

1990-91

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA  
THE SENATE

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*(Presented and read a first time, 14 November 1991)*

(MINISTER REPRESENTING THE MINISTER FOR HEALTH, HOUSING  
AND COMMUNITY SERVICES, SENATOR TATE)

**A BILL**

FOR

**An Act to amend the *Therapeutic Goods Act 1989*, and for  
related purposes**

The Parliament of Australia enacts:

**Short title etc.**

**1.(1)** This Act may be cited as the *Therapeutic Goods Amendment Act 1991*.

5 **(2)** In this Act, "**Principal Act**" means the *Therapeutic Goods Act 1989*<sup>1</sup>.

**Commencement**

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

**Object of Act**

3. Section 4 of the Principal Act is amended by adding the following subsection:

“(2) The reference in subsection (1) to a system of controls is a reference to a system that is consistent with the need to ensure the timely availability of therapeutic goods.”.

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**Exempt goods**

4.(1) Section 18 of the Principal Act is repealed and the following section substituted:

**Exempt goods**

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“18.(1) The regulations may, subject to such conditions (if any) as are specified in the regulations, exempt:

- (a) all therapeutic goods, except those included in a class of goods prescribed for the purposes of this paragraph; or
- (b) specified therapeutic goods; or
- (c) a specified class of therapeutic goods;

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from the operation of this Part.

“(2) An exemption in terms of paragraph (1)(a) has effect only in relation to such classes of persons as are prescribed for the purposes of this subsection.

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“(3) Where the regulations revoke an exemption, the revocation takes effect on the day, not being earlier than 28 days after the day on which the regulations are made, specified in the regulations.”.

(2) Regulations for the purposes of section 18 of the Principal Act in force immediately before the commencement of this section continue in force as if they had been made under section 18 of the Principal Act as amended by this Act.

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**Exemptions for special and experimental uses**

5. Section 19 of the Principal Act is amended by adding at the end the following subsections:

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“(5) The Secretary may, in writing, authorise a specified medical practitioner to supply:

- (a) specified therapeutic goods for use in the treatment of humans; or
- (b) a specified class of such goods;

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to the class or classes of recipients specified in the authority.

“(6) An authority under subsection (5) may only be given:

- (a) to a medical practitioner included in a class of medical practitioners prescribed by the regulations for the purposes of this paragraph; and

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(b) in relation to a class or classes of recipients prescribed by the regulations for the purposes of this paragraph.

5 “(7) The regulations may prescribe the circumstances in which therapeutic goods may be supplied under an authority under subsection (5).

10 “(8) The giving of an authority under subsection (5) 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 therapeutic goods by that person or another person.

“(9) In this section, ‘**medical practitioner**’ means a person who is registered, in a State or internal Territory, as a medical practitioner.”.

#### **Offences by sponsors**

6. Section 20 of the Principal Act is amended:

- 15 (a) by inserting in paragraph (1)(f) “or authority” after “approval”;  
(b) by omitting paragraph (2)(b).

#### **Offence relating to wholesale supply**

7. Section 21 of the Principal Act is amended by inserting in paragraph (b) “or authority” after “approval”.

#### 20 **General offences relating to this Part**

8. Section 22 of the Principal Act is amended:

- (a) by omitting subsection (2) and substituting the following subsection:

25 “(2) A person must not, in or in connection with an application for listing of therapeutic goods, knowingly or recklessly make a statement that is false or misleading in a material particular.”;

- (b) by inserting after subsection (7) the following subsection:

30 “(7A) A person to whom an authority under subsection 19(5) has been granted must not supply the therapeutic goods to which the authority relates except in accordance with:

(a) the authority; and

(b) any regulations made for the purpose of subsection 19(7).”;

- 35 (c) by inserting in subsection (8) “or authority” after “approval”.

9. After section 22 of the Principal Act the following section is inserted in Division 1 of Part 3:

**False statements in applications for registration**

“22A. A person must not, in or in connection with an application for registration of therapeutic goods, knowingly or recklessly make a statement that is false or misleading in a material particular. Penalty: \$40,000.”.

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**Applications for registration**

10.(1) Section 24 of the Principal Act is amended by omitting subsection (2) and substituting the following subsections:

“(2) Subject to section 24D, an application for registration of therapeutic goods lapses if:

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- (a) any part of the evaluation fee payable in respect of those goods remains unpaid at the end of the period of 2 months after the day on which the amount became due and payable; or
- (b) the application contains information that is inaccurate or misleading in a material particular; or
- (c) information given to the Secretary by, or on behalf of, the applicant in connection with the application, including information given for the purpose of a requirement under section 31, is inaccurate or misleading in a material particular; or
- (d) the applicant fails to comply with a requirement under section 31 to give information consisting of individual patient data in relation to the goods.

