Therapeutic Goods Legislation Amendment Act 1999

No. 3, 1999

An Act to amend the law relating to therapeutic goods, and for related purposes

Contents

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[*Assented to 29 March 1999*]

The Parliament of Australia enacts:

1 Short title

This Act may be cited as the *Therapeutic Goods Legislation Amendment Act 1999*.

2 Commencement

(1) Subject to this section, this Act commences on a day to be fixed by Proclamation.

(2) If this Act (other than Schedule 2) does not commence under subsection (1) within the period of 6 months beginning on the day on which this Act receives the Royal Assent, it commences on the first day after the end of that period.

(3) Schedule 2 is taken to have commenced immediately after the commencement of Part 2 of Schedule 1 to the *Therapeutic Goods Amendment Act 1997*.

3 Schedule(s)

Subject to section 2, each Act that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.

Schedule 1—Amendment of the Therapeutic Goods Act 1989

1 Subsection 3(1)

Insert:

current Poisons Standard has the meaning given by section 52A.

2 Subsection 3(1)

Insert:

first Poisons Standard has the meaning given by section 52A.

3 Subsection 3(1) (definition of *foods*)

Repeal the definition.

4 Subsection 3(1)

Insert:

medicine means:

(a) therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human or animal; and

(b) any other therapeutic goods declared by the Secretary, for the purpose of the definition of ***therapeutic device***, not to be therapeutic devices.

5 Subsection 3(1)

Insert:

poison means an ingredient, compound, material or preparation which, or the use of which, may cause death, illness or injury and includes any ingredient, compound, material or preparation referred to in a schedule to the current Poisons Standard.

6 Subsection 3(1) (definition of *restricted goods*)

Omit "drugs within regulation 2 of the Therapeutic Goods Regulations", substitute "medicines".

7 Subsection 3(1)

Insert:

scheduling has the meaning given by section 52A.

8 Subsection 3(1) (paragraph (e) of the definition of *therapeutic goods*)

Repeal the paragraph, substitute:

(e) goods for which there is a prescribed standard in the Australia New Zealand Food Standards Code as defined in subsection 3(1) of the *Australia New Zealand Food Authority Act 1991*; or

(f) goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

9 Section 4

Repeal the section, substitute:

4 Objects of Act

(1) The objects of this Act are to do the following, so far as the Constitution permits:

(a) provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are:

(i) used in Australia, whether produced in Australia or elsewhere; or

(ii) exported from Australia;

(b) to provide a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and ensure the safe handling, of poisons in Australia.

(2) 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.

10 At the end of section 17

Add:

(5) The Minister may by notice published in the *Gazette* require that specified therapeutic goods be included in the part of the Register for listed goods.

(6) If the regulations are amended to require any of those goods to be included in the part of the Register for listed or registered goods, then the *Gazette* notice ceases to have effect in respect of the goods included in the regulations.

11 At the end of section 28

Add:

(6) If:

(a) in, or in connection with, an application for the listing of therapeutic goods, a claim is made by the applicant in relation to the goods; and

(b) the claim is included in the Register in respect of the goods;

the listing of the goods is subject to the following conditions:

(c) a condition that the sponsor of the goods had, at the time when the claim was made, information or evidence that supported the claim and complied with the requirements (if any) of the regulations;

(d) a condition that the sponsor retains the information or evidence at all times while the goods remain listed;

(e) a condition that, at any time while the goods remain listed, the sponsor will, if asked to do so by the Secretary, give the information or evidence to the Secretary.

(7) The regulations may prescribe the amount, standard or type of information or evidence required for the purposes of paragraph (6)(c).

12 After Part 4

Insert:

Part 4A—Advertising

42A Application

This Part applies only to advertisements to which Division 2 of Part 2 of the Therapeutic Goods Regulations applies.

42B Definitions

In this Part, unless the contrary intention appears:

approval number means the distinguishing number allocated to an approved advertisement by the Secretary under regulation 5J of the Therapeutic Goods Regulations.

approved advertisement means an advertisement:

(a) approved under regulation 5G, or taken to be approved by the Secretary under subregulation 5H(2), or approved by the Minister on review under regulation 5M, of the Therapeutic Goods Regulations; and

(b) the approval of which has not been withdrawn.

mainstream media means any magazine or newspaper for consumers containing a range of news, public interest items, advertorials, advertisements or competitions.

publisher means a person whose business it is to publish or insert, or to arrange for the publication or insertion of, advertisements in any publication.

