



# Health and Community Services Legislation Amendment Act (No. 2) 1993

No. 76 of 1993

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## An Act to amend legislation relating to health and community services, and for related purposes

[Assented to 25 November 1993]

The Parliament of Australia enacts:

### PART 1—PRELIMINARY

#### Short title

1. This Act may be cited as the *Health and Community Services  
5 Legislation Amendment Act (No. 2) 1993*.

#### Commencement

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

10 (2) Paragraph 29(h) and sections 30, 31 and 32 commence on a day to  
be fixed by Proclamation.

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(3) Paragraphs 29(i), 37(b) and 38(b), section 47 and paragraph 50(1)(d) commence on a day to be fixed by Proclamation.

(4) The day fixed for the purposes of subsection (3) must not be earlier than the day on which the Mutual Recognition Convention enters into force in relation to Australia.

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**PART 2—AMENDMENTS OF THE DISABILITY SERVICES ACT  
1986**

**Principal Act**

3. In this Part, “**Principal Act**” means the *Disability Services Act 1986*<sup>1</sup>.

**Information about Minister’s declaration may be made available to the public** 10

4. Section 14J of the Principal Act is amended by adding at the end the following subsection:

“(2) An action or proceeding, whether criminal or civil, does not lie against a person for publishing in good faith a copy of the information, or a fair extract from, or a fair abstract of, the information.”. 15

**Agreements may be entered into with transferees of land etc.**

5. Section 16 of the Principal Act is amended by inserting after subsection (1) the following subsection:

“(1A) Without limiting subsection (1), an agreement may contain terms and conditions providing for the other person to repay the whole, or part of, the grant that was made to the transferor in respect of the land, building or equipment.”. 20

**PART 3—AMENDMENTS OF THE HEALTH INSURANCE ACT  
1973**

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**Principal Act**

6. In this Part, “**Principal Act**” means the *Health Insurance Act 1973*<sup>2</sup>.

**Medicare benefits in relation to pathology services**

7. Section 16A of the Principal Act is amended:

(a) by omitting paragraph (2)(c) and substituting the following paragraphs: 30

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“(c) the proprietor of the laboratory was an approved pathology authority;

(ca) there was no other proprietor of the laboratory; and”;

(b) by omitting from subparagraph (2)(d)(i) and sub-subparagraph (2)(d)(ii)(B) “, or a proprietor,”;

(c) by omitting from paragraph (5AB)(c) and subparagraph (5AB)(d)(ii) “(or a proprietor)”;

(d) by omitting from paragraphs (5A)(a), (5A)(b), (8)(b) and (8)(c) “, or a proprietor,”.

10 **Request forms and confirmation forms**

**8.** Section 23DK of the Principal Act is amended:

(a) by inserting after subsection (1) the following subsection:

“(1A) Subsection (1) does not apply to the approved pathology practitioner in relation to a particular pathology service if:

15 (a) at the time the service was rendered, he or she was employed by an approved pathology authority; and

(b) he or she is no longer employed by the approved pathology authority; and

20 (c) before ceasing to be so employed, he or she notified the Managing Director of the Commission in writing of the place where the written request, or written confirmation of the request, relating to the service is stored and the approved pathology authority who is retaining it;

25 but the approved pathology authority shall retain the written request, or written confirmation of the request, until the end of the period referred to in subsection (1).”;

(b) by omitting from paragraph (2)(a) “subsection” and substituting “section”;

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

30 “(2A) Subsection (2) does not apply to the relevant pathologist in relation to a request if:

(a) at the time the request is made, he or she was employed by an approved pathology authority; and

35 (b) he or she is no longer employed by the approved pathology authority; and

(c) before ceasing to be so employed, he or she notified the Managing Director of the Commission in writing of the place where the written request, or written confirmation of the request, relating to the service is stored and the approved pathology authority who is retaining it;

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but the approved pathology authority shall retain the written request, or written confirmation of the request, until the end of the period referred to in subsection (2).”;

- (d) by inserting in subsection (3) “or an approved pathology authority” after “approved pathology practitioner” (wherever occurring); 5
- (e) by adding at the end of subsection (3) “or by the approved pathology authority under subsection (1A) or (2A)”.

