

1993-94-95

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA  
HOUSE OF REPRESENTATIVES

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Presented and read a first time

*(Human Services and Health)*

**THERAPEUTIC GOODS AMENDMENT BILL 1995**

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THE NATIONAL ARCHIVES  
COLLECTION OF THE NATIONAL ARCHIVES

OFFICE OF THE REPRESENTATIVE

OF THE HOUSE OF REPRESENTATIVES  
WASHINGTON, D. C.

OFFICE OF THE REPRESENTATIVE

JIM A.

1991

At the time of the 1991 election, Jim A. was the Representative for the 1st District of California.

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*(Human Services and Health)*

**A BILL**

FOR

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

The Parliament of Australia enacts:

**Short title**

1. This Act may be cited as the *Therapeutic Goods Amendment Act 1995*.

**Commencement**

2 (1) Subject to this section, this Act commences on the day on which it receives the Royal Assent.

(2) Item 39 of the Schedule commences, or is taken to have commenced, immediately after the commencement of the *Audit (Transitional and Miscellaneous) Amendment Act 1995*.

5

**Schedule**

3 The Act specified in the Schedule is amended in accordance with the applicable items in the Schedule, and the other items in the Schedule have effect according to their terms.

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**SCHEDULE**

Section 3

**AMENDMENTS OF THE THERAPEUTIC GOODS ACT 1989**

**1. Subsection 3(1) (paragraph (b) of the definition of authorised person):**

Omit "Part 6", substitute "Part 5A".

**2. Subsection 3(1):**

Insert:

**"foods means goods for oral consumption:**

(a) that have a principal use, in the form in which they are presented, of:

(i) providing nutrition or hydration; or

(ii) satisfying hunger or thirst; or

(iii) satisfying a desire for taste, flavour or texture; or

(b) that, in the form in which they are presented, are goods of a kind standardised by the Food Standards Code as defined in subsection 3(1) of the *National Food Authority Act 1991*;

but does not include goods whose presentation includes a prescribed dose and frequency of administration, unless that is required or expressly permitted by the Food Standards Code as so defined."

**3. Section 3:**

Add at the end:

"(7) A reference to an offence against this Act includes a reference to:

(a) an offence against the regulations; and

(b) an offence against section 6, 7 or 7A, or subsection 86(1), of the *Crimes Act 1914* in relation to an offence against this Act or the regulations.

"(8) A maximum penalty specified:

(a) at the foot of a section of this Act (other than a section that is divided into subsections); or

(b) at the foot of a subsection of this Act;

indicates that a person who contravenes the section or subsection is guilty of an offence against the section or subsection and is punishable, on conviction, by a penalty up to that maximum."

**4. Subsection 8(2):**

Add at the end:

"Maximum penalty: 60 penalty units."

**SCHEDULE—continued****5. Subsection 8(3):**

- (a) Omit “knowingly,”, substitute “intentionally”.
- (b) Omit the penalty, substitute:  
“Maximum penalty: 60 penalty units.”.

**6. Subsections 14(1) and (3):**

Omit the penalty, substitute:  
“Maximum penalty: 240 penalty units.”.

**7. Subsection 15(2):**

Omit the penalty, substitute:  
“Maximum penalty: 120 penalty units.”.

**8. Subsection 19(1):**

Omit “either exempt goods or goods included in the Register”, substitute “registered goods, listed goods or exempt goods”.

**9. After section 19:**

Insert:

**Exemptions where unavailability etc. of therapeutic goods**

“19A.(1) The Secretary may, by notice in writing, grant an approval to a person for the importation into Australia, or the supply in Australia, of specified therapeutic goods if the Secretary is satisfied that:

- (a) registered goods that could act as a substitute for the goods are unavailable or are in short supply; and
- (b) either:
  - (i) the goods that are the subject of the application are registered or approved for general marketing in at least one foreign country specified by the Secretary in a determination under subsection (3); or
  - (ii) an application that complies with section 23 has been made under that section for registration of the goods; and
- (c) the goods are of a kind:
  - (i) included in Schedule 10 of the Therapeutic Goods Regulations; or
  - (ii) specified by the Secretary in a determination under subsection (4); and
- (d) the approval is necessary in the interests of public health.

**SCHEDULE**—continued

“(2) The Secretary may, by notice in writing, grant an approval to a person for the importation into Australia, or the supply in Australia, of specified therapeutic goods if the Secretary is satisfied that:

- (a) registered goods that could act as a substitute for the goods do not exist; and
- (b) an application that complies with section 23 has been made under that section for registration of the goods; and
- (c) the goods are of a kind:
  - (i) included in Schedule 10 of the Therapeutic Goods Regulations; or
  - (ii) specified by the Secretary in a determination under subsection (4); and
- (d) the approval is necessary in the interests of public health.

“(3) The Secretary may, for the purposes of subparagraph (1)(b)(i), make written determinations specifying the foreign countries in which registration or approval for general marketing of the goods is a pre-requisite for approval by the Secretary under this section.

“(4) The Secretary may make written determinations specifying the kinds of goods that can be the subject of an approval under this section.

