exemptions from liability to pay charges. According to the second reading speech by the Hon Bill Shorten MP, Parliamentary Secretary for Disabilities and Children's Services:

The Australian National Audit Office also recently raised some concerns on the lack of ability of the TGA to review the eligibility of sponsors applying for, or who have been granted, exemption. Under the current provisions, the TGA does not have power to seek evidence verifying the eligibility of persons applying for, or who have been granted, the exemption for paying annual charges for low turnover of therapeutic goods.<sup>7</sup>

The Explanatory Memorandum for the Bill states that the 'changes will ensure that persons who apply for or are granted the exemption from paying annual charges have the requisite supporting evidence that is certified by a third party'.<sup>8</sup> It goes on to say:

This will address the concern raised by the Australian National Audit Office in their Financial Statement Audit Report for 2006–2007 for the Department of Health and Ageing in relation to the lack of third party confirmation that the applicant does meet the eligibility criteria for the low value exemption.<sup>9</sup>

**Proposed subsection 44A(4)**, for example, states that the regulations may provide for 'the obtaining of additional information or documents from applicants for exemptions or

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6. Therapeutic Goods Administration, 'Annual charges for therapeutic goods', <http://www.tga.gov.au/fees/ac-theragoods.htm> (accessed on 23 June 2008).
  7. The Hon Bill Shorten MP, Parliamentary Secretary for Disabilities and Children's Services, 'Second reading speech: Therapeutic Goods Legislation Amendment (Annual Charges) Bill 2008', House of Representatives, *Debates*, 18 June 2008, p. 3. An electronic copy is available at <http://www.aph.gov.au/hansard/reps/dailys/dr180608.pdf>, accessed on 23 June 2008.
  8. Explanatory Memorandum for the Therapeutic Goods Legislation Amendment (Annual Charges) Bill 2008, p. 2.
  9. *ibid.* Note that this document is not readily located.

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persons granted exemptions'. **Proposed paragraph 44A(1)(c)** states that the regulations may make provision for 'cancelling an exemption and requiring payment of that charge for the current year'. It is not clear why matters such as these are to be the subject of regulations, rather than just being contained in the parent Act itself.

**Proposed subsection 44A(2)** states that the regulations may require an application for an exemption to be accompanied by a fee and goes on to say that the fee 'must not be such as to amount to taxation'.

The TGA is a division of the Department of Health and Ageing, which is an agency subject to the *Financial Management and Accountability Act 1997* (Cth) and is thus required to comply with the Government's cost recovery policy, including the imposition of fees and charges where appropriate.<sup>10</sup> **Proposed subsection 44A(2)** permits the imposition of such a fee for the processing of an application for exemption from liability to pay a charge. It is not clear if, or in what circumstances, such a fee can be waived—although that may be an issue for the regulations.

Many of the matters contained in **proposed section 44A** are currently contained in the Therapeutic Goods (Charges) Regulations 1990. However, the difficulty is that those regulations are made under the Therapeutic Goods (Charges) Act, not the Therapeutic Goods Act itself. Amendments will be required to the Therapeutic Goods Regulations 1990 and the existing regulations (in the Therapeutic Goods (Charges) Regulations 1990) dealing with charges may need to be repealed (unless there is no possibility of inconsistency between the two). In some instances, a proposed amendment to the Therapeutic Goods Act is meaningless without new regulations being made. For example, the term 'turnover' in **proposed subsection 44A(9)** is defined by cross-reference to the definition of the term 'prescribed by the regulations'. However, the term is not currently defined in the Therapeutic Goods Regulations 1990.

**Item 3** provides that the amendment made by **item 1** applies in relation to the financial year beginning 1 July 2009. Persons who are liable to pay annual charges and licensing fees are thus given just over 12 months' notice of the proposed change to the invoice and payment arrangement (from the time of the introduction of the Bill).

### Amendments to the *Therapeutic Goods (Charges) Act 1989*

**Items 4 and 5 of Schedule 1** contain proposed amendments to the Charges Act. The proposed changes seem to be little more than consequential amendments to the Act which ought properly to have been made in 2002 (or shortly thereafter) when the *Therapeutic*

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10. Department of Finance and Deregulation, 'Finance Circular 2005/09: Australian Government Cost Recovery Guidelines', [http://www.finance.gov.au/finframework/fc\\_2005\\_09.html](http://www.finance.gov.au/finframework/fc_2005_09.html), accessed on 25 June 2008.

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*Goods and Other Legislation Amendment Act 2002* (Cth) was passed. By that Act, section 6A of the Therapeutic Goods Act was repealed, and sections 6AAA–6AAE were enacted in its place.<sup>11</sup> It is not clear why the proposed amendments did not occur in 2002 or at some other time in the past five or six years. It is also not clear what effect the delay in making these consequential amendments may have on the validity of charges imposed under the Charges Act in the intervening period. Neither the second reading speech nor the Explanatory Memorandum for the Bill mentions these issues.

**Item 4** repeals subsections 4(3) to (6) of the Charges Act and inserts **proposed subsections 4(3) to (7)**. Ostensibly, apart from tidying up some language, **item 4** replaces references to the repealed section 6A of the Therapeutic Goods Act with references to sections 6AAA–6AAE of that Act where appropriate.

**Item 5** repeals subsection 5(3) of the Charges Act. As quoted above, subsection 5(3) provides that the regulations may exempt from the payment of such charges ‘persons whose turnover of those goods or devices is of low volume and low value’. **Proposed subsection 44A** of the Therapeutic Goods Act will perform this function instead (see above discussion in relation to **item 2** of the Bill).

**Item 6** provides that current section 5(3) of the Charges Act (which is to be repealed by **item 5**) continues to apply when working out annual charges payable in respect of the financial year beginning on 1 July 2008 and all earlier financial years.

## Concluding comments

None of the amendments in the Bill appears to be controversial. The proposed amendments to the Therapeutic Goods Act dealing with changes to dates for the payment of annual charges simply bring the legislative framework into line with administrative practice, noting that while this order seems to be the reverse of the usual situation, it was permissible under the current legislative framework. The proposed amendments dealing with exemptions from liability to pay such charges expand on the requirements currently set out in regulations, and also give the TGA the power to require applicants for exemptions (or persons granted exemptions) to provide additional information or documents. Such amendments empower the TGA to implement fully its obligations to comply with the Government’s cost recovery guidelines, particularly by enabling it to verify information supplied by applicants and to require applicants to provide additional information not previously supplied by them.

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11. The text of the Therapeutic Goods and Other Legislation Amendment Bill 2002 is available electronically at: <http://www.austlii.edu.au/au/legis/cth/bill/tgaolab2002470/> (accessed on 24 June 2008).

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The proposed amendments to the Charges Act are a somewhat delayed response to the passage of the *Therapeutic Goods and Other Legislation Amendment Act 2002* (Cth). The amendments are also consequential upon the passage of **item 2** of the Bill.

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