**Restricted meaning of approved pathology authority**

9. Section 23DNAA of the Principal Act is amended by omitting paragraph (b) and substituting the following paragraphs: 10

“(b) an authority (a ‘**public authority**’) that is a corporation established by a law of the Commonwealth, of a State or of an internal Territory; or

(c) an undertaking that is partly owned or partly operated by a State, a Territory or a public authority.”. 15

**Determination of circumstances in which additional licensed collection centres may operate**

10. Section 23DNC of the Principal Act is amended by inserting after subsection (3) the following subsections:

“(3A) The Minister may review a determination made under subsection (1), but the review may only take place after: 20

(a) if the determination has never been reviewed under this subsection—the end of the 12 month period starting on the day on which the determination was made; or

(b) otherwise—the end of the 12 month period starting on the day on which the decision was made on the last review of the determination. 25

“(3B) If after reviewing a determination under subsection (3A) the Minister is satisfied, having regard to the principles determined under subsection (5), that, because of special circumstances, the determination should continue in force, the Minister must inform the approved pathology authority in writing that he or she is so satisfied. 30

“(3C) If after reviewing a determination under subsection (3A) the Minister is satisfied, having regard to the principles determined under subsection (5), that special circumstances no longer exist, he or she must cancel the determination and inform the approved pathology authority in writing of the cancellation.”. 35

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**Partial refund of licence fee on cancellation of certain licences**

**11.** Section 23DNI of the Principal Act is amended by omitting from subsection (3) all words from and including:

$$\frac{\text{“365 – Licence days”}}{365} \times \text{Fee”}$$

5 to and including “remained in force” and substituting the following:

$$\text{“ Fee } \times \frac{\text{Expected licence days – Actual licence days}}{\text{Expected licence days}}$$

where:

‘Actual licence days’ means the number of days for which the licence remained in force; and

10 ‘Expected licence days’ means the number of days for which the licence was granted.”.

**Review of decisions**

**12.** Section 23DO of the Principal Act is amended:

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

15 “(2DA) An approved pathology authority aggrieved by a decision of the Minister to cancel a determination under subsection 23DNC(3C) may, not later than 28 days after being informed of the decision of the Minister, apply to the Minister for a reconsideration of the decision by the Minister.

20 “(2DB) On receiving an application under subsection (2DA), the Minister must reconsider his or her decision and may:

(a) affirm the decision; or

(b) revoke the decision and substitute a decision under subsection 23DNC(3B).”;

25 (b) by inserting in subsection (3) “(2DB),” after “(2D),”;

(c) by inserting in paragraph (5)(c) “(2DB),” after “(2D),”.

**Offences in relation to request forms and confirmation forms**

**13.** Section 23DP of the Principal Act is amended:

30 (a) by omitting from subsection (1) “\$1,000” and substituting “10 penalty units”;

(b) by inserting after subsection (1) the following subsection:

35 “(1A) An approved pathology authority who, without reasonable excuse, contravenes subsection 23DK(1A), (2A) or (3) is guilty of an offence punishable, upon conviction, by a fine not exceeding 10 penalty units.”;

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- (c) by omitting from subsection (2) and from the penalty at the foot of subsection (3) “\$1,000” and substituting “10 penalty units”.

**PART 4—AMENDMENTS OF THE HEARING SERVICES ACT  
1991**

**Principal Act**

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14. In this Part, “**Principal Act**” means the *Hearing Services Act 1991*<sup>3</sup>.

**Eligible persons**

15. Section 5 of the Principal Act is amended:

- (a) by omitting paragraph (1)(a) and substituting the following paragraphs:

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“(a) a person who holds a card issued by the Commonwealth and known as a Pensioner Health Benefits Card, a Health Benefits Card, a Service Pensioner Benefits Card, a Dependant Treatment Entitlement Card or a Personal Treatment Entitlement Card; or

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(ab) a person who, for purposes connected with obtaining treatment for an injury, disease or condition that involves hearing loss, holds a card issued by the Commonwealth and known as a Specific Treatment Entitlement Card; or”;

- (b) by inserting in paragraph (1)(b) “or (ab)” after “paragraph (a)”.