“(5) Determinations under subsections (3) and (4) are disallowable instruments for the purposes of section 46A of the *Acts Interpretation Act 1901*.

“(6) The Secretary may grant the approval subject to any conditions that are specified in the notice of approval.

“(7) The Secretary may grant the approval for such period as is specified in the notice of approval.

“(8) The approval lapses if:

- (a) the period specified in the notice of approval expires; or
- (b) a decision has been made under section 25 in relation to the goods.

“(9) The approval lapses if:

- (a) the Secretary is satisfied that paragraph (1)(a), (b), (c) or (d), or paragraph (2)(a), (b), (c) or (d), as the case requires, no longer applies in relation to the goods, or that a condition of the approval has been contravened; and
- (b) the Secretary has given to the person to whom the approval was granted a notice stating that the Secretary is so satisfied.

**SCHEDULE—continued**

“(10) The lapsing of the approval on the expiry of the period specified in the notice of approval does not prevent another approval being granted under this section in relation to the goods before the lapsing of the first-mentioned approval. The other approval may be expressed to take effect on the expiry of that period.”.

**10. Subsections 20(1) and (2):**

Omit the subsections, substitute:

“(1) A person must not intentionally or recklessly:

- (a) import therapeutic goods into Australia for use in humans; or
- (b) export therapeutic goods from Australia for use in humans; or
- (c) manufacture in Australia therapeutic goods for supply for use in humans; or
- (d) supply therapeutic goods in Australia for use in humans;

unless:

- (e) the goods are registered goods or listed goods in relation to the person; or
- (f) the goods are exempt goods; or
- (g) the goods are the subject of an approval or authority under section 19; or
- (h) the goods are the subject of an approval under section 19A.

Maximum penalty: 240 penalty units.

“(1A) It is a defence to a prosecution under subsection (1) if the defendant proves that the defendant was not the sponsor of the goods at the time of the importation, exportation, manufacture or supply, as the case may be.

“(2) A person in relation to whom therapeutic goods are registered or listed must not, intentionally or recklessly, import those goods into Australia, or supply those goods in Australia, unless:

- (a) the registration number or listing number of the goods is set out on the label of the goods in the prescribed manner or, in the case of an importation, that number is so set out, or is to be so set out before the goods are supplied in Australia; or
- (b) the goods are devices that are listed goods.

Maximum penalty: 60 penalty units.”.

Note: The heading to section 20 is replaced by the heading “**Offences relating to importation, exportation, manufacture and supply of therapeutic goods**”.



**SCHEDULE—continued**

**11. Section 21:**

- (a) Omit “knowingly”, substitute “intentionally”.
- (b) Omit the penalty, substitute:  
“Maximum penalty: 120 penalty units.”.

**12. Paragraph 21(b):**

Omit the paragraph, substitute:

- “(b) the goods are exempt goods; or
- (c) the goods are the subject of an approval or authority under section 19; or
- (d) the goods are the subject of an approval under section 19A.”.

**13. Subsections 22(1), (2), (3), (4), (5), (6) and (7):**

- (a) Omit “knowingly”, substitute “intentionally”.
- (b) Add at the end:  
“Maximum penalty: 60 penalty units.”.

**14. After paragraph 22(4)(c):**

Insert:

- “; or (d) represent therapeutic goods that are not the subject of an approval or authority under section 19 as being the subject of such an approval or authority; or
- (e) represent therapeutic goods that are not the subject of an approval under section 19A as being the subject of such an approval.”.

**15. Subsection 22(7):**

Add at the end:

- “; or (c) an approval under section 19A.”.

**16. Subsection 22(7A):**

Add at the end:

- “Maximum penalty: 60 penalty units.”.

**17. Subsection 22(8):**

Omit the subsection, substitute:

- “(8) A person must not intentionally or recklessly use therapeutic goods, other than exempt goods, listed goods, registered goods or goods that are the subject of an approval under section 19A:
  - (a) for use in the treatment of another person; or

**SCHEDULE—continued**

(b) for use solely for experimental purposes in humans; except in accordance with an approval or authority under section 19. Maximum penalty: 60 penalty units.”.

**18. Section 22A:**

- (a) Omit “knowingly”, substitute “intentionally”.
- (b) Omit the penalty, substitute:  
“Maximum penalty: 400 penalty units.”.

**19. After paragraph 26(1)(b):**

Insert:

“; and (ba) the goods are not goods which may be listed under section 26A;”.

**20. Paragraph 26(1)(j):**

After “manufactured in Australia” insert “, or imported into Australia,”.

**21. After section 26:**

Insert:

**Listing of certain types of therapeutic goods**

“26A.(1) If:

- (a) an application is made for the listing of therapeutic goods in relation to a person in accordance with section 23; and
- (b) the person has complied with any requirements made by the Secretary under section 31 in relation to the goods; and
- (c) the requirements of subsection (2) and (where applicable) subsection (3) have been complied with; and
- (d) the goods are not:
  - (i) manufactured in Australia for export only; or
  - (ii) imported into Australia for export only; or
  - (iii) therapeutic devices; or
  - (iv) device kits within the meaning of the regulations made for the purposes of this subparagraph;

the Secretary is not to refuse to list the goods in relation to the person.