42C Offences relating to publication of advertisements

(1) This section does not apply to a publisher in respect of an advertisement received by the publisher for publication or insertion in the ordinary course of business.

(2) A person must not publish or insert in mainstream media an advertisement that is not an approved advertisement.

Penalty: 100 penalty units.

(3) Subject to subsection (4), a person must not publish or insert in mainstream media an approved advertisement that differs from the advertisement that was approved.

Penalty: 100 penalty units.

(4) Subsection (3) does not apply if the advertisement differs only in respect of a matter mentioned in paragraph 5C(2)(b), (d), (e) or (f) of the Therapeutic Goods Regulations.

(5) A person must not publish or insert in mainstream media an approved advertisement:

(a) without its approval number; or

(b) with a number purporting to be its approval number but which is not its approval number; or

(c) with an approval number that has expired.

Penalty: 50 penalty units.

(6) A person must not publish or insert in mainstream media an approved advertisement in contravention of a condition of its approval.

Penalty: 100 penalty units.

(7) An offence against this section is an offence of strict liability.

42D Offences relating to publishers

A publisher must not, knowingly or recklessly, publish or insert in mainstream media an advertisement that is not an approved advertisement.

Penalty: 100 penalty units.

13 After Part 5A

Insert:

Part 5B—National Drugs and Poisons Schedule Committee

52A Definitions

In this Part, unless the contrary intention appears:

Committee means the National Drugs and Poisons Schedule Committee referred to in section 52B.

current Poisons Standard means:

(a) if no document has been prepared under paragraph 52D(2)(b)—the first Poisons Standard; or

(b) otherwise—the document last prepared under that paragraph.

first Poisons Standard means the latest edition at the commencement of this Part of the document known as the *Standard for the Uniform Scheduling of Drugs and Poisons* published by the Australian Health Ministers' Advisory Council.

scheduling, in relation to a substance, means determining the schedule or schedules to the current Poisons Standard in which the name or a description of the substance is to be included.

substance means any medicine or poison.

52B Establishment and constitution of Committee

(1) There is established a committee to be known as the National Drugs and Poisons Schedule Committee.

(2) Subject to subsection (3), the Committee is to be constituted, and to hold meetings and to make decisions, in accordance with the regulations.

(3) The Commonwealth, each State, the Northern Territory and the Australian Capital Territory are each entitled to nominate a representative on the Committee.

52C Functions of Committee

The functions of the Committee are:

(a) to make decisions in relation to the classification and scheduling of substances; and

(b) to provide technical advice to governments in relation to:

(i) the legislative restrictions (including restrictions as to accessibility and availability) to be imposed in respect of particular substances; and

(ii) the policies to be adopted with respect to the labelling, packaging and advertising of substances; and

(c) to maintain the current Poisons Standard; and

(d) to facilitate the harmonisation between Australia and New Zealand of the legislative provisions relating to the classification and scheduling of substances; and

(e) to undertake public consultation with respect to matters relating to the classification and scheduling of substances that are of public interest or significance; and

(f) to consider any matters referred to it by:

(i) the Minister or Secretary; or

(ii) the subcommittee of the Australian Health Ministers' Advisory Council known as the National Co-ordinating Committee on Therapeutic Goods;

and report to the Minister, Secretary or subcommittee the results of its consideration; and

(g) any other functions that are prescribed by the regulations.

52D Poisons Standard

(1) On the commencement of this Part, the first Poisons Standard is taken to have been prepared and made available by the Committee.

(2) Subject to this Act and the regulations, the Committee has power:

(a) to amend the current Poisons Standard; or

(b) to prepare a document (a ***new Poisons Standard***) that includes schedules containing the names or descriptions of substances, in substitution for the current Poisons Standard.