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**Person not to use protected names or protected symbols**

16. Section 66 of the Principal Act is amended:

- (a) by omitting from paragraph (1)(f) “the” (wherever occurring) and substituting “a”;

- (b) by omitting from subsections (3) and (4) “the” (first occurring) and substituting “a particular”;

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- (c) by omitting from subsection (5) the definition of “protected symbol” and substituting the following definition:

“ ‘**protected symbol**’ means:

(a) the official symbol of the National Acoustics Laboratories, the design of which is set out in Schedule 1; or

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(b) the official symbol of Australian Hearing Services, the design of which is set out in Schedule 2;”;

- (d) by omitting from the definition of “protection time” in subsection (5) “the” (first occurring) and substituting “a”;

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- (e) by omitting paragraph (a) of the definition of “protection time” in subsection (5) and substituting the following paragraph:

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“(a) in the case of the official symbol of Australian Hearing Services—the commencement of Part 4 of the *Health and Community Services Amendment Act (No. 2) 1993*; or”.

**Addition of Schedule**

5       **17.** The Principal Act is amended by adding at the end the following Schedule:

**“SCHEDULE 2**

Section 66

**“OFFICIAL SYMBOL OF AUSTRALIAN HEARING SERVICES**



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10       **PART 5—AMENDMENTS OF THE NATIONAL HEALTH ACT  
1953**

**Principal Act**

**18.** In this Part, “**Principal Act**” means the *National Health Act 1953*<sup>4</sup>.

**Benefit payable for up to 2 days prior to admission**

15       **19.** Section 46AB of the Principal Act is repealed and inserted immediately after section 46A.

**Approved pharmacists**

**20.(1)** Section 90 of the Principal Act is amended by inserting after subsection (5) the following subsections:

“**(5A)** A pharmacist who:

- 20       (a) before 18 December 1990, was granted an approval to supply pharmaceutical benefits at or from particular premises; and  
      (b) supplied pharmaceutical benefits on or before 18 December 1990 from other premises without the Secretary having granted approval under subsection (3) in respect of those other premises;

25       is to be taken to have been granted in respect of those other premises, or whichever of those premises was the premises from which the pharmacist last supplied pharmaceutical benefits before 18 December 1990, an approval under subsection (3).

30       “**(5B)** The reference in paragraph (5A)(b) to supplying pharmaceutical benefits includes a reference to supplying drugs and medicinal preparations for which payment was made as if they were pharmaceutical benefits.

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“(5C) Subsection (5A) does not apply if:

- (a) the approval referred to in paragraph (5A)(a) was not in force immediately before the commencement of section 20 of the *Health and Community Services Legislation Amendment Bill (No. 2) 1993*; or
- (b) the pharmacist is not permitted, under the law of the State or Territory in which the premises referred to in paragraph (5A)(b) are situated, to carry on business at those premises.”.

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(2) If:

- (a) before the commencement of this section, a pharmacist (including a person to whom subsection 90(6) of the Principal Act applies) received from the Commonwealth a payment purportedly made under this Part in respect of the supply of pharmaceutical benefits from particular premises; and
- (b) at the time of the supply, the pharmacist was not approved under section 90 of the Principal Act in respect of those premises; and
- (c) had subsections 90(5A) and 98(4A) of the Principal Act as amended by this Act been in force at the time the payment was made, the payment would have been a payment under this Part;

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any right of the Commonwealth to recover the payment is, by force of this subsection, extinguished.

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**Cancellation by Secretary of approval of pharmacists etc.**

21. Section 98 of the Principal Act is amended by inserting after subsection (4) the following subsection:

“(4A) If a pharmacist:

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- (a) before 18 December 1990, was granted an approval to supply pharmaceutical benefits at or from particular premises; and
- (b) because of the operation of subsection 90(5A), is taken to have been granted such an approval in respect of other premises;

the Secretary is taken, immediately after the commencement of section 20 of the *Health and Community Services Legislation Amendment Act (No. 2) 1993*, to have cancelled the approval in respect of the premises referred to in paragraph (a).”.