“(2) The applicant must certify that:

- (a) the goods are eligible for listing; and
- (b) the goods are safe for the purposes for which they are to be used; and

SCHEDULE—continued

- (c) the presentation of the goods is acceptable; and
- (d) the goods conform to every standard (if any) applicable to the goods and to every requirement (if any) relating to advertising applicable under the regulations; and
- (e) if the goods have been manufactured in Australia—each step in the manufacture of the goods has been carried out by a person who is the holder of a licence to carry out that step granted under section 38; and
- (f) the goods comply with all prescribed quality or safety criteria; and
- (g) the goods do not contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; and
- (h) the information included in or with the application is correct.

“(3) Subject to subsection (7), if a step in the manufacture of the goods has been carried out outside Australia, the Secretary must have certified, prior to the application being made, that the manufacturing and quality control procedures used in each such step are acceptable.

“(4) In deciding whether so to certify for the purposes of subsection (3), the matters that may be taken into account include:

- (a) whether the applicant has provided an acceptable form of evidence from a relevant overseas authority to establish that the manufacture of the goods is of an acceptable standard; and
- (b) whether the applicant has agreed to provide, if the Secretary considers inspection of the manufacturing procedures used in the manufacture of the goods to be necessary:
  - (i) funds for the carrying out of that inspection by the Department; and
  - (ii) evidence that the manufacturer has agreed to such an inspection.

“(5) If therapeutic goods are exempt from the operation of Part 4 or a person is exempt from the operation of that Part in relation to the manufacture of the goods, subsection (2) has effect, in relation to the goods, as if paragraph (2)(e) were omitted.

“(6) If a person (*the manufacturer*) is exempt from the operation of Part 4 in relation to a step in the manufacture of therapeutic goods, subsection (2) has effect, in relation to the goods, as if the reference in paragraph (2)(e) to a person who is the holder of a licence were a reference to the manufacturer to the extent that Part 4 applies to the manufacturer in relation to the manufacture of the goods.

### SCHEDULE—continued

“(7) If:

- (a) therapeutic goods were made outside Australia; and
- (b) had the goods been made in Australia, they would have been exempt from the operation of Part 4;

subsection (3) does not apply in relation to the goods.

“(8) The Secretary must notify the applicant in writing of his or her decision on the application within 28 days of the making of the decision and, in the case of a decision not to list the goods, of the reasons for the decision.

“(9) As soon as practicable after an applicant has been informed that therapeutic goods in respect of which an application was made are acceptable for listing, the Secretary must give to the applicant a certificate of listing of the goods. The listing of the goods commences on the day specified for the purpose in the certificate.”

Note: The heading to section 25 is replaced by the heading “**Evaluation and registration of therapeutic goods**”.

#### 22. Subsection 29A(1):

Omit the penalty, substitute:

“Maximum penalty: 400 penalty units.”

#### 23. Subsection 29B(3):

Omit the penalty, substitute:

“Maximum penalty: 400 penalty units.”

#### 24. Subsection 29B(4):

(a) Omit “knowingly”, substitute “intentionally”.

(b) Omit the penalty, substitute:

“Maximum penalty: 400 penalty units.”

#### 25. Subsection 30(1):

Add at the end:

“; or (e) in the case of goods listed under section 26A, it appears to the Secretary that any of the certifications under paragraph 26A(2)(a), (e) or (g) are incorrect or (if applicable) the requirements under subsection 26A(3) are not fulfilled.”

#### 26 After paragraph 30(2)(b):

Insert:

“(ba) in the case of goods listed under section 26A, it appears to the Secretary that any of the certifications under paragraph 26A(2)(b), (c), (d), (f) or (h) are incorrect; or”

**SCHEDULE—continued**

**27 Paragraph 30(6)(a):**

Omit “require the person”, substitute “impose on the person one or both of the following requirements”.

**28 Subparagraph 30(6)(a)(i):**

Omit “or” (last occurring).

**29 Subsection 30(7):**

(a) Omit “knowingly”, substitute “intentionally”.

(b) Omit the penalty, substitute:

“Maximum penalty: 60 penalty units.”.

**30. After section 30:**

Insert:

**Recovery of wrongly supplied therapeutic goods**

“30A.(1) This section applies if:

(a) any person supplies therapeutic goods; and

(b) the goods are not registered goods, listed goods, exempt goods, goods that are the subject of an approval or authority under section 19 or goods that are the subject of an approval under section 19A.

“(2) The Secretary may, in writing, impose on the sponsor of the goods one or both of the following requirements:

(a) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, that the goods have been wrongly supplied;

(b) to take steps to recover any of the goods that have been distributed.

“(3) The Secretary must cause to be published in the *Gazette*, as soon as practicable after imposing such a requirement, a notice setting out particulars of the requirement.

“(4) A person who intentionally or recklessly refuses or fails to comply with a requirement under subsection (2) is guilty of an offence.

Maximum penalty: 60 penalty units.”.

**31. Subsection 31(4):**

Omit the penalty, substitute:

“Maximum penalty: 60 penalty units.”.

