

2008

The Parliament of the
Commonwealth of Australia

HOUSE OF REPRESENTATIVES

Presented and read a first time

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

No. , 2008

(Health and Ageing)

**A Bill for an Act to amend the law relating to
therapeutic goods, and for related purposes**

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1 **A Bill for an Act to amend the law relating to**
2 **therapeutic goods, and for related purposes**

3 The Parliament of Australia enacts:

4 **1 Short title**

5 This Act may be cited as the *Therapeutic Goods Legislation*
6 *Amendment (Annual Charges) Act 2008*.

7 **2 Commencement**

8 (1) Each provision of this Act specified in column 1 of the table
9 commences, or is taken to have commenced, in accordance with
10 column 2 of the table. Any other statement in column 2 has effect
11 according to its terms.
12

Commencement information

| Column 1 | Column 2 | Column 3 |
|---|--|---------------------|
| Provision(s) | Commencement | Date/Details |
| 1. Sections 1 to 3 and anything in this Act not elsewhere covered by this table | The day on which this Act receives the Royal Assent. | |
| 2. Schedule 1 | A single day to be fixed by Proclamation. However, if any of the provision(s) do not commence within the period of 6 months beginning on the day on which this Act receives the Royal Assent, they commence on the first day after the end of that period. | |

1 Note: This table relates only to the provisions of this Act as originally
2 passed by both Houses of the Parliament and assented to. It will not be
3 expanded to deal with provisions inserted in this Act after assent.

4 (2) Column 3 of the table contains additional information that is not
5 part of this Act. Information in this column may be added to or
6 edited in any published version of this Act.

7 **3 Schedule(s)**

8 Each Act that is specified in a Schedule to this Act is amended or
9 repealed as set out in the applicable items in the Schedule
10 concerned, and any other item in a Schedule to this Act has effect
11 according to its terms.

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Schedule 1—Amendments

Therapeutic Goods Act 1989

1 Section 44

Repeal the section, substitute:

44 Time for payment of charges

Annual registration charge, annual listing charge or annual charge for inclusion in the Register

- (1) An annual registration charge, annual listing charge or annual charge for inclusion in the Register for a financial year becomes payable:
 - (a) if the registration, listing or inclusion in the Register of the therapeutic goods concerned commenced in that financial year—on the day worked out under the regulations; and
 - (b) in any other case:
 - (i) on 1 October in that year; or
 - (ii) if the regulations specify another day for the purposes of this subparagraph—on that other day in that year.

This subsection is subject to subsection (3).

Annual licensing charge

- (2) An annual licensing charge for a financial year becomes payable:
 - (a) if the licence commenced in that financial year—on the day of that commencement; and
 - (b) in any other case:
 - (i) on 1 October in that year; or
 - (ii) if the regulations specify another day for the purposes of this subparagraph—on that other day in that year.

This subsection is subject to subsection (3).

Charge may become payable on a later day

- (3) The Secretary may, by notice in writing given to a person, specify a later day on which a charge referred to in subsection (1) or (2)

1 becomes payable by the person for a financial year. The notice has
2 effect accordingly.

3 *Interpretation*

4 (4) This section is subject to section 44A.

5 **2 After section 44**

6 Insert:

7 **44A Exemptions from liability to pay charges**

- 8 (1) The regulations may make provision for and in relation to:
- 9 (a) exempting a person from liability to pay annual registration
10 charge, annual listing charge or annual charge for inclusion
11 in the Register for a financial year (the *current year*) if the
12 person's turnover of the therapeutic goods concerned for the
13 financial year specified in the regulations is of low value; and
- 14 (b) the making of an application for an exemption and requiring
15 payment of that charge for the current year if the application
16 is refused; and
- 17 (c) cancelling an exemption and requiring payment of that
18 charge for the current year.

19 *Fees*

- 20 (2) The regulations may require applications for exemptions to be
21 accompanied by a specified fee. A fee must not be such as to
22 amount to taxation.

23 *Statements prepared by approved persons*

- 24 (3) The regulations may require a person who is applying for an
25 exemption, or who has been granted an exemption, to provide a
26 statement:
- 27 (a) that is prepared by an approved person; and
- 28 (b) that specifies whether the person's turnover of the therapeutic
29 goods concerned for the financial year concerned is of low
30 value.

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Additional information

(4) The regulations may provide for the obtaining of additional information or documents from applicants for exemptions or persons granted exemptions.

Merits review

(5) The regulations may provide for review by the Administrative Appeals Tribunal of decisions of the Secretary to refuse applications for exemptions or to cancel exemptions.

No limit on subsection (1)

(6) Subsections (2) to (5) do not limit subsection (1).

Low value turnover

(7) For the purposes of this section, the regulations may specify when a person's turnover of therapeutic goods for a financial year is of low value. The regulations may specify different rules for different therapeutic goods.

Interpretation

(8) This section does not limit paragraph 63(3)(b) (about the refund, reduction or waiving of fees or charges).

Definitions

(9) In this section:

approved person means a person included in a class of persons specified in regulations made for the purposes of this definition.

turnover has the meaning prescribed by the regulations.

3 Application

(1) The amendment made by item 1 applies in relation to the financial year beginning on 1 July 2009 and all later financial years (regardless of whether the registration, listing or inclusion in the Register of the therapeutic goods, or whether the licence, commenced before, on or after 1 July 2009).

- 1 (2) The amendment made by item 2 applies for the purposes of working out
2 whether a person is exempt from liability to pay annual registration
3 charge, annual listing charge or annual charge for inclusion in the
4 Register for the financial year beginning on 1 July 2009 and all later
5 financial years.

6 ***Therapeutic Goods (Charges) Act 1989***

7 **4 Subsections 4(3) to (6)**

8 Repeal the subsections, substitute:

9 *Corresponding State laws*

- 10 (3) If, because of the operation of section 6AAE of the Therapeutic
11 Goods Act, goods are included in the part of the Register for goods
12 known as registered goods, this section has effect as if the goods
13 had been registered under Part 3-2 of that Act.
- 14 (4) If, because of the operation of section 6AAE of the Therapeutic
15 Goods Act, goods are included in the part of the Register for goods
16 known as listed goods, this section has effect as if the goods had
17 been listed under Part 3-2 of that Act.
- 18 (5) If, because of the operation of section 6AAE of the Therapeutic
19 Goods Act, goods are included in the part of the Register for
20 medical devices included under Chapter 4, this section has effect as
21 if the goods had been included in the Register under Chapter 4 of
22 that Act.
- 23 (6) If:
- 24 (a) because of the operation of section 6AAA, 6AAB or 6AAC
25 of the Therapeutic Goods Act, the Secretary issues a licence;
26 and
- 27 (b) the licence is issued for the purposes of provisions of a
28 corresponding State law that correspond to Part 3-3 of the
29 Therapeutic Goods Act;
- 30 this section has effect as if the licence had been issued under
31 Part 3-3 of that Act.

32 *Definitions*

- 33 (7) In this section:
-

1 *amount* includes a nil amount.

2 *Therapeutic Goods Act* means the *Therapeutic Goods Act 1989*.

3 **5 Subsection 5(3)**

4 Repeal the subsection.

5 **6 Saving**

6 Despite the repeal of subsection 5(3) of the *Therapeutic Goods*
7 (*Charges*) *Act 1989* made by this Act, that subsection continues to apply
8 after the commencement of this item in relation to working out whether
9 the annual charges mentioned in that subsection are payable by persons
10 for the financial year beginning on 1 July 2008 and all earlier financial
11 years.