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**PART 6—AMENDMENTS OF THE NATIONAL HEALTH AND  
MEDICAL RESEARCH COUNCIL ACT 1992**

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**Principal Act**

22. In this Part, “Principal Act” means the *National Health and Medical Research Council Act 1992*<sup>5</sup>.





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- (d) by omitting from paragraph (a) of the definition of “manufacturing premises” in subsection (1) “is” and substituting “are”;
- (e) by omitting from paragraph (d) of the definition of “therapeutic goods” in subsection (1) “used or labelled” (wherever occurring) and substituting “used, advertised, or presented for supply”; 5
- (f) by omitting from subsection (1) the definition of “authorised person” and substituting the following definition:  
“**‘authorised person’** means:  
(a) in relation to any provision of this Act, a person authorised by the Secretary to exercise powers under that provision; or 10  
(b) in relation to a provision of Part 6, a member of the Australian Federal Police;”;
- (g) by inserting in subsection (1) the following definition:  
“**‘gazetted kits group’** means a group of kits identified in an order in force under subsection 16(3A);” 15
- (h) by inserting in subsection (1) the following definitions:  
“**‘corresponding State law’** means a State law declared by the regulations to correspond to this Act or the regulations, including such a law as amended from time to time;  
**‘State law’** means a law of a State, of the Australian Capital Territory 20  
or of the Northern Territory;”;
- (i) by inserting in subsection (1) the following definition:  
“**‘Mutual Recognition Convention’** means the Convention for the Mutual Recognition of Inspections in respect of the Manufacture of Pharmaceutical Products done at Geneva on 8 October 1970;” 25
- (j) by inserting “, other than members of the Australian Federal Police,” in subsection (3) after “persons” (first occurring).

30. Section 4 of the Principal Act is repealed and the following section is substituted:

**Object of Act** 30

“4.(1) The object of this Act is to promote the development of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods used in Australia or exported from Australia, whether the goods are produced in Australia or elsewhere.

“(2) The provisions made by this Act are intended, as far as the Constitution permits, to impose those controls forming part of the national system that are appropriate to be imposed by legislation of the Commonwealth. 35

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“(3) It is the intention of the Parliament that the other controls forming part of the national system be imposed by the laws of the States, of the Australian Capital Territory and of the Northern Territory.

5 “(4) This Act is therefore not intended to apply to the exclusion of a law of a State, of the Australian Capital Territory or of the Northern Territory to the extent that the law is capable of operating concurrently with this Act.”.

**Operation of Act**

31. Section 6 of the Principal Act is amended by omitting subsection (3).

10 32. After section 6 of the Principal Act the following sections are inserted:

**State and Territory functions and powers of Secretary**

“6A.(1) If a corresponding State law confers a function or power on the Secretary, the Secretary may, with the written approval of the Minister, perform the function or exercise the power, as the case may be.

15 “(2) While an approval is in force for the purpose of subsection (1):

(a) subsection 39(6) of the *Public Service Act 1922* has effect as if a function or power to which the approval relates were a function or power of the Secretary under this Act; and

20 (b) section 57 of this Act has effect as if such a function or power were a function or power under this Act.

“(3) If:

(a) a corresponding State law is expressed to confer on the Secretary:

(i) the function of including goods in the Register; or

(ii) the power to include goods in the Register; and

25 (b) an approval under subsection (1) is in force in relation to the function or power;

the Secretary may include the goods in the Register in accordance with the State law.

30 “(4) If a corresponding State law is expressed to authorise or require the Secretary to cancel the inclusion of goods in the Register, the Secretary may cancel the inclusion of the goods in the Register in accordance with the State law.

35 “(5) The inclusion of goods in the Register under subsection (3) does not subject any person to any liability whatever under this Act, except a liability under Part 5.

“(6) The Secretary may make any notations in the Register that he or she thinks necessary to identify entries that relate to goods included in the Register under subsection (3).

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“(7) Goods may be included in the Register under subsection (3) even though the same goods have already been included in the Register under another provision of this Act.

“(8) A reference in this section to the inclusion of goods in the Register is a reference to the inclusion of the goods: 5

- (a) in the part of the Register for goods known as registered goods; or
- (b) in the part of the Register for goods known as listed goods.

**Review of certain decisions under State laws**

“6B.(1) Application may be made to the Administrative Appeals Tribunal for review of a reviewable State decision. 10

“(2) A decision made by the Secretary in the performance of a function, or the exercise of a power, conferred by a corresponding State law is a reviewable State decision for the purposes of this section if:

- (a) the law under which the decision was made provides for review by the Administrative Appeals Tribunal; and 15
- (b) the decision is declared by the regulations to be a reviewable decision for the purposes of this section.