**SCHEDULE—continued****32. Subsection 31(5):**

- (a) Omit “knowingly”, substitute “intentionally”.
- (b) Omit the penalty, substitute:  
“Maximum penalty: 60 penalty units.”.

**33. Subsection 32(1):**

Omit all the words after “in relation to the goods”.

**34. After subsection 32(1):**

Insert:

“(2) If the person makes such a request, the Secretary must send to the person a copy of so much (if any) of that entry as is contained in any computer database maintained by the Department for purposes connected with the administration of this Act (other than any part of that entry that was supplied in confidence by another person).”.

**35. Subsection 32(2A):**

Omit “a person”, substitute “the person”.

**36. Subsection 35(1):**

- (a) Omit “knowingly”, substitute “intentionally”.
- (b) Omit the penalty, substitute:  
“Maximum penalty: 240 penalty units.”.

**37. Subsection 35(2):**

- (a) Omit “knowingly”, substitute “intentionally”.
- (b) Omit the penalty, substitute:  
“Maximum penalty: 120 penalty units.”.

**38. Subsection 35(3):**

Omit the penalty, substitute:

“Maximum penalty: 60 penalty units.”.

**39. After section 44:**

Insert:

**Therapeutic Goods Administration Reserve**

“45.(1) This subsection establishes a reserve called the Therapeutic Goods Administration Reserve.

“(2) The Reserve is a component of the Reserved Money Fund.

**SCHEDULE—continued**

“(3) Money standing to the credit of the Therapeutic Goods Administration Trust Account immediately before the commencement of the *Audit (Transitional and Miscellaneous) Amendment Act 1995* must be transferred to the Reserve.

“(4) There must be transferred to the Reserve from the Consolidated Revenue Fund:

- (a) money appropriated by the Parliament for the purposes of the Reserve; and
- (b) amounts equal to amounts received by the Commonwealth by way of annual registration charge, annual listing charge and annual licensing charge; and
- (c) amounts equal to interest received by the Commonwealth from the investment of money from the Reserve; and
- (d) amounts equal to money received by the Commonwealth in relation to property paid for with money from the Reserve; and
- (e) amounts equal to money received by the Commonwealth for services provided or to be provided, by or on behalf of the Commonwealth, using money from the Reserve (including amounts received by way of fees payable under the regulations); and
- (f) amounts equal to donations for the furtherance of a purpose of the Reserve that are received by the Commonwealth; and
- (g) amounts equal to receipts relating to the recovery of debts (other than debts in respect of statutory fines and penalties) by the Commonwealth that are associated with expenditure of money from the Reserve.

“(5) The purposes of the Reserve are to make payments:

- (a) to further the objects of this Act (as set out in section 4); and
- (b) to enable the Commonwealth to participate in the international harmonisation of regulatory controls on therapeutic goods and other related activities.”.

**40. Part 6 (heading):**

Omit the heading, substitute:

**“PART 5A—ENTRY, SEARCHES AND WARRANTS”.**

**41. Sections 46 and 47:**

Repeal the sections, substitute:

**Definitions**

“45A. In this Part, unless the contrary intention appears:

**SCHEDULE—continued**

***evidential material*** means:

- (a) any thing with respect to which an offence against this Act has been committed or is suspected, on reasonable grounds, to have been committed; or
- (b) any thing as to which there are reasonable grounds for suspecting that it will afford evidence as to the commission of any such offence; or
- (c) any thing as to which there are reasonable grounds for suspecting that it is intended to be used for the purpose of committing any such offence.

***occupier***, in relation to premises, includes a person present at the premises who is in apparent control of the premises.

***seize*** includes secure against interference.

***thing*** includes a substance, and a thing in electronic or magnetic form.

**Searches to monitor compliance with Act**

“46.(1) Subject to subsections (2) and (3), an authorised person may, for the purpose of finding out whether this Act or the regulations have been complied with:

- (a) enter any premises; and
- (b) exercise the powers set out in subsection 48(1).

“(2) The authorised person must not enter the premises unless:

- (a) the occupier of the premises has consented to the entry; or
- (b) the entry is made under a warrant issued under section 49.

“(3) An authorised person is not entitled to exercise any powers under subsection (1) in relation to premises if:

- (a) the occupier of the premises has required the authorised person to produce his or her identity card for inspection by the occupier; and
- (b) the authorised person fails to comply with the requirement.

**Searches of certain premises to monitor compliance with Act**

“46A.(1) An authorised person may, subject to subsections (2) and (3), and to the extent that it is reasonably necessary for the purpose of finding out whether this Act or the regulations have been complied with, enter premises to which this section applies and do any of the following:

- (a) search the premises and any thing on the premises;
- (b) inspect, examine, take measurements of, or conduct tests (including by the taking of samples) concerning, any thing on the premises that relates to therapeutic goods;



**SCHEDULE—continued**

(c) take photographs (including video recordings) or make sketches of the premises or any thing on the premises;

(d) inspect any book, record or document on the premises.

“(2) An authorised person must not, under subsection (1), enter premises that are a residence unless:

(a) the occupier of the premises has consented to the entry; or

(b) the premises are used for commercial purposes in relation to therapeutic goods, in addition to residential purposes.

