

Therapeutic Goods Legislation Amendment Act 1998

No. 34, 1998

An Act to amend the Therapeutic Goods Act 1989 and the Customs Act 1901

[Assented to 17 April 1998]

The Parliament of Australia enacts:

1 Short title

This Act may be cited as the *Therapeutic Goods Legislation Amendment Act 1998*.

2 Commencement

This Act commences on the day on which it receives the Royal Assent.

3 Schedule(s)

Each Act that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.

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Schedule 1

Amendment of the Therapeutic Goods Act 1989

1 Subsection 3(1)

Insert:

protected information, in relation to therapeutic goods, has the meaning given by [section 25A](#).

2 At the end of subsection 25(1)

Add:

Note: The Secretary must not use protected information when evaluating therapeutic goods for registration: see [section 25A](#).

3 After section 25

Insert:

25A When the Secretary must not use protected information

- (1) When evaluating therapeutic goods for registration, the Secretary must not use information about other therapeutic goods that is protected information.
- (2) Information is *protected information* if:
 - (a) the information was given to the Secretary in relation to an application to register therapeutic goods (the *new goods*):
 - (i) not being therapeutic devices; and
 - (ii) consisting of, or containing, an active component; and
 - (b) the information is about the active component and is not available to the public; and
 - (c) when the application to register the new goods was lodged:
 - (i) no other therapeutic goods consisting of, or containing, that active component were included in the Register; and
 - (ii) no such therapeutic goods had been included in the Register at any time before then; and
 - (d) the new goods became registered on or after the commencement of this subsection; and
 - (e) 5 years have not passed since the day the new goods became registered; and
 - (f) the person in relation to whom the new goods are registered has not given the Secretary permission in writing for the Secretary to use the information.
- (3) For the purposes of [subsection \(2\)](#), an *active component*, in relation to therapeutic goods, is a substance that is, or one of the substances that together are, primarily responsible for the biological or other effect identifying the goods as therapeutic goods.
- (4) The use of protected information contrary to [subsection \(1\)](#) does not render the Commonwealth, the Secretary or a delegate of the Secretary liable to a person in respect of loss, damage or injury of any kind suffered by the person as a result of, or arising out of, the use of that information.

4 After subsection 30(4)

Insert:

- (4A) The Secretary must, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration of the goods if the Secretary becomes aware that protected information was used when evaluating the goods for registration.

5 Paragraph 31(2)(d)

Repeal the paragraph, substitute:

- (d) the method and place of manufacture or preparation of the goods and the procedures employed to ensure that proper standards are maintained in the manufacture and handling of the goods;

6 After subparagraph 38(1)(f)(ii)

Insert:

- (ia) controls a body corporate (whether directly, or indirectly through one or more interposed entities) that has been convicted of an offence against this Act or a law of a State or Territory relating to therapeutic goods; or
- (ib) controlled a body corporate (whether directly, or indirectly through one or more interposed entities) when the body committed an offence against this Act or a law of a State or Territory relating to therapeutic goods, and the body has been convicted of that offence; or
- (ic) is controlled by another person (whether directly, or indirectly through one or more interposed entities) and that other person has been convicted of an offence against this Act or a law of a State or Territory relating to therapeutic goods; or

7 After paragraph 41(1)(a)

Insert:

- (aa) the holder controls a body corporate (whether directly, or indirectly through one or more interposed entities) that has been convicted of an offence against this Act or a law of a State or Territory relating to therapeutic goods; or
- (ab) the holder controlled a body corporate (whether directly, or indirectly through one or more interposed entities) when the body committed an offence against this Act or a law of a State or Territory relating to therapeutic goods, and the body has been convicted of that offence; or

- (ac) the holder is controlled by another person (whether directly, or indirectly through one or more interposed entities) and that other person has been convicted of an offence against this Act or a law of a State or Territory relating to therapeutic goods; or

8 Subsection 61(8)

Omit “Therapeutic goods information”, substitute “Subject to [section 25A](#), therapeutic goods information”.

9 After subsection 63(3)

Insert:

(3A) The regulations may provide for:

- (a) the granting of a licence or permission to import or export therapeutic goods; and
 - (b) licences or permissions to import or export therapeutic goods to be subject to conditions or requirements; and
 - (c) the assignment of a licence or permission to import or export therapeutic goods; and
 - (d) the surrender of a licence or permission to import or export therapeutic goods; and
 - (e) the revocation of a licence or permission to import or export therapeutic goods.
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