“(3) For the purposes of subsection (1), the *Administrative Appeals Tribunal Act 1975* has effect as if a corresponding State law were an enactment. 20

**Fees payable to Commonwealth under State laws**

“6C.(1) This section applies to fees payable to the Commonwealth under a State law in respect of the performance or exercise of functions or powers conferred by that law on the Secretary.

“(2) The Secretary may make arrangements with the appropriate authority of a State, of the Australian Capital Territory or of the Northern Territory in relation to the payment to the Commonwealth of fees to which this section applies.”. 25

**Declaration that goods are/are not therapeutic goods**

33.(1) Section 7 of the Principal Act is amended: 30

- (a) by omitting from subsection (1) “used or labelled” (wherever occurring) and substituting “used, advertised, or presented for supply”;
- (b) by omitting from subsection (3) “notice” and substituting “order”.

(2) A declaration in force under section 7 of the Principal Act immediately before the commencement of this Act has effect after that commencement as if: 35

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- (a) the declaration had been made under section 7 of the Principal Act as amended by this Act; and
- (b) any reference in the declaration to goods being labelled in a particular way were a reference to the goods being advertised or presented for supply when labelled in that way.

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34. After section 7 of the Principal Act the following sections are inserted:

**Authorised persons**

10 “7A. The Secretary may, in writing, authorise any of the following persons to exercise powers under a specified provision of this Act:

- (a) an officer of the Department, of another Department or of an authority of the Commonwealth;
- (b) an officer of:
  - (i) a Department of State of a State; or
  - 15 (ii) a Department or administrative unit of the Public Service of a Territory; or
  - (iii) an authority of a State or of a Territory;being a Department, unit or authority that has functions relating to health matters or law enforcement matters.

20 **Kits**

“7B.(1) A package and therapeutic goods in the package together constitute a kit for the purposes of this Act if:

- (a) the package and the therapeutic goods are for use as a unit; and
- 25 (b) each item of the therapeutic goods consists of goods that are registered or listed or are exempt goods in relation to Part 3; and
- (c) the package and therapeutic goods do not constitute a composite pack.

“(2) A package and therapeutic goods in the package together constitute a composite pack if:

- 30 (a) the therapeutic goods are of 2 or more kinds; and
- (b) the package does not contain any therapeutic devices; and
- (c) the therapeutic goods are for administration as a single treatment or as a single course of treatment; and
- (d) it is necessary that the therapeutic goods be combined before
- 35 administration or that they be administered in a particular sequence.

“(3) To avoid doubt, it is declared that a kit constitutes therapeutic goods.”.

**Therapeutic goods and gazetted groups**

35. Section 16 of the Principal Act is amended:

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(a) by inserting after subsection (3) the following subsection:

“(3A) The Secretary may, by order published in the *Gazette*, determine that a group of kits identified in the order is a gazetted kits group.”;

(b) by omitting from subsection (4) “subsection (2) or (3)” and substituting “subsection (2), (3) or (3A)”. 5

**Applications generally**

**36.(1)** Section 23 of the Principal Act is amended by omitting paragraph (2)(a) and substituting the following paragraph:

“(a) the prescribed application fee has been paid; and” 10

(2) The amendment made by subsection (1) does not apply to an application delivered to an office of the Department in accordance with subsection 23(1) of the Principal Act before the commencement of this section.

**Evaluation of therapeutic goods** 15

**37.** Section 25 of the Principal Act is amended:

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

“(2B) 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 (1) has effect, in relation to the goods, as if paragraph (h) were omitted. 20

“(2C) If a person is exempt from the operation of Part 4 in relation to a step in the manufacture of therapeutic goods, subsection (1) has effect, in relation to the goods, as if the reference in paragraph (h) to Part 4 were a reference to that Part to the extent that it applies to that person in relation to the manufacture of the goods. 25

“(2D) 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; 30

subsection (1) has effect, in relation to the goods, as if paragraph (g) were omitted.”;

(b) by inserting after subsection (2D) the following subsections:

“(2E) A decision for the purposes of paragraph (1)(g) may also take into account any information provided to the Secretary by a health authority of a Convention country and relating to: 35

(a) the general standards of manufacturing practice of a particular manufacturer; or

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(b) the specific standards of manufacture or control adopted by a particular manufacturer in relation to particular goods.