“(3) An authorised person is not entitled to exercise any powers under subsection (1) in relation to premises if:

(a) the occupier of the premises has required the authorised person to produce his or her identity card for inspection by the occupier; and

(b) the authorised person fails to comply with the requirement.

“(4) This section applies to:

(a) premises of a person:

(i) who has been granted an approval or authority under section 19; or

(ii) who has been granted an approval under section 19A; or

(iii) in relation to whom therapeutic goods are registered or listed;

being premises connected with the importation, export, manufacture or supply of therapeutic goods, or the keeping of records relating to the importation, export, manufacture or supply of therapeutic goods; and

(b) premises to which the person in relation to whom therapeutic goods are registered or listed, or the sponsor of the goods, must allow access as a condition of the registration or listing of the therapeutic goods; and

(c) premises in relation to which a licence has been granted under Part 4 for the manufacture of therapeutic goods, or premises at which records are kept in relation to such manufacture.

**Searches and seizures on public health grounds**

“46B.(1) Subject to subsection (2), if an authorised person has reasonable grounds for suspecting that:

(a) there may be on any premises a particular thing in respect of which this Act or the regulations have not been complied with; and

(b) it is necessary in the interests of public health to exercise powers under this section in order to avoid an imminent risk of death, serious illness or serious injury;

**SCHEDULE—continued**

the authorised person may, to the extent that it is reasonably necessary for the purpose of avoiding an imminent risk of death, serious illness or serious injury, enter the premises and do any of the following:

- (c) search the premises for the thing;
- (d) if the authorised person finds the thing on the premises—seize it.

“(2) An authorised person is not entitled to exercise any powers under subsection (1) in relation to premises if:

- (a) the occupier of the premises has required the authorised person to produce his or her identity card for inspection by the occupier; and
- (b) the authorised person fails to comply with the requirement.

**Searches and seizures related to offences**

“47.(1) Subject to subsections (2) and (3), if an authorised person has reasonable grounds for suspecting that there may be evidential material on any premises, the authorised person may:

- (a) enter the premises; and
- (b) exercise the powers set out in subsection (4) and subsection 48(1); and
- (c) if the authorised person finds the thing on the premises—seize it.

“(2) The authorised person must not enter the premises unless:

- (a) the occupier of the premises has consented to the entry; or
- (b) the entry is made under a warrant issued under section 50.

“(3) An authorised person is not entitled to exercise any powers under subsection (1) in relation to premises if:

- (a) the occupier of the premises has required the authorised person to produce his or her identity card for inspection by the occupier; and
- (b) the authorised person fails to comply with the requirement.

“(4) If:

- (a) in the course of searching, in accordance with a warrant, for a particular thing, an authorised person finds another thing that the authorised person believes on reasonable grounds to be evidential material; and
- (b) the authorised person believes, on reasonable grounds, that it is necessary to seize that other thing in order to prevent its concealment, loss or destruction, or its use in committing, continuing or repeating an offence against this Act;

the warrant is taken to authorise the authorised person to seize that other thing.”

**SCHEDULE—continued**

**42. Subsections 48(1) and (2):**

Omit the subsections, substitute:

“(1) The powers an authorised person may exercise under paragraphs 46(1)(b) and 47(1)(b) are as follows:

- (a) to search the premises and any thing on the premises;
- (b) to inspect, examine, take measurements of, or conduct tests (including by the taking of samples) concerning, any thing on the premises that relates to therapeutic goods;
- (c) to take photographs (including video recordings) or make sketches of the premises or any thing on the premises;
- (d) if the authorised person was only authorised to enter the premises because the occupier of the premises consented to the entry—to require the occupier to:
  - (i) answer any questions put by the authorised person; and
  - (ii) produce any book, record or document requested by the authorised person;
- (e) if the authorised person was authorised to enter the premises by a warrant under section 49 or 50—to require any person in or on the premises to:
  - (i) answer any questions put by the authorised person; and
  - (ii) produce any book, record or document requested by the authorised person;
- (f) to inspect any book, record or document on the premises;
- (g) to take extracts from or make copies of any such book, record or document;
- (h) to take onto the premises such equipment and materials as the authorised person requires for the purpose of exercising powers in relation to the premises.”.

**43. Subsection 48(3):**

Omit the penalty, substitute:

“Maximum penalty: 30 penalty units.”.

**44. After section 48:**

Insert:

**Details of warrant to be given to occupier etc.**

“48A.(1) If a warrant in relation to premises is being executed and the occupier of the premises or another person who apparently represents the occupier is present at the premises, the authorised person must make available to that person a copy of the warrant.

**SCHEDULE—continued**

“(2) The authorised person must identify himself or herself to that person.

“(3) The copy of the warrant referred to in subsection (1) need not include the signature of the magistrate who issued the warrant.

**Announcement before entry**

“48B.(1) An authorised person must, before entering the premises under a warrant:

- (a) announce that he or she is authorised to enter the premises; and
- (b) give any person at the premises an opportunity to allow entry to the premises.