(3) As soon as practicable after a new Poisons Standard is prepared, the Committee must cause a notice to be published in the *Gazette* stating:

(a) that a new Poisons Standard has been prepared; and

(b) the date on which the new Poisons Standard comes into effect; and

(c) a place from which copies of the new Poisons Standard can be purchased.

(4) As soon as practicable after an amendment is made to the current Poisons Standard, the Committee must cause a notice to be published in the *Gazette* stating:

(a) that an amendment has been made to the Poisons Standard; and

(b) the date on which the amendment comes into effect; and

(c) a place from which copies of the amendment can be purchased.

(5) In this section:

amend, in relation to the current Poisons Standard, means:

(a) alter any provision (including a reference to a substance) in the current Poisons Standard; or

(b) omit any provision (including a reference to a substance) from the current Poisons Standard; or

(c) insert any provision (including a reference to a substance) in the current Poisons Standard.

52E Matters to be taken into account in exercising powers

(1) In exercising its powers under subsection 52D(2), the Committee must take the following matters into account (where relevant):

(a) the toxicity and safety of a substance;

(b) the risks and benefits associated with the use of a substance;

(c) the potential hazards associated with the use of a substance;

(d) the extent and patterns of use of a substance;

(e) the dosage and formulation of a substance;

(f) the need for access to a substance, taking into account its toxicity compared with other substances available for a similar purpose;

(g) the potential for abuse of a substance;

(h) the purposes for which a substance is to be used;

(i) any other matters that the Committee considers necessary to protect public health, including the risks (whether imminent or long-term) of death, illness or injury resulting from its use;

and may take into account the labelling, packaging and presentation of a substance.

(2) In taking into account the matters referred to in subsection (1), the Committee must comply with any guidelines of the Australian Health Ministers' Advisory Council or the subcommittee of the Council known as the National Co-ordinating Committee on Therapeutic Goods, notified to the Committee for the purposes of this section.

Part 5C—Complementary medicines

52F Definitions

In this Part, unless the contrary intention appears:

active ingredient means the therapeutically active component in a medicine's final formulation that is responsible for its physiological or pharmacological action.

complementary medicines means therapeutic goods consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and:

(a) a traditional use; or

(b) any other use prescribed in the regulations.

designated active ingredient means an active ingredient, or a kind of active ingredient, mentioned in Schedule 14 to the Therapeutic Goods Regulations.

traditional use, in relation to a designated active ingredient, means use of the designated active ingredient that:

(a) is well documented, or otherwise established, according to the accumulated experience of many traditional health care practitioners over an extended period of time; and

(b) accords with well-established procedures of preparation, application and dosage.

Note: An example of traditional use is use in Chinese traditional medicine.

52G Establishment and constitution of Committee

(1) There is established a committee to be known as the Complementary Medicines Evaluation Committee.

(2) The Committee is to have the functions prescribed in the regulations in relation to complementary medicines.

(3) The Committee is to be constituted, and to hold meetings and to make recommendations, in accordance with the regulations.

14 After section 54

Insert:

54AA Offences for contravening conditions or requirements imposed under the regulations

(1) The holder of a licence or permission to import or export therapeutic goods who contravenes a condition or requirement to which the licence or permission is subject under the regulations is guilty of an offence punishable, on conviction, by a fine of not more than the number of penalty units specified for such a contravention in whichever of subsection (2) or (3) is applicable.

(2) If:

(a) the condition or requirement relates to the possession, custody, transport, use or disposal of the goods; or

(b) the regulation providing for the condition or requirement states that the purpose of the condition or requirement is to protect the safety of the public;

the number of penalty units for the contravention is 240 penalty units.

(3) If subsection (2) does not apply, the number of penalty units for the contravention is 50 penalty units.

Schedule 2—Amendment of the Therapeutic Goods Amendment Act 1997

1 Item 9 of Schedule 1

Omit:

9 After section 25

Insert:

25A Registration of therapeutic device to which conformity assessment certificate applies

substitute:

9 After section 25A

Insert:

25B Registration of therapeutic device to which conformity assessment certificate applies

[*Minister's second reading speech made in—*
Senate on 17 February 1999
House of Representatives on 25 March 1999]

(11/99)