“(2F) For the purposes of subsection (2E), a Convention country is a country that is a party to the Mutual Recognition Convention.

5       “(2G) Information referred to in subsection (2E) and provided in accordance with the Mutual Recognition Convention is to be treated as equivalent to information obtained as a result of an inspection under Part 4 of this Act.”;

10       (c) by omitting paragraph (3)(b) and substituting the following paragraph:

      “(b) if the decision is to register the goods—include the goods in the Register and give the applicant a certificate of registration.”;

(d) by omitting subsection (4).

15   **Listing of therapeutic goods**

**38.** Section 26 of the Principal Act is amended:

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

20       “(2A) 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 (1) has effect, in relation to the goods, as if paragraph (h) were omitted.

25       “(2B) If a person is exempt from the operation of Part 4 in relation to a step in the manufacture of therapeutic goods, subsection (1) has effect, in relation to the goods, as if the reference in paragraph (h) to Part 4 were a reference to that Part to the extent that it applies to that person in relation to the manufacture of the goods.

      “(2C) If:

      (a) therapeutic goods were made outside Australia; and

30       (b) had the goods been made in Australia, they would have been exempt from the operation of Part 4;

      subsection (1) has effect, in relation to the goods, as if paragraph (g) were omitted.”;

(b) by inserting after subsection (2C) the following subsections:

35       “(2D) A decision for the purposes of paragraph (1)(g) may also take into account any information provided to the Secretary by a health authority of a Convention country and relating to:

      (a) the general standards of manufacturing practice of a particular manufacturer; or

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(b) the specific standards of manufacture or control adopted by a particular manufacturer in relation to particular goods.

“(2E) For the purposes of subsection (2D), a Convention country is a country that is a party to the Mutual Recognition Convention.

“(2F) Information referred to in subsection (2D) and provided in accordance with the Mutual Recognition Convention is to be treated as equivalent to information obtained as a result of an inspection under Part 4 of this Act.”; 5

(c) by omitting from subsection (3) “include the goods in the list” and substituting “list the goods”; 10

(d) by omitting from subsection (4) “the therapeutic goods in respect of which the application” and substituting “therapeutic goods in respect of which an application”.

**Conditions of registration or listing**

39. Section 28 of the Principal Act is amended by omitting subsection (6). 15

**Secretary may require information**

40. Section 31 of the Principal Act is amended by adding at the end the following subsections:

“(4) A person in relation to whom therapeutic goods are registered or listed must not, without reasonable excuse, fail to comply with a notice given to the person under this section. 20

Penalty: 60 penalty units.

“(5) A person in relation to whom therapeutic goods are registered or listed must not, in purported compliance with a notice under this section, knowingly or recklessly provide information that is false or misleading in a material particular. 25

Penalty: 60 penalty units.”.

**Inspection and variation of entries in Register**

41.(1) Section 32 of the Principal Act is amended: 30

(a) by omitting subsection (2);

(b) by omitting subsection (5) and substituting the following subsection:

“(5) Where:

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

(b) subsection (4) does not apply to the request; and



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(c) 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;

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

5       (2) Regulations in force for the purposes of subsection 32(2) of the Principal Act immediately before the commencement of this section have effect, after that commencement, as if they had been made under section 63 of the Principal Act as amended by this Act.

**Application for licence**

10       42. Section 37 of the Principal Act is amended by omitting from paragraph (1)(c) “premises” and substituting “manufacturing premises”.

**Grant of licence**

43. Section 38 of the Principal Act is amended by omitting from paragraph (1)(a) “premises” and substituting “manufacturing premises”.

15       **Conditions of licences**

44. Section 40 of the Principal Act is amended by omitting from subparagraph (4)(b)(i) “premises” and substituting “manufacturing premises”.

**Publication of list of manufacturers etc.**

20       45. Section 42 of the Principal Act is amended by omitting “premises” and substituting “manufacturing premises”.

**Entry and search of premises—evidence of offences**

46. Section 47 of the Principal Act is amended by adding at the end the following subsections:

25       “(5) An authorised person may, before the end of the period mentioned in paragraph (2)(b), apply to a magistrate for an extension of that period.