“(2) An authorised person is not required to comply with subsection (1) if he or she believes on reasonable grounds that immediate entry to the premises is required to ensure:

- (a) the safety of a person; or
- (b) that the effective execution of the warrant is not frustrated.

**Use of electronic equipment at premises**

“48C.(1) The authorised person may operate electronic equipment at the premises to see whether evidential material is accessible by doing so if he or she believes on reasonable grounds that the operation of the equipment can be carried out without damage to the equipment.

“(2) If the authorised person, after operating the equipment, finds that evidential material is accessible by doing so, he or she may:

- (a) seize the equipment and any disk, tape or other associated device; or
- (b) if the material can, by using facilities at the premises, be put in documentary form—operate the facilities to put the material in that form and seize the documents so produced; or
- (c) if the material can be transferred to a disk, tape or other storage device that:

- (i) is brought to the premises; or

- (ii) is at the premises and the use of which for the purpose has been agreed to in writing by the occupier of the premises;

operate the equipment or other facilities to copy the material to the storage device and take the storage device from the premises.

“(3) An authorised person may seize equipment under paragraph (2)(a) only if:

- (a) it is not practicable to put the material in documentary form as mentioned in paragraph (2)(b) or to copy the material as mentioned in paragraph (2)(c); or

**SCHEDULE—continued**

(b) possession by the occupier of the equipment could constitute an offence.

“(4) If the authorised person believes on reasonable grounds that:

(a) evidential material may be accessible by operating electronic equipment at the premises; and

(b) expert assistance is required to operate the equipment; and

(c) if he or she does not take action under this subsection, the material may be destroyed, altered or otherwise interfered with;

he or she may do whatever is necessary to secure the equipment, whether by locking it up, placing a guard or otherwise.

“(5) The authorised person must give notice to the occupier of the premises of his or her intention to secure equipment and of the fact that the equipment may be secured for up to 24 hours.

“(6) The equipment may be secured:

(a) for a period not exceeding 24 hours; or

(b) until the equipment has been operated by the expert;

whichever happens first.

“(7) If the authorised person believes on reasonable grounds that the expert assistance will not be available within 24 hours, he or she may apply to the magistrate for an extension of that period.

“(8) The authorised person must give notice to the occupier of the premises of his or her intention to apply for an extension, and the occupier is entitled to be heard in relation to the application.

**Compensation for damage to electronic equipment**

“48D.(1) If:

(a) damage is caused to equipment as a result of it being operated as mentioned in section 48C; and

(b) the damage was caused as a result of:

(i) insufficient care being exercised in selecting the person who was to operate the equipment; or

(ii) insufficient care being exercised by the person operating the equipment;

compensation for the damage is payable to the owner of the equipment.

“(2) Compensation is payable out of money appropriated by the Parliament for the purpose.

**SCHEDULE—continued**

“(3) In determining the amount of compensation payable, regard is to be had to whether the occupier of the premises and his or her employees and agents, if they were available at the time, had provided any warning or guidance as to the operation of the equipment that was appropriate in the circumstances.

**Copies of seized things to be provided**

“48E.(1) Subject to subsection (2), if an authorised person seizes, under a warrant relating to premises:

- (a) a document, film, computer file or other thing that can be readily copied; or
- (b) a storage device the information in which can be readily copied; the authorised person must, if requested to do so by the occupier of the premises or another person who apparently represents the occupier and who is present when the warrant is executed, give a copy of the thing or the information to that person as soon as practicable after the seizure.

“(2) Subsection (1) does not apply if:

- (a) the thing that has been seized was seized under paragraph 48C(2)(b) or (c); or
- (b) possession by the occupier of the document, film, computer file, thing or information could constitute an offence.

**Occupier entitled to be present during search**

“48F.(1) If a warrant in relation to premises is being executed and the occupier of the premises or another person who apparently represents the occupier is present at the premises, the person is entitled to observe the search being conducted.

“(2) The right to observe the search being conducted ceases if the person impedes the search.

“(3) This section does not prevent 2 or more areas of the premises being searched at the same time.

**Receipts for things seized under warrant**

“48G.(1) If a thing is seized under this Part, the authorised person must provide a receipt for the thing.

“(2) If 2 or more things are seized or moved, they may be covered in the one receipt.

**Retention of seized things**

“48H.(1) Subject to any contrary order of a court, if an authorised person seizes a thing under this Part, an authorised person must return it if:

**SCHEDULE—continued**

- (a) the reason for its seizure no longer exists or it is decided that it is not to be used in evidence; or
- (b) the period of 90 days after its seizure ends;

whichever first occurs, unless the thing is forfeited or forfeitable to the Commonwealth.

“(2) At the end of the 90 days specified in subsection (1), an authorised person must take reasonable steps to return the thing to the person from whom it was seized, unless:

- (a) proceedings in respect of which the thing may afford evidence were instituted before the end of the 90 days and have not been completed (including an appeal to a court in relation to those proceedings); or
- (b) an authorised person may retain the thing because of an order under section 48J; or
- (c) an authorised person is otherwise authorised (by a law, or an order of a court, of the Commonwealth or of a State or Territory) to retain, destroy or dispose of the thing.

“(3) The thing may be returned under subsection (2) either unconditionally or on such terms and conditions as the Secretary sees fit.