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“(3) In this section, ‘individual patient data’, in relation to therapeutic goods, means information, derived from clinical trials, relating to individuals before, during and after the administration of the goods to those individuals, including, but not limited to, demographic, biochemical and haematological information.”.

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(2) The amendment made by subsection (1) applies to applications made under section 23 of the Principal Act before the commencement of this Act as well as to applications made under that section after that commencement.

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**When evaluation fee due for payment**

11. Section 24A of the Principal Act is amended by omitting “section 24B” and substituting “sections 24B and 24D”.

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12. After section 24C of the Principal Act, the following section is inserted:

**Reduction of evaluation fee where evaluation not completed within prescribed period**

“24D.(1) This section applies to an application under section 23 in relation to therapeutic goods for the evaluation of which a period is prescribed under paragraph 63(2)(da).

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“(2) Nothing in section 24, 24A or 24B requires the applicant to pay more than three-quarters of the evaluation fee before the completion of the evaluation of the goods.

5 “(3) If the evaluation is not completed within the period referred to in subsection (1), this Act has effect as if the evaluation fee were reduced to three-quarters of the fee that, under the regulations, would have been the evaluation fee.

“(4) If:

- 10 (a) the evaluation is completed within the period referred to in subsection (1); and  
(b) part of the evaluation fee under section 24 is unpaid when the evaluation is completed;

that part becomes due and payable on the completion of the evaluation.

15 “(5) For the purposes of subsections (2), (3) and (4), the evaluation is to be taken to be completed when the applicant is notified according to subsection 25(3) of the Secretary’s decision on the application.”.

#### **Evaluation of therapeutic goods**

13.(1) Section 25 of the Principal Act is amended:

(a) by inserting after subsection (2) the following subsection:

20 “(2A) An evaluation under this section of goods in relation to which a period has been prescribed under paragraph 63(2)(da) must be completed within that period.”;

(b) by adding at the end the following subsection:

25 “(6) The failure to complete an evaluation within the period mentioned in subsection (2A) 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 caused by, or arising out of, the failure.”.

30 (2) The amendment made by paragraph (1)(a) does not apply in the case of an application made before the commencement of this Act.

#### **Inspection and variation of entries in Register**

14. Section 32 of the Principal Act is amended by adding at the end the following subsections:

“(4) Where:

35 (a) the person in relation to whom therapeutic goods are registered or listed has asked the Secretary to vary product information included in the entry in the Register that relates to the goods; and

40 (b) the only effect of the variation would be to reduce the class of persons for whom the goods are suitable or to add a warning or precaution, being a warning or precaution that does not

include any comparison of the goods with any other therapeutic goods by reference to quality, safety or efficacy;

the Secretary must vary the entry in accordance with the request.

“(5) Where:

- (a) the person in relation to whom therapeutic goods are registered or listed has asked the Secretary to vary information, other than product information, included in the entry in the Register that relates to the goods; and 5
- (b) the Secretary is satisfied that the variation requested does not indicate any reduction in the quality, safety or efficacy of the goods for the purposes for which they are to be used; 10

the Secretary may vary the entry in accordance with the request.

“(6) In this section, ‘**product information**’, in relation to therapeutic goods, means information relating to the safe and effective use of the goods, including information regarding the usefulness and limitations of the goods.”. 15

### **Offences**

15. Section 54 of the Principal Act is amended by omitting from subsection (1) “or 21” and substituting “, 21 or 22A”.

### **Delegation**

16. Section 57 of the Principal Act is amended:

- (a) by omitting from subsection (1) “subsection (2)” and substituting “subsections (2) and (6)”; 20
- (b) by adding at the end of subsection (2) “or as a pharmacist”;
- (c) by adding at the end the following subsections: 25

“(6) The powers of the Secretary under subsection 19(5) may be delegated only to an officer of the Department who is registered, or eligible for registration, in a State or internal Territory as a medical or dental practitioner.

“(7) The regulations may prescribe the circumstances in which, and the requirements subject to which, delegates may grant authorities under subsection 19(5).” 30

### **Regulations**

17. Section 63 of the Principal Act is amended by inserting the following paragraph in subsection (2) after paragraph (d): 35

- “(da) provide for the periods within which evaluations under section 25 in relation to specified therapeutic goods or specified classes of such goods are to be completed;”.

**NOTE**

1. No. 21, 1990, as amended. For previous amendments, see No. 141, 1990; and No. 84, 1991.