“(6) A person who would be entitled to possession of the evidence if it had not been seized is entitled to make representations to the magistrate about the application.

30       “(7) The magistrate may extend the period if satisfied that it is necessary to do so in order that an authorised person may have a reasonable opportunity of completing the investigation of an offence against this Act.

“(8) The period may not be extended:

(a) after it has ended; or

35       (b) so that it exceeds 2 years.

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“(9) Where the period referred to in paragraph (2)(b) has been extended, a reference in subsection (5), (7) or (8) to that period is a reference to that period as extended.”.

47. After section 51 of the Principal Act the following section is inserted:

**Searches at request of manufacturer** 5

“51A.(1) A person may request the Secretary to arrange for an authorised person to inspect premises, and specified processes being carried out on those premises, for the purposes of paragraph 2 of Article 3 of the Mutual Recognition Convention.

“(2) An authorised person may make an inspection in accordance with arrangements under subsection (1).” 10

**Offences**

48. Section 54 of the Principal Act is amended by adding at the end the following subsection:

“(6) A prosecution in respect of an indictable offence against this Act may be commenced at any time within 2 years after the commission of the offence.” 15

**Export certifications**

49.(1) Section 58 of the Principal Act is amended by omitting paragraph (3)(a) and substituting the following paragraph: 20

“(a) an application for a certification under this section; and”.

(2) The amendment made by subsection (1) does not apply in relation to an application pending under section 58 of the Principal Act at the commencement of this Act.

**Release of information** 25

50.(1) Section 61 of the Principal Act is amended:

(a) by omitting from subsection (6) all words after “regulations” and substituting:

“relating to:

(a) therapeutic goods included in the Register; or 30

(b) therapeutic goods in relation to which an application for registration or listing has been made.”;

(b) by omitting subsections (8A) and (8B) and substituting the following subsection:

“(8A) Regulations prescribing fees in respect of applications for information under the regulations: 35

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- (a) may include provision for the payment of deposits on account of such fees; and
- (b) may provide for fees that take into account the time spent by officers of the Department in:

- (i) searching for or retrieving information; or
- (ii) making, or doing anything related to the making of, a decision on an application; and

- (c) may provide for fees that take into account the direct costs incurred by the Commonwealth in making available an officer to supervise the inspection by an applicant of any document containing information to which an application relates.”;

- (c) by omitting from subsection (8C) “in accordance with regulations made for the purposes of subsection (8A),” and substituting “under the regulations,”;

- (d) by omitting subsection (10) and substituting the following subsections:

“(10) Nothing in this or any other Act requires the Secretary to disclose to any person, court or tribunal information referred to in subsection 25(2E) or 26(2D) if the disclosure would constitute a breach of the Mutual Recognition Convention.

“(11) This section (except subsection (10)) has effect subject to the *Freedom of Information Act 1982*.”.

(2) Regulations in force for the purposes of subsection 61(8A) of the Principal Act immediately before the commencement of this section have effect after that commencement as if they had been made for the purposes of paragraph 63(2)(h) of the Principal Act as amended by this Act.

**Regulations**

**51.(1)** Section 63 of the Principal Act is amended:

- (a) by omitting from paragraph (2)(g) “, and prescribe fees for those services”;

- (b) by omitting paragraph (2)(h) and substituting the following paragraph:

“(h) prescribe fees in respect of matters under this Act or the regulations; and”.

(2) Regulations in force for the purposes of paragraph 63(2)(h) of the Principal Act immediately before the commencement of this section continue in force as if they had been made for the purposes of paragraph 63(2)(h) of the Principal Act as amended by this Act.

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**Transitional arrangements for goods required to be registered or listed**

**52.** Section 66 of the Principal Act is amended:

(a) by inserting after subsection (3) the following subsection:

“(3A) If, on an application under subsection (3), goods have been registered without having been evaluated, the Secretary may, if he or she thinks it appropriate, give the person in relation to whom the goods are registered written notice that the goods are to be evaluated to determine whether they should continue to be registered.”;

(b) by inserting after subsection (4) the following subsections: 10

“(4A) In relation to an evaluation conducted for the purposes of this section:

(a) section 25 has effect as if:

(i) the person in respect of whom the goods are registered were an applicant for the registration of the goods; and 15

(ii) the reference in paragraph (1)(b) to an evaluation fee under section 24 were a reference to a fee payable under subsection (4) of this section; and

(b) sections 24A, 24B and 24C have effect as if any reference in those sections to section 24 were a reference to subsection (4) of this section; and 20

(c) sections 24D and 24E do not apply.