**Magistrate may permit a thing to be retained**

“48J.(1) An authorised person may apply to a magistrate for an order that he or she may retain the thing for a further period if:

- (a) before the end of 90 days after the seizure; or
- (b) before the end of a period previously specified in an order of a magistrate under this section;

proceedings in respect of which the thing may afford evidence have not commenced.

“(2) If the magistrate is satisfied that it is necessary for an authorised person to continue to retain the thing:

- (a) for the purposes of an investigation as to whether an offence against this Act has been committed; or
- (b) to enable evidence of an offence against this Act to be secured for the purposes of a prosecution;

the magistrate may order that an authorised person may retain the thing for a period (not being a period exceeding 3 years) specified in the order.

“(3) Before making the application, the authorised person must:

- (a) take reasonable steps to discover who has an interest in the retention of the thing; and

**SCHEDULE—continued**

(b) if it is practicable to do so, notify each person whom the authorised person believes to have such an interest of the proposed application.”.

**45. Subsection 49(2):**

Omit the subsection, substitute:

“(2) Subject to subsection (3), the magistrate may issue the warrant if the magistrate is satisfied, by information on oath, that it is reasonably necessary that one or more authorised persons should have access to the premises for the purposes of finding out whether this Act or the regulations have been complied with.”.

**46. Paragraph 49(4)(a):**

Omit “an authorised person”, substitute “one or more authorised persons”.

**47. Subsection 50(2):**

Omit “a particular thing (in this section called the ‘**evidence**’) that may afford evidence of the commission of an offence against this Act”, substitute “evidential material”.

**48. Paragraph 50(4)(a):**

Omit the paragraph, substitute:

“(a) name one or more authorised persons; and”.

**49. Paragraph 50(4)(b):**

Omit “the authorised person”, substitute “the persons so named”.

**50. Subparagraph 50(4)(b)(ii):**

Omit “subsection 48(1)”, substitute “subsections 47(4) and 48(1)”.

**51. Subparagraph 50(4)(b)(iii):**

Omit “evidence”, substitute “evidential material”.

**52. Subparagraph 51(5)(a)(ii):**

Omit “the person”, substitute “the authorised person”.

**53. Paragraph 51(5)(b):**

Omit “the person”, substitute “the authorised person”.

**54. Subsection 51(6):**

Omit “The person”, substitute “The authorised person”.



**SCHEDULE—continued**

**55. After section 51A:**

Insert:

**Offences relating to warrants**

“51B.(1) A person must not make, in an application for a warrant, a statement that the person knows to be false or misleading in a material particular.

Maximum penalty: Imprisonment for 2 years.

“(2) A person must not:

- (a) state in a document that purports to be a form of warrant under section 51 the name of a magistrate unless that magistrate issued the warrant; or
- (b) state on a form of warrant under that section a matter that, to the person’s knowledge, departs in a material particular from the form authorised by the magistrate; or
- (c) purport to execute, or present to another person, a document that purports to be a form of warrant under that section that the first mentioned person knows:
  - (i) has not been approved by a magistrate under that section; or
  - (ii) to depart in a material particular from the terms authorised by a magistrate under that section; or
- (d) give to a magistrate a form of warrant under that section that is not the form of warrant that the person purported to execute.

Maximum penalty: Imprisonment for 2 years.”.

**56. Subsection 52(2):**

Omit the subsection.

**57. Subsection 52(3):**

Omit the penalty, substitute:

“Maximum penalty: 1 penalty unit.”.

**58. After section 52:**

Insert:

**“PART 6—MISCELLANEOUS”.**

**59. Subsections 54(1) and (2):**

Omit the subsections, substitute:

“(1) An offence against section 22A, 29A or 29B is an indictable offence.”.

**SCHEDULE—continued****60. Subsection 54(3):**

Omit “(other than an indictable offence)”.

**61. Subsection 54(6):**

Omit the subsection.

Note: The heading to section 54 is replaced by the heading “**Indictable offences and forfeiture**”.

**62. After section 54:**

Insert:

**Time for bringing prosecutions**

“54A. A prosecution for an offence against this Act may be commenced at any time within 3 years after the commission of the offence.”.

**63. Subsection 55(9):**

Omit the subsection.

**64. After section 56:**

Insert:

**Certificates to provide evidence of certain matters**

“56A.(1) The Secretary or a person authorised in writing by him or her to give certificates under this section may certify in writing that, at a specified time, or at all times during a specified period:

- (a) there was no exemption in effect under section 18 in relation to particular therapeutic goods; or
- (b) there was no approval or authority under section 19 granted to a particular person in relation to particular therapeutic goods; or
- (c) there was no approval under section 19A granted to a particular person in relation to particular therapeutic goods; or
- (d) particular therapeutic goods were or were not included in the Register as registered goods; or
- (e) particular therapeutic goods were or were not included in the Register as listed goods; or
- (f) particular therapeutic goods were included in the Register subject to conditions including those specified in the certificate; or
- (g) the registration or listing of the particular therapeutic goods had been cancelled; or

**SCHEDULE—continued**

- (h) there was no declaration under section 7 which applied to particular therapeutic goods; or
- (i) a person was or was not the holder of a licence in force under Part 4; or
- (j) the licence is subject to conditions including those specified in the certificate; or
- (k) there was no exemption in effect under subsection 34(1) that applied to particular therapeutic goods or a particular class of therapeutic goods; or
- (l) there was no exemption in effect under subsection 34(2) that applied to a particular person in relation to one or more of the following:
  - (i) the manufacture of particular therapeutic goods;
  - (ii) a particular step in the manufacture of particular therapeutic goods;
  - (iii) the manufacture of a particular class of therapeutic goods;
  - (iv) a particular step in the manufacture of a particular class of therapeutic goods.