“(4B) If, on an application under subsection (3), goods have been listed without consideration of the matters mentioned in paragraphs 26(1)(c) to (m), the Secretary may, if he or she thinks it appropriate, give the person in relation to whom the goods are listed written notice that the Secretary intends to determine whether the goods should continue to be listed. 25

“(4C) If notice is given under subsection (4B), section 26 applies as if the person in relation to whom the goods are listed were an applicant for the listing of the goods.”; 30

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

“(6) Where a person suffers any kind of loss, damage or injury caused by, or arising out of, the use by the person of therapeutic goods to which this section applies, no liability in respect of that loss, damage or injury attaches to the Commonwealth, the Secretary or any delegate of the Secretary.”. 35

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**NOTES**

1. No. 129, 1986, as amended. For previous amendments, see Nos. 80 and 99, 1988; No. 141, 1990; Nos. 70 and 73, 1991; and No. 88, 1992.
2. No. 42, 1974, as amended. For previous amendments, see No. 58, 1975; Nos. 59, 91, 101, 109 and 157, 1976; No. 75, 1977; Nos. 36, 89 and 133, 1978; Nos. 53 and 123, 1979; No. 132, 1980; Nos. 118 and 176, 1981; Nos. 49, 80 and 112, 1982; Nos. 54 and 139, 1983; Nos. 15, 46, 63, 120, 135 and 165, 1984; Nos. 24, 65, 70, 95 and 167, 1985; Nos. 28, 75 and 94, 1986; Nos. 44, 131, 132 and 141, 1987; Nos. 85, 87, 99 and 155, 1988; Nos. 59, 84, 95 and 164, 1989; Nos. 3, 106 and 141, 1990; Nos. 6, 57, 68, 70, 73, 84, 116, 141, 171, 172, 175, 190, 193 and 211, 1991; Nos. 88, 136, 192, 204, 226, 229 and 230, 1992.
3. No. 169, 1991, as amended. For previous amendments, see Nos. 88, 118 and 136, 1992.
4. No. 95, 1953, as amended. For previous amendments, see No. 68, 1955; Nos. 55 and 95, 1956; No. 92, 1957; No. 68, 1958; No. 72, 1959; No. 16, 1961; No. 82, 1962; No. 77, 1963; No. 37, 1964; Nos. 100 and 146, 1965; No. 44, 1966; Nos. 14 and 100, 1967; No. 100, 1968; No. 102, 1969; No. 41, 1970; No. 85, 1971; No. 114, 1972, Nos. 49 and 202, 1973; No. 37, 1974; Nos. 1, 13 and 93, 1975; Nos. 1, 60, 91, 99, 108, 157 and 177, 1976; Nos. 98 and 100, 1977; Nos. 36, 88, 132 and 189, 1978; Nos. 54, 91 and 122, 1979; Nos. 117 and 131, 1980; Nos. 40, 74, 92, 118, 163 and 176, 1981; Nos. 49, 80 and 112, 1982; Nos. 35, 54 and 139, 1983; Nos. 46, 63, 72, 120, 135 and 165, 1984; Nos. 24, 53, 65, 70, 95, 127 and 167, 1985; Nos. 28, 75, 94 and 115, 1986; Nos. 22, 44, 72, 118, 131 and 132, 1987; Nos. 79, 87, 99 and 155, 1988; No. 95, 1989; Nos. 3, 84, 106 and 141, 1990; Nos. 6, 68, 70, 73, 83, 84, 115, 116, 119, 122, 141, 169, 175, 208 and 211, 1991; Nos. 70, 81, 88, 136, 192, 200, 204 and 230, 1992; and No. 28, 1993.
5. No. 225, 1992.
6. No. 115, 1986.
7. No. 21, 1990, as amended. For previous amendments, see No. 141, 1990; Nos. 84 and 204, 1991; and No. 88, 1992.

*[Minister's second reading speech made in—  
House of Representatives on 7 September 1993  
Senate on 30 September 1993]*