“(2) A certificate under subsection (1) may relate to more than one of the matters referred to in paragraphs (1)(a) to (l).”

“(3) In proceedings for an offence against this Act, a certificate under subsection (1) is *prima facie* evidence of the matters specified in the certificate.

“(4) In proceedings for an offence against section 14, a certificate by the Secretary to the effect that:

- (a) the Secretary did not consent to the importation, supply or exportation that is the subject of the proceedings; or
- (b) the Secretary consented to that importation, supply or exportation subject to conditions specified in the certificate;

is *prima facie* evidence of the matters specified in the certificate.

“(5) In proceedings for an offence against this Act, a document purporting to be a certificate given under this section is, unless the contrary is proved, taken to be such a certificate and to have been duly given.”

**65. Subsection 57(1):**

Omit “subsections (2) and (6)”, substitute “subsections (2), (6) and (8)”.

**66. Paragraph 57(4)(b):**

Omit “authorised”, substitute “authorised”.

## SCHEDULE—continued

**67. After subsection 57(7):**

Insert:

“(8) The powers of the Secretary under section 19A may be delegated only to either or both of the following persons:

- (a) the National Manager of the Therapeutic Goods Administration;
- (b) the Director of the Drug Safety and Evaluation Branch of the Therapeutic Goods Administration.”.

**68. Subsection 60(1):**

Omit “In this section”, substitute “In this section and section 60A”.

**69. Subsection 60(3):**

Omit “The Minister”, substitute “Subject to paragraph 60A(2)(b), the Minister”.

**70. Subsection 60(4):**

After “on reconsideration” insert “, or (if applicable) notice that the matter has been remitted under paragraph 60A(2)(b),”.

**71. After section 60:**

Insert:

**New information on review—discretion to remit**

“60A.(1) This section applies only if the Secretary or an authorised delegate makes a decision under section 25 in relation to therapeutic goods.

“(2) If a person (*the appellant*) whose interests are affected by the decision requests the Minister to reconsider the decision, and lodges new information in support of that request, the Minister must either:

- (a) take that information into account when he or she reconsiders the decision; or
- (b) remit the matter to an authorised delegate for a fresh decision.

“(3) If the appellant applies to the Administrative Appeals Tribunal for review of the decision on reconsideration, and lodges new information in support of that application, the Tribunal may, if the Tribunal thinks fit, remit the matter to an authorised delegate for a fresh decision.

“(4) The Tribunal must not remit the matter under subsection (3) if all of the new information is information that the Minister took into account under paragraph (2)(a) in making the decision on reconsideration.

## SCHEDULE—continued

“(5) If:

- (a) the appellant lodges new information in support of an application to the Administrative Appeals Tribunal for review of the decision on reconsideration; and
  - (b) the Tribunal does not remit the matter under subsection (3);
- the Tribunal, in reviewing the decision on reconsideration:
- (c) may consider new information (if any) that the Minister took into account under paragraph (2)(a) in making the decision on reconsideration; and
  - (d) must not consider any other new information, except new information that indicates that the quality, safety or efficacy of the therapeutic goods is unacceptable.

“(6) If:

- (a) the Minister or the Tribunal remits the matter; and
  - (b) the appellant has paid, as a further evaluation fee, the evaluation fee that the appellant would have to pay under section 24 on making a new application for registration of the therapeutic goods;
- the authorised delegate must make a decision under section 25, taking into account the new information, as if a fresh application for registration had been made.

“(7) To remove any doubt, the authorised delegate’s fresh decision is to be treated, for the purposes of subsequent applications of section 60 and this section, as a decision under Part 3.

“(8) In this section:

**authorised delegate** means a delegate of the Secretary exercising a power to decide whether to register therapeutic goods.

**new information** means information that:

- (a) was in existence at the time the decision referred to in subsection (1) was made; and
- (b) was not made available to the Secretary or authorised delegate for the purpose of making the decision; and
- (c) is relevant to that decision;

and includes any opinions that are wholly or substantially based on such information (whether or not the opinions were formed before or after the decision was made).”.

**72. Paragraph 63(2)(j):**

Omit “\$1,000”, substitute “10 penalty units”.

**SCHEDULE—continued****73. Saving provision**

Regulations made for the purposes of paragraph 20(2)(d) of the *Therapeutic Goods Act 1989* that were in force immediately before the commencement of this item continue in force after that commencement as if they had been made for the purposes of paragraph 20(2)(a) of that Act as amended by this